The Effectiveness of Family-based Weight Loss Treatment Implemented in Primary Care: A Randomized Control Trial

Study Protocol

Protocol Identifying Number: U01 HL131552
Principal Investigator: Leonard H. Epstein, PhD
IND/IDE Sponsor: National Heart, Lung and Blood Institutes (NHLBI)
Funded by: NIH
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I. **Contents**

II. List of Abbreviations

AAP	American Academy of Pediatrics
AE	Adverse Event
ANCOVA	Analysis of Covariance
BMI	Body Mass Index
BOV	Percent over weight
CCC	Clinical Coordinating Center
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative
COI	Conflict of Interest
CME	Continuing Medical Education
CMP	Clinical Monitoring Plan
CRO	Clinical Research Office
CTSI	Clinical Translational Science Institute
DCC	Data Coordinating Center
DD	Delay Discounting
DSMB	Data Safety Monitoring Board
DSMP	Data Safety and Monitoring Plan
UC	Usual Care
EMR	Electronic Medical Records
FBT	Family-Based Treatment
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FRG	Food Reference Guide
FWA	Federalwide Assurances
GCP	Good Clinical Practice
GR-PBRN	Greater Rochester Practice Based Research Network
HIPAA	Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
MOC	Maintenance of Certification
MOP	Manual of Procedures
NCH	Nationwide Children's Hospital
NIH	National Institutes of Health
NPP	Non-participating parent
NHLBI	National Heart, Lung and Blood Institutes
OHRP	Office for Human Research Protections
PBRN	Practice Based Research Network
PC	Project Coordinator
PCN	Primary Care Network
PCP	Primary Care Provider
PLAN	Primary Care Pediatrics, Learning, Activity, Nutrition
PHI	Private Health Information
PI	Principal Investigator

REDCap	Research Electronic Data Capture
RGH	Rochester General Hospital
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SEC	Study Executive Committee
SMC	Safety Monitoring Committee
SMH	Strong Memorial Hospital
TFC	Training and Fidelity Core
UB	University at Buffalo
UBIRB	University at Buffalo Institutional Review Board
UP	Unanticipated Problem
URMC	University at Rochester Medical Center
US	United States
USPSTF	United States Preventive Services Task Force
WU	Washington University in St. Louis

III. Statement of Compliance

PLAN with Families will be conducted according to the study protocol developed to follow the Good Clinical Practice guidelines (GCP) set by the United States (US) Code of Federal Regulations (CFR) regarding clinical trials with the approval of the University at Buffalo Internal Review Board (UBIRB). All personnel responsible for conducting this trial will be trained through the Collaborative Institutional Training Initiative (CITI). The Principal Investigators agree that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the UBIRB, except where necessary to eliminate an immediate hazard(s) to the trial participants

We agree to ensure that all staff members involved in the conduct of this study are informed about their obligations in meeting the above requirements.

Principal Investigator: _____
Print/Type Name

Signature: _____ Date: _____

Principal Investigator: _____
Print/Type Name

Signature: _____ Date: _____

IV. Introduction and Study Rationale

Background Information

Childhood obesity is associated with a risk for the development of adult obesity, with children with obesity at all ages at increased risk of becoming adults with obesity.[1,2] In addition to the risk of becoming an adult with obesity, obesity during childhood is associated with cardio-metabolic changes including increases in blood pressure, cholesterol and triglyceride levels, and insulin resistance that initiate a trajectory of cardiovascular and metabolic disease as an adult.[3] Childhood obesity is also associated with psychological and behavioral changes that negatively impact the child's quality of life.[4,5] Obesity is a familial disorder. The most reliable risk factor for childhood obesity is parental obesity.[2] Beginning in infancy,[6] and extending through adolescence,[2] parents with obesity increase the risk of the child or adolescent experiencing obesity. Parents with obesity may also suffer from cardio-metabolic disease, initiating a cycle of both obesity and cardiovascular and metabolic disease that impacts both generations. Parental behaviors, such as modeling and support of child unhealthy behaviors, are associated with childhood obesity.[7-10] Given the relationship between child and parental obesity and that parents arrange family eating and exercise environments, model behaviors for their children, and reinforce healthy or unhealthy behavior patterns, it is logical that targeting both the parent and child can have a positive impact on childhood weight control.

Family-based childhood obesity treatment (FBT) was developed over 30 years ago and has proven effective in decreasing child and parent weight.[11] FBT targets changes in eating and physical activity through child and parent behavior change. One implication of FBT is that it may be more cost-effective than separate treatments of the child with obesity by his or her pediatrician and the parent with obesity by his or her primary care doctor. To test this, we randomized families to FBT or separate and simultaneous treatment for the parent and child with obesity. Results at 12 months showed FBT was associated with superior child and parent weight loss than separate treatment and was significantly more cost-effective per pound of weight loss.[12] Family-based weight loss programs also convey additional health benefits beyond weight loss, such as improvements in cardio-metabolic risk factors[13] and health related quality of life.[14,15]

Study Summary

Family-based treatment (FBT) is a behavioral weight control intervention that targets children with overweight/obesity and their parents,[16-18] and has the capacity to improve the weight status of non-targeted family members such as siblings.[19] FBT has significant positive effects on body weight in children for up to 10-years of follow-up,[20,21] and a robust relationship is observed between child and parent outcomes.[22,23] FBT's concurrent care of two generations of obesity in the family is more efficacious and cost-effective than if parents and children are treated separately.[12] Despite its recognized efficacy, FBT is mainly available in specialty clinics[13,16,24] and many children fail to receive this evidence-based level of treatment,[25-28] as recommended by the U.S. Preventive Services Task Force. [25-28] Primary care offers an optimal setting for delivery of FBT by capitalizing on the established relationship between primary care providers and families.[29] Using behavioral interventionists co-located within the primary care setting overcomes barriers posed by fragmentation of care, and lack of provider time and training. One of the challenges to integrating childhood obesity treatment into primary care is optimizing limited health care resources. In behavioral weight loss programs, some individuals learn diet, physical activity, and behavior change information quickly, while others learn more slowly. Individuals also differ in their ability to implement treatment recommendations due to individual differences, such as problems with

delaying gratification. FBT accommodates these individual differences by using a personalized system of instruction, or a mastery model, in which the content and dose of treatment is calibrated to the needs of the family, ensuring that treatment effort is consistent with need. This multi-site, clinical trial aims to evaluate over a two-year period the effectiveness of FBT delivered by a trained behavioral interventionist co-located within primary care compared to usual care alone (UC). Participants will be a representative sample of 528 families with a 6-12-year-old child with overweight/obesity and a participating parent with overweight/obesity. Weight changes in approximately 228 siblings with overweight/obesity and between 2-18 years of age will also be studied. Additionally, this study provides the opportunity to explore factors important to successful implementation of FBT in a primary care setting. Provider attitudes, such as those related to evidence-based practices in general[30] as well as their specific perceptions of FBT,[31] may predict their intended use of co-located FBT,[31] as intentions are reliable predictors for future behavior.[32,33]

Scientific Rationale

Obesity in youth has tripled in the last 30 years, a trend that is particularly disturbing because the majority of youth with obesity remain obese as adults. Because childhood obesity is associated with increased risk of adult cardiovascular diseases such as hypertension, hyperlipidemia, and type 2 diabetes, improved access to evidence-based treatments is vital. Many organizations are responding to the demand for services by implementing programs for childhood obesity. However, obesity care is currently dominated by high-intensity behavioral treatment implemented in specialty clinics or by less effective, low- intensity treatments implemented in primary care. Effective family-based treatment delivered within primary care, matching national recommendations, has never been evaluated in a randomized, controlled trial. If we can demonstrate effectiveness in this setting, we will be establishing for the first time that childhood obesity can be addressed by trained behavioral interventionists in a setting that provides routine access to large numbers of children with obesity without requiring the intense environment of a specialty clinic. Moreover, by studying approximately 228 siblings with obesity in our initial secondary aim, we are asking a seminal question about whether the "family" component of FBT translates into benefits for family members not directly participating in the program. Affirmative evidence regarding this question will suggest multiple avenues of future research that have the potential to reorder our thinking about how best to implement cost-effective family-based obesity programs. The proposed study continues our efforts to translate FBT for widespread implementation and dissemination for treatment of children with overweight or obesity and families into primary care settings. It aims to shift current research and clinical practice paradigms by demonstrating the effectiveness of delivering FBT within primary care using a behavioral health provider who is co-located in a primary care setting.

V. Study Design

Description of Study Design

The study is an individually randomized group treatment (IRGT) [34] trial such that the individual, in this case the family, is the unit of randomization. It differs from a classic individually randomized trial in that the intervention is either a group intervention or conducted by an agent responsible for implementing the intervention in a defined set of individuals. The PLAN study will evaluate the effectiveness of family based treatment (FBT) delivered by a coach versus usual care (UC) treatment delivered by primary care providers. Both FBT and UC will be delivered in pediatric offices. In PLAN, participants are randomized at the family level and only one eligible child (the index child) is included in the primary outcome analysis. The trial will enroll up to 1284 subjects from 528 randomized families at four sites, each having at least one overweight/obese participating child age 6-12 and at least one participating parent. Since the study

*has four sites with three coaches per site, the analysis plan involves a nesting of the coach within the site. Some sites have backup and floating coaches that are involved in delivering FBT to study participants, which will also be accounted for when outcome data is analyzed (**This change was made on 12.4.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.18.19**). While this nesting suggests a classic cluster randomized trial, an IRGT trial is different because the nesting applies only to the intervention group. Since the UC group has no nesting factor in this IRGT trial, a proper analysis must reflect the fact that the FBT group and the UC group must use different covariance structures. In addition to one participating child and parent from each family, the sample will also include up to 228 overweight/obese siblings and non-participating parents who will not be direct recipients of the intervention. There will be two years of follow-up with comprehensive assessments at baseline, 6, 12, 18 and 24 months. The primary outcome is percent over BMI at 24 months in the child. Our primary hypothesis is that the FBT intervention will be superior to UC alone in the participating child **(DSMB approved protocol addenda, 11.2.18).***

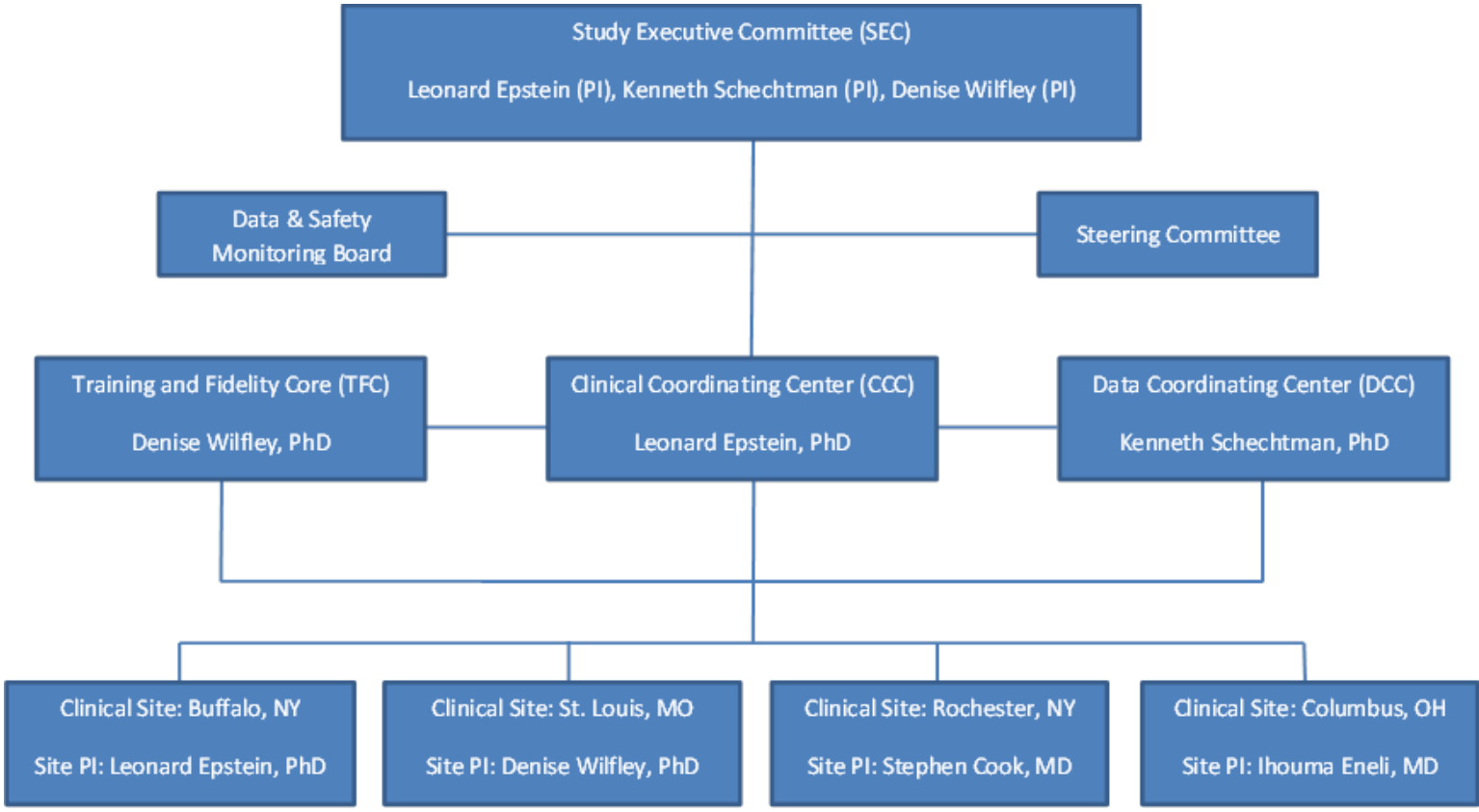
Outcome and Objectives

*This study will test between-group differences in child (**Primary Specific Aim 1**) weight change, as well as weight change in parents (**Secondary Aim 1**), siblings with overweight/obesity (**Secondary Aim 2**), changes in parent and child delay of gratification and how changes in delay of gratification are related to parent and child weight changes (**Secondary Aim 3**), participant level predictors of treatment success (**Secondary Aim 4**), and how provider attitudes toward evidence-based treatment and perceptions of FBT may relate to their intention to use co-located FBT in their practices in the future (**Exploratory Aim 1**). Establishing that FBT can be effectively implemented within real world settings is crucial to creating a system by which children and their families who suffer from obesity can be treated in a centralized primary care setting **(DSMB approved protocol addenda, 11.2.18).** To investigate the discussions between PLAN FBT coaches and their PLAN FBT families regarding perception of food cost and food choices PRE and POST COVID. **(Exploratory Aim 2) (DSMB requested protocol addenda, 9.22.20).***

Study Organization and Roles and Responsibilities

This project continues long-standing collaborations between study PIs: Drs. Epstein, Wilfley, and Schechtman, and an enhanced partnership from prior professional associations with Drs. Cook and Eneli. The organizational structure includes a Clinical Coordinating Center, a Data Coordinating Center, and four clinical sites (see **Figure 1** below).

FIGURE 1. Study Organization Chart



1. Study Executive Committee (SEC)

Members of the SEC will include Drs. Epstein, Schechtman, and Wilfley. The three PIs will alternate responsibility for the development of SEC meeting agendas and will co-lead regular meetings throughout the study. The SEC will be responsible for decision-making related to the overall scientific conduct of the study and monitoring the overall progress of the study to ensure timely study completion. In addition, the SEC will be responsible for final approval of the study protocol and for any changes to the developed protocol, all of which will be documented in writing as part of the SEC minutes. Throughout the study, the PIs will communicate weekly by teleconference to make decisions on the scientific direction of the grant (e.g., data collection, data analysis) and guidance regarding study procedures. Daily decisions about the project will be made by email and phone as needed.

2. Steering Committee

The PIs and Co-Is will form a Steering Committee (Drs. Epstein, Wilfley, Schechtman, Cook, Eneli, and Quattrin) that will manage the oversight and coordination of project management, research administration, publications and data sharing, and integration of all resources needed for the project. The University at Buffalo will subdivide the award funds and each PI will be responsible for their own budget. The Steering Committee will oversee decisions on minor changes in research direction and have the authority to reallocate funds and resources among PIs. Dr. Epstein will be first to serve as Chair of the Steering Committee and be responsible for communication among PIs and Co-Is, including meeting schedules and agendas. The position of Chair will rotate among the PIs on a yearly basis. Dr. Epstein will be designated the contact PI

and be responsible for submitting all necessary documents to NIH, including IRB approvals and annual progress reports. The Steering Committee will meet as needed and at least on a quarterly basis by phone to discuss study-related decisions and to evaluate the overall scientific conduct of the study.

3. Clinical Coordinating Center (CCC)

Located within the University at Buffalo and directed by Dr. Epstein, PI, with Dr. Teresa Quattrin, Co-I, the CCC will be responsible for study oversight, including developing the treatment and assessment protocol, study website development, and coordination and monitoring of study procedures and progress across sites. Dr. Quattrin is experienced in overweight assessment and treatment in the primary care setting and will provide general medical guidance to the study as well as oversee the evaluation and adjudication of adverse event reports.

4. Training and Fidelity Core (TFC)

The TFC will be housed at Washington University in St. Louis. Dr. Wilfley will serve as PI for the TFC. Dr. Wilfley will provide leadership to the TFC and will be responsible for the content and integrity of behavioral interventionist training activities and implementation of the intervention across all clinical sites. The TFC will conduct the trainings and will supervise the interventionists to ensure adherence to the treatment protocol during the training and active treatment phases of the study.

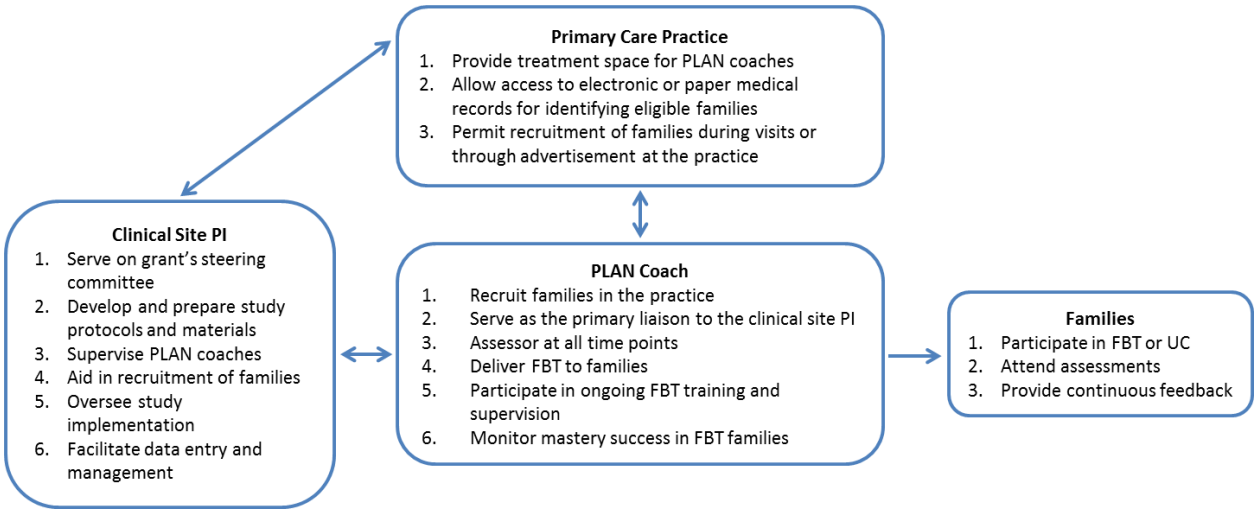
5. Data Coordinating Center (DCC)

The DCC will also be housed at Washington University in St. Louis under the direction of Dr. Schechtman as PI. The DCC will provide scientific, organizational, statistical, quality control, and operational leadership in support of the present study. Dr. Schechtman has directed many NIH-funded DCCs and has served as head of the DCC for a weight loss maintenance study for which Dr. Wilfley was PI and Dr. Epstein was Co-I.

6. Clinical Sites

Dr. Wilfley will serve as PI for the St. Louis, Missouri clinical site. Dr. Epstein, will serve as the PI for the Buffalo, New York clinical site with Dr. Teresa Quattrin serving as Co-I. Dr. Quattrin is experienced in overweight assessment and treatment in the primary care setting and will provide general medical guidance to the study team. She will also evaluate adverse event reports to determine appropriate disposition. Two additional clinical sites in Rochester, New York and Columbus, Ohio will be directed by Drs. Stephen Cook and Ihuoma Eneli, respectively. Drs. Cook and Eneli will serve as PIs for their clinical sites and will be primarily responsible for recruitment of practices and oversight of study-related processes within these practices (see **Figure 2** below).

FIGURE 2. Clinical Site Organization



Additional Committees

1. Safety Monitoring Committee

The Safety and Monitoring Committee (SMC), chaired by Dr. Teresa Quattrin, will oversee the assessment and reporting of adverse events (AE), serious adverse events (SAE), and unanticipated problems (UP). The SMC will be responsible for evaluating adverse event reports from the DCC and determining appropriate disposition. Additional members include: Drs. Ihuoma Eneli and Rebecca Campo.

2. Interventionist Committee

The Interventionist Committee, co-chaired by Dr. Leonard Epstein and Colleen Kilanowski, will meet on a monthly basis to discuss participant progress in the intervention and to trouble-shoot areas of concern (e.g., non-compliance to treatment). Each clinical site will be represented by a lead interventionist who will summarize site progress with the project coordinators and chairs of the Interventionist Committee. Additional members include: Dr. Rebecca Campo, Gracie Matychak, Megan Dahlman, Andrea Goard, and Sarah Kruger.

3. Recruitment and Retention Committee

The Recruitment and Retention Committee, chaired by Dr. Ihuoma Eneli, will oversee accrual milestones related to the recruitment and retention of families in the study. The Committee will monitor and communicate recruitment and retention strategies across sites and will make site-specific recommendations based on recruitment reports from the DCC. Additional members include: Drs. Charlotte Pratt and R. Robert Welch.

4. Quality Control and Measurement Committee

The Quality Control Committee, chaired by Dr. Denise Wilfley, will oversee the accuracy and completeness of computerized data, the common administration of protocols across sites, adherence to protocol requirements, and training and certification of study staff in assessment procedures and data collection. Additional members include: Nasreen Moursi, and Peter Dore.

5. Ancillary Study Committee

The Ancillary Study Committee, chaired by Dr. Stephen Cook, will oversee the submission process for ancillary study proposals and will evaluate the feasibility of these proposals in regard to their cost, impact on IRB protocols, and burden to participants. The Committee will meet monthly to review proposals and will provide recommendations to the Steering Committee. Additional members include: Drs. Charlotte Pratt and Rebecca Campo.

6. Publication and Presentations Committee

The Publication and Presentation Committee, chaired by Dr. Kenneth Schechtman, will be responsible for defining publication policies, prioritizing if multiple papers and abstracts challenge resources, and encouraging the involvement of junior investigators in the dissemination of study results. This Committee will oversee the creation of a publications and presentations database that will facilitate the tracking of completed publications and the notification of abstract due dates and pending timelines for preparing material for publications and presentations. Additional members include: Doctors Leonard Epstein, Denise Wilfley, Stephen Cook, Ihuoma Eneli, and Nancy Geller. All proposed publications will be disseminated to the Publication and Presentation Committee, and forwarded to Colleen Kilanowski and Alexandria Phipps for proper filing of documents.

Study Timeline

The first 12 months of the study will be devoted to study organization and training of staff in their research and clinical functions (see **Table 1**). Website development will occur in order to facilitate training and initiate recruitment and study implementation. Behavioral interventionists called PLAN coaches and study support staff will be hired and fully trained in their roles. PLAN coaches will attend a live training at WU led by the TFC and will also utilize online and printed materials. Recruitment of study participants utilizing the research match design will also begin, as it entails passive collection of information from families interested in participating in studies aimed at weight loss. Active recruitment will begin in month 16 and will continue through month 30. It is expected that all 528 families across all of the practices will be enrolled during this time period. Treatment initiation will also begin in month 17, as recruitment allows, and will continue through month 54. This will allow all participants recruited by month 31 to finish two years of treatment and final assessments. Months 55-60 will be used for study closeout and data analysis.

TABLE 1. Study Timeline

Study Activity	Study Months									
	Year 1		Year 2		Year 3		Year 4		Year 5	
	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Planning & Data Base Development	X									
Web Development	X	X								
Interventionist Hiring & Training	X	X								
Piloting & Participant Recruitment			X	X	X					
Treatment Delivery			X	X	X	X	X	X	X	
Data Monitoring Reports				X	X	X	X	X	X	X
Data Analysis									X	X
Study Closeout										X

II. Study Procedures and Schedule

Study procedures will be carried out within primary care practices. The general roles and responsibilities of: 1) the PIs at the four clinical sites; 2) the administrators and providers at participating practices; 3) the PLAN coaches; and 4) the families randomized to the two conditions are summarized in the sections that follow. An overview of study flow is provided in following sections as well as in **Figure 1** in **Appendix D**.

Recruitment

1. Participants

Families will be recruited from pediatric practices in our Practice-based Research Networks (PBRNs) in several ways. Each practice will have children who meet age, height, and weight criteria flagged in their charts, and we will use multiple approaches to recruit families. First, we will establish a ResearchMatch approach to recruiting in each PBRN. ResearchMatch, an online recruitment tool, will accrue families in one of two ways. At intake for a well- or sick-child visit, forms designed to acquaint families with the study will be introduced by PLAN coaches, and families can sign up for additional information about this study. Their information will be entered into a database by the PLAN coaches, and they will be contacted if they meet criteria. In addition, we will set up a website that they will be directed to in a flyer, and they can sign up to participate from the website. Since the pediatrician generally will not have information on parental health, this will need to be collected prior to deciding study eligibility, and the family database will assist in this endeavor by including information about all family members after a phone screen is conducted by the PLAN coaches with the participating parent. Second, PBRN practices post study advertisement at offices for interested families to visit the study website to complete questionnaires to ensure they meet eligibility criteria. If the families meet eligibility criteria, a PLAN coach will follow up with the families to schedule their first appointment at their earliest convenience. At this appointment, the PLAN coach will confirm the families' interest to participate and eligibility prior to participation. Third, Plan coaches will meet with families during well-child visits to introduce the study, assess their interest, and explain next steps. Each of these methods in collecting their information regarding interest and eligibility will be preceded by getting their verbal consent over the phone or a check box indicated on the web pages.

During recruitment, PLAN coaches will explain that there is a 50/50 possibility of getting one treatment over the other treatment. This will be like a flip of the coin and no one can just pick one treatment or the other. This study is testing if the FBT is as good as the care provided by their doctors normally given or better. Randomization will occur after the first appointment.

Inclusion Criteria

The PLAN study inclusion criteria and methods for assessing these criteria are summarized in **Table 2**. The screening surveys and measures may be found in **Appendix B**.

TABLE 2. PARTICIPANT INCLUSION CRITERIA

Participant	Inclusion Criteria	Measurement
Targeted Child	Between the ages of 6 and 12 years[1]	Initial Eligibility Survey[2]
	BMI above the 85th percentile for age and sex	Initial Eligibility Survey[3]

	At least one parent with overweight or obesity (BMI>25) who is willing to participate	Initial Eligibility Survey
	Able to speak and comprehend English at a first grade level	Eligibility Phone Screen *(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)*
	Resides with targeted parent at least 50% of the time[4]	Eligibility Phone Screen
	Supplemental evaluation of eligibility as needed	PCP Medical Clearance Form
Targeted Parent	*(DSMB approved protocol addenda, 11.2.18)*	~~*Initial Eligibility Survey*~~[5] *(DSMB approved protocol addenda, 11.2.18)*
	Agrees to attend all treatment meetings	Eligibility Phone Screen
	Able to speak and comprehend English at a first grade level	Eligibility Phone Screen~~, *WRAT*~~ *(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)*
	Must be targeted child's biological or adoptive parent or legal guardian	Eligibility Phone Screen
	Supplemental evaluation of eligibility as needed	PCP Medical Clearance Form
Sibling (if applicable)	Between the ages of 2 and 18 years[6]	Eligibility Phone Screen [2]
	BMI above the 85th percentile for age and sex	Eligibility Phone Screen [3]
	Must reside with targeted child and parent	Eligibility Phone Screen

(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18) [1]If family has two children between the ages of 6 and 12 years, it will be encouraged that the older sibling be the primary participant, as it is more likely the older sibling will serve as a role-model for the younger sibling; [2]Calculate age using screen date and birth date; [3]BMI Percentile Calculator: https://nccd.cdc.gov/dnpabmi/calculator.aspx; [4]If 50/50 split, it will be encouraged that non-targeted parent sign an agreement to be supportive of study goals and to allow contact from study team; [5]BMI: https://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html; [6]In families where more than one eligible sibling is available, we will enroll the sibling whose age is closest to that of the study child.

Exclusion Criteria

The PLAN study exclusion criteria and methods for assessing these criteria are summarized in **Table 3**. The screening surveys and measures, including a table of exclusionary medications, may be found in **Appendix B**.

TABLE 3. PARTICIPANT EXCLUSION CRITERIA

Participant	Exclusion Criteria	Measurement
Targeted Child and/or Parent	Concussion in the last 3 months[1]	Initial Eligibility Survey
	Planning to move away from the area within the next 2 years	Initial Eligibility Survey

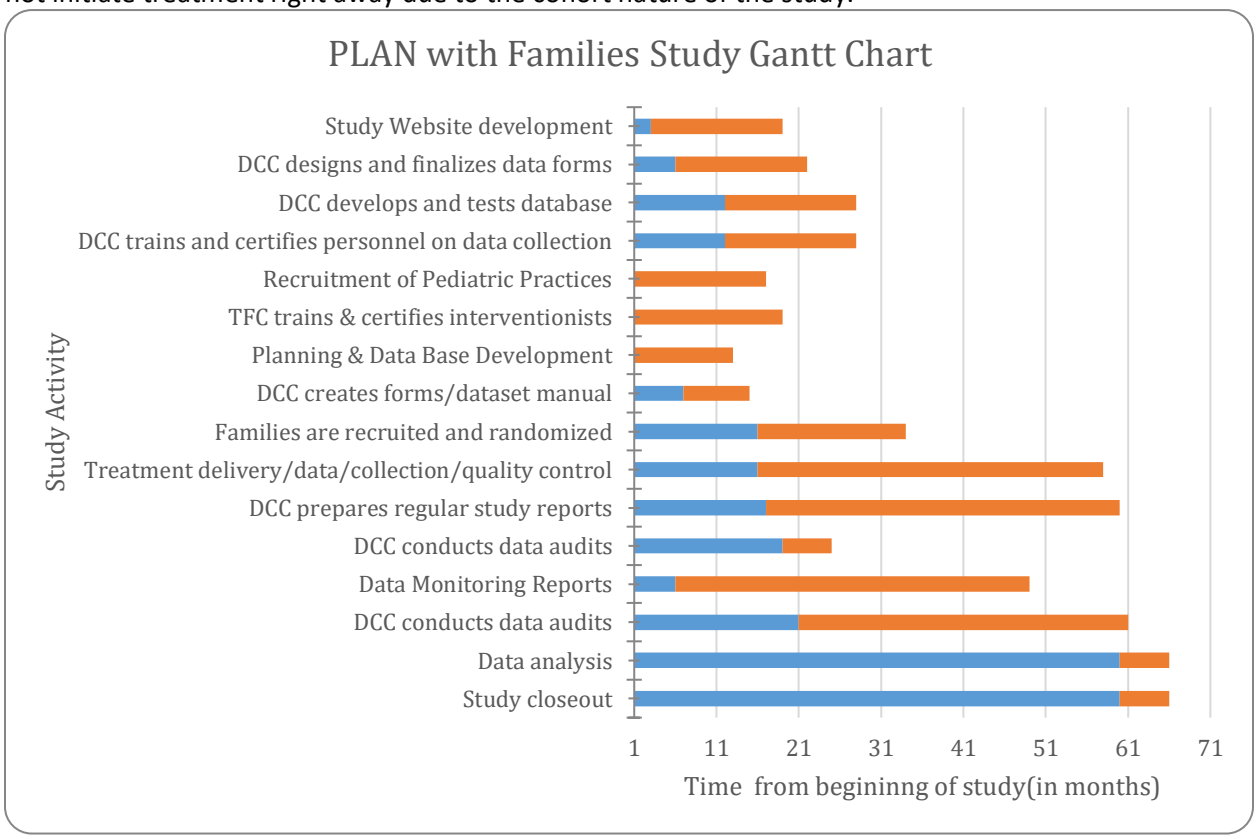
	Pregnant or is planning on becoming pregnant during the two-year study period	Eligibility Phone Screen
	Participation to any degree in weight-management/weight-loss program[2]	Eligibility Phone Screen
	Weight-related surgeries (e.g., gastric bypass) *within the last two years. (DSMB approved protocol addenda, 11.2.18)*	Eligibility Phone Screen
	Weight-affecting medications known to cause weight gain or loss if at current dose for < 6 months	Eligibility Phone Screen
	Medications affecting growth (e.g., systemic corticosteroids 2+ weeks in the past year, insulin, oral hypoglycemics, thyroid hormone, growth hormone)	Eligibility Phone Screen
	Medical condition altering nutritional status or intestinal absorption (e.g., inflammatory bowel disease, diabetes and taking insulin)	Eligibility Phone Screen
	Medical condition that affects growth (i.e., genetic or metabolic disease/syndrome associated with obesity)	Eligibility Phone Screen
	Chronic medical conditions, including: Type 1 diabetes, heart disease or heart failure, HIV or AIDS, muscular dystrophy, renal diseases, hypothyroidism (if untreated or if treated with medication for <6 months)	Eligibility Phone Screen
	Severe restriction of diet that would inhibit family from reasonably following the Traffic Light Eating Plan	Eligibility Phone Screen
	Significant developmental delays, intellectual disabilities, or Autism Spectrum Disorder	Eligibility Phone Screen
	Unmanaged/active psychiatric conditions (e.g., binge eating disorder or schizophrenia) meeting full DSM-5 criteria or impairing clinical symptoms (e.g., suicidality)	Child: PSC, QEWP-5 (Child Self-Report & Parent Report of Child), KSADS if warranted Parent: PHQ, SCID if warranted
	Disability that prevents performance of physical activity at the level of a brisk walk	PCP Medical Clearance Form

PSC=Pediatric Symptom Checklist; QEWP-5=Questionnaire on Eating and Weight Patterns; KSADS=Kiddie Schedule for Affective Disorders and Schizophrenia; PHQ=Patient Health Questionnaire; SCID=Structured Clinical Interview for DSM Disorders; [1]Eligible once 3 months since concussion passes; [2]Eligible if willing to stop program.

2. Primary Care Pediatric Practices

Practice recruitment will begin during the planning stage of the study (see Table 4. PLAN with families Study Gantt Chart). Each clinical site is responsible for recruiting appropriate numbers of practices to ensure participant recruitment goals can be met. Given differing practice and caseload sizes across sites, the number of practices recruited may vary across each site. As a minimum benchmark, by July 1 2017, all sites must have identified sufficient pediatric practices to give them access to a minimum of 3303 children with overweight or obesity, or a minimum of 9714 total children study-wide (assuming a 34% prevalence rate of overweight/obesity). This number was identified assuming 57.1% of children with overweight/obesity will have a parent with overweight/obesity based upon 1286 families with an age-eligible overweight/obese child in a screening database maintained by Dr. Epstein in Buffalo, in which 734 (57.1%) had at least one obese parent. It is estimated that 10% of these families will express

willingness to participate in the study. This estimate is based on previous experience of the former study Co-I Dr. Jane Garbutt as she ran a recent trial assessing an asthma intervention for families recruited from a primary care setting. Dr. Garbutt's study was low intensity and she described a 20% uptake rate. Given the intensity of our intervention, a more conservative 10% is estimated. Additionally, after agreeing to be screened, it is estimated that only 70% of willing families will meet eligibility criteria and/or will decide they are interested in participating. This estimate is based on the recent COMPASS trial conducted by Dr. Wilfley, which found that approximately 66% of families that attended a study orientation meeting entered the study. It is believed our rate will be slightly higher, as participation in the study will begin soon after study orientation, whereas families in the COMPASS trial generally did not initiate treatment right away due to the cohort nature of the study.



Gantt Chart Updated, (DSMB approved protocol addenda, 11.2.18).

Additionally, given the recruitment goal for minority families, all sites must have access to a minimum of 826 (30%) minority children with overweight or obesity, or 2,429 total minority children must be available study-wide. (Table 5. DCVS Accrual Milestones below).

DCVS Accrual Milestones: QUARTERLY Reporting

PI: DR. LEONARD EPSTEIN

Grant # / Project: HL131552-01

Title: Effectiveness of Family-based Weight Loss Treatment Implemented in Primary Care

Program Director: Charlotte Pratt

Total Target Pop.: 528
Target Minorities. %: 29.2%
Target Women %: 50.2%

Start Date Recruitment: November 1, 2017

End Date Recruitment: May 31, 2019

End Date Grant: * May 31, 2021

Calendar Year	1st Quarter Jan - Mar	2nd Quarter Apr - June	3rd Quarter July - Sep	4th Quarter Oct - Dec	Total
2016	0	0	0	0	0
2017	0	0	0	56	56
2018	84	84	84	84	336
2019	82	54	0	0	136
2020	0	0	0	0	0
2021	0	0	0	0	0
2022	0	0	0	0	0
Total	166	138	84	140	528

*** Number yrs of funding:** 5

Signature of Authorized Representative:

Date Signed

MAP Updated, (DSMB approved protocol addenda, 11.2.18).

Screening

At the initiation of the screening process, the participating parent will complete the Initial Eligibility Survey in person, over the phone, or online via REDCap (Research Electronic Data Capture) with the assistance of the PLAN coach or Research Support Specialist. The survey will gather preliminary eligibility criteria including height, weight, and age. If eligible based on this survey, a PLAN coach will contact the parent to discuss the study in further detail and to answer any questions the parent may have. The PLAN coach will obtain the parent's verbal consent to continue with the screening process and will then complete the Eligibility Phone Screen, which gathers additional information on medical and psychiatric history for both parent and child. For families found to meet eligibility criteria on both the Initial Eligibility Survey and the Eligibility Phone Screen, an orientation appointment will be scheduled following the Phone Screen, to complete the process of determining eligibility to participate in the study.

Prior to the orientation appointment, the parent and child will complete survey questionnaires via REDCap, including the Patient Health Questionnaire (PHQ), Pediatric Symptom Checklist (PSC), and Questionnaire on Eating and Weight Patterns Parent Report of Child (QEWP-5). These questionnaires assess for symptoms of eating disorders and other psychiatric disorders (e.g., depression, anxiety, and substance abuse). If the respondent's scores are above clinical cut-offs on these questionnaires, they will be flagged in REDCap and a PLAN coach will follow-up with the parent over the phone prior to the orientation appointment to further assess for the presence of eating disorders or other psychopathology by administering the relevant modules of the Structured Clinical Interview for DSM Disorders (SCID) and Kiddie Schedule for Affective Disorders and Schizophrenia (KSADS). A score of "Yes, present" for any of the psychiatric conditions assessed by these semi-structured clinical interviews will prompt the PLAN coach to inquire about any current or past treatment to gauge impairment level. This information will be entered into the Eligibility Tracking Form.

Each week, the clinical site PI, with guidance from the doctoral-level psychologists on the study team as needed, will review participants flagged in this way and will make all final decisions regarding eligibility. If the parent or child only exhibits subthreshold symptoms of a disorder, the family will be eligible to participate assuming there are no impairing symptoms present (e.g., suicidality). If the parent or child meets full DSM-5 criteria for any psychiatric disorder, the family is ineligible to participate, and the PLAN coach will provide a referral for treatment to the family. Once the parent or child has been symptom-free for six months, the family is eligible to re-screen for enrollment into the study. The Eligibility Tracking Form (see **Appendix B**) will be completed to document the process by which each participant's eligibility or ineligibility is determined

(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18). The pediatrician or parent's physician will be contacted if information about the family meeting inclusion or exclusion criteria is needed. Families will be asked to provide a standard form requesting information about the patient's current specified medical condition, and to forward or have the PCP send the form to site clinical PI.

Consenting Process

All participants will meet with a trained study staff member and will be consented following the Manual of Procedures of the University at Buffalo Institutional Review Board (UBIRB), the IRB of Record for the study. Coaches will file the paper consent forms in the following order:

1. *Child Assent*
2. *Parental Permission for Child*
3. *Parent Consent*
4. *Sibling Assent 7-13*
5. *Sibling Assent 14-17*
6. *Adult Sibling Consent*
7. *Parental Permission for Sibling*
8. *Non-Participating Parent Consent*
9. *Targeted Child – 7-13 Re-assent*
10. *Targeted Child – 14-17 Re-assent*
11. *Sibling – 7-13 Re-assent*
12. *Sibling – 14-17 Re-assent*
13. *Sibling – Adult – Re-consent*

14. Coronavirus Addendum

a. Example consent/assent templates for all study participants are included in **Appendix A.**

1. Family Consent

Families who are eligible for the study will meet with a trained study staff member and will be given written and verbal information about the study. Full disclosure of the purpose of the study, the benefits and risks to individuals who participate, and the confidential nature of information obtained during the study will be explained to participants. Families will be aware from the outset that they will be randomly assigned to an active treatment condition (FBT) or a usual care control condition (UC) following baseline assessment completion. They will also be aware that their expected participation will be 2 years and may require anywhere from 26 to 96 sessions of FBT. Families will be informed of alternative lifestyle change resources available to them, such as physical activity programs or sports teams for youth at the YMCA or other organizations, other commercially available child fitness or weight loss programs, or pediatric dieticians or fitness trainers, and if so desired, referrals will be made. Potential participants will also be informed that they may drop out at any time during the study and that their withdrawal from the study will in no way impact their ability to receive medical care through their primary care practice. The staff member will answer any questions the family has about the study, and then participants will be consented according to the policies and procedures of the UBIRB

Each capable parent 18-years or older will sign the consent form for himself/herself and will also sign the parent permission form, which provides consent for his/her child age 6-12 to participate. In addition, the parent will sign a separate permission form that provides consent for participating siblings (i.e., a sibling who is overweight/obese) age 2-17 to participate. Older siblings will sign assent forms, which will be written and explained at a reading level appropriate for the child population. Non-participating parents and siblings who are 18 years of age will sign their own consent form. A copy of the signed consent, permission, and assent forms and study staff contact information will be given to the potential participants, and all original forms will be kept in the participant's confidential research record. Participants will also be asked to give written consent for the PLAN coach to audio record their treatment sessions so the study team can assess adherence to the treatment protocol; however, participants will not be excluded from the study if they refuse audio recording. In our experience, less than 1% of participants refuse audio recording.

Since the children involved directly (as targeted children) and indirectly (as siblings) will mature throughout the course of their time in the PLAN program, a PLAN Coach or Measurement Coach will re-assent and re-consent impacted children using assent and consent forms that explain their participation using age appropriate language. The re-assenting and consenting processes will take place at the next assessment appointment after they age into a new category. Example consent/re-assent templates for impacted children are included in **Appendix A** (*This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19*)**.**

2. Primary Care Provider Consent

Since we are interested in primary care *providers'* knowledge of evidence-based treatments as well as their attitudes toward and their satisfaction with the treatment conditions implemented

within their practices, we plan to collect basic demographic data (e.g., age, years in practice, highest degree obtained) and responses to self-report questionnaires from the physicians providing UC to the participating families. Primary care *providers* willing to participate in this research will sign a consent form that outlines the purpose of their participation in providing research data, the benefits and risks to individuals who participate, and the confidential nature of information obtained. Participation in the research portion is completely optional and a decision not to participate will in no way affect their role as a care *provider* on the study nor their current job status, which will be clearly outlined in the consent form. A trained study staff member will answer any questions the primary care *provider* has about his or her participation in the study *(This change was made on 2.27.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*

3. PLAN Coach Consent

PLAN coaches will also be asked to participate in research designed to assess the delivery and implementation of FBT in the primary care setting through reporting of demographic data and responses to self-report questionnaires. As with the primary care providers, if they are willing participants, they will be asked to sign a consent form that outlines the purpose of their participation in providing research data, the benefits and risks to individuals who participate, and the confidential nature of information obtained. Additionally, a separate section of the consent form will allow researchers access to FBT session recordings for analysis and reporting in future publications. While the monitoring of audio-recordings for training and quality control purposes will be part of the expected duties of the PLAN coaches, participation in the research portion (e.g., providing demographic information, and the use of audio recordings for data analysis and scientific publication purposes) is completely optional, and a decision not to participate will in no way affect their role as a PLAN coach on the study, which will be clearly outlined in the consent form. This consent form will be administered by a trained study staff member who will answer any questions the PLAN coach has about his or her participation in the study prior to the on-site training seminar.

Additionally, PLAN coaches will be asked to participate in an audio-recorded semi-structured interview; interested coaches will provide consent over the phone and will be asked a series of questions by a trained post-doctoral researcher on the study. The questions are based on the coaches' discussions with FBT families pre-COVID and amid-COVID regarding food cost, perception, and behaviors. The telephone interviews are voluntary and will be completed based on the coaches' availability. (*This change was made 7.13.20, DSMB approval 12.16.2020)*

Randomization

The DCC will use the REDCap randomization module to create an online password protected randomization system that will facilitate the random assignment of families. When the website is entered, the user will provide information that establishes the eligibility of the family. Group assignments will be revealed only if all eligibility criteria are satisfied. To avoid temporal bias, randomization will be blocked within clinic using random block sizes in order to preclude the possibility that investigators might know in advance the assignment of the last family in a particular block.

Families who enroll in the study will be scheduled for a baseline assessment to gather preliminary study data. Following this visit, the family will be randomized and then informed of the treatment condition to which they have been assigned. *A PLAN coach will follow up with families randomized to FBT to schedule the first FBT visit (Session 0; This change was made on 9.18.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18). Ideally, all treatment sessions will take place in the pediatric practices. If there are issues with space at the pediatric practices, FBT families can be seen at alternate locations (i.e., satellite office, university setting, etc.) for their weekly and assessment sessions. Usual care assessments can also be conducted at an alternate setting. (This change was made on 10.17.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)*

Participant randomization will begin *November 2017 (This change was made on 11.9.2017 prior to review and approval by the DSMB, DSMB approved protocol addenda, 11.2.18) and will go through August 15th, 2019 (This change was made on 6.6.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*

36 families will be randomized each month of this period (9 families per site) with the last three months (Sept. 2018-Nov. 2018) decreasing to 32 families each month (8 families per site) in order to reach 528 families (132 families per site). It is estimated that 43.2% of randomized families will have an age- and weight-eligible sibling; however, sibling recruitment goals will not be included in randomization benchmarks. This estimate is based upon unpublished data in which 163 of the 377 screened families for a similar weight control program (43.2%) had at least one age and weight-eligible sibling.

Randomization benchmarks will be overseen by the Recruitment and Retention Committee. The DCC will prepare a recruitment report for review by the Recruitment and Retention Committee each month indicating the number of randomized total families and randomized minority families. If a clinical site is not meeting randomization benchmarks, the committee will make recommendations on how to improve their recruitment strategies such as identification of alternative sources of participants at the sites, the possible need for increased recruitment resources, more efficient use of existing resources, or the addition of new clinics at one or more site. An official review of randomization benchmarks will be conducted by the Study Executive Committee (SEC) and will occur quarterly at 20%, 40%, 60%, 80%, and 100% of the accrual period. At these time points, if sites are not at 100% or more of their randomization targets, despite remediation efforts, recommendations to redistribute funds across sites may be made at the discretion of the Study Executive Committee to ensure study recruitment milestones are met.

Assessments

Participating parent and child weight will be measured at each major assessment (at baseline and every 6 months), and weight will be assessed throughout FBT as part of a goal setting and reinforcement system by the blind assessors. *Child height will also be measured at each major assessment or as needed to determine progress (This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).* Weight will be measured using a wireless, portable scale (SR Scales, Tonawanda NY), calibration certified. Two weights for each participant will be taken according to a uniform protocol and will be written on hard copy measurement sheets. The handwritten weights will be manually entered into the REDCap database by a blinded measurement coach, which will

eliminate potential measurement bias and minimize errors in data entry (*DSMB approved change, 11.18.19*). *Height will be measured using the portable stadiometer HM200P PortStad by the Charder manufacturing company within the pediatric practices (This change was made on 4.6.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18). Hard copy height and weight measurement forms will be uploaded to the secure REDCap database to allow the CCC, DCC and TFC to check for transcription and/or unit of measurement errors.* All assessors will be provided with the height and weight protocol (see Height and Weight Measurement in **Appendix C**) in order to ensure that participants are being measured accurately and consistently and we will retain the written record of participant height and weight, as well. On the basis of height and weight, BMI is calculated according to the following formula: BMI = kg/m2. Children will be considered overweight at or above the 85th BMI percentile for their age and sex.[35] Parents will be considered overweight if their BMI is greater than or equal to 25 kg/m2, and obese if their BMI is greater than or equal to 30.[36]

In line with Secondary Aim 1, overweight sibling height and weight will also be assessed at each major assessment time point in the same manner described above. *Alternatively, parents also have the option to give consent for assessors to review the non-participating sibling(s)'s medical records to access height and weight data (DSMB approved protocol addenda, 11.2.18).* Additionally, non-participating parent and other sibling heights and weights will be assessed at each major assessment time point if feasible.

Delay discounting will be assessed at baseline and again at 12 and 24 months through use of a brief computer task administered via REDCap on a laptop. Additionally, baseline predictors of treatment outcome will be assessed, specifically, parental inconsistency in rewards and environmental enrichment of the home. Data will be collected using self-report questionnaires designed to assess these constructs administered on-line via REDCap (see **Appendix C**). Finally, for the FBT group, treatment adherence will be measured throughout the study by treatment session attendance and completion of diet and physical activity self-monitoring in habit books or specialized mobile applications.

Participant Timeline

1. Enrollment/Baseline

Families who are eligible for the study will meet with a trained study staff member and will be given written and verbal information about the study. Full disclosure of the purpose of the study, the benefits and risks to individuals who participate, and the confidential nature of information obtained during the study will be explained to participants. Families will be aware from the onset that they will be randomly assigned to an active treatment condition (FBT) or a Usual Care (UC) control condition following baseline questionnaire completion. They will also be aware that their expected participation will be 2 years and may require anywhere from 26 sessions to 96 sessions of FBT if randomized to that condition. The study staff member will answer any questions the family has about the study, and then participants will be consented according to the policies and procedures of the University at Buffalo Institutional Review Board (IRB), the IRB of Record for the study. Study staff will follow-up with families by phone to inform them of their randomization status and will schedule the first FBT visit for those families randomized to FBT. PLAN coaches will also send reminders for FBT visits to their families throughout the study to decrease missed appointments.

2. Follow-up

Following baseline, families will be assessed at months 6, 12, 18, and 24. Links to brief self-report questionnaires via REDCap will be sent by study staff to all randomized families to complete prior to their assessment time point and families will be scheduled for assessment visits to collect height and weight measures and to complete the delay discounting task (DD; at 12 and 24 months only). Families will be greeted by the blinded PLAN coach or assessor at the practices to complete the DD computer task and collect heights and weights according to the protocols. Families will also have the opportunity to complete the REDCap questionnaires if they were unable to do so prior to the in-person assessment. Blinded PLAN coaches and assessors will complete all necessary forms and submit them into REDCap following this appointment. Families will be reminded of their next assessment in the series until it is the final visit. Home visits can be arranged for assessment appointments if necessary, and will be attended by two PLAN staff members.

3. Final Study Visit

The final study visit will be conducted similarly to the previous measurement appointments, although families will not be scheduled for any additional appointments.

4. Early Termination Visit

Families that are terminated early will be notified by phone or an in-person meeting to relay the reason(s) for the termination and provide any resources that would be available and appropriate. The families' access to the website and data links will be eliminated.

5. Unscheduled Visit

PLAN coaches will be available to meet with families at the practices for scheduled appointments. Should a family arrive at the practice without an appointment, the office staff will be instructed to encourage the family to notify their PLAN coach or assessor. The PLAN coach or assessor will follow up with the family by phone, email or text to confirm their next appointment or to schedule an alternate visit time and will then record the contact in the participant tracking form in REDCap.

6. Schedule of Events

See **Table 4** below for an outline of events for study participants.

7. Remote Assessments

Due to the serious nature of Covid-19 and instructed social distancing, in person assessments and sessions are halted. Assessments and sessions will be held through University and Hospital approved platforms such as Zoom, Webex, and Skype for business. An instructional video will be sent to all PLAN participating families to show how to correctly measure height and weight at home with supplies sent from PLAN. Supplies will include a foldable yard stick, a scale and carpenters edge if the families do not have access to one. Remote assessment protocol and scripts have been included in Appendices on page 239.

Table 4. Measurement Timeline

Measures	Method	Time (min)	Examinee	Time point				
				0	6	12	18	24
Primary and Secondary Aim 1 Outcomes								

Weight[1] & Height	Scale and stadiometer	5	P,C,S, NPP	X	X	X	X	X
Delay Discounting (Secondary Aim 2)								
Delay of Gratification	Computer Task	20	P,C	X		X		X
Participant Level Predictors (Secondary Aim 3)								
Parental Survey	Questionnaire	2	C	X				
Environmental Enrichment	Questionnaire	10	P	X				
SAE/AE Survey	Questionnaire	5	P,C		X	X	X	X
Provider Level Predictors (Exploratory Aim)								
Attitudes towards Evidence-Based Treatments	Questionnaire	5	PCP	X				
Attributes of FBT[2]	Survey Questions	5	PCP			X		
Intended Adoption[3]	Questionnaire	1	PCP					X
Participant and Provider Level Descriptors								
Family Demographics	Questionnaire	10	P, P_c	X				
Family Nutrition and Physical Activity (*DSMB approved protocol addenda, 9.29.19*).	Questionnaire	10	P	X		X		X
Participant Adherence to FBT	Session Attendance[1]	NA	P,C	X	X	X	X	X
Participant Acceptability	Client Satisfaction Questionnaire	5	P,C					X
24 Month Survey (*DSMB approved protocol addenda, 9.29.19*).	Questionnaire	15	P,C					X
Provider Demographics	Questionnaire	10	PCP	X				
Provider Usual Care Survey	Questionnaire	10	PCP	X				X
Chart review	Questionnaire	--	Plan Coach					X
Coach Demographics *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*	Questionnaire	5	PLAN Coach					X
Coach Treatment Knowledge *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*	Questionnaire	10	PLAN Coach					X
Coach Attitudes Toward Evidence Based Treatment *(This change was made on*	Questionnaire	10	PLAN Coach					X

7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).								
Coach Attributes of FBT *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*	Questionnaire	5	PLAN Coach					X
Total Time for Each Group								
Child				12	5	10	5	10
Parent				55	5	10	5	15
Provider				25	0	5	0	11
PLAN Coach *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*				0	0	0	0	30

II. Treatments

Usual Care (UC)

The usual care control group will consist of the care typically delivered by the family's pediatrician for children with overweight or obesity. *(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).* The implementation of UC may vary between physicians but typically include an assessment of the child's weight, help removing barriers to weight loss, and introduction of goals for better weight management.

Family-based Behavioral Weight Loss Treatment (FBT)

1. Introduction

Each PLAN coach will provide FBT to families randomized to FBT. FBT utilizes behavior change techniques to target family-wide changes in diet and physical activity habits with the goal of promoting weight loss and subsequently healthy weight maintenance in both the participating child and his or her parent. Preliminary evidence demonstrates effects may even extend to other family members not enrolled in the program. Due to social distancing as a result of Covid-19, all participating families will be shown an instructional video intended to aid in gathering reliable height measurements.

2. Conceptual Components

Dietary Goals

Consume 1200-*1800* kcal/day *(This change was made on 4.6.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)*. Increase fruit and vegetable consumption and decrease consumption of high energy dense and/or low nutrition density foods and beverages to help shape food preferences. Calories will be adjusted according to weight change without reducing calories below 1000 to ensure essential calories are being met for a healthy diet (http://health.gov/dietaryguidelines/2015/guidelines/appendix-2/).

Physical Activity Goals

90 minutes of moderate to vigorous physical activity each day for children and 60 minutes of moderate to vigorous physical activity 5 days per week for adults. Decrease time spent engaging in sedentary activities such as watching TV and playing computer games *to two hours or less per day (This change was made on 4.7.2017 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)*. Information on achieving a healthy number of sleep hours each night will also be given. Moderate to vigorous physical activity goals will be shaped and mastered at different increments.

Behavior Change Tools

Self-monitoring, goal setting, problem solving, stimulus control, positive parenting techniques such as the provision of incentives for behavior change, assistance in reducing the need for immediate gratification using episodic future thinking (EFT) – a method for improving impulse control, and finding behavioral substitutes for highly reinforcing food. Families will have access to traditional paper and pencil self-monitoring, and after self-monitoring skill is acquired, families can choose to use traditional or technology-based self-monitoring systems such as use of a FitBit or MyFitnessPal.

Delay of Gratification

The ability to delay gratification can be quantified by delay discounting (DD), or the tendency to discount large future rewards for smaller, immediate rewards.[37] Research suggests that children with obesity are more likely to choose a small immediate food reward over a larger delayed food reward.[38-40] Inconsistent parenting and less enriched environments also have a negative impact on ability to delay gratification. Thus, we use FBT to improve parental consistency to reduce DD, alter the shared family environment to reduce DD, and provide individual skills in parents and children to reduce DD.

Social Facilitation Approaches

Social facilitation approaches are designed to help families engage in social events and activities as alternate reinforcers to unhealthy eating and activity behaviors. Participants are taught assertion and communication skills to improve their social interactions within their existing social networks and participants are encouraged to form new relationships that serve to support and reinforce healthy behaviors. Additionally, children are coached on their abilities to deal with teasing to reduce negative social interactions.

Educational Tools

The Traffic Light Eating Plan and Food Reference Guide, which utilizes GREEN, YELLOW, and RED labels for food to guide families toward the goal of consuming low energy-dense, high nutrient-dense foods will be used. Foods are assigned a traffic light color based on the average calories to obtain basic nutrients for each food group in the Food Guide Pyramid. For example, if a serving of a vegetable is less than 60 kcals/serving it is a GREEN food, if it is between 60-80 kcals/serving it is a YELLOW food, and if the vegetable is greater than 80 kcals/serving it is a RED food. Foods in the other food group categories are designated YELLOW or RED based on how many calories it takes to provide nutrients for foods in that food group (vegetables are the only food group with GREEN food designations)

The Traffic Light Activity Program and Activity Reference Guide also utilize GREEN, YELLOW, and RED labels for different levels of caloric expenditure to guide families toward increasing physical activity and reducing sedentary behaviors. Sedentary activities, those that are 1.9 3 METS (Metabolic Equivalents) or less, are considered RED activities, and the goal is to reduce them, particularly, screen time. YELLOW activities are 2.0 to 2.9 METS, equivalent to the lower end of MVPA (moderate to vigorous physical activity). Activities that are 3.0 METS or greater are considered GREEN activities. The goal is for child participants to obtain 90 minutes of MVPA per day and for parents to obtain 60 minutes of MVPA at least 5 days per week. Activities can include lifestyle behaviors (e.g., walking to school, biking with friends), or participating in organized sports, but must be engaged in for bouts of at least 10 minutes.

3. Mastery-Based FBT Level System[41,42]

FBT will be implemented on an individual basis to adapt the dose of treatment to the individual participant needs. While adaptable, FBT "dose" will be consistent with the USPSTF recommendation of 26 or more hours of individualized, intensive intervention.[13,43] The minimal FBT dose includes 8 weekly visits, 8 two times per month visits, and 6 monthly visits for the first year, and 4 quarterly visits for the second year of intervention. A mastery system will be used to ensure parent and child are reading and understanding the program materials. Families are encouraged to initiate behavior change at their pace, and are rewarded for incremental changes. The goal for all families is for children to show a reduction of percent over BMI of at least 10 percent.

Mastery of program information recognizes that not everyone learns at the same rate. Master of program content includes five areas: 1) changes in individual diet and activity; 2) changes in the family; 3) changes in peer networks; 4) changes in community; and 5) relapse prevention. Instruction on parenting will be given throughout each section. Progression through treatment topics will be based on mastery of treatment knowledge as demonstrated by scores of at least 80% on quizzes related to the content of each unit. If scores of 80% are not achieved at the end of each unit, areas for remediation will be targeted and corrective feedback will be given until scores of 80% are obtained (multiple versions of unit quizzes will exist for this purpose).

Changes in eating, activity and parenting are rewarded using a point system. Children and parents work independently toward their goals at their own pace. They will focus on the behavioral goals in the areas in diet, physical activity and parent/child interactions as part of the reinforcement system. The other supporting behaviors skills are encouraged through program materials, interactions with coaches, and parental praise. Participants move toward the ultimate behavioral goals of FBT independently of each of the specific goals or other participant in the family (children and parents move at their own independent pace). The behavioral skills we are emphasizing have demonstrated success over traditional FBT through 1-year follow-up.[42] These behavioral skills have demonstrated associations with weight loss and weight loss maintenance (e.g., changes in diet, monitoring, sleep[44]; episodic future thinking[45-48]; skills related to the family/home and social environment[49]; relapse prevention skills[50,51]). **Table 5**, displays the behavioral goals, and the frequency of sessions based on the families weight loss success. The bolded behaviors will be reinforced with points, all others will be reinforced by praise.

MASTERY-BASED FBT BEHAVIORAL SKILLS LEVEL SYSTEM					
Session Frequency					
Session frequency will be determined solely by weight change[1], as measured in each treatment session. In order to reduce session frequency, both parent and child must meet weight loss goals for 2 consecutive weeks. Any subsequent weight gain will result in an increase in session frequency until pattern of loss has been restored.					
Weight		Weekly	Bi-Weekly	Monthly	Quarterly
	Reduction in Percent Over BMI (C)	15%	Weight loss ≥20%	Maintain weight loss ≥20%	Maintain weight loss ≥20%
	Reduction in Percent of Total Body Weight (P)	10%	Maintain weight loss ≥10%	Maintain weight loss ≥10%	Maintain weight loss ≥10%
Mastery Behaviors					
Mastery behaviors to be assigned by PLAN coach according to treatment protocol; families must demonstrate mastery (meeting goal 5 of 7 days) for 2 consecutive sessions in order to progress to next mastery level. Behaviors will be tracked via P & C Habit Books.					
Nutrition	**Calorie Range** *total per day*	1200-*1800*[2] *(*This change was made on 4.6.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18*).*		Adjusted[3]	
	GREEN Foods/Drinks *total per day*	2	3	4	≥5
	RED Foods/Drinks *total per day*	≤10	≤7	≤4	≤2
Physical Activity (PA)	**GREEN PA (C)** *minutes X days per week (DSMB approved protocol addenda, 11.2.18).*	30x3	45x4	60x5	90x5
	GREEN PA (P) *minutes X days per week (DSMB approved protocol addenda, 11.2.18).*	20x3	30x4	45x4	60x5
Driving Behaviors					
Driving behaviors to be assigned by PLAN coach according to treatment protocol and individual needs. Targets listed reflect overall PLAN goals to be achieved through shaping; session goals will be assigned to progress from baseline to target.					
Parenting *(This change was made on 10.17.18 prior to*	**Praise** *times per day*	1	2	3	4
	Stimulus Control *times per week*	1	2	3	4
	Daily Check In *days per week*	4	5	6	7

review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)	**Meal Planning** *days per week*	2	3	4	5
Weight Graph*	**Graphing Weight (C)**	2 days per week			
	Graphing Weight (P)	7 days per week			
Nutrition	Dinner Prepared at Home	≥3 days per week			
Routines	EFT Practice (P)	≥5 times per week			
	Recreational Screen Time	*≤2 hours per day or ≤15 hours per week* (This change was made on 4.7.2017 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)			

	Healthy Sleep Routines (C)	**9-11 hours per night**
	Healthy Sleep Routines (P)	7-9 hours per night
Social	Engaging in PA with Family	≥3 times per week
	Engaging in Healthy Eating & PA with Friends	≥3 times per week
	Accessing Healthful Community Eating & PA Resources	≥3 times per week

NOTES ON MASTERY-BASED FBT BEHAVIORAL SKILLS LEVEL SYSTEM:

- C = child; P = parent; PA = physical activity; EFT = episodic future thinking
- Weight percentages are a guide
  - Weight loss will be individualized based on initial participant weight and subsequent weight loss
  - [1]Weight change will be assessed in reference to lowest measured weight (e.g., if loss in week 3 and gain in week 4, loss can only occur in week 5 if weight is below week 3 measurement)
- Bolded behaviors will be reinforced by the point system
- Calorie ranges individually assigned based on weight loss
- [2]Calories for weight loss will range from 1200-1800 to promote 0.5 lb. loss for children and 1 lb. loss for parents each week
- [3]*Adjusted* refers to adjustment of caloric intake (as monitored by coach) designed to maintain body weight in a healthier weight range
- **Completing the weight graph involves having families weigh at home. If families do not have access to a home scale, the coach will lend them a commercial-grade scale for the duration of the study (This change was made on 10.17.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*
- *Specific and timely praise statements*
  - Verbal praise statements
  - Physical gestures such as hugs

- *Stimulus control*
    - Arranging the environment so triggers are less impactful (i.e., reducing cues for less healthy behaviors and increasing cues for healthy behaviors)
    - Number of stimulus control changes in the environment that were operating that week
- *Episodic future thinking practice*
    - Practicing simulating future events when making decisions about small immediate rewards vs. larger delayed rewards

Meeting behavioral goals is assessed by the FBT PLAN coach during sessions by reviewing parent and child daily habit books and a self- report FBT monitoring checklist completed by the parent that tracks behavioral goal progress over the previous week. Weight loss is conjointly required, in addition to self-reported habit changes, to increase assurance in the accuracy of self-reported behavior changes. Since weight loss is related to these self-reported behavioral changes, we do not want to reinforce participants who report making the changes but who are not losing weight. In this way, participants who report behavioral changes are not moved to the next phase of session frequency unless they show expected weight loss. Likewise, participants who show weight loss but who do not report behavioral change will remain at the same session frequency until behavioral change meets mastery criteria. This is to ensure that behavioral skills that are known to promote weight loss and weight maintenance are acquired and maintained over time. Weight loss goals were selected based on literature demonstrating a 5-10% loss in body weight yields clinically significant changes[52,53]; however, they may be individualized based on initial participant weight and subsequent weight loss. Participants will be moved from weekly sessions to biweekly sessions to monthly sessions to quarterly sessions when they have met the specified behavioral goals for at least 2 weeks and when they have met the weight loss criterion. Weight loss criteria for weekly, biweekly, and monthly sessions were designed for weight loss, and quarterly sessions for weight maintenance.

Dosage will be based on mastery of program material, progress in behavior change, and weight change. Sessions will be weekly for at least 8 weeks and until at least a decrease of 10% percent over BMI is observed. Sessions will go to 2 times per month and will continue for at least 8 weeks or until a new weight loss goal is attained. Treatment will transition to maintenance goals and less frequent meetings. If a family is able to reach the weight maintenance after 6 months, they will switch to quarterly meetings until the end of the study. If participants are unable to maintain behavioral goals or weight loss/maintenance goals of any level at any point, they will be returned to intensive weekly sessions to prevent relapse. This will occur until participants are able to maintain their weight loss for 2 weeks at the given level at which point they will continue to progress through the dosing schedule. See **Table 6** for examples of different “dosing” based on rates of progress through the program.

TABLE 6. FBT Sessions Over 24 Months Based on Differential Rates of Mastery of FBT

	Maximum Dose	Moderate Dose	Minimum Dose
Number of Weekly Sessions	48	24	**8**
Number of Biweekly Sessions	24	12	**8**
Number of Monthly Session		12	**6**
Number of Quarterly Sessions			**4**
Total Number of Contacts Over 24 Months	72*	48	**26**

Note: *With the mastery model, it is possible that a family could be seen weekly for the duration of the study

a. (approximately 96 visits over the course of the entire study). However, we have chosen to illustrate a more typical visit frequency for families slow to master behavioral skills of 72 sessions over the course of the study. If a family is showing signs of becoming a retention risk, then we will adjust the frequency of FBT sessions to a treatment schedule that is acceptable to the family (*This change was made on 3.18.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19*).

4. Family Sessions

Session Structure

Each treatment session will be structured as follows: parents and children are first weighed and then have a 30-60-minute individual family meeting with their PLAN coach, during which time the family: 1) reviews habit books and self-report checklists with their PLAN coach; 2) receives feedback on behavioral skill acquisition, weight goals, and progression through the levels of FBT; 3) receives education on diet and physical activity (See **Table 7** for a list of education topics); 4) is taught behavior change techniques; 5) sets behavioral goals for the week; and 6) reviews and addresses any barriers to goal attainment or to adherence with the weight loss behaviors.

Table 7. Overview of FBT Education Topics

Unit	Chapter	Topics
1	**1**	Introduction to PLAN; Pediatric Care Practice, Learning, Activity and Nutrition
2	**2**	Traffic Light Eating Plan
3	**3**	Monitoring Food; Recording Daily Intake
	4	Monitoring Red Foods
4	**5**	Measuring Foods; Portions
5	**6**	Recognizing Hunger and Satiety Cues
6	**7**	Reading and Understanding Food Labels
7	**8**	Pre-Planning
8	**9**	Positive Parenting and Praise
	10	Being a Good Model for Your Child
	11	Encouragement; Daily Meetings
9	**12**	Goal Setting; Cutting Calories
10	**13**	Traffic Light Activity Program
11	**14**	Energy Balance

12	**15**	Stimulus Control
13	**16**	Healthy Shopping and Budgeting
14	**17**	Healthy Routines: Behavior Chains; Meal Regulations
	18	Healthy Routines: Sleep; Self-Weighing
15	**19**	Reviewing Traffic Light Eating Plan Concepts
16	**20**	Reinforcement and Rewards
17	**21**	Prospection
18	**22**	Problem Solving Skills
19	**23**	High Risk Situations: Restaurants, Parties, Holidays and Vacations
20	**24**	Recipes and Healthy Cooking
21	**25**	Decreasing Red Activity
22	**26**	Social Support and Making Social Networks Even Healthier
	27	Planning Physically Active Social Gatherings
23	**28**	Taking on Teasing
	29	Stigma and Body
24	**30**	Emotional Eating
25	**31**	Focusing on Health at School, Work and Neighborhood
26	**32**	Consolidating Healthy Living Skills
	33	Maintaining Motivation and Relapse Prevention
	34	Long-Term Maintenance

Session Content

FBT focuses on parents as the gatekeepers of health-related behaviors by improving parenting skills for the modification of child eating and activity behaviors as well as general child-parent interactions. Parents will be trained in general parenting methods to foster positive behavior change, such as learning to praise their child and implementing a parent-delivered reinforcement system. Reinforcers, such as additional time spent with a parent engaging in a favorite activity or a sleepover with a friend can be earned for meeting dietary and activity goals. Parents will be provided with strategies to modify the shared home environment in order to facilitate the behaviors that are targeted. Children and their parents will be taught problem solving and preplanning to deal with challenging situations, as well as techniques for coping with teasing. A unique aspect of FBT is the emphasis on creating an ecology that supports long-term change, which includes modifying the family environment, reshaping peer group networks, and ensuring that there are community resources available to the family to maintain behavior change. In this way, barriers to weight loss and maintenance of the loss are addressed across contexts, reinforcing healthy lifestyle changes and making them more readily sustainable.

5. Technological Support

A study website will provide information to families about FBT, provide downloadable versions of the Traffic Light Eating Plan and Food Reference Guide and the Traffic Light Activity Program and Activity Reference Guide, and provide links to handouts with information on healthy cooking and recipes, getting more physical activity, and positive parenting tips. All quizzes to assess mastery of educational materials will also be accessible via the study website, with multiple versions of quizzes on each topic available, recognizing that some participants will acquire mastery of the required behavior change information more slowly than others.

III. Training and Fidelity Monitoring

General Training in Study Procedures

The DCC will work closely with clinic investigators to ensure the training and certification of all staff that perform study procedures. These efforts will focus on ensuring that (1) investigators, coordinators, and designated backups have appropriate familiarity with the details of the protocol; (2) all evaluations are carried out by individuals certified as being knowledgeable about and experienced with relevant study procedures; and (3) relevant staff are comfortable with data entry and management procedures. To accomplish these goals, the following procedures will be carried out.

a. During the multisite FBT training at WU, the DCC will facilitate a meeting to discuss the details of the protocol and the standardization of data collection and to provide hands on experience with data collection procedures. During that meeting, staff will be certified to perform the task to which they are assigned by demonstrating the appropriate competencies and knowledge.
b. Certification of data entry personnel will require that they establish familiarity with the system by entering data on at least four test subjects.
c. At least two individuals will be certified to perform every task to ensure that backup is always available.
d. ID numbers of individuals performing assessments will be included on data forms and will be computerized. Using a DCC maintained list of certified personnel, it will be routinely confirmed that assessments have been performed by certified individuals.
e. Modified data on forms will be initialed and dated by the person making the change.
f. When new personnel are hired during the study, individual clinics will be empowered to certify the new person as an alternative to less efficient centralized efforts.

PLAN Coach Training and Fidelity

FBT PLAN coaches will be hired by the clinical site PI. Clinical site PIs will be encouraged to hire individuals with at least a bachelor's degree, and who possess, or are pursuing, an advanced degree in a related field of study such as dietetics, social work, or clinical psychology. Basic demographic information will be gathered regarding PLAN coach age, gender, educational background, race/ethnicity, prior experience with families or behavioral health interventions, etc. to help tailor training to their level of experience and to identify any PLAN coach level descriptors associated with ease of acquiring fidelity and competency in intervention delivery. These PLAN coaches will be trained using a combination of education, interactive role-playing, simulations, and treatment practice with pilot patients.

https://buffalo.zoom.us/j/2320132211?pwd=VUJHMGRVSlU1NzYwUHZVMjh3MUYrdz09

1. Multisite FBT Training

PLAN coaches will attend a multisite FBT training at Washington University in St. Louis during the week of April 24-28, 2017 and at the University at Buffalo on July 11-12, 2017. All PLAN coaches will complete the on-site training workshops and must earn an 80% or above on the post-training assessment at the end of these trainings in order to be certified to initiate recruitment. If any coaches do not achieve this score, remedial instruction will occur and they may repeat the quiz.

2. Educational Materials

The study website will include articles on FBT for the PLAN coaches to read, and it will also provide a thorough training manual to teach behavioral, diet, and exercise principles used in the study, as well as other relevant readings. The website will also include web-based pre- and post-assessments of FBT knowledge. PLAN coaches will need to demonstrate mastery of the material prior to working with families.

3. Interactive Role Playing and Simulation

Live and Skype training sessions will provide the opportunity to role play important behavioral skills. Training will conclude with a treatment session simulation, during which PLAN coaches will be rated on their utilization of FBT components to ensure competency. If the written and simulated assessments demonstrate lack of knowledge and skills, FBT concepts will be retaught until mastery is achieved.

4. Pilot Patients

PLAN coaches will practice delivering FBT to two families (at least 12 sessions each) not randomized to the study. They must demonstrate competency on at least four consecutive FBT sessions for each family, as determined by ratings of their audio- recorded treatment sessions, before they may begin treatment with a randomized family.

5. Post-Training

Training acceptability will be assessed using a 6-item self-report questionnaire adapted from Lyons and colleagues. PLAN coaches will receive supervision throughout their delivery of FBT. Manuals and checklists will be used during FBT treatment sessions, and each FBT session will be audio recorded. Supervision will be provided for all PLAN coaches by study staff experienced in FBT from the Training and Fidelity Core (TFC). Treatment fidelity will be evaluated by random audits of audio recordings using integrity checklists. Audits will be conducted by trained TFC raters who were not involved in training the PLAN coaches. The text below provides a summary of the PLAN coach training and quality control process for the present study.

6. Alternate Training

As some turnover in PLAN coach staffing is inevitable following the initial training workshop and piloting of families, an alternative method for training and certifying PLAN coaches has been developed. Within the first two weeks of hiring, new PLAN coaches must complete HIPAA and CITI training, watch the video recordings of the first training and pass the post-training quiz with a score of 80%. They will then role play four mock sessions with their fellow PLAN coaches, which will be audio recorded. FBT supervisors will review these sessions and provide feedback. The coaches will then schedule four simulations with the Training and Fidelity Core. After completing these simulations, the coach will begin seeing families randomized to FBT. All sessions will be audio recorded, reviewed by supervisors and feedback will be provided in writing and over the phone until 8 consecutive sessions have been rated 'competent'. Once the replacement coach receives satisfactory ratings on at least eight consecutive sessions, they will be certified to work with randomized families *(DSMB approved protocol addenda, 3.18.19).*

7. Summary of FBT Training Process:

a. Complete HIPAA/CITI training as required by IRB of Record and/or participating clinical sites
b. Read and become familiar with:

i. Study Protocol
ii. General Articles Describing FBT
iii. Treatment Manuals
iv. Traffic Light Eating Plan and Food Reference Guide
v. Traffic Light Activity Program and Activity Reference Guide

c. Participate in on-site training workshops to be held prior to the randomization of the first participant
d. Earn a score of 80% or greater on post-training assessment
e. Engage in role plays *and simulations* with a TFC FBT expert to practice key behavioral intervention strategies *(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*
f. Conduct at least 12 treatment sessions with two pilot families
g. Participate in regularly scheduled teleconference Clinical Case Review Groups for supervision with a TFC FBT expert and other PLAN coaches
h. Provide audio recordings of the first four sessions with each pilot family and then two audio recordings from randomly selected visits with pilot patients for rating by the TFC FBT expert; if audits of any of these recordings result in competency ratings by the TFC FBT expert of less than "competent," the PLAN coach will receive written and verbal corrective feedback and must submit audio recordings of all subsequent pilot sessions until two consecutive sessions (for each family) are rated as "competent" before working with families randomized to FBT
i. "Certification of Interventionist" form signed by TFC FBT expert and returned to DCC prior to starting intervention with participants which confirms that:
    i. Appropriate human subjects training has been completed
    ii. Readings have been done and understood
    iii. Pilot training has been successfully completed
    iv. The PLAN coach agrees to uphold the highest ethical and professional standards while working with participants in the study

8. Booster Training

a. Booster training workshops will occur every 6 months; PLAN coaches must score 80% or greater on quizzes given after workshops.
b. Two intervention session recordings will be randomly selected by the TFC FBT expert every 6 months to ensure PLAN coach adherence to the treatment protocol
c. Recordings must receive a competency rating of "competent." If rated "not competent," corrective feedback is provided to the PLAN coach and session audio recording reviews will be repeated until two randomly selected recordings are rated as competent.

Assessment Training and Fidelity

Assessments will be performed only by trained and certified staff members. Details of the assessment protocol and the standardization of data collection procedures will be presented at the FBT training. Additionally, assessment staff will gain hands on experience with the relevant data collection procedures and will be certified to perform these tasks during the training. At least two individuals at each site will be certified to perform each task to ensure that backup is always available. The DCC will maintain lists of certified personnel. Individual clinics will be empowered to certify new personnel as an alternative to the initial centralized training session. Video-recordings of skilled assessors conducting the assessment procedures will be available following the training workshop to aid in standardization of training across sites.

1. Initial Training

All PLAN coaches and assessors will complete assessment training at the WU FBT training during the week of April 24-28, 2017 and the UB FBT training on July 11-12, 2017. During these trainings, staff will learn standardized procedures for collecting height and weight, *(This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18),* and collecting data via REDCap (including family surveys). Staff will have the opportunity to pilot these procedures on volunteer staff and study team members throughout the training. Additionally, all sites will be provided with the necessary educational materials to ensure adherence to assessment procedures following the training.

Study tasks will be performed only by staff that are trained and certified to perform their assigned task. At the in-person trainings or video-taped instructional trainings, the standardization of data collection procedures will be discussed. Additionally, staff will gain hands on experience with the relevant data collection procedures and will be certified to perform these tasks. The DCC will maintain lists of certified personnel, and individual sites will be empowered to certify new personnel as an alternative to the initial centralized training session. During the initial session, staff will be rigorously trained to certify new personnel that may be added during the implementation of the study via procedures detailed by the DCC. The DCC assessor training will be recorded, and video-recordings of skilled assessors conducting the assessment procedures will be available following the training workshop to aid in standardization of training across sites.

2. Certification

All PLAN coaches and assessors will be required to reach reliability *for height and weight measurements* (3mm for height, .25 lbs for weight, *this change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).* Coaches will complete 10 different measurements according to the height procedures. If the reliable staff member and new staff member do not meet acceptable reliability criteria, additional participants should be measured by both staff members until adequate reliability is established. Additionally, they must prove competent in administering REDCap surveys as assessed by the clinical site project coordinator (*This change was made on 11.9.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).* When PLAN coaches and assessors reach reliability or competency for each of these measures, they will receive a "Certification of Assessment."

II. Research Procedures and Approach

Practice Retention

1. Expectations

a. Create realistic expectations *prior* to recruitment.
b. Provide practice with information regarding the study (e.g., recruitment, treatment, space considerations).
c. Explain to practices how this study may impact their workflow.
d. Keep clear and timely communication with the practices.

2. Ongoing Strategies

a. Prepare and post/distribute recruitment materials for practices.

b. Remain friendly and open to answer any questions or concerns.
c. Lend solutions to any issues that may arise in the practice concerning the study.
d. Pay out incentive money
e. Update progress of study and recruitment goals (This change was made on 3.23.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).

Participant Retention

Each of the sites has experience in subject retention, and both the University at Buffalo and Washington University have experience in retention in FBT. We will use a 3-step evidence-based approach to retention.[54-56] First, we will gather names, addresses and phone numbers of at least two family members or friends who have regular contact with the participating families. Second, we will send greeting cards for birthdays and holidays to the participant over the course of the study. Third, we will provide personal and telephone contacts with the same staff over time whenever possible to facilitate familiarity and rapport. We will also provide continued emphasis on the importance of their contribution to their community and the legitimacy of the project.

1. Expectations

a. Emphasize up front the common challenges families face.
    i. Big time commitment
    ii. Family emergencies
    iii. Changes in routine
    iv. Resistance from family members
    v. Some difficulty reaching goals
b. Discuss how the study is a big commitment.
c. Discuss why participation in the study is worth it.
    i. State-of-the-art program that teaches the child and parent how to lose weight and maintain the loss
    ii. Decreased risk for health problems for the child and parent now and in the future
    iii. Prevention of heart disease and type 2 diabetes
    iv. Increased energy, better sleep, and better overall fitness from regular exercise
    v. Improvement in mood and sense of accomplishment from completing the program
    vi. Mastering skills earlier in life to reduce the social stigma of obesity
d. Discuss commonality of resistance from child and how to handle it.
e. Emphasize the expertise of the staff and their ability to help with this problem.

2. Ongoing Strategies

a. Always have a positive attitude and treat all participants in a caring, person-centered manner.
b. Thank the families for coming and praise efforts from week to week.
c. Treat each participant as an individual and demonstrate respect for cultural practices.
d. Emphasize the potential importance of the study in conversations.
e. Respect the family's and school's schedule and demonstrate appreciation for their efforts to attend.
f. Show consideration for the family's schedule by starting and ending on time.

3. Participation and Retention Benchmarks

Intervention Participation

Participants are expected to attend at least 70% or more of their prescribed FBT meetings, as indicated by their level of mastery of program knowledge and skills. The study staff will use a "case management approach" to ensure that each participant's active involvement is cultivated and tracked, which will include opportunities for make-up sessions, telephone sessions, and home visits to maintain participation.

Families randomized into the UC group will attend medical appointments at the discretion of the physician according to their usual practices and availability, as well as the preferences of the participating family. As such, no benchmarks for usual care visits are specified.

Assessment Participation

Retention guidelines indicate that at least 80% of participants who are randomized will be retained at the 24-month assessment. It is estimated that drop-out rates will be higher in the first six months, as a steeper dropout rate was observed in the first four months of the recently completed, NIH funded COMPASS trial, than in the following 20 months. In order to maintain participation in assessment time points, we will offer flexible scheduling, make-up audio sessions, and home visits.

4. Participant Tracking

Participants will be tracked in REDCap in order to maximize retention in the study and, as necessary, to capture any drop-outs or withdrawals that occur during the study period. PLAN coaches can verify the status of their FBT families by accessing the REDCap Record Status Dashboard, which will list all existing records/responses and their status (i.e., incomplete or complete) for every data collection instrument in the study. PLAN coaches can verify that FBT families and UC families at their site have completed assessment time points as well as the family members that participated in these assessments. Additionally, PLAN coaches can utilize the REDCap calendar to manage participants and appointments, and they will complete Tracking Forms each week to document session attendance or absence of their FBT families. In order to ensure that families in both arms are captured at all necessary time points, the DCC will send regular reports to indicate participant status and subsequent required actions on behalf of the study team.

5. Participant Withdrawal or Termination

Children and parents can withdraw from the research at any time, and siblings and non-participating parents can withdraw or be withdrawn without any consequences to the other family members' status in the study. If participants withdraw, they will be debriefed about the nature of the study, asked permission to obtain data collection through medical records or brief appointments, and, if terminated, provided with the reason for their removal as well as a referral if deemed appropriate. Any information that had been provided may be retained by the researcher and analyzed. This includes permission to collect body composition information from their physicians at determined measurement time points (if not revoked upon their withdrawal).

Participants who exhibit unhealthy weight loss, clinically concerning symptoms of disordered eating, or develop an illness or condition that would bias the data may be withdrawn from research analyses, as determined by the SEC, SMC, and the Data Safety and Monitoring board (see **section IX**) *and referred to an appropriate professional (This change was made on 3.23.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*

Lost to Follow-Up for FBT Families (DSMB approved protocol addenda, 9.29.19)*:* A designation of Lost to Follow-Up (LTF) is applied to intervention families that we have not had contact with for 3 months (*90 Days).*

a. During the 3 months after last contact the Coach should:
    i. Attempt all retention strategies outlined by the retention algorithm (Appendix Z of Manual of Procedures.
        1. For instance, handwritten note, text, call (day, evening, and weekend), email, etc.
    ii. Note: Families going on a scheduled hiatus are NOT LTF.
b. Once the family is labeled lost to follow up, Coaches will attempt contact them monthly
c. A family can come back to the study after being marked LTF.
    i. When an LTF family comes back, re-engagement will include:
        1. Review of contact info, alt. contacts, and best methods of contact and time of day.
        2. Review of initial motivation for study and link it to why they want to continue.
        3. Problem solving barriers to attendance and make plan for future
            a. Attempt to rebuild momentum.
        4. Review weight change during break.

Risks to Human Subjects

1. Potential Risks

Safety of human participants is of utmost concern especially in a trial involving children. Efforts will be made to limit the use and disclosure of participants' personal information, including research study and medical or education records, to people who have a need to review this information. We will collect information on changes in height and weight from medical records as needed if a family discontinues study participation or is unable to provide data at the 24-month time point. The assessment process may carry potential risks. For example, some of the questions may be upsetting to participants, and some participants might feel uncomfortable having their height and weight measured. Other risks associated with participation in the intervention include possibly feeling hungry when dieting or sore after exercising. In addition, in select children, excessive attention paid to dieting may lead to an eating disorder or to growth problems. There are also several potential risks to family members in the course of therapy. First, there is a degree of inconvenience for family members who may miss work, school activities, meetings, etc. Second, there is the risk, as there is in any therapy, of a stress reaction occurring. Third, there may be some family disagreements during the implementation of the intervention as issues of family functioning, communication, and discipline may be discussed.

Finally, there is the risk of a breach of confidentiality. Coach interviews are expected to be no or minimal risk of asking the interview questions.

2. Adequacy of Protection Against Risks

All key personnel involved in the design or conduct of research involving human subjects will receive the required education on the protection of human research participants prior to the start of the study. The PLAN coaches will collect and manage data collected from these participants and will not engage the pediatricians in the research. If required by a site's individual IRB, PLAN coaches will complete Business Associate Agreements prior to their work within the practices.

Individuals administering assessments will be made aware of the possibility of a participant's discomfort about answering questions or having height and weight measured. Participants will be informed that they do not have to answer any questions that make them uncomfortable, and height and weight will be measured in private to minimize embarrassment. Participants will be advised of the possibility of hunger with dieting or soreness after exercise. In order to reduce the risk of exercise-related injury, all participants will be encouraged to follow their primary care physician's instructions regarding exercise.

On an ongoing basis, the family meetings will serve as the primary venue to detect and address any eating disturbance, and study PLAN coaches will be trained to monitor, recognize, and intervene if symptoms of disordered eating behaviors or attitudes emerge. If a PLAN coach notices that a participant is consuming a nutritionally inappropriate quantity or quality of foods, he or she will assist the participant in achieving appropriate intake. Should a participant show symptoms consistent with an eating disorder during treatment, the PLAN coach, in consultation with the treatment supervisor at the Training and Fidelity Core, will decide whether to recommend that the family be withdrawn from treatment and/or refer them for treatment elsewhere. This will be stated in the consent form.

To the extent possible, flexibility in scheduling treatment sessions and assessments will help minimize the inconvenience of missing work, school activities, or meetings due to treatment obligations. Having expert and well-supervised PLAN coaches conduct treatments will mitigate the risk of a stress reaction occurring. The PLAN coaches will be aware of how to recognize such stress responses in their early form, and will conduct sessions in such a way as to reduce such responses. PLAN coaches will also be trained to deal with potential family disagreements. If any participant appears to be in crisis, appropriate action will be taken based on established suicide and crisis assessment protocols, and any adverse event will be reported promptly to NIMH and to the IRB of Record.

3. Confidentiality

Patient confidentiality will be maintained in compliance with HIPAA regulations. Any identifying information will be kept confidential, and patient records will be kept in locked files protected by two locks and accessible only by those directly involved with the implementation of the study. The locked files will be housed in the clinical site PI's office at each site, and no data, files, or any other study participant information will leave these offices. Treatment session audio recordings will be securely stored at each center, and will be labeled by study ID, date and session number, without further identifiers. These recordings will be stored in locked cabinets with restricted access and will be destroyed three years after the end of the study, depending

on the policy set by the Study Executive Committee and the IRB of record. Copies of selected session audio recordings, labeled as above, will be sent to the Training and Fidelity Center at WU for auditing.

All coach interview audio files will be stored in a double password protected computer and a de-identified file name. The audio files will be transcribed using Amazon Transcribe, once this is completed the audio files will be destroyed. The transcription file will be de-identified and also stored in a double password protected computer.

All materials, discussions, and proceedings of the Data and Safety Monitoring Board (DSMB) are completely confidential, and members and other participants in DSMB meetings are expected to maintain confidentiality. All employees of the study with access to protected health information are required to complete HIPAA and CITI training and comply with the privacy procedures in place at their institutions.

Potential Benefits to Human Subjects and Others

The prevalence of overweight in both children and adults has been increasing at an alarming rate. Effective treatments for childhood obesity have the potential to provide substantial health benefits and to decrease the number of children tracking obesity into adulthood. Although we do not guarantee any benefits from this study, the intervention, if successful and if it replicates our previously completed studies, has several potential benefits. Potential benefits to participants include improved physical health, improvements in the quality of nutritional intake, increases in physical activity, reduction in body weight, and long-term maintenance of this reduced body weight. The treatment may also reduce the stress on the family posed by the burden of obesity. In addition, it is possible that skills to solve ongoing problems that perpetuate obesity may improve. The growing prevalence of obesity and its health-related consequences highlight the need to examine potential treatments that may help children to lose weight and sustain weight loss over time, and to investigate the effectiveness of providing these treatments within primary care settings. Therefore, the potential risks that are associated with this study are reasonable when considering the many health-related benefits that the participants and their families may gain. Coach interviews has no benefits to the coaches. Potential benefits to researchers include: detailed accounts of discussions of food cost and perception between PLAN FBT coaches and families, direct discussions with coaches (implementers of the treatment intervention), and a deeper understanding of when/how/why coaches tailor pieces of the treatment.

II. Data Safety and Monitoring Plan

Safety Oversight

An independent panel of experts with experience in clinical trials, health services research, biostatistics, and pediatric and adult obesity, consisting of at least three members who are not affiliated with the study – including a clinician with expertise in childhood obesity, an epidemiologist, and a patient advocate – will be appointed to constitute a DSMB. Members named include study staff and a representative of NIH. In addition, the study PIs, Drs. Leonard Epstein and Denise Wilfley, the director of the DCC, Dr. Ken Schechtman, and designated staff will attend the DSMB meetings (as non-voting participants) and will be responsible for preparing

and presenting data reports from the study. The DSMB will provide oversight and ongoing monitoring of participant safety, recruitment and retention rates, quality of data collection, and integrity of the study and will convene during the first 3 months of the study to allow for a full review of the study protocol. The study data will be reviewed by the DSMB every 6 months via teleconference or more frequently if preferred by the DSMB. The DSMB will receive a report from the study DCC approximately 4 weeks before each review date. These reports will include the major variables necessary for monitoring safety and quality of data collection and integrity of the study and will include otherwise blinded outcome data. Because study protocol and consent forms are relevant to the safety and quality of data, the DSMB will also review these documents before the onset of the study. Based on this review, the DSMB will possess the authority to prevent the study from starting or to recommend that the study be stopped after it has begun. The DSMB will prepare a report based on the material received from the DCC, which will be forwarded to the PIs to review at study executive committee meetings and also to be forwarded to the IRB of Record, as well as project officer, by Dr. Epstein.

1. Safety Monitoring Committee

First, we have established an internal Safety and Monitoring Committee (SMC) to oversee the assessment and reporting of adverse events (AE), serious adverse events (SAE), and unanticipated problems (UP). This committee, which will be chaired by Dr. Teresa Quattrin, will regularly review reports of AEs, SAEs, and unanticipated problems in collaboration with the DSMB. Additional members include Rebecca Campo, PhD.

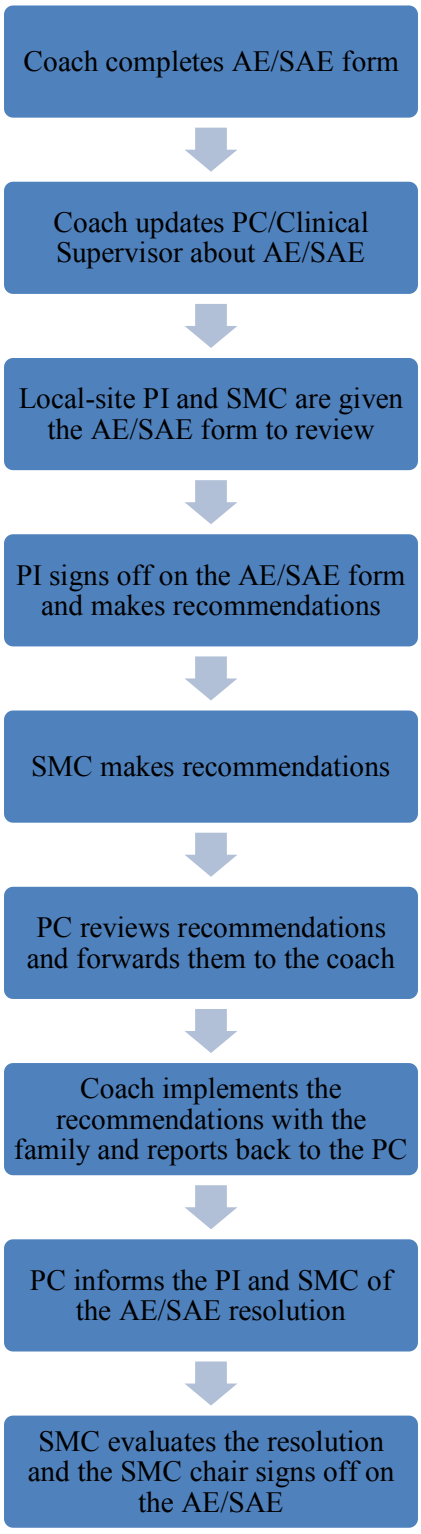
Should a member of the study staff become aware of a possible AE, SAE, or UP (see section IX.D in the study protocol), s/he will notify the clinical site PI, local site PI, and *PC with a detailed email summarizing the event (This change was made on 3.23.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18),* complete an Adverse Event Form or Serious Adverse Event Form, and as recommended by the site PI and PC contacts the SMC. The local site PI will sign off on the AE/SAE and will forward this and a recommendation for action to the Safety Monitoring Committee (SMC). Each site PI will make sure that the AE/SAE is reported to the IRB within the allotted time frame *(DSMB approved protocol addenda, 3.18.19).* The SMC will then evaluate the severity of the event and determine the necessity for immediate action on behalf of the study group. If immediate action is necessary, the SMC will consult with the Steering Committee to recommend a course of action. If immediate action is not necessary, the event will be documented in the study database and discussed at the next scheduled DSMB meeting. The PC will review any recommendations from the SMC and/or local-site PI and forward them to the coach. The Coach will implement the recommendations with the family and report the outcome back to their site PC. The PC then informs the PI and SMC of the AE resolution. After the AE/SAE and event resolution is reviewed, the chair of the SMC will sign off on all AEs/SAEs (see Figure 1; *DSMB approved protocol addenda, 9.29.19*). Additionally, the DCC will prepare monthly reports that summarize adverse events and assess whether there is evidence of a between group difference in AE and SAE rates.

All serious adverse events will follow an expedited reporting timeline, which includes immediately notifying all participating IRBs through the designated PIs in accordance with OHRP guidance.

Lastly, all AEs, SAEs, UPs, and study withdrawals will be forwarded to the DSMB accompanied by a detailed explanation according to the timeline in Table 10 of the study protocol. The DSMB will

ensure that all corrective and/or preventative action plans have been appropriately implemented.

Figure 1. Internal AE/SAE Reporting Procedures (*DSMB approved protocol addenda, 9.29.19*)



Specification of Safety Parameters

1. Adverse Events

For the purpose of this study, an adverse event (AE) will be defined as any untoward or unfavorable occurrence (e.g., symptom, sign, or disease) that is temporally associated with a subject's participation in the study, whether or not it is related to participation.

2. Serious Adverse Events

For the purpose of this study, a serious adverse event (SAE) will be defined as any untoward occurrence that results in death, is life threatening, requires hospitalization or prolongs existing hospitalization, or creates persistent and significant disability.

3. Unanticipated Problems

For the purpose of this study, an unanticipated problem (UP) will be defined as any event that is unexpected, is related or possibly related to participation in the research study, and suggests the research places participants or others at a greater risk of harm than was previously known or recognized.

Classification of Adverse Events

1. Severity

AEs will be assessed for severity and can thereby be classified as mild, moderate, or severe in nature. Mild AEs require minimal or no treatment and do not interfere with the participant's daily activities. Moderate AEs result in a low level of inconvenience or concern with the therapeutic measures and may cause some interference with functioning. Severe AEs interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

2. Relatedness

AEs will be assessed for their relatedness to the procedures involved in the research study and can thereby be classified as: (1) definitely related, (2) possibly related, or (3) not related (see Table 8 and 9; *DSMB approved protocol addenda, 9.29.19*).

3. Expectedness

Expectedness will be assessed in terms of the event's nature, severity, and frequency. Events are considered unexpected when they are not listed in the protocol and consent forms *or* are not listed at the specificity or severity that has been observed (see Table 8 and 9; *DSMB approved protocol addenda, 9.29.19*).

TABLE 8. Adverse Events Determination Table (*DSMB approved protocol addenda, 9.29.19*).

Classification	**Adverse Events**	*Expected*	Relatedness*
Physical Activity	Broken Bones/Fractures	X	(Possibly) Related
	Bruising	X	(Possibly) Related
	Concussion	X	(Possibly) Related
	Cuts	X	(Possibly) Related
	Joint Swelling/Pain/Sprain	X	(Possibly) Related
	Muscle Pulls	X	(Possibly) Related
	Tendonitis	X	(Possibly) Related
	Shin Splints	X	(Possibly) Related
	Sprains	X	(Possibly) Related
	Strains	X	(Possibly) Related
	Soreness	X	(Possibly) Related
	Asthma Exacerbated during PA	X	(Possibly) Related
Mental Health	Eating Disorders: Nor present before study enrollment	X	(Possibly Related)
	Loss of Control: Due to external causes		Not Related
	Loss of Control: No external causes mentioned	X	(Possibly Related)
	Emotional outbursts during sessions	X	(Possibly Related)
	General anxiety or depression due to external causes		Not Related
	Anxiety or Depression with any mention of the study	X	(Possibly Related)
	Extreme depression or suicidal idealization		(Possibly Related)

TABLE 9. Very Common Pediatric Events Table (*DSMB approved protocol addenda, 9.29.19*).

Very Common Pediatric Events	Expected	Relatedness
Abdominal pain and/or vomiting and/or diarrhea for ≤48 hours	X	Not Related
Allergic/seasonal rhinitis	X	Not Related
Cold or URI	X	Not Related
Ear infection	X	Not Related
Influenza and flu-like symptoms	X	Not Related
Pharyngitis/tonsillitis	X	Not Related
Worsening of asthma symptoms **not** related to physical activity in patient with known asthma or reactive airway Disease (RAD) **and** NOT requiring pediatrician or ED visit	X	Not Related
Note: The SMC created a list of very common pediatric events to account for AEs that typically occur within the target population regardless of study participation.		

Adverse Event Assessment and Tracking

The occurrence of an adverse event (AE), serious adverse event (SAE), or unanticipated problem (UP) may come to the attention of research staff during treatment sessions, assessment visits, or other participant contact (e.g., scheduling phone call or e-mail). PLAN coaches and assessors will be made aware of possible expected events, including: adverse emotional experiences (e.g., discomfort, embarrassment), or stress, hunger with dieting, soreness after exercise, and emergence of potential eating disordered attitudes or behaviors. As outlined in Adequacy of Protection Against Risks (**VIII.C.2**), measures will be in place to reduce the likelihood of these events occurring.

To account for differences in the frequency of participant contact between the two study groups, blinded measurement staff will systematically assess for AEs in both the intervention and control groups through use of a standardized questionnaire (see MOP) that is administered at each major assessment time point. If any items are endorsed on the questionnaire, the blinded measurement staff will gather additional information and, if necessary, follow the steps for recording and reporting adverse events outlined below and in section **IX.E**. AEs uncovered in the course of treatment will also be subject to the procedures below. Combining between visit and at visit AEs will result in an alternative count that the DSMB requested. This alternative count will be comprised of all AEs, whether reported at or between visits. Blinded coaches will be unaware if an AE was reported between visits, and any duplicates will be removed by an unblinded reviewer (*DSMB Approval,12.16.2020)*

All AEs, including those not meeting the criteria for SAEs, will be captured on an Adverse Event Form or Serious Adverse Event Form (see **Appendix D**), which must be approved of and signed by the clinical site PI. Information to be collected includes event description, time of onset (and offset if applicable), assessment of severity, relationship to study treatment, expectedness, actions taken,

and outcome of the event. Additionally, all SAEs will require categorization (e.g., death, hospitalization, permanent impairment, etc.) and documentation of any interventions implemented in response to the event.

All AEs occurring during a participant's study participation must be documented appropriately regardless of relationship. All AEs will be followed by the DSMB to adequate resolution and will be recorded in the data collection system. Any medical condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. However, if the study participant's condition deteriorates at any time during the study, it will be recorded as an AE. Changes in the severity of an AE will be documented to allow for an assessment of the duration of the event at each level of severity. AEs characterized as intermittent require documentation of onset and duration of each episode.

The clinical site PIs will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Events will be followed by the DSMB for outcome information until resolution or stabilization.

It is important to note that in previous similar clinical trials in the PIs' respective laboratories, the procedures outlined above have been used to protect against and minimize potential risks to participants, and they have proved effective in preventing emotional and physical complaints as well as adverse events.

Due to the fluid situation of COVID-19, 3 additional questions have been added to the AE questionnaire. Asking these questions could give us data on the effects of the pandemic and could help explain changes in FBT attendance and assessment retention.

i. Do you have a positive COVID-19 test?
ii. Did you have exposure to someone with a known positive COVID-19 test?
iii. Did you need to get tested for COVID-19?

(emergency status implemented 3.16.2020, DSMB approval, 5.7.2020)

Adverse Event Reporting Procedures

Upon initial receipt of information, all fatal or life-threatening suspected serious adverse events will be immediately reported to the IRB of Record, internal IRBs, NHLBI, SMC, and DCC via Dr. Epstein and the clinical site PIs. All non-fatal, non-life-threatening suspected SAEs will be reported within 15 calendar days to the IRB of Record, internal IRBs, NHLBI, SMC, and DCC via Dr. Epstein and the clinical site PIs. Any unanticipated problems that do not classify as SAEs will be reported within 14 days of the investigator becoming aware of the problem to the IRB of Record, internal IRBs, NHLBI, SMC, and DCC via Dr. Epstein and the clinical site PIs. All UPs will also be reported within 30 days of the IRB's receipt of information to the Office for Human Research Protection via the IRB. Non-serious adverse events will be documented in the study database following their occurrence and will be reported annually to the IRB of Record and internal IRBs via Dr. Epstein and the clinical site PIs. See Table 6 for a detailed outline of reporting timelines.

Adverse event questionnaires and reporting forms are included in Appendix D of the study protocol. Once a site's research staff becomes aware of an adverse event's occurrence, that staff (i.e., PLAN coach or assessor) will consult with the clinical site PI or project coordinator to complete the appropriate event form and notify the SMC. Adverse event questionnaires will only be administered after assessment measurement by blinded measurement staff, who will correspondingly complete an adverse event log *(10.12.20; DSMB approval,12.16.2020*). The SMC will then evaluate the severity of the event and determine the necessity for immediate action on behalf of the study group. If immediate action is necessary, the SMC will consult with the Steering Committee to recommend a course of action (e.g., discontinuation of treatment, referral to higher level care). If immediate action is not necessary, the event will be documented in the study database and discussed at the next scheduled DSMB meeting. Additionally, the DCC will prepare monthly reports that summarize adverse events and assess whether there is evidence of a between group difference in AE and SAE rates.

All adverse events and study withdrawals, together with a detailed explanation of the event and withdrawal, will be forwarded to the DCC and the DSMB. In addition, at its regular meeting, the DSMB will summarize all adverse events of any severity, to be forwarded to the IRB via the designated PI. All serious adverse events will be immediately recorded by the clinical site PI and reported to the IRB and DCC~~,~~ via the designated PI; information (i.e., event, actions, and implications for study) will then be distributed to the other clinical sites. Any SAEs and AEs that are judged to be possibly or probably related to participation in the study and/or change their assessment of risk of participation will be immediately reported to the DSMB. The remaining SAE/AEs will be sent to the DSMB with the 6 month reports (***DSMB approved protocol addenda, 3.18.19****).* If any participant appears to be in crisis but the event is not classified as an SAE, appropriate action will be taken based on established suicide and crisis protocols, and any adverse event will be reported promptly to the DSMB and IRB.

In addition to the existing procedures referenced above, the SMC recommends that as soon as child mental health SAEs are reported, to a coach or a PLAN staff designee verbally informs the participants' primary care provider and/or pediatric office staff designee with the description of the SAE, date, and referral so that they may follow-up according to their office procedure. Specifically, if a child enrolled in the study reports self-injury, a suicide attempt, or harm to others, then this will be addressed as a SAE and reported verbally to the pediatrician. The event will be reported by the individual with the most amount of information within 24 business hours of learning about the event. If a medical, behavioral, or mental health intervention is deemed necessary to address this event, it is the pediatrician's responsibility to follow up with their patient to ensure appropriate care is provided. Before this procedure goes into effect, the PLAN coach will communicate this plan with each pediatric practice to develop a practice-specific protocol with who to contact and how. In the event that a coach is unsure about the severity of the child mental health AE, they will collaborate with the local-site PI to determine the severity of the event and whether or not it should be reported to the pediatric office. All other mental health AEs will not be reported to the pediatrician, but will be reported to the IRB and DSMB as part of normal reporting procedures (***DSMB approved protocol addenda, 11.18.19****).*

If a parent becomes pregnant, the PLAN coach will notify the clinical site PI and all weight loss treatments will be stopped. The family's continuation in the study will be limited to the child, siblings and non-participating parent if enrolled. The DCC, DSMB, and IRBs will be notified through

AE reports and a standard form for excluding participants from further data collection and treatment. Please see **Table 10** below for further details regarding AE reporting.

TABLE 10. Adverse Event Reporting Guidelines

What Event is Reported	When is Event Reported	By Whom	To Whom
Fatal or life-threatening unexpected, suspected serious adverse event	**Immediately** upon initial receipt of information	Contact PI	• IRB of Record • NHLBI • SMC • DCC • All PIs and Co-Is
		Clinical Site PIs	• Internal IRBs
Non-fatal, non-life-threatening unexpected, suspected serious adverse event	Within **15 calendar days** of initial receipt of information	Contact PI	• IRB of Record • NHLBI • SMC • DCC • All PIs and Co-Is
		Clinical Site PIs	• Internal IRBs
Unanticipated problem that is not an SAE	Within **14 days** of the investigator becoming aware of the problem	Contact PI	• IRB of Record • NHLBI • SMC • DCC • All PIs and Co-Is
		Clinical Site PIs	• Internal IRBs
All unanticipated problems	Within **30 days** of the IRB's receipt of the report of the UP from the investigator.	IRB	• OHRP
		Contact PI	• IRB of Record
		Clinical Site PIs	• Internal IRBs
All non-serious AEs that are not UPs	Documented in study database and reported annually	Contact PI	• IRB of Record
		Clinical Site PIs	• Internal IRBs

Study Halting Rules for Participant Safety

There are few risks to family-based behavioral interventions. The intervention focuses on improving child and parent health behaviors through behavioral strategies and improved parenting and parent/child relations. The main risks are development of disordered eating or psychopathology and risks due to a sedentary person beginning to exercise. We will be carefully monitoring participants for excess weight loss, psychopathology, and activity-induced injuries. Although we expect that there will be very few serious adverse events, we will employ the following stopping guideline based on the number of SAEs in the intervention group. The guideline is summarized in **Table 11**, which provides data for maximum acceptable SAE rates of 2%, 4%, 6%, 8%, and 10% and for observed numbers of SAEs of 2, 3, 4, and 5. **Table 11** is calculated using 1-sided 95% binomial confidence intervals and can be interpreted as presenting the maximum total sample size N that is required in order to conclude that the toxicity level of the intervention may be excessive for a given number of

observed SAEs and a given defined acceptable SAE rate. For example, suppose we define 2% as the maximum acceptable SAE rate. Then **Table 11** indicates that if the third SAE occurs in fewer than 41 intervention group subjects, then the guideline will have been exceeded because the SAE rate is greater than the acceptable 2% value with 95% certainty.

TABLE 11. MAXIMUM ACCEPTABLE SAE RATES

Number of Observed SAEs	Maximum Acceptable SAE Rate				
	2%	**4%**	**6%**	**8%**	**10%**
2	18	9	6	4	3
3	41	21	14	10	8
4	69	34	23	17	14
5	99	50	33	25	20

Several points about the above discussion are worth mentioning. First, we have used the term "guideline" instead of "rule" because we view the decision making process as one in which the guideline triggers a multifaceted discussion with the DSMB of whether the study should be stopped or modified because of the observed SAE rate. We do not view reaching the stopping boundary as a rule that should automatically lead to the termination of the study. Second, the rule will be applied both to parents and children separately. Third, we propose setting 2% as the maximum acceptable SAE rate because of the low anticipated SAE rate in this study.

At each DSMB meeting, recruitment and retention data will be presented to the DSMB. If recruitment is less than 90% of the target or if retention is less than 80% among randomized subjects, study investigators will present proposals for improvements in each of these two domains. Note that we use an 80% figure for retention because the original power computations had assumed a 20% dropout rate. Thus, an 80% retention rate is not an indication of reduced statistical power. If under performance by these definitions in either of these domains is present, the DCC will perform conditional power computations based on various scenarios regarding the degree of improvement that can be anticipated in recruitment and/or retention. As was the case in our original power computations, we will adopt the conservative approach of assuming that study dropouts provide no data. We propose that early termination be considered if the conditional power under the recruitment/retention scenarios the DSMB views as most realistic is less than 50%. Any final decision about recommending early termination will consider factors such as the impact of early stopping on information about secondary endpoints and covariate effects. It will also consider the adequacy of the measures that are proposed to increase recruitment and retention.

II. Data Processing and Management

A central focus of the DCC will be on the development and testing of a secure web based data entry and management system. In the sections that follow, we discuss the REDCap system that will serve our needs in this domain.

REDCap

Data management will be accomplished using REDCap, a secure password protected and HIPAA compliant web-based system developed at Vanderbilt University that has become a workhorse for Clinical and Translational Science Awards around the country, has served as the data entry system of

choice for more than 1400 research projects at Washington University, and has become a standard data entry and management tool for the Division of Biostatistics. REDCap facilitates a variety of quality control procedures such as drop down menus for categorical variables, range checks, and skip logic. It also facilitates automated transfer to SAS where further quality control procedures will be implemented and through which queries will be generated when errors or inappropriately missing data are identified.

Testing the Data Management System

After REDCap data entry screens have been created and before data entry personnel have entered any test forms, the first step in testing the system will be internal to the DCC where at least three sets of draft forms will be completed and entered into REDCap. The data will then be transferred to SAS datasets and item by item comparisons between forms and SAS printouts will be performed. The preliminary test forms will intentionally contain outlying and missing observations to confirm that range checks and requirements for completing certain fields are functioning properly. A second level of testing which will precede the enrollment of subjects will occur when data entry personnel are asked, as part of their training and certification, to enter data from all data forms on at least three individuals. In addition to confirming the convenience and completeness of the data entry screens, these procedures will evaluate all components of the data management process ranging from edit checking, to skip logic in REDCap, to the automated transfer of REDCap data to SAS, to the correctness of the programs we write to create and store the SAS datasets. These procedures will be closely integrated with searches for ambiguous wording, the training of data entry personnel, and the modification of an original set of draft forms into a final version.

Data Security and Confidentiality

Standard features of REDCap and automated procedures of the Division of Biostatistics provide a high degree of certainty that subject confidentiality will be maintained and that data will never be lost. In accordance with the two key HIPAA requirements, password protection will be required for access to study computers and REDCap. Only authorized personnel will have access to the data entry system and access will be restricted to data from one's own clinic. Data entered into REDCap are encrypted when transferred to SAS. Standard security and confidentiality measures at the DCC include requiring that employees sign confidentiality agreements, that personal identifiers are included in electronic databases only under strong necessity, and that encryption is used when identifiers are present in SAS datasets. Access to our Division computers is restricted to our faculty, staff, and collaborators. Access to accounts that store data from this study will be restricted to DCC personnel and the division's network manager. All file transfers to outside computers use secure transfer methods which ensure that all such traffic is encrypted. The entire network wiring plant within the Division is behind a firewall and is contained within space physically controlled by us. Access to all computers and to REDCap is automatically logged.

Forms and Datasets Manual

All data entered into REDCap will be transferred to SAS using automated procedures for use in future data analyses and reports. Each dataset in the database will contain labels and formats. To facilitate use of this database, the DCC will prepare and maintain a detailed "Forms and Datasets Manual", an easy-to-use roadmap for finding the dataset where a particular data item is stored. The key component of the manual will be a codebook which contains an alphabetical list of all variable names in the entire database, with associated labels and formats for each variable. The codebook will also contain the name of the dataset in which each variable is stored. In addition to the codebook, the Forms and Datasets Manual will include detailed contents of each dataset, a

comprehensive set of data forms with variable names next to each entry, and a format library. We routinely use such manuals in large studies for a variety of reasons, the most important being that they greatly facilitate data management and analysis by making it very easy to find where in a large database an item on a particular form is stored.

Archiving Data

All data will be archived for long-term storage when the study is completed and datasets are cleaned and closed. Decisions regarding the timing and procedures that determine eventual public access to datasets will be made in accordance with institute guidelines. All publically accessible datasets will first be de-identified using the confidentially principles mandated by HIPAA.

Quality Control

We have a broad view of quality control in clinical research as a multifaceted process that addresses concerns such as the accuracy and completeness of computerized data, the common administration of protocols across sites, monitoring adherence to protocol requirements, and the training and certification of personnel. Other quality control measures we will implement include:

1. Data Accuracy and Completeness

REDCap has a number of built-in quality control features that help ensure accurate and complete data and that are accomplished at the clinics when the data are entered. Other quality control measures involve actions taken at the DCC, features of the data forms that help facilitate high quality data, and steps taken at the clinic as data forms are completed. We already noted that the system keeps a log of who entered or changed all data, a feature which permits us to discuss with the data enterer any concerns we have about a particular data item. Other quality control measures that will help ensure accurate and complete data include:

a. Double data entry of selected forms where complete accuracy is judged to be most critical to the study.
b. Range checks will flag values that are outside a predefined acceptable range.
c. Accept only a predefined set of values for categorical measures.
d. All data forms will contain the identification number of the person who completed the form, facilitating easy access to the source if there are legibility or other problems with a form.
e. Forms will frequently have a “not done” option so the associated missing data will be understood as appropriate.
f. Investigators and study coordinators will be expected to do visual checks of all completed forms to confirm legibility, completeness, and reasonableness as each form is filled out.

Our strategy in the first item above of using double data entry for only those forms that contain the most critical data is based both on our own experience and a literature that supports this approach. Studies suggest that the number of errors that are detected by double data entry in a well conducted study is 4-10 per 10,000 key strokes, with range checks detecting about half of randomly introduced errors.[57,58] Moreover, analytic results are extremely robust to small random error rates.[59] Based on these considerations and out of concern for the resource expenditure that is required of double data entry, our longstanding approach has been to employ this approach only for those variables and data forms that are most critical to the study.

2. Data Audits

The DCC will conduct an annual item by item random audit of 10% of data. Logistical considerations will determine whether the audit will be performed during site visits or by the Project Manager at the DCC using requested copies of forms. Every item on the forms will be compared with computerized data and clinic specific error rates will be recorded. We will confirm that changes on forms have been initialed and documented, and all identified problems will be discussed with clinic personnel and, if necessary, with the Steering Committee. Following each audit, a detailed report will be distributed to all clinics. Audits will be timed as feasible to precede meetings of the DSMB so we can respond to questions about data quality.

3. Quality Control of Forms and Data Entry System

Section B above discussed the procedures for testing the data management system at the DCC itself. Closely integrated with those efforts will be approaches to field testing the data entry system, training data entry personnel, and ensuring that the wording of forms is unambiguous. To these ends, the following activities will precede enrollment of the first subject.

a. Staff at each clinic will enter data from one set of draft forms in a formal search for ambiguous wording.
b. Data collection personnel will collect data on two “practice” subjects (who may be friends or colleagues) with a view towards getting the outsiders view of ambiguity so we can subsequently modify the forms as needed. Outlying data values will be encouraged so they can be used in familiarizing data enterers with the quality control components of the data management system.
c. Data collection personnel will test the relevant forms on two “real” subjects. These subjects will not become part of the study even though they may be technically eligible.
d. The forms collected from the “practice” and the “real” subjects will be entered into REDCap to confirm the familiarity of data entry personnel with the system, as a test of the system itself, and as part of the certification process discussed.
e. After these procedures yield potential modifications of the draft forms, the DCC will modify the REDCap screens and will perform a final set of internal tests focused on ensuring that any needed modifications have been correctly incorporated into the revised system.
f. To facilitate the above series of sequential steps, the DCC and Steering Committee will develop a timeline for completing tasks, and the DCC will send reminders to relevant personnel as deadlines approach.

4. Summary Reports

The DCC will prepare summary reports of study progress in response to requests by the Steering Committee and the DSMB. It will also prepare regular reports which, using automated features to be built into our SAS database, will consider such issues as (1) recruitment rates, (2) the proportion of recruited subjects who are eligible, (3) missing form and data rates, (4) the time interval between completing a form and entering it on the computer, (5) compliance rates, and (6) adverse event rates. These reports will, with the exception of adverse events, be updated monthly and made available online through the study website. Because they will be site-specific as well as aggregate in their presentation, the reports will contribute significantly to our quality control efforts as they will help identify areas of inadequate performance at clinics. Although experience suggests that adverse events will be relatively uncommon in a behavioral study such as this, the adverse event report will differ from other reports in that severe events that may be

study related will be reported within 72 hours to the IRB of Record and to the chair of the DSMB.

5. Site Visits

The DCC will organize annual site visits to all clinics that will focus on a detailed review of study procedures. Special additional site visits may occur if routine quality control measures determine that a clinic is having difficulty with some aspect of the protocol. Site visitors will prepare an agenda that will include observations of the performance of study procedures and of the filing system that is used to store completed data forms. They will confirm that data forms are correctly filed, that IRB approvals are available, and that changes on forms are appropriately initialed and dated by the person who made the changes. In addition, site visitors may do random data audits in accordance with section **X.F.2**. Site visits will generally be conducted by a DCC staff person and by an investigator from another clinic.

III. Statistical Considerations

A. Statistical Analysis Plan

Data will be analyzed with SAS using the intention-to-treat principle. P-values less than 0.05 will be considered significant and all tests are two-sided. Details of how the intention-to-treat principle will be implemented are contained in a later section.

B. Primary Analysis

The primary goal of this study is to determine whether the change in weight status among children who have overweight/obesity (*Primary Specific Aim 1*, *DSMB approved protocol addenda, 11.2.18*) is superior among those who are randomized to family-based treatment (FBT) as compared to those who are randomized to usual care (UC) when treated in a primary care setting. The primary outcome measure in children is the percent over the age- and sex-specific 50th BMI percentile. The specific question of interest in the primary analysis is whether the change from baseline to 24 months in the intervention group is greater in the FBT group than in the UC group.

The primary analytic strategy reflects the fact that this is an individually randomized group treatment (IRGT) trial.[34] An IRGT trial is one in which the individual, in this case the family, is the unit of randomization. It differs from a classic individually randomized trial in that the intervention is either a group intervention or, alternatively, is conducted by an agent who is responsible for implementing the intervention in a defined set of individuals. In PLAN, participants are randomized at the family level and only one randomly chosen eligible child (the index child) is included in the primary analysis. The intervention is conducted by a coach who assumes responsibility for a set of families that receive individualized interventions. Since the study has four sites with three coaches per site, the analysis plan involves a nesting of the coach within the site. *Some sites have backup and floating coaches that are involved in delivering FBT to study participants, which will also be accounted for when outcome data is analyzed (**This change was made on 12.4.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.18.19**).* While this nesting suggests a classic cluster randomized trial, an IRGT trial is different because the nesting applies only to the intervention group. Since the control group, in this case the UC group, has no nesting factor in an IRGT trial, a proper analysis must reflect the fact that in an IRGT trial, the intervention group and the control group must use different covariance structures.

With the above comments in mind and with the focus of the study being on a between-group comparison of the change from baseline to 24 months, the primary analysis will be an analysis of covariance with the 24-month value as the dependent variable and with the baseline value as a predictor variable. The statistical model we employ reflects the parametrization described by Baldwin and Colleagues.[60] It takes the initial form $Y24_{ij} = \beta_{0j} + \beta_{1j}X_{ij} + Y0_{ij} + e_{ij}$. In this model, $Y24_{ij}$ is the 24-month value of the percent over the age and sex matched 50th BMI percentile (the primary outcome) for subject i and cluster j, with the "clusters" being defined by the coach in the intervention group and by individual children in the control group; β_{0j} and $\beta_{1j}X_{ij}$ are the intercept and intervention effect for cluster j; $Y0_{ij}$ is the baseline value of the outcome measure; and e_{ij} is the normally distributed error term. *In these models, the intercept and baseline are fixed effects while the intervention effect is random (DSMB approved protocol addenda, 11.2.18)*. To reflect the partial clustering structure of the IRGT design, the above expression is modified by using the cluster-level equations $\beta_{0j} = \lambda_{00}$ and $\beta_{1j} = \lambda_{10} + \mu_{1j}$ to describe how the coefficients β_{0j} and β_{1j} vary across clusters. *The reparametrization of β_{1j} yields two random effects (DSMB approved protocol addenda, 11.2.18)* and the term μ_{1j} permits between-cluster variability in the outcome measure only within the intervention group (coded as 1). Substituting in the initial equation above yields the final model:

$$Y24_{ij} = \lambda_{00} + \lambda_{10}X_{ij} + \mu_{1j}X_{ij} + Y0_{ij} + e_{ij}$$

Using PROC MIXED in SAS, separate covariance structures will be fit to the FBT group and the UC group to account for the fact that the coach is nested within the site in the FBT group while there is no such nesting in the UC group. All analyses other than the above are secondary or exploratory analyses. One of those secondary analyses will supplement the primary analysis by adjusting for the sex and race of the participating child, family income, the educational level of the participating parent, and whether there are one or two parents in the household. These secondary analyses will provide insight regarding the impact the covariates may have on the primary outcome.

1. Sample Size and Statistical Power

Power computations for PLAN employ simulations and two-sided tests at the 0.05 level of significance. The simulations reflect the planned primary analysis of covariance and the fact that this is an individually randomized group treatment trial with the coach (N=3 per site) nested within the site (N=4 sites) in the FBT group but with no such nesting in the UC group. The analysis of covariance that is simulated in the power computations treats the 24-month value of the outcome measure as the dependent variable and the baseline value as a covariate. The use of this approach reflects the primary study goal of comparing 24-month values across groups, with the outcome being compared being percent over normalized BMI in the participating child. Each result is based on 1000 simulations.

Tabulated power values employ sample sizes of 528 and that are between 65% and 95% of that total. Effect size estimates are generated using considerations and preliminary data discussed below. Usual care data involving an intervention and subjects most similar to our UC group is provided by Kalarchian[61] who randomized 81 8-12-year-old children with obesity to a usual care control condition and found an average percent overweight change of -0.17 $\pm$ 10.08 at 1 year. We expect some deterioration in this group at 2 years but will assume conservatively for the purpose of power computations that the two-year change will be 0 $\pm$ 10.08 in the UC group in the proposed research. Our estimated change in the FBT group begins with a review of seven studies[20,62-67] authored by Dr. Epstein. There were 314 overweight/obese children in those studies who received FBT interventions similar to the one we will employ. When we combined

the data for those 314 children, we found an overall average decrease in percent over BMI of 10.6 ± 15.3 at 24 months.

In translating the above decrease of 10.6 ± 15.3 in percent over BMI at 24 months into the setting of the proposed research, we emphasize that the seven referenced studies implemented FBT in controlled academic settings where we anticipate better performance than is likely in the family practices we will employ in this study. To estimate the degree to which the effect is likely to be attenuated when we switch from highly controlled to more "real life" settings, we considered the following. The child weight management intervention MEND (Mind, Exercise, Nutrition, Do it) focused on children age 7-13 who exceeded the 91st weight percentile. MEND employed both (1) a community-based mass-implementation intervention[68] involving many programs and 9563 subjects who provided complete data and (2) a rigorous randomized trial[69] (N=116) analogous to the seven Epstein studies referenced in the preceding paragraph. The 12-month results were reductions in BMI of 0.79 kg/m^2 in the community study as compared to 1.04 kg/m^2 in the intervention arm of the randomized trial. Thus, the reduction in the community-based MEND intervention was 76.0% of the magnitude that was observed in the family-based arm of the randomized trial.

Based on this 76.0%, our computations conservatively assume changes in the intervention group that are 50%, 60%, and 70% of the previously observed change of 10.6 ± 15.3 that was observed in the rigorous academic environment of Dr. Epstein's studies.[20,62-67] Thus, we base our power on a comparison of projected reductions of 5.3 ± 15.3 (50% of 10.6 ± 15.3), 6.4 ± 15.3 (60% of 10.6), and 7.4 ± 15.3 (70% of 10.6) in the FBT group as compared to 0 ± 10.08 in the UC group. In addition, given projected standard deviations of 15.3 and 10.08 in the two groups, we use the maximum and the mean of those two values and thereby compute power assuming standard deviations of both 15.3 and 12.7. In performing the calculations summarized below, we emphasize that we will have actual or imputed 24-month data on all subjects. To see details of how we will impute the 24 month values when necessary, please see the section below titled "Implementation of the Intention-to-Treat Principle."

Table 1 contains the results of the power computations using the parameters discussed above, assuming the compound symmetry covariance structure in both study arms and assuming an intraclass correlation coefficient (ICC) in the UC group of 0.01 and ICCs in the FBT group of 0.04, 0.06, 0.10, and 0.15. We assume a small ICC in the UC group of 0.01 because there is no clustering within that group meaning that the ICC should be essentially zero. While we do not have data with which to estimate the ICC in the FBT group, we note that many cluster trials that involve group interventions have reported ICCs in the 0.01 to 0.05 range. Since the PLAN intervention is individualized and since we expect PLAN children to have no contact with one another, we do not face the impact on the ICC that is present in many cluster trials. This argues for a very small ICC in the FBT group. By contrast, the fact that the same coach will be responsible for multiple children will inevitably increase the ICC above where it might otherwise be. Based on these considerations, we tabulate power for ICCs in the FBT group that range from 0.04 to 0.15. However, the many other studies that have used group interventions while yielding ICCs below 0.05 suggests that the ICC ultimately observed in PLAN will be substantially less than 0.1.

Results in Table 1 indicate that if we recruit 100% of our original target of 528 families, power will be excellent for all tabulated scenarios with an ICC in the FBT group of 0.1 or less. For an ICC

no bigger than 0.1, power remains adequate for most scenarios if we recruit at least 80% of the target (N = 432). If recruitment is below the 80% figure, an adequate power of at least 0.8 requires either the smaller of the two tabulated standard deviations or a mean difference that is at least 60% of the value observed in Dr. Epstein's studies (difference at least 6.4).

Table 1: Statistical power for two sided tests at the 0.05 level of significance.
Computations are for the primary outcome which is the percent over the 50th percentile of BMI in children. Results are generated using 1000 simulations of the primary analytic model: an analysis of covariance with the 24-month value as the dependent variable and the baseline value as a covariate. The analysis reflects the fact that this is an individually randomized group treatment trial in which the coach is nested within the site within the FBT group but which is different from a classic cluster randomized trial in that there is no such nesting within the control (UC) group. The total number of randomized families is assumed to range from 65% to 100% of the target of 528. Tabulations assume an ICC of 0.01 in the UC group and of 0.04, 0.06, 0.10, and 0.15 in the FBT group, mean differences of 5.3, 6.4 and 7.4 (which represent 50%, 60%, and 70% of observed results in previous studies), and standard deviations of 12.7 and 15.3.

(N's Adjusted Below, DSMB approved protocol addenda, 9.29.19).

ICC		SD	Mean diff	Statistical power associated with sample sizes ranging from 65% to 100% of original target of 528							
FBT grp	UC grp			N=528 (100%)	N=502 (95%)	N=476 (90%)	N=449 (85%)	N=422 (80%)	N=396 (75%)	N=370 (70%)	N=344 (65%)
0.04	0.01	12.7	5.3	0.95	0.95	0.94	0.92	0.93	0.92	0.89	0.89
			6.4	0.99	0.98	0.99	0.98	0.99	0.98	0.98	0.97
			7.4	1.00	1.00	1.00	1.00	1.00	1.00	0.99	1.00
		15.3	5.3	0.84	0.83	0.83	0.81	0.80	0.76	0.76	0.74
			6.4	0.96	0.94	0.95	0.92	0.91	0.91	0.88	0.87
			7.4	0.99	0.99	0.99	0.98	0.97	0.97	0.97	0.96
0.06	0.01	12.7	5.3	0.92	0.91	0.90	0.90	0.88	0.87	0.85	0.84
			6.4	0.98	0.98	0.98	0.98	0.97	0.96	0.95	0.95
			7.4	1.00	1.00	1.00	1.00	0.99	0.99	0.99	0.99
		15.3	5.3	0.80	0.79	0.77	0.78	0.74	0.73	0.70	0.68
			6.4	0.92	0.91	0.92	0.91	0.88	0.87	0.85	0.84
			7.4	0.97	0.97	0.96	0.97	0.96	0.95	0.93	0.94
0.10	0.01	12.7	5.3	0.85	0.83	0.81	0.83	0.80	0.80	0.76	0.76
			6.4	0.95	0.94	0.94	0.93	0.91	0.92	0.91	0.88
			7.4	0.98	0.98	0.98	0.98	0.98	0.97	0.97	0.97
		15.3	5.3	0.69	0.68	0.69	0.63	0.67	0.65	0.62	0.60
			6.4	0.84	0.82	0.84	0.81	0.81	0.77	0.76	0.78
			7.4	0.94	0.94	0.92	0.92	0.91	0.89	0.89	0.87
0.15	0.01	12.7	5.3	0.73	0.75	0.71	0.72	0.69	0.70	0.70	0.68
			6.4	0.86	0.85	0.83	0.85	0.85	0.84	0.83	0.81
			7.4	0.95	0.95	0.95	0.94	0.94	0.93	0.93	0.92
			5.3	0.57	0.59	0.55	0.56	0.53	0.53	0.52	0.52

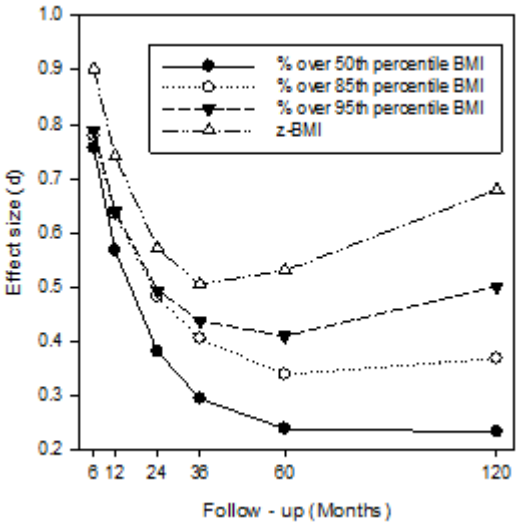
		15.3	6.4	0.73	0.74	0.70	0.73	0.71	0.67	0.68	0.65
			7.4	0.86	0.82	0.86	0.83	0.82	0.81	0.80	0.79

2. Rationale for Percent Over BMI as the Primary Dependent Variable for Child Weight Change

We will use the percent over the 50th percentile BMI for our primary dependent measure for the children.[61] This is commonly labeled as percent over BMI. This measure compares the child BMI to children who are at the average BMI for same age and sex. Twenty percent over the average value is approximately equivalent to the 85th BMI percentile. Using this metric, based on our previous research,[20] we expect a reduction in percent over BMI at 2 years of at least 5.3 due to the impact of the intervention. One of the strengths of this measure is the large database of studies that have used this measure.

There are other approaches to assessing child relative weight change, which include percent over the 95th BMI percentile and zBMI. Percent over the 85th or 95th BMI percentile is a recently developed measure that has an advantage of comparing children to children with overweight or obesity, rather than to the average weight child. In other words, when using the percent over the 85th BMI percentile, a positive number means the child is overweight, and a negative number means they are below the 85th BMI percentile. We have assessed the relationship between values obtained using the percent over 50 versus percent over 85 or percent over 95 in a sample of 987 children, and to no surprise, they are correlated greater than 0.98. However, this does not mean they are equivalent. Using our database of children for whom we have 10-year follow-up,[62,63] we have also calculated the effect sizes for a sample of 193 children who we have studied for 10 years, which provides the largest and only dataset of truly long-term changes in the behavioral childhood obesity literature. The effect sizes for the different measures are similar at the end of treatment, being about 0.80, but they diverge as the length of the follow-up increases. As shown in Figure 1 below, the effect size gets smaller as length of follow-up increases, up to approximately the five-year follow-up, when the effect size increases for the percent over 85 and percent over 95, but not for the percent over 50. Thus, the percent over 50 that we have been using is the most conservative approach to assessing change in child relative weight among the percent overweight measures.

Figure 1. Effect size for zBMI at follow-up.



We have also included changes in zBMI over time for comparison. As can be seen in Figure 1, zBMI has the greatest effect sizes at all-time points. zBMI also compares BMI values to population values based on the child's age and sex and attempts to standardize the values using z-scores. Reductions in zBMI scores are obtained when child weight decreases in relationship to their growth. The z-scores that are used to calculate zBMI are also the basis for calculating the 85th and 95th BMI percentiles. While zBMI has been used in studies, it has been criticized in part since baseline zBMI correlates negatively with change, while all other measures of child relative weight discussed show a positive relationship. In other words, using zBMI children with the lowest zBMI values show larger changes,

while children with higher zBMI values show smaller changes.

It is also possible to use BMI values, which do not take into account the child's age or sex. There are two major disadvantages of this approach. First, a child may show a reduction in relative weight to height for the other dependent measures, but an increase in BMI. This makes determination of success challenging, as you would not expect a child who is showing an increase in BMI to be successful. This is due to the fact that population based child BMI curves show an increase throughout development until about age 18, so that an increase in absolute BMI may be a reduction in BMI relative to normal growth for children that age and sex. Secondly, since boys and girls differ in their rates of maturation in terms of height and weight trajectories and height and weight velocity, an absolute change in BMI may have very different meanings for boys and girls as they develop.

3. Longitudinal Analyses of Child Outcome Data

Secondary analyses involving the child will look more comprehensively at the pattern of change over time. While there is no specific literature on the use of mixed model repeated measures analyses in IRGT trials, these analyses are known to inflate the type I error in cluster trials[70] and it is likely that this also occurs in IRGT trials. The general recommendation is therefore that random coefficient models that may use different covariance structures in the two study arms should be employed in the longitudinal analysis of IRGT trials.[70] With that in mind our secondary analysis of child outcome data will apply these models to all data collected at baseline and at 6, 12, 18 and 24 months. In light of the fact that weight changes in intervention studies sometimes occur more quickly at the beginning with a subsequent leveling off at later time points, these analyses will explore non-linear possibilities such as quadratic models. They will also adjust for the same covariates that were listed in the secondary analysis of the primary outcome to understand the impact of the covariates on longitudinal change.

4. Covariance Structures and Missing Data

There are two key considerations that will guide us as we pursue these secondary random coefficient models: (1) the selection of appropriate covariance structures and (2) the handling of missing data.

5. Selection of a Covariance Structure

PROC MIXED in SAS contains many covariance structure options, including the ability to identify covariance structures that are specific to the UC group and the FBT group separately. Our model-selection process for choosing the appropriate covariance structures will reflect several considerations including information criteria; the pattern of change in the correlation between observations as the time between measurements increases; and the *a priori* preference for structures that, all other things being equal, minimize the number of parameters that must be estimated; and whether data collection is equally spaced. *While confirmation will have to await the availability of the final dataset, we anticipate using an unstructured covariance structure in the primary analysis (DSMB approved protocol addenda, 11.2.18).*

6. Missing Data

Our handling of missing data begins with consideration of the pattern of missingness. If missing data in longitudinal analyses are missing completely at random or at random, they do not produce bias. In this setting, we will apply our random coefficient models to all data that are available. However, because this approach can yield a meaningful decrease in statistical power if

large amounts of data are missing, we will use multiple imputation[71-73](using PROC MI in SAS) to impute missing values when missingness is excessive and will treat this imputation approach as a sensitivity analysis. When data are not missing at random, ignoring the pattern of missingness can yield biased analyses.

We will begin our consideration of missing data while the trial is being implemented so we can minimize the amount and best understand the pattern of missingness. First, we will do everything we can to determine why subjects drop out of the study early and we will ask non-dropouts the reason for missing a particular visit. If data are missing, for example, because of bad weather, it may be likely that they are randomly missing whereas a family that drops out because the child is not losing weight will suggest non-ignorable missingness. Information such as this will help guide our analytic strategy. Second, we will encourage subjects who wish to drop out early to continue to provide key follow-up data, at 24 months in particular. Our experience is that many dropouts appreciate the scientific value of their contributions and are willing to cooperate in this way. Third and most importantly, we will do all we can do avoid dropout and missing data in the first place. In the recently completed 24-month multicenter COMPASS study, we collected 24-month data on 165 of 172 children in randomized families (95.9%) and 18-month data on five of the 7 who were missing at 24 months. Because the COMPASS intervention was performed at our own facilities with us having complete control, the dropout rate is likely to be higher in the proposed research where we rely on family practices. Nevertheless, if we can come close to the low missing data rate in COMPASS, the potential problem posed by missingness will be very limited.

The section that follows on the implementation of the intention-to-treat principle provides further insight into the handling of missing data (DSMB approved protocol addenda, 11.2.18).

7. Implementation of the Intention-to-Treat Principle

The primary analysis will be an intention-to-treat analysis of the child that includes all subjects**.** Recalling that the primary analysis involves an analysis of covariance with the 24-month value of percent over BMI (the primary outcome measure) as the dependent variable, the inclusion of all subjects will reflect the following three considerations.

1. If the 24-month value of the primary outcome is available, the child will be included in the primary analysis without the need for further considerations.
2. If the 24-month value of height and/or weight (the defining components of the primary outcome) is missing and the child had height and weight data collected by his or her pediatrician at a clinic visit that occurred within 30 days of the targeted 24-month PLAN assessment, the following considerations will be used in imputing the 24-month value to be used in the primary analysis. Those considerations are designed to account for the anticipated imprecision of values measured at the pediatrician's office.
    a. Within each clinic, a regression model that will allow us to impute 24-month values will be generated. Using all PLAN children who attend a particular clinic and who have both precisely measured PLAN height and weight data and less precise height and weight data measured at the clinic within 30 days of the PLAN measurement, clinic-specific regression models will separately predict the true height and weight using the age and sex of the subject as well as the height and weight value measured at the clinic. The goal will be to perform these calculations on a clinic-specific basis because the causes and magnitude of measurement error may differ

from clinic to clinic. However, if the number of subjects at a clinic who have the requisite height and weight data is less than 15 (less than 5 times the number of predictors), we will use all data from all clinics at the relevant study site to perform the desired imputation.

b. Recalling that the children of interest in this scenario have clinic data collected within 30 days of the targeted 24-month PLAN assessment, the clinic-specific height and weight value calculated above will be used to impute the PLAN 24 month values from the contemporaneous value measured at the clinic. This imputed value will be used in the primary analysis.

c. If there is no clinic visit within 30 days of the 24-month target but there are visits both before and after the 24-month time point, we will interpolate linearly between predicted height and weight values at those time points to determine the predicted 24-month value. *Because we will only employ this option if height and weight data are available no more than three months before and three months after the target date for the 24-month visit, we anticipate that this interpolation approach will be performed infrequently in practice (DSMB approved protocol addenda, 11.2.18).*

3. If the 24-month value of height and/or weight is missing and the child did not have height and weight data collected by his or her pediatrician at a clinic visit that took place within 30 days of the planned 24-month assessment and did not have height and weight data measured at the clinic *within three months* both before and after the targeted 24-month visit, the 24-month value will be imputed using multiple imputation *(DSMB approved protocol addenda, 11.2.18)*. Variables that will be used to facilitate the imputation process will be baseline height and weight, age, sex, and race. Any height and weight data collected using PLAN assessments at 6, 12, or 18 months will also be included in the multiple imputation.

   Two points about the methods discussed in this section are in order. First, the rational for using multiple imputation only after it has been determined that clinic visit data are not available as a vehicle for imputing values is as follows. We anticipate that while values measured at the clinic will not employ the same rigor that will be employed in our protocol governed visits every six months, it is likely that the magnitude of the error will be relatively small and probably systematic rather than random within clinics. We therefore anticipate that this use of real measured data will yield more accurate results than multiple imputation. This is especially so for individuals who provide no data beyond their baseline measurement.

   The second point concerns the definition of a missed visit. The goal for all clinics is that PLAN participants should attend their six-month visits within $\pm$ 30 days of the target date. However, we will not declare a given visit as having been missed until 3 months after the target date. For example, if the six-month visit has not occurred by nine months, the six-month visit will be declared to be missing and will therefore need to be imputed for analyses that include these intermediate time points. With the six-month visit having been declared missing, the next visit will be defined to be the twelve-month visit and the target date for it to occur will be twelve months after the randomization date. We recognize that a three-month difference between a scheduled visit and the actual visit is substantial, especially for growing children. But the use of this three-month difference before a visit will be declared missing will minimize the number of missed visits. Moreover, using the methods discussed in the last section of this analysis plan, we will account for any between-group differences in

time to the final study visit when we perform the primary analysis (DSMB approved protocol addenda, 11.2.18).

8. Assessing the Appropriateness of Analytic Strategies

In addition to the above concerns about covariance structures and missing data, we will routinely give careful attention to the appropriateness of the analyses we perform. For example, t-tests comparing baseline values across groups will be performed only after assessing equal variance and normality assumptions, with data transformations being pursued if assumptions are violated and Wilcoxon's test being a nonparametric alternative if an appropriate transformation cannot be found. Similar attention will be given to the appropriateness of random coefficient models where the distributional properties of variables will be evaluated and residual plots will be examined. To ensure that our conclusions are robust in the face of outlying values, sensitivity analyses that may exclude or attenuate outlying values will be pursued. The latter considerations will ensure that we are appropriately cautious about any conclusion that might have been altered if 1 or 2 subjects with outlying values had not been in the study or had had less extreme data points.

C.Analysis of Secondary Aim 1 *(DSMB approved protocol addenda, 11.2.18).*

The **goal of secondary aim 1 is to compare the effectiveness of the FBT group with that of the UC group in the participating parent**. The primary outcome variable in the parent is BMI. Since BMI is a continuous variable measured at the same time points as was the case with the participating child, the data analytic strategy for this secondary analysis is identical to what was described for the child.

C. ***Analysis of Secondary Aim 2*** *(DSMB approved protocol addenda, 11.2.18).*

The **goal of this aim is to determine if the weight loss impacts of FBT extend beyond the participating child by assessing the intervention in overweight/obese siblings**. We hypothesize that FBT will be superior to UC for weight-eligible siblings. Analytic strategies will be similar to those used in the primary aim, the key difference being that while prior data[74] support our hypothesis of FBT benefits for siblings, power for this aim may be limited. The most important reason for this is that we have chosen not to require that participating children have a weight-eligible sibling because of the recruitment challenge such a requirement would pose. Prior data from the NHLBI-funded COMPASS study we coordinated at Washington University indicate that among 377 screened families with a participating child, 163 (43.2%) had at least one age (age 2-18) and weight-eligible sibling. Based on these numbers, we expect that there will be about 228 (= 43.2% of 528) participating families with at least one eligible sibling, with the actual number recruited being somewhat smaller because some siblings will choose not to participate.

While the above sample size may not provide the robust statistical power that would be ideal, we emphasize that this is a secondary aim that will study by far the largest number of overweight/obese siblings ever evaluated in this setting. Thus, this aim will provide a unique set of data that will yield valuable insights into whether FBT may benefit non-participating siblings while generating preliminary effect size data to guide future studies. A positive finding would provide a compelling incentive for the future dissemination of FBT to family practices. In cases where more than one eligible sibling is available, we will enroll the sibling whose age is closest to that of the study child. Data analyses will reflect the wide age eligibility range for siblings and current uncertainty regarding the impact of sibling age on outcome. We will address this uncertainty by adjusting for sibling age and whether the sibling is older or younger than the participating child, with particular concern for the possibility that sibling age may have a non-linear relationship with FBT effectiveness. The wide age eligibility range for siblings reflects our desire to maximize information generated about this population and the limited resource expenditure

that is required to study these non-participants. We will also adjust for whether the sex of the sibling is the same as that of the targeted child since prior data suggest that same sex siblings respond better than opposite sex siblings.[19]

E.Analysis of Secondary Aim 3 *(DSMB approved protocol addenda, 11.2.18).*

The **goal of this aim is to assess changes in delay discounting for children and parents assigned to FBT versus UC and to assess the relationship between those changes and weight control**. We hypothesize that FBT will be associated with reductions in delay discounting for children and parents compared with UC, and that the degree of change in delay discounting will be related to success in weight control. *All analyses in this aim will be performed separately for the index child and the index parent (DSMB approved protocol addenda, 11.2.18).* Delay discounting will be measured using the k-value detailed by Johnson and Bickel.[75] These parameters will be measured at baseline, 12, and 24 months. One set of analyses in this aim will involve random coefficient models that compare the pattern of change in the k value in the UC group with corresponding changes in the FBT group. We will also use bivariate linear mixed models implemented by PROC MIXED in SAS[76] to evaluate the association between changing k-values and changes in weight.

D.Analysis of Secondary Aim 4 *(DSMB approved protocol addenda, 11.2.18).*

The **goal of this aim is to examine participant level baseline predictors of outcomes, with the measures of interest being parental inconsistency and environmental enrichment**. We hypothesize that FBT, as compared to UC, will benefit families with higher parental inconsistency and less enriched environments. Parental inconsistency will be measured using a validated parenting style inventory[77] while environmental enrichment will be evaluated using questions from the HOME[78] scale developed by Rosenberg et al[79] and the Land Use Mix-Diversity subscale from the Neighborhood Environment Walkability Scale (NEWS)[80] that we have employed previously[81] in a pediatric weight loss study involving FBT. The same random coefficient models with two covariance structures that we described earlier with the same IRGT design will be applied here with the modification that we will focus on the two baseline measures of current interest (parental inconsistency and environmental enrichment) as covariates. Because we anticipate that the efficacy of the intervention may be influenced by these measures, we will also evaluate interaction terms between group assignment and both our parental inconsistency and environmental enrichment measures. The analyses will be performed separately in both participating children and parents.

D. Analysis of Exploratory Aim 1

The **goal of this exploratory aim is to examine provider attitudes towards evidence-based treatment at baseline and perceptions of FBT at mid study (after experience with the intervention has been gained) as predictors of providers' future intention to use co-located FBT in their practices at the end of the study.** We hypothesize that positive provider attitudes toward evidence-based treatment and perceptions of FBT will predict their intention to incorporate FBT into their practice settings. Appendix C provides details of the measures we will use in this aim. Because a provider's intention to incorporate FBT into their practice settings is measured on a broad scale ranging from 0% to 100%, we will treat the variable as a continuous variable and expect that random coefficient models will again be appropriate. Specifically, we plan to implement these models using PROC MIXED in SAS, with the provider nested within sites in those analyses. A strength of the planned analysis is that the anticipated 185 providers at the four sites will provide a rich opportunity to understand predictors of future intentions regarding the use of FBT. An uncertainty is that we currently have little data with which to predict the distribution of the of the 0% to 100% response variable. It is possible, therefore, that analyses in this exploratory aim will require data transformations, breaking the outcome measure into categories, or the use of

generalized estimating equations instead of mixed models. It should be noted that in contrast to earlier analyses, analyses of this aim do not involve group assignment and do not therefore reflect the overall IRGT trial design. Thus, only one covariance structure will be required.

E. Sensitivity Analyses

Sensitivity analyses to be performed in PLAN are as follows.

1. A modified intention-to-treat analysis of the primary outcome in which subjects who provided no follow-up data are excluded. These analyses will include imputed 24-month data using subjects who did provide data beyond baseline but who did not provide 24-month data.
2. To further facilitate an understanding of the impact of missing data on the primary result, the primary analysis will be repeated without imputation and using only subjects who provide both baseline and 24-month primary outcome data.
3. A per protocol dataset will be defined as including all subjects who attend at least 80% of the prescribed sessions. Sensitivity analyses will assess whether applying the primary analysis to the per protocol dataset yields the same result as the primary ITT analysis. *All control group subjects who do not drop out of the study will be considered to be part of the per protocol dataset. We recognize that this implies a somewhat different definition in the two study arms. But we do not consider this to be a problem since this is a sensitivity analysis whose goal is to repeat the primary analysis in a different setting (DSMB approved protocol addenda, 11.2.18).*
4. Random coefficient models that potentially use different covariance structures in the two study arms will include all primary outcome data collected at baseline, 6, 12, 18, and 24 months. Since weight change often occurs at a more rapid rate early in a weight loss study, these sensitivity analyses will include an exploration of non-linear possibilities such as quadratic models. They will also assess contrasts that compare changes from baseline to 24 months across groups in order to use an alternative model for testing the central hypothesis of the primary analysis.
5. Repeat the primary analysis after adjusting for baseline covariates. The covariates to be used are the race and sex of the participating child, family income, the educational level of the participating parent, and whether there are one or two parents in the household.

F. The Time Between Randomization and the Measurement of the Primary Outcome

The time between randomization and the measurement of the primary outcome will vary among participants and will potentially differ between groups. Our approach to addressing the potential impact of this reality is described below.

Our first step in addressing this issue will involve an assessment of whether the time to the outcome measure differs across groups. To address this question, we will compare Kaplan Meier survival curves measuring time to assessment using a generalized Wilcoxon test. The Wilcoxon test will be used instead of a logrank test because dropouts in weight loss studies tend to occur early and because the Wilcoxon test is more sensitive to early dropout than the logrank test. In performing these analyses, subjects who provide no data beyond baseline will be assumed to be on study for one month. To ensure consistency across all participants, one month will also be added to the follow-up time of children who do provide data beyond baseline. If the Wilcoxon test yields non-significant results, we will not modify our covariate-adjusted secondary analyses. If the Wilcoxon test suggests that there is a between-group difference in time to the final assessment, we will adjust for the time to the final assessment in the covariate-adjusted analyses Similar considerations will determine whether the time to the 24 month assessment will serve as a covariate in the sensitivity analyses discussed above that involve random coefficient models, that include data collected at all intermediate time points, and that employ

statistical contrasts to compare the change from baseline to the final assessment across groups. In all of these analyses, the median time to the final follow-up along with 95% confidence bounds will be calculated.

G. Analysis of Exploratory Aim 2

Twelve PLAN coaches will be asked to participate in an audio-recorded semi-structured interview; interested coaches will provide consent over the phone and will be asked a series of questions by a trained post-doctoral researcher on the study. The questions are based on the coaches' discussions with FBT families pre-COVID and amid-COVID regarding food cost, perception, and behaviors. The telephone interviews are voluntary and will be completed based on the coaches' availability. All responses will be de-identified and aggregated with the other coaches' responses. The data will be transcribed, and summary data will be compiled. The audio file will be destroyed once the data has been transcribed and aggregated. *(DSMB approval,5.7.2020)*

Measures to Minimize Bias

1. Enrollment and Randomization Procedures

The DCC will use the REDCap randomization module to create an online password protected randomization system that will facilitate the random assignment of families. When the website is entered, the user will provide information that establishes the eligibility of the family. Group assignments will be revealed only if all eligibility criteria are satisfied. To avoid temporal bias, randomization will be blocked within clinic using random block sizes in order to preclude the possibility that investigators might know in advance the assignment of the last family in a particular block.

2. Standardization of Height and Weight Measurements

Verifications for collecting and entering the data for the height and weights will be followed to decrease bias. All stadiometers and scales used will be calibrated and consistent between all sites. PLAN coaches and assessors will be trained and tested on protocols for obtaining these measures. All weight measurements will be taken according to a uniform protocol and written on hard copy measurement sheets. The handwritten weights will be manually entered into the REDCap database by a blinded measurement coach, which will eliminate potential measurement bias and minimize errors in data entry (*DSMB approved change, 11.18.19*). Both the written record and the measure in REDCap will be verified. *Hard copy height and weight measurement forms will be uploaded to the secure REDCap database to allow the CCC, DCC and TFC to check for transcription and/or unit of measurement errors.* Any malfunctions of equipment will be reported to the study staff to resolve immediately. Any measurements outside of the range of normal will be flagged in REDCap and staff notified to retake measurements.

3. Masking Procedures

Masking refers to no knowledge regarding treatment assignment. It is not the same as concealment, which refers to random assignment to groups. Treatment masking represents an extension of concealment, to minimize bias in how participants assigned to different groups are treated. In the current study, the research assistants and coaches who are doing the measurements will be blinded, or masked as to treatment assignment, and the PIs for the Clinical Coordinating Center and Training and Fidelity Cores (Drs. Epstein and Wilfley) and the DSMB will be masked as to treatment assignment. However, it is impossible to mask families, the family's PLAN coach, or pediatricians to group assignment. Families and PLAN coaches will

know the intervention arm by the very nature of implementing a behavioral intervention. Pediatricians will not be told group assignment, but that is possible to discern since they may see FBT families coming to their clinic more than the UC families.

Masking of Assessment Staff

We recognize the importance of blinding research personnel who are collecting data to study arms. The primary height and weight data will be collected coaches conduct assessments for each other's families at the different pediatric sites (for which they will be blinded to those families). Families will be explained that they are to not discuss anything regarding their group assignment, how often they come to the pediatric office or their coaches and the measurement assessor has to remain blinded to their treatment arm.

Coaches will be blinded to the families' randomization. They will conduct assessments, home visits, remote assessments, and AE data collection.

There are three coaches at each site, with *some sites having backup and floating coaches that are involved in delivering FBT to study participants*. *A backup coach delivers treatment for another coach's caseload in the event that a coach goes on vacation, leaves the position, or is otherwise unable to complete treatment with their families. Backup coaches are assigned based on coach letter assignment (i.e., coach B is the backup for coach A, coach A is the backup for coach C, coach C is the backup for coach B). This ensures that there is always a blinded measurement coach to complete assessments. A floating coach delivers treatment to families at multiple pediatric practices regardless of coach assignment. Floating coaches remain blinded to other caseloads, but see families at different practices when a practice's coach does not have space in their caseload for more families (**This change was made on 12.4.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.18.19**).* The plan is for Coach 1 to collect height and weight for families assigned to Coach 2, Coach 2 will collect height and weight for families assigned to Coach 3, and Coach 3 will collect height and weight for families assigned to Coach 1. Thus, coaches will not collect height and weight measures from families from their caseload. We will use block scheduling to reduce travel time (e.g., Coach 1 can do assessments at Coach 2's site one Friday per month).

In order to mask assessment of outcome measures,-all sites have implemented blinded measurement coaches that complete assessments and AE data collection, so that the PLAN coaches can focus on treatment. Coaches will remain blinded to group assignment outside of their caseload (***This change was made on 2.28.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18***). *To further ensure blinding, families will be notified that the assessor is unaware of their group assignment and will be asked not to discuss the frequency of them coming in to the practice, their group assignment, or the coach they normally see (**DSMB approved protocol addenda, 3.18.19**).*

Although not possible to guarantee that coaches are blind to condition for families that are not in their caseload due to the families not being blinded, use of a standard protocol (see **Appendix C**) ensures objective and reliable measurement of the primary outcome. Assessors will be blind to prior heights/weights, further protecting against assessment bias.

Reducing Bias in Unmasked Groups

We recognize that there are numerous ways that the PLAN coaches or pediatricians can treat FBT UC families differently. We have several approaches to reduce bias. We are able to standardize interactions with PLAN coaches through extensive training, supervision and fidelity checks, which can help reduce bias from the PLAN coaches. Part of the training will include instructions not to state or imply that FBT may be better than usual care. We will not be directly training or assessing fidelity for usual care, as that would deviate from the reason for using UC as the control condition. However, we will be collecting information on usual care practices from participating providers at baseline and 24 months via REDCap surveys. Group assignment will not be in the families' charts, and unless a family directly says something to the pediatrician, the pediatrician may be unaware of group assignment.

II. Study Administration

Study Website

A study website will be used to: 1) provide information to families about FBT; 2) provide downloadable manuals for the Traffic Light Eating Plan and Activity Program; 3) manage the EFT component of the intervention; and 4) provide tools for cooking, getting more physical activity, and parenting skills. Quizzes to assess mastery of educational materials will be implemented on the study website, with multiple versions of quizzes on each module available with the recognition that some people will acquire the information more slowly than others. Families will have access to traditional paper and pencil self-monitoring, and consistent with current implementation of FBT, after self-monitoring skill is acquired, families can choose to use traditional or technology-based recording. Information on learning the modules, and eating, exercise, and parenting change will be coordinated in an online family dashboard. Families will have access to the family dashboard for feedback, and PLAN coaches will have access to the dashboard to assess patient progress, assist with problem solving, and communicate with families to structure solutions.

The website will also contain password-protected sections that are for internal use by study personnel and will serve as a repository for study documents as well as a communications hub for the study. The study website will be created and maintained by the CCC. The DCC will be responsible for uploading to the website documents under its purview such as regular reports prepared for DSMB and Steering Committee meetings, the forms and datasets manual, lists of certified personnel, and instructions on the use of the data entry system. The website will not contain protected health information.

Conflicts of Interest

Dr. Schechtman has a long history of collaboration with Dr. Wilfley, the PI for the TFC and of the WU clinical site for the proposed research, and because both reside at WU, there is at least the appearance of a potential for conflict of interest. We will take two steps in addressing this issue. First, the reports we regularly generate regarding the progress of the study will be separated by clinic and shared with the SEC and/or DSMB whenever potential problems with clinical sites, including the WU clinical site, are identified. Second, we have asked a colleague, Dr. Mae Gordon (Professor of Ophthalmology and Biostatistics at WU), to address any concerns about the performance of the WU clinical site should Dr. Schechtman feel conflicted. Dr. Gordon has not worked previously with Dr. Wilfley and has years of experience as Director of the DCC for several NIH-funded clinical trials, including at least one where a participating clinic was at WU.

Disagreements regarding any of the study functions will be resolved by discussion and vote of the SEC.

Publications and Presentations Policy

The Steering Committee will manage the oversight and coordination of publication and presentation materials. The DCC director, along with members of the Steering Committee, will participate in a subcommittee defining publication policies, prioritizing when multiple papers and abstracts challenge resources, and encouraging the involvement of junior investigators in the dissemination of study results. The DCC director will oversee the creation of a publications and presentations database that will facilitate the tracking of completed publications. He will also facilitate the development of an automated reminder system for study investigators of abstract due dates and pending timelines for preparing material for publications and presentations. The publications database will be stored on the study website.

Protocol Amendments

All protocol amendments will be submitted to the UB IRB and DSMB for approval, and any consequent changes will be documented in the study database. Amendments will not be implemented until both the UB IRB and DSMB have given their approval.

Protocol Deviations

A protocol deviation is any noncompliance with the approved protocol, Good Clinical Practice (GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly. These practices are consistent with ICH E6: 4.5 Compliance with Protocol (sections 4.5.1, 4.5.2, and 4.5.3), 5.1 Quality Assurance and Quality Control (section 5.1.1), and 5.20 Noncompliance (sections 5.20.1, and 5.20.2). It is the responsibility of the site to use continuous vigilance to identify and report deviations within working days of identification of the protocol deviation, or within working days of the scheduled protocol-required activity. All deviations must be addressed in study source documents, reported to Program Official. Protocol deviations must be sent to the IRB of Record per their guidelines. The site PI/study staff is responsible for knowing and adhering to their IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

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IV. Appendices

A. Consent Form Samples: *(Adjusted Primary Aim and added that there is an increased risk posed to participants by using third-party platforms, this change was made on 5.23.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18*).

B. **Coronavirus Addendum**: Added to address the changes in assessments due to social distancing as a result of the serious nature of Covid-19 (UB IRB approved 5.19.20; DSMB approved protocol addenda on 5.7.20)

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Sibling Adult Consent to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, PhD

Why am I being invited to take part in a research study?
You are being invited to take part in a research study because:

- You are an adult sibling of a child participating in a study through your doctor's office.
- You are able to read the English language.
- You fall into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex).

This research study is supported by a grant through the National Heart Blood and Lung Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings. Such as primary care and how it effects siblings living with participating parents and children.

How long will the research last?
We expect that you will be in this treatment and research study for 24 months.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location. Out of 528 families in the entire study nationally.

What happens if I say yes, I want to be in this research?
To determine if your family is eligible to participate, you and your family will be asked to complete an eligibility assessment at an orientation session about this study. Your height and weight will be measured.

If your family is eligible for this research study and agrees to participate, you will attend the baseline assessment with your sibling. You will complete a baseline assessment and an initial appointment with your doctor. Your family will be randomized to one of two treatment conditions described below.

Groups
At the start of the study, your family will be assigned to one of two groups. Participants in one group will receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group will receive family-based behavioral treatment for weight management (FBT).

FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED, YELLOW, and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED, YELLOW and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) A variety of behavioral techniques including changing and controlling your environment. tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So that weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a coin. Neither you nor your sibling's doctor will choose what treatment your family will receive. Your family will have an equal chance of being assigned to each group. You will be informed of the group your family is in following an initial physician visit.

Treatment Schedule
Every family will follow their pediatrician recommended schedule of appointments for weight management. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT PLAN Coach during the 24 months of the study. The amount of sessions completed within this range will be based on progress through the program. The amount will vary for each family. You will not attend the sessions with the PLAN Coach.

Assessments, Interviews, Questionnaires
You will attend five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Measurement assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric office, or a home visit can be arranged.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to attend the baseline assessment, all measurement assessments, and the follow-up assessment. Your participation in any other meetings with your family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

What happens if I do not want to be in this research?
Your participation in this research study is voluntary. You may choose not to enroll in this study. There are no other research alternatives other than to participate in this study.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. It will not be held against you, or affect your family's participation in the study. You do not have to answer every question. You may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included below. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way being in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments.

Less Likely

- You may find having your height and weight measured uncomfortable.

Rare

- Although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. This study may provide information that will help you to lose weight and keep it off. However, we cannot guarantee that you will receive any benefits from this study.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. If you withdraw from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).
If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__√__ Information from your full medical records (height, weight, dietary restrictions and physical activity restrictions.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institutes (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√__ Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this

authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.	
Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Sibling Assent to be in a Research Study - (for Children 7-13 years of age)

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, PhD

Who are we?
My name is Dr. Leonard H. Epstein and I am a researcher at the UB. I work in the Department of Pediatrics.

Why are we meeting with you?
We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

Why are we doing this study?
We want to look at siblings of kids participating in a study through your doctor's office.

What will happen to you if you are in the study?
You, your sibling, and a parent will first come to the doctor's office. We will tell you about this study. It teaches kids about healthy eating and activities. We will ask you if you want to be a part of the study. If you want to, we will ask to you come back for more visits.

You will be asked to come in 5 times over 2 years so we can measure your height and weight. This will be done in private. Only your parent, your sibling, and the study member will be with you. You do not have to answer any questions if you don't want to. You do not have to do any activities you do not want to do.

What are the good things and bad things that may happen to you if you are in the study?
Most Likely:

Good: You can learn how you are growing.

Maybe:

Good: You could learn what is like to be in a research study. You might lose weight.
Bad: You might not like getting your height and weight taken.

Do you have to be in the study?
No you don't. No one will get angry or upset with you if you don't want to do this. If you do not want to be in the study at any time, it will not affect your family being in the study. Just tell us if you don't want

to be in the study. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: *Leonard H. Epstein, Ph.D.*
Phone Number: *(716) 829-3400*

Signature Block for Sibling Assent of Child

Your signature documents your permission to take part in this research.		
Signature of subject		Date
Printed Name of Subject		

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent		Date
Printed name of person obtaining consent		

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Sibling Assent of a 14-17-year-old to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, PhD

Why am I being invited to take part in a research study?
You are being invited to take part in a research study because:

- You are a sibling between the ages of 14-17 able to read the English language and you fall into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex)

This research study is supported by a grant through the National Heart Blood and Lung Institutes (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your doctor's office, or you can contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity, but there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care and how it effects siblings living with participating parents and children.

How long will the research last?
We expect that you will be in this treatment and research study for 24 months.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location, out of 528 families in the entire study nationally.

What happens if I say yes, I want to be in this research?
To determine if your family is eligible to participate, you and your family will be asked to complete an eligibility assessment at an orientation session about this study. Your height and weight will be measured.

If your family is eligible for this research study and agrees to participate, you will attend the baseline assessment with your sibling. After the baseline assessment and an initial appointment with your sibling's doctor, your family will be randomized to one of two treatment conditions described below. Additionally, approximately every 6 months, you will get your height and weight measurements taken.

Groups
At the start of the study, your family will be assigned to one of two groups. Participants in one group will receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group will receive family-based behavioral treatment for weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan, which uses RED, YELLOW, GREEN labels for food to guide families toward the goal of eating nutritious foods; 2) the Traffic Light Activity Program, which also uses RED, YELLOW and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors; and 3) a variety of behavioral techniques including changing and controlling your environment, tracking eating and physical activity, setting goals, problem solving, setting up a reward system, incentives for behavior change and weight loss, finding substitutes for unhealthy foods, and improving positive parenting. FBT also involves making changes in the home, so weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family will be in, will be chosen by chance, like flipping a coin. Neither you nor your sibling's doctor will choose what treatment your family will receive. Your family will have an equal chance of being assigned to each group. You will be informed of the group your family is in following an initial physician visit.

Treatment Schedule
Every family will follow their pediatricians recommended schedule of appointments for weight management. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT interventionist during the 24 months of the study. The amount of sessions completed within this range will be based on progress through the program and will vary for each family. You will not attend the sessions with the PLAN coach.

Assessments, Interviews, Questionnaires
You will attend five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Measurement assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 30-90 minutes to complete at your sibling's pediatric office, or a home visit can be arranged. Your height and weight will be taken at each major assessment.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to attend the baseline assessment, all measurement assessments, and the follow-up assessment. Your participation in any other meetings with your family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

What happens if I do not want to be in this research?
Your participation in this research study is voluntary. You may choose not to enroll in this study, it will not affect your family being in the study. ***There are no other research alternatives other than to participate in this study.***

What happens if I say yes, but I change my mind later?
You can leave the research at any time, it will not be held against you. You do not have to answer every question and may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included below. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way being in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments.

Less Likely

- You may find having your height and weight measured uncomfortable.

Rare

- Although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. This study may provide information that will help you to lose weight and keep it off. However, we cannot guarantee that you will receive any benefits from this study.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. If you withdraw from the study, no further data will be collected, but any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).
If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

Signature Block for Assent of Child

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	

THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Participating Child Assent to be in a Research Study (for Children 7-13 yrs. of age)

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Who are we?
My name is Dr. Leonard H. Epstein and I am a researcher at the University at Buffalo. I work in the Department of Pediatrics.

Why are we meeting with you?
We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

Why are we doing this study?
We want to look at a certain kind of weight loss program for kids. We want to know if it will work at a doctor's office.

What will happen to you if you are in the study?
You and a parent will first come to the doctor's office. We will tell you about this study that teaches kids about healthy eating and activities. We will ask you if you want to be a part of the study. If you do, we will measure your height and weight. We will ask you to answer some questions about yourself and your parents. You will do a task that asks you to make choices between different amounts of money. If you want to, we will ask to you come back for more visits.

After this, you and your parent will be put in one of two groups:

- If you are in one group, you will follow the recommendations of your doctor.
- If you are in the other group, you could come to your doctor's office once a week. You would do this for 2 years. This would be at least 26 visits. At the visits you would meet with someone from the study. Your weight will be taken. You will learn about healthy food. We will teach you fun ways to exercise.

Every 6 months we will ask you some questions about yourself. We will measure your height and weight. At your baseline, 12-month and Follow-up appointments, we will ask you to do a computer task that asks you to make choices between different amounts of money.

You do not have to answer any questions that you do not want to answer. You do not have to do any activities that you do not want to do.

What are the good things and bad things that may happen to you if you are in the study?
Most Likely: You can have fun learning about healthy food and exercise. You could become healthy.

Maybe: You could become hungry when trying to eat healthy. Your muscles could feel sore from exercise. That will go away once you are used to exercising.

Do you have to be in the study?
No you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you don't want to be in the study. Also, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: *Leonard H. Epstein, Ph.D.* Phone Number: *(716) 829-3400*

Signature Block for Assent of Child

Your signature documents your permission to take part in this research.		
Signature of subject		Date
Printed name of subject		
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Adult Consent (Non-Participating Parent) to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Why am I being invited to take part in a research study?
You are being invited to take part in a research study because:

- You are a parent of a child participating in a study through your child's doctor's office.
- You are able to read the English.

This research study is supported by a grant through the National Heart, Lung and Blood Institutes (NHLBI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

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- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein**.** You may also contact the PLAN coach at your child's doctor's office, or you can contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings. Such as primary care and how it effects siblings living with participating parents and children.

How long will the research last?
We expect that you will be in this treatment and research study for 24 months.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location. Out of 528 families in the entire study nationally.

What happens if I say yes, I want to be in this research?
To determine if you are eligible to participate, you will be asked to complete an eligibility assessment at an orientation session about this study. Your height and weight will be measured.

If you are eligible for this research study and agree to participate, you will attend the baseline assessment with your participating child(ren), and the participating parent. After the baseline assessment your participating family members will attend an initial appointment with your child's doctor. Your family will be randomized to one of two treatment conditions described below. Additionally, you will get your height and weight measurements taken at 24 months.

Groups
At the start of the study, your family will be assigned to one of two groups. Participants in one group will receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group will receive family-based behavioral treatment for weight management (FBT).

FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan, which uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program, which also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family will be in/the treatment they get will be chosen by chance, like flipping a coin. Neither parent nor your child's doctor will choose what treatment they get. Your participating family members will have an equal chance of being assigned to each group. Your family will be informed of the group they are in following an initial physician visit.

Treatment Schedule
Every family will follow their pediatricians recommended schedule of appointments for weight management. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT interventionist during the 24 months of the study. The amount of sessions completed within this range will be based on progress through the program. The amount will vary for each family. You will not attend the sessions with the PLAN coach.

Assessments, Interviews, Questionnaires
You will attend two major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 15 minutes to complete at your child's pediatric office, or a home visit can be arranged. Your height and weight will be taken at each major assessment.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to get your height taken at baseline and weight taken at baseline and final assessment sessions. Your participation in any other meetings with your family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

What happens if I do not want to be in this research?
Your participation in this research study is voluntary. You may choose not to enroll in this study it will not affect your family being in the study. There are no other research alternatives other than to participate in this study.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. It will not be held against you, or affect your family's participation in the study. You do not have to answer every question. You may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included below. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way being in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments.

Less Likely

- You may find having your height and weight measured uncomfortable.

Rare

- Although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your family taking part in this research. This study may provide information that will help you to lose weight and keep it off. However, we cannot guarantee that you will receive any benefits from this study.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. If you withdraw from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).
If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__√__ Specific information from your medical records related to height and weight.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√_ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

_√__ Clinical staff not involved in this research study who may become involved in you and your child's care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study (National Heart, Lung and Blood Institutes (NHLBI) cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After

such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√__ Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.		
Signature of subject		Date
Printed name of subject		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Parental Permission for Targeted Child to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Why is my child being invited to take part in a research study?
Your child is being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- Your child is between the ages of 6 and 12 years old, falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and your child has at least one parent that is willing to participate in the study.

This research study is supported by a grant through the National Heart Lung Blood Institutes (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should my child and I know about a research study?

- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

Who can my child and I talk to?
If you or your child has questions, concerns, or complaints, or think the research has hurt your child, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your child's rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings. Such as primary care.

Your child has been asked to participate because he/she is between the ages of 6 and 12 years old, falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and your child has at least one parent that is willing to participate in the study.

How long will the research last?
We expect that your child will be in this treatment and research study for 24 months.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location, out of 528 families in the entire study nationally.

What happens if I say yes, my child wants to be in this research?
To determine if your child is eligible to participate, you and your child will be asked to complete an eligibility assessment at an orientation session about this study. You and your child's height and weight will be measured, and standard questions regarding medical and psychological history will be asked by a trained interviewer to determine eligibility.

If your family is eligible for this research study and agrees to participate, you and your child will be asked to come to your pediatric office to complete a baseline assessment (detailed below). Additionally, we hope to collect information about how participation in FBT may affect others in your home. Therefore, if you have another child who meets eligibility criteria (between the ages of 2-18 who is at or above the 85th percentile for age and sex), we ask that this child also attend the baseline assessment. After the baseline assessment and an initial appointment with your child's doctor, your family will be randomized to one of two treatment conditions described below.

Groups
At the start of the study, your family will be assigned to one of two groups. Participants in one group will receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group will receive family-based behavioral treatment for weight management (FBT).

FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; GREEN labels for food to guide families toward the goal

of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So that weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a coin. Neither you nor your doctor will choose what treatment your family will receive. Your family will have an equal chance of being assigned to each group. You will be informed of the group your family is in and your treatment following an initial physician visit.

Treatment Schedule
Every family will follow their pediatricians recommended schedule of appointment for weight management. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT PLAN coach during the 24 months of the study. The amount of session completed within this range will be based on progress through the program. The amount will vary for each family.

Assessments, Interviews, Questionnaires
Attendance will be taken and both you and your child will be weighed at every session. In addition, there will be five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Measurement assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric office, or a home visit can be arranged. Height and weight will be taken on you and your child as well as the identified other family members (if applicable). Your height will be taken at the beginning of the study, and your child(ren)'s height will be taken at each major assessment. You and your participating child will also complete short questionnaires. At your baseline, 12-month, and follow-up appointment, you will be asked to complete a computer task. You both will be asked questions about parenting behaviors and the home food and activity environment. Throughout the study, you will have access to a website that contains study materials and interactive tools. At the very end of the study, the PLAN coach will review your child's chart to collect data on Usual Care.

Audio Recording
Your interviews and individual family and will be audiotaped or digitally recorded for research purposes, but you will not be identified on the recording and the recordings will not be labeled with your name. Recording the sessions is the best way to make sure we collect accurate information. It also helps us make sure that all our staff delivers the study to participants in the same way. The recordings will be stored on password-protected computers with restricted access within the University at Buffalo, and then transferred to Washington University School of Medicine. The recordings will be labeled only with your study ID, date, and session number. The Principal Investigator and research staff may use these recordings for purposes of evaluation, treatment, research, and training related to this study. Recordings may also be used to train staff implementing these or similar interventions at other sites. The recordings will be destroyed at the end of the study when all data analysis is complete. You do not have to agree to be audio recorded in order to participate in this study.

Please check and initial below if you agree for you and your child to be audio recorded during your sessions with the PLAN coach:

_____YES, PARENT INITIAL_____ , I give my permission to be audio recorded during sessions with a PLAN Coach. Date: _____

_____NO, PARENT INITIAL_____ , I do **not give** my permission to be audio recorded during sessions with a PLAN Coach. Date: _____

What are my child's responsibilities if he/she takes part in this research?
If your child takes part in this research, he/she will be responsible to: attend the baseline assessment, attend all measurement assessments, attend at least 26 treatment sessions if your family is in the group receiving FBT, and attend the follow-up assessment.

What happens if my child does not want to be in this research?
Your child's participation in this research study is voluntary. You or your child may choose not to enroll in this study. There are no other research alternatives other than to participate in this study.
What happens if my child and I say yes, but change our mind later?
Your child can leave the research at any time. It will not be held against him/her. Your child does not have to answer every question. He/she may refuse to answer any questions that he/she does not want to answer.

If your child decides to leave the research, you may not be able to find this kind of family treatment in your area outside of this research study. Other types of treatment may be available in your community. In which case we will provide a list of these and how to find them if you prefer this option. However you and/or your insurance company would be responsible for any costs associated with these options. You also may not receive full compensation for your participation. If your child decides to leave the research, contact the investigator at the contact information included below. If your child stops being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your child's routine medical care.

Is there any way being in this study could be bad for my child?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- Your child might feel hungry when dieting or sore after exercising.

Less Likely

- Your child may find some of the questions embarrassing or be uncomfortable having his/her height and weight measured.
- There may be some family disagreements as issues of family functioning; communication; and discipline are discussed.
- Your child may be inconvenienced at times by having to miss school activities, meetings, etc., to attend assessments and family sessions.

Rare

- There is a risk of audio recordings being lost. All recordings will be immediately stored in a locked drawer or saved to a password-protected computer in the research office after the individual family and group weight loss and maintenance sessions. Your family name will not be on these recordings, which will be identified only by a study ID number.

- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.
- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.

Other Risks

- In this study your child will be given a physical activity goal. Given that some people may have medical risks associated with increasing their physical activity, these recommendations for your child will be given in consultation with his/her doctor.
- **Randomization** - As mentioned before, this study has two groups. Because chance decides which group your child will be in, the treatment your child receives as part of this study may not be what your own doctor would choose for your child.

Will being in this study help my child in any way?

We cannot promise any benefits to you, your child, or others from your taking part in this research. However, possible benefits could include your child losing weight, becoming more physically active, and eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to better relationships and better mood. However, we cannot guarantee your child will receive any benefits from this study. This study may provide information that will help other children inside and outside your household to lose weight and keep it off.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization. Information related to your child will be treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not be associated with any published results. Your child's code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your child's participation in this study and the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal Investigator until the end of the study. At which point they will be destroyed. If your child withdraws from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Social and Behavioral Sciences Institutional Review Board (SBSIRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your child's identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your child's medical records and related health information. These are described in the HIPAA section of this document.

Can my child be removed from the research without our OK?
The principal investigator of the study can remove your child from the research study without your or your child's approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons. We will tell you about any new information that may affect your child's health, welfare, or choice to stay in the research.

What else do my child and I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).

If your child needs medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury. If your child agrees to take part in this research study, we will pay your family up to $175 for your time and effort. The amount you are paid depends upon your attendance to visits in the study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes
This section describes information about your child and about your child's health that will be obtained by the researchers when your child participates in the research study. Health information is considered "protected health information" when it may directly identify your child as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about your child as part of this research study?

__√__ Information from your child's full medical records.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in your child's care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institutes (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your child's individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your child's protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about your child unless you revoke this authorization in writing.

__√__ Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you and your child will not be able to participate in the research study.

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child	
Signature of parent or individual legally authorized to consent to the child's general medical care	Date
Printed name of parent or individual legally authorized to consent to the child's general medical care	❑ Parent ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent Process

- ❑ Child is birth-6 yrs. old - Assent is not required
- ❑ Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- ❑ Assent will be obtained Verbally
- ❑ Assent has been waived by the IRB

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Parental Permission of Sibling to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, PhD

Why is my child being invited to take part in a research study?
Your child is being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 2-18 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex) and is willing to participate by getting his/her height and weight taken every 6 months over the two-year study.
- You have another child between the ages of 6 and 12 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and your child has at least one parent that is willing to participate in the study.

This research study is supported by a grant through the National Heart Lung Blood Institutes (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should my child and I know about a research study?
- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

Who can my child and I talk to?
If you or your child has questions, concerns, or complaints, or think the research has hurt your child, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your child's rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care.

Your child has been asked to participate because he/she is between the ages of 2 and 18 years old, falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), has one sibling who is also considered overweight or obese (BMI greater than 25), and has at least one parent that is willing to participate in the study.

How long will the research last?
We expect that your child will be in this research study for 24 months.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location, out of 528 families in the entire study nationally.

What happens if I say yes, my child wants to be in this research?
To determine if your child is eligible to participate you, your participating (target) child, and this participating sibling will be asked to complete an eligibility assessment at an orientation session about this study. You and your children's height and weight will be measured.

If your family is eligible for this research study and agrees to participate, the participating sibling (between the ages of 2-18 who is at or above the 85th percentile for age and sex) will attend the baseline assessment with you and your target child. After the baseline assessment and an initial appointment with your child's doctor, your family will be randomized to one of two treatment conditions described below.

Groups
At the start of the study, your family will be assigned to one of two groups. Participants in one group will receive the current standard of care offered by their physician for the treatment of childhood weight management. FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral

techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a coin. Neither you nor your doctor will choose what treatment your family will receive. Your family will have an equal chance of being assigned to each group. You will be informed of the group your family is in and your treatment following an initial physician visit.

Treatment Schedule

Every family will follow their pediatrician recommended schedule of appointments for weight management to have at least 4 visits with their child's doctor over the course of the 24 months of the study. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT PLAN coach during the 24 months of the study. The amount of session completed within this range will be based on progress through the program. The amount will vary for each family. The participating sibling will not attend the sessions with the PLAN coach.

Assessments, Interviews, Questionnaires

The participating sibling will attend five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Measurement assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric office, or a home visit can be arranged. Height and weight will be taken on you, your participating child, as well as the participating sibling and identified other family members (if applicable).

What are my child's responsibilities if he/she takes part in this research?

If your child (participating sibling) takes part in this research, he/she will be responsible to attend the baseline assessment, the three measurement assessments, and the follow-up assessment to obtain height and weight information. Your child's (participating sibling) participation in any other meetings with your family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

What happens if my child does not want to be in this research?
Your child's participation in this research study is voluntary. You or your child may choose not to enroll in this study. There are no other research alternatives other than to participate in this study.

What happens if my child and I say yes, but change our mind later?
Your child can leave the research at any time. It will not be held against him/her. Your child does not have to answer every question. He/she may refuse to answer any questions that he/she does not want to answer. If your participating sibling child leaves the research, this will not affect the status of you or your participating (target) child in the study.

If you or your child decides to leave the research, you may not be able to find this kind of family treatment in your area outside of this research study. Other types of treatment may be available in your community. In which case we will provide a list of these and how to find them if you prefer this option. However you and/or your insurance company would be responsible for any costs associated with these options. You also may not receive full compensation for your participation. If your child decides to leave the research, contact the investigator at the contact information included below. If your child stops being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your child's routine medical care.

Is there any way being in this study could be bad for my child?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments.

Less Likely

- Your child may be uncomfortable having his/her height and weight measured.

Rare

- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.

Will being in this study help my child in any way?
We cannot promise any benefits to you, your child, or others from your taking part in this research. This study may provide information that will help your child to lose weight and keep it off. However, we cannot guarantee your child will receive any benefits from this study.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization. Information related to your child will be treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not

be associated with any published results. Your child's code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your child's participation in this study and the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal Investigator until the end of the study. At which point they will be destroyed. If your child withdraws from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Social and Behavioral Sciences Institutional Review Board (SBSIRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your child's identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your child's medical records and related health information. These are described in the HIPAA section of this document.

Can my child be removed from the research without our OK?
The principal investigator of the study can remove your child from the research study without your or your child's approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons. We will tell you about any new information that may affect your child's health, welfare, or choice to stay in the research.

What else do my child and I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).

If your child needs medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury. If your child agrees to take part in this research study, we will pay your family up to $175 for your time and effort. The amount you are paid depends upon your attendance to visits in the study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your child and about your child's health that will be obtained by the researchers when your child participates in the research study. Health information is considered "protected health information" when it may directly identify your child as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about your child as part of this research study?

__√__ Information from your child's full medical records.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in your child's care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institutes (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your child's individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your child's protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√__ Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this

authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you and your child will not be able to

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child	
Signature of parent or individual legally authorized to consent to the child's general medical care	Date
Printed name of parent or individual legally authorized to consent to the child's general medical care	❑ Parent ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent Process

- ❑ Child is birth-6 yrs. old - Assent is not required
- ❑ Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- ❑ Assent will be obtained Verbally
- ❑ Assent has been waived by the IRB

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Parental Permission of Sibling to Participate in a Research Study – Chart Review

Version Date: 1.2.19
Investigators: Leonard H. Epstein, PhD

Why is my child being invited to take part in a research study?
Your child is being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 6 and 12 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and your child has at least one parent who also is considered overweight or obese (BMI greater than 25).
- You have another child between the ages of 2-18 years old that is willing to grant access to his/her Medical Records for height, weight, age, and sex data and/or participate by getting his/her height and weight taken every 6 months over the two year study.

This research study is supported by a grant through the National Heart Lung Blood Institute (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should my child and I know about a research study?
- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

Who can my child and I talk to?
If you or your child has questions, concerns, or complaints, or think the research has hurt your child, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your child's rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care.

Your child has been asked to participate because he/she is between the ages of 2 and 18 years old and may fall into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex) and has at least one parent and one sibling who are also considered overweight or obese (BMI greater than 25) that are participating in this study.

How long will the research last?
We expect that your child will be in this research study for 24 months.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location, out of 528 families in the entire study nationally.

What happens if I say yes, my child wants to be in this research?
If your family is eligible for this research study and agrees to participate, the participating sibling (between the ages of 2-18) will grant access to his/her Medical Records at specified time points (i.e., 0, 6, 12, 18, & 24 months) and/or attend the baseline assessment with you and your target child to get his/her height and weight taken. After the baseline assessment and an initial appointment with your child's doctor, your family will be randomized to one of two treatment conditions described below.

Groups
At the start of the study, your family will be assigned to one of two groups. Participants in one group will receive the current standard of care offered by their physician for the treatment of childhood weight management. FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested

treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a coin. Neither you nor your doctor will choose what treatment your family will receive. Your family will have an equal chance of being assigned to each group. You will be informed of the group your family is in and your treatment following an initial physician visit.

Treatment & Assessment Schedule
Every family will follow their pediatrician recommended schedule of appointments for weight management to have at least 4 visits with their child's doctor over the course of the 24 months of the study.

The participating sibling will grant access to Medical Records and/or attend five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Measurement assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric office, or a home visit can be arranged. Height and weight will be taken on you, your participating child, as well as the participating sibling and identified other family members (if applicable).

What are my child's responsibilities if he/she takes part in this research?
If your child (participating sibling) takes part in this research, he/she will be responsible to attend the baseline assessment, the three measurement assessments, and the follow-up assessment to obtain height and weight information. Your child's (participating sibling) participation in any other meetings with your family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

What happens if my child does not want to be in this research?

Your child's participation in this research study is voluntary. You or your child may choose not to enroll in this study. There are no other research alternatives other than to participate in this study.

What happens if my child and I say yes, but change our mind later?
Your child can leave the research at any time. It will not be held against him/her. Your child does not have to answer every question. He/she may refuse to answer any questions that he/she does

not want to answer. If your participating sibling child leaves the research, this will not affect the status of you or your participating (target) child in the study.

If you or your child decides to leave the research, you may not be able to find this kind of family treatment in your area outside of this research study. Other types of treatment may be available in your community. In which case we will provide a list of these and how to find them if you prefer this option. However, you and/or your insurance company would be responsible for any costs associated with these options. You also may not receive full compensation for your participation. If your child decides to leave the research, contact the investigator at the contact information included below. If your child stops being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your child's routine medical care.

Is there any way being in this study could be bad for my child?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments.
- Your child might feel hungry when dieting, sore after exercising, or experience common exercise injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

Less Likely

- Your child may be uncomfortable having his/her height and weight measured.

Rare

- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.

Will being in this study help my child in any way?
We cannot promise any benefits to you, your child, or others from your taking part in this research. This study may provide information that will help your child to lose weight and keep it off. However, we cannot guarantee your child will receive any benefits from this study.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization.

Information related to your child will be treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not be associated with any published results. Your child's code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your child's participation in this study and the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal Investigator until the end of the study. At which point they will be destroyed. If your child withdraws from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Social and Behavioral Sciences Institutional Review Board (SBSIRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your child's identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your child's medical records and related health information. These are described in the HIPAA section of this document.

Can my child be removed from the research without our OK?
The principal investigator of the study can remove your child from the research study without your or your child's approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons. We will tell you about any new information that may affect your child's health, welfare, or choice to stay in the research.

What else do my child and I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).

If your child needs medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury. If your child agrees to take part in this research study, we will pay your family up to $175 for your time and effort. The amount you are paid depends upon your attendance to visits in the study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your child and about your child's health that will be obtained by the researchers when your child participates in the research study. Health information is considered "protected health information" when it may directly identify your child as an individual. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about your child as part of this research study?

__√__ Information from your child's full medical records.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in your child's care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institute (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your child's individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your child's protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√__ Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside

the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you and your child will not be able to participate.

Signature Block for Parental Permission

Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care | Date

Printed name of parent or individual legally authorized to consent to the child's general medical care

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent Process

- ❑ Child is birth-6 yrs. old - Assent is not required
- ❑ Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- ❑ Assent will be obtained verbally
- ❑ Assent has been waived by the IRB

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent | Date

Printed name of person obtaining consent

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

PLAN Coach Adult Consent to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Why am I being invited to take part in a research study?
You are being invited to take part in a research study because you are a PLAN coach delivering family-based treatment (FBT) into a practice-based research network associated with University at Buffalo, Washington University, University of Rochester, or Nationwide Children's Hospital.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about the study. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-829-3400 for Dr. Leonard Epstein. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
There is currently a gap between the use of evidence-based treatment for children with obesity and its use within the community. The rationale behind this study is to understand how best to implement these interventions in primary care settings. We chose to test these implementation methods using FBT because it has been established as an effective, short- and long term treatment for weight loss psychotherapy that focuses on linking healthy dietary and physical activity behaviors to a child's overall environment (e.g., parents, peers, school) and overcoming barriers by using problem solving techniques. FBT is an evidence-based treatment for overweight and obesity as well as for eating disorders.

The goal of this study is to determine whether FBT for children who are overweight can be included in the primary care setting by using a co-located PLAN coach. Extensive information has been gathered by our research team about the treatment of childhood obesity, but there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care. Families at your assigned practices have been asked to participate because they have a child between the ages of 6 and 12 years old who is overweight (defined as at or above the 85th percentile for body mass index), and have at least one parent who is willing to participate in the study.

How long will the research last?
We expect that you will be in this research study for 5 years.

How many people will be studied?
We expect about 3 PLAN coaches will be in this research study in your geographical location out of approximately 12 PLAN coaches in the entire study nationally at 4 different clinical sites.

What happens if I say yes, I want to be in this research?
By reading and signing this form, you agree to answer questions about yourself and your thoughts and opinions regarding your job, childhood obesity, and childhood obesity treatments, including FBT.

Additionally, you allow audio recordings collected for the purpose of quality control of treatment to be used for research purposes. After reading and signing this form, the following procedures will occur:

- You will complete a demographics form and take a baseline assessment to measure your knowledge in the area of obesity and evidence-based intervention prior to completing training.

- Following training, you will complete the same assessment to assess your growth of knowledge and opinions of obesity and the evidence-based intervention.

- At multiple time points during the study you will be asked to submit audio recordings of sessions you have with families to ensure the quality of care being delivered and for assessing your fidelity to the training protocol. These audio recordings may be transcribed and no identifying information will be presented to the public.

- At multiple time points during the study, you will be asked to complete a short assessment on your thoughts regarding the study and evidence-based interventions.

- The assessments taken during this study will only be reported in aggregate form to the public and will exclude any identifying information.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to: answer several questionnaires and have your FBT sessions recorded.

What happens if I do not want to be in this research?
If you have agreed to treat families for the study, treatment related tasks will be considered part of your job responsibilities, not as part of the research. You are not required to participate in the PLAN coach research portion of the study. You may choose not to fill out questionnaires regarding the implementation of FBT into the primary care practice; however, there are certain questions we will ask you to answer in your role as a care provider on the study. You may also choose not to have your audio recordings be used for research purposes (separate section at the end); however, you will still be asked to record and submit treatment sessions in your role as a care provider on the study for quality control purposes.

What happens if I say yes, but I change my mind later?
You can leave the research at any time; it will not be held against you and will not impact your current job status.

If you decide to leave the research, contact the investigator. You will be asked to withdraw your participation in writing. There will be no penalty or loss of benefits to which you are otherwise entitled.

Is there any way being in this study could be bad for me?
A risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure, and we think the risk of accidental disclosure is very small.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

- Learning how evidence-based treatments for childhood obesity may function in primary care and gaining insight into how it may be effective for treatment of childhood obesity.

- Other people might benefit from this study due to identification of the best way to train PLAN coaches in FBT best practices. This may lead to more widespread adoption of evidence-based childhood obesity treatments into primary care.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The information you provide in this study will be strictly confidential and will not be provided to your employer and will not impact your current job status in the workplace.

Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. If you withdraw from the study, no further data will be collected, but any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at any time.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons from removal include: lack of adherence to study protocol.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).

You will not be paid for participating in this study.

Audio Recording Permission:
Your initial below documents your permission to use audio recorded sessions for *research purposes*:

_____ Yes, I give my permission to use my audio recorded sessions for research purposes.

_____ No, **I do not** give my permission to use my audio recorded sessions for research purposes.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.
Signature of subject Date
Printed name of subject
Signature of person obtaining consent ____ Date

Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.	
Signature of witness to consent process	Date
Printed name of person witnessing consent process	

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Adult Primary Care Provider Consent to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Why am I being invited to take part in a research study?
You are being invited to take part in a research study because you are a provider who is part of a practice-based research network with University at Buffalo, Washington University, University of Rochester, or Nationwide Children's Hospital.

You are being invited to take part in a research study supported by a grant through the National Heart Blood Lung Institutes(NHBLI). Research studies only include individuals who choose to take part in them.
Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about or if you wish to discuss this matter with your family. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-829-3400 for Dr. Leonard Epstein. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

- You want to get information or provide input about this research.

Why is this research being done?
This is a research study. We invite you to participate in this research study by the University at Buffalo because you are a provider at a primary care practice that has indicated interest in participating in this study.

There is currently a gap between the use of evidence-based treatment for children with obesity and its use within the community. The rationale behind this study is to test the effectiveness of FBT in primary care settings, and to understand how best to implement these interventions in primary care settings. We chose to test FBT because it has been established as an effective treatment for weight loss in children in the short- and long term and may have a positive impact on others in the household. FBT is a manual-based psychotherapy that focuses on linking healthy dietary and physical activity behaviors to a child's overall environment (e.g., parents, peers, school) and overcoming barriers by using problem solving techniques.

The goal of this study is to determine whether family-based weight loss treatment (FBT) for children who are overweight/obese can be included in the primary care setting by using a co-located PLAN Coach. Extensive information has been gathered by our research team about the treatment of childhood obesity, but there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care. Families at your practice have been asked to participate because they have a child who is between the ages of 6 and 12 years old, is overweight/obese (defined as at or above the 85th percentile for body mass index), and have at least one parent who is willing to participate in the study.

How long will the research last?
We expect that you will be in this research study for 4 years.

How many people will be studied?
We expect about 3 primary care providers will be in this research study in your geographical location, and similar numbers of primary care providers at three other sites nationally.

What happens if I say yes, I want to be in this research?
Currently, the practice you work in has agreed to participate in this research study. By reading and signing this form, you agree to answer questions about yourself and your thoughts and opinions regarding your job, childhood obesity, and childhood obesity treatments, including FBT. After reading and signing this form, the following procedures will occur:

- You will be asked about your demographics, job, attitudes, and prior knowledge of FBT and obesity care delivery. The assessments will take about 20 minutes to complete. You are free to skip any questions you don't want to answer.
- You will be asked to give permission for PLAN coaches to review participant charts at the end of the study to gather data on Usual Care.

The treatment that participants will get will be chosen by chance, like flipping a coin. You will not choose which treatment participants will get. You will not know which treatment participants will get, however, some participants will inevitably inform you of their group assignment in the normal course of events.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to: answer several questionnaires about the study.

What happens if I do not want to be in this research?
If you have agreed to treat families with Usual Care for the study, you are not required to participate in the provider research portion of the study. You may choose not to fill out questionnaires regarding the implementation of FBT into the primary care practice; however, there are certain questions we will ask you to answer in your role as a care provider on the study.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. It will not be held against you and will not impact your current job status.

If you decide to leave the research, contact the investigator. You will be asked to withdraw your participation in writing. There will be no penalty or loss of benefits to which you are otherwise entitled.

Is there any way being in this study could be bad for me?
A risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure, and we think the risk of accidental disclosure is very small.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

- Learning how evidence-based treatments for childhood obesity may function in primary care and gaining insight into how it may be effective for treatment of childhood obesity.

- Other people might benefit from this study due to identification of the best way to train providers in expert recommendations. This may lead to more widespread adoption of evidence-based treatments into primary care.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The information you provide in this study will be strictly confidential and will not be provided to your employer and will not impact your current job status in the workplace.

Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. If you withdraw from the study, no further data will be collected, but any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this website at any time.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons from removal include: lack of adherence to study protocol.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).

You will not be paid for participating in this study.

Signature Block for Capable Adult

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Do you agree to allow us to send your protected heath information via email?
We will only send you PLAN related emails and we will not share your email with anyone.

- □ Yes
- □ No

If yes, please provide your preferred email address below.

_____

Please verify your preferred email.

_____

If yes, please provide your preferred phone number below.

_____

Please verify your preferred phone number.

_____

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Type your name below:

Typed Signature of Primary Care Provider	Date

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Parent Adult Consent to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Why am I being invited to take part in a research study?
You and your child are being invited to take part in a research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 6 and 12 years old. Falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex). You are interested in weight loss and are willing to participate in the study.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHLBI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.0
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu

if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care.

How long will the research last?
We expect that you will be in this treatment and research study for 24 months.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location. Out of 528 families in the entire study nationally.

What happens if I say yes, I want to be in this research?
To determine if your family is eligible to participate, you and your child will be asked to complete an eligibility assessment at an orientation session about this study. You and your child's height and weight will be measured. Standard questions regarding medical and psychological history will be asked by a trained interviewer to determine eligibility.

If your family is eligible for this research study and agrees to participate, you and your child will be asked to come to your pediatric office to complete a baseline assessment (detailed below). Additionally, we hope to collect information about how participation in FBT may affect others in your home. Therefore, if you have another child who meets eligibility criteria (between the ages of 2-18 who is at or above the 85th percentile for age and sex), we ask that this child also attend the baseline assessment. After the baseline assessment and an initial appointment with your child's doctor, your family will be randomized to one of two treatment conditions described below.

Groups

At the start of the study, your family will be assigned to one of two groups. Participants in one group will receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group will receive family-based behavioral treatment for weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight

changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family will be in/the treatment you get will be chosen by chance. Like flipping a coin. Neither you nor your doctor will choose what treatment your family will receive. Your family will have an equal chance of being assigned to each group. You will be informed of the group your family is in and your treatment following an initial physician visit.

Treatment Schedule

Every family will follow their pediatrician's recommended schedule of appointments for weight management to have at least 4 visits with their child's doctor over the course of the 24 months of the study. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT PLAN Coach during the 24 months of the study. The amount of sessions completed within this range will be based on progress through the program and will vary for each family.

Assessments, Interviews, Questionnaires

Attendance will be taken and both you and your child will be weighed at every session. In addition, there will be five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Treatment assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric office, or a home visit can be arranged. Height and weight will be taken on you and your child as well as the identified other family members (if applicable). Your height will be taken at the beginning of the study, and your child(ren)'s height will be taken at each major assessment. You and your participating child will also complete short questionnaires. You both will be asked questions about parenting behaviors and the home food and activity environment. At your baseline, 12-month, and follow-up appointments, you will be asked to complete a computer task. Throughout the study, you will have access to a website that contains study materials and interactive tools.

Audio Recording

Your interviews and individual family will be audiotaped or digitally recorded for research purposes, but you will not be identified on the recording and the recordings will not be labeled with your name. Recording the sessions is the best way to make sure we collect accurate information. It also helps us make sure that all our staff delivers the study to participants in the same way. The recordings will be stored on password-protected computers with restricted access within the University at Buffalo, and

then transferred to Washington University School of Medicine. The recordings will be labeled only with your study ID, date, and session number. The Principal Investigator and research staff may use these recordings for purposes of evaluation, treatment, research, and training related to this study. Recordings may also be used to train staff implementing these or similar interventions at other sites. The recordings will be destroyed at the end of the study when all data analysis is complete. You do not have to agree to be audio recorded in order to participate in this study.

Please check and initial below if you agree or do not agree to give permission for you and your child to be audio recorded during your sessions with the PLAN coach.

YES _____ NO_____ Parent INITIAL_____ Date: _____

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to attend the baseline assessment, all treatment assessments, at least 26 treatment sessions if your family is in the group receiving FBT, and the follow-up assessment.

What happens if I do not want to be in this research?
Your participation in this research study is voluntary. You may choose not to enroll in this study. There are no other research alternatives other than to participate in this study.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. It will not be held against you. You do not have to answer every question and may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not be able to find this kind of family treatment in your area outside of this research study. Other types of treatment may be available in your community. In which case we will provide a list of these and how to find them if you prefer this option. However, you and/or your insurance company would be responsible for any costs associated with these options. You also may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included below. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way being in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You might feel hungry when dieting or sore after exercising.

Less Likely

- You may find some of the questions embarrassing or be uncomfortable having your height and weight measured.
- There may be some family disagreements as issues of family functioning; communication; and discipline are discussed.

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments and family sessions.

Rare

- There is a risk of audio recordings being lost. All recordings will be immediately stored in a locked drawer or saved to a password-protected computer in the research office after the individual family and group weight loss and maintenance sessions. Your family name will not be on these recordings, which will be identified only by a study ID number.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.
- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.

Other Risks

- In this study you will be given a physical activity goal. Given that some people may have medical risks associated with increasing their physical activity, these recommendations for your child will be given in consultation with his/her doctor. As an adult, you may consider getting approval from your doctor for setting physical activity goals. Adult participants will be responsible for consulting their doctor for approval.
- **Randomization** - As mentioned before, this study has two groups. Because chance decides which group you will be in, the treatment you receive as part of this study may not be what your own doctor would choose for you.

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits could include you and your child losing weight, becoming more physically active, and eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to better relationships and better mood. However, we cannot guarantee that you or your child will receive any benefits from this study. This study may also provide information that will help other children inside and outside your household to lose weight and keep it off.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal Investigator until the end of the study. At which point they will be destroyed. If you withdraw from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP

(Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institutes (NHLBI). If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury. If you agree to take part in this research study, we will pay you up to $175 for your time and effort. The amount you are paid depends upon your attendance to visits in the study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__√__ Specific information from your medical records related to height, weight, dietary restrictions, and physical activity restrictions.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in you and your child's care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institutes (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√__ Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall

Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.		
Signature of subject		Date
Printed name of subject		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

PILOT Participating Child Assent to be in a Research Study (for Children 7-13 years of age)

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, PhD

Who are we?
My name is Dr. Leonard H. Epstein and I am a researcher at the University at Buffalo. I work in the Department of Pediatrics.

Why are we meeting with you?
We want to tell you about a study that involves children like yourself. We want to see if you would like to be in this study too.

Why are we doing this study?
We want to look at a certain kind of weight loss program for kids. We want to know if it will work at a doctor's office.

What will happen to you if you are in the study?
You and a parent will first come to the doctor's office. We will tell you about this study that teaches kids about healthy eating and activities. We will ask you if you want to be a part of the study. If you do, we will measure your height and weight. We will ask you to answer some questions about yourself and your parents. You will do a task that asks you to make choices between different amounts of money. If you want to, we will ask to you come back for more visits.

After this, you and your parent will visit the doctor's office once a week for 3 months. At the visits you would meet with someone from the study. This would be at least 12 visits. Your height and weight will be taken. You will learn about healthy food. We will teach you fun ways to exercise.

At your first visit and at your last visit, we will ask you some questions about yourself. We will measure your height and weight. At your baseline and Follow-up appointment, we will ask you to do a computer task that asks you to make choices between different amounts of money.

You do not have to answer any questions that you do not want to answer. You do not have to do any activities that you do not want to do.

What are the good things and bad things that may happen to you if you are in the study?
Most Likely: You can have fun learning about healthy food and exercise. You could become healthy.

Maybe: You could become hungry when trying to eat healthy. Your muscles could feel sore from exercise. That will go away once you are used to exercising.

Do you have to be in the study?
No you do not. No one will get angry or upset with you if you don't want to do this. Just tell us if you do not want to be in the study. And remember, you can change your mind later if you decide you do not want to be in the study anymore.

Do you have any questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: *Leonard H. Epstein, Ph.D.* Phone Number: *(716) 829-3400*

Signature Block for Assent of Child

Your signature documents your permission to take part in this research.		
Signature of subject		Date
Printed name of subject		
I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

PILOT Parental Permission for Targeted Child to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Why is my child being invited to take part in a research study?
Your child is being invited to take part in a pilot research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- Your child is between the ages of 7 and 12 years old. Your child falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex). Your child has at least one parent who is interested in participating in the study.

This research study is supported by a grant through the National Heart, Lung and Blood Institutes (NHLBI). Research studies only include individuals who choose to take part in them. Your decision for your child to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating. You may wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should my child and I know about a research study?

- Someone will explain this research study to you and your child.
- Whether or not your child takes part is up to you and your child.
- You and your child can choose for your child not to take part.
- You and your child can agree to take part and later change your mind.
- You and your child's decision will not be held against you.
- You and your child can ask all the questions you want before you decide.

Who can my child and I talk to?
If you or your child has questions, concerns, or complaints, or think the research has hurt your child, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein**.** You may also contact the PLAN coach at your child's doctor's office; or you can contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your child's rights as a participant in this research.
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this pilot study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity, but there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care.

Your child has been asked to participate because he/she is between the ages of 7 and 12 years old, falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and has at least one parent who is interested in participating in the study.

How long will the research last?
We expect that your child will be in this treatment and research study for 3 months.

How many people will be studied?
We expect about 6 families will be in pilot phase of this research study in your geographical location.

What happens if I say yes, my child wants to be in this research?
To determine if your child is eligible to participate: you and your child will be asked to complete an eligibility assessment at an orientation session about this study. You and your child's height and weight will be measured. Standard questions regarding medical and psychological history will be asked by a trained interviewer to determine eligibility.

If your family is eligible for this research study and agrees to participate: you and your child will be asked to come to your pediatric office to complete a baseline assessment (detailed below). After the baseline assessment, your family will be enrolled. You will meet with a PLAN coach weekly.

Group

At the start of the study, your family will be assigned to receive family-based behavioral treatment for weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan, which uses RED, YELLOW, GREEN labels for food to guide families toward the goal of eating nutritious foods; 2) the Traffic Light Activity Program, which also uses RED, YELLOW and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors; and 3) a variety of behavioral techniques including changing and controlling your environment, tracking eating and physical activity, setting goals, problem solving, setting up a reward system, incentives for behavior change and weight loss, finding substitutes for unhealthy foods, and improving positive parenting. FBT also involves making changes in the home. Weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

Treatment Schedule

Every family will receive FBT and will complete at least 12 sessions with the FBT PLAN Coach during the 3 months of the study.

Assessments, Interviews, Questionnaires

Attendance will be taken and both you and your child will be weighed at every session. In addition, there will be two major assessments throughout the entire 3 months of the pilot study:

- 1 Baseline assessment upon starting study (0 months)
- 1 Follow-up assessment at end of study (3 months)

Each major assessment will take approximately 30-90 minutes to complete at your child's pediatric office, or a home visit can be arranged. Height and weight will be taken on you and your child. Your height will be taken at the beginning of the study. Your child's height will be taken at each major assessment. At your baseline and Follow-up appointment, we will ask you to do a computer task that asks you to make choices between different amounts of money.

Audio Recording

Your interviews and individual family will be audiotaped or digitally recorded for research purposes. You will not be identified on the recording and the recordings will not be labeled with your name. Recording the sessions is the best way to make sure we collect accurate information. It also helps us make sure that all our staff delivers the study to participants in the same way. The recordings will be stored on password-protected computers with restricted access within the University at Buffalo; then transferred to Washington University School of Medicine. The recordings will be labeled only with your study ID, date, and session number. The Principal Investigator and research staff may use these recordings for purposes of evaluation, treatment, research, and training related to this study. Recordings may also be used to train staff implementing these or similar interventions at other sites. The recordings will be destroyed at the end of the study when all data analysis is complete. You do not have to agree to be audio recorded in order to participate in this study.

Please check and initial below if you agree for you and your child to be audio recorded during your sessions with the PLAN coach:

_____YES, PARENT INITIAL_____, I give my permission to be audio recorded during sessions with a PLAN Coach. Date: _____

_____NO, PARENT INITIAL_____, I do **not give** my permission to be audio recorded during sessions with a PLAN Coach. Date: _____

What are my child's responsibilities if he/she takes part in this research?
If your child takes part in this pilot research, he/she will be responsible to: attend the baseline assessment, follow-up assessment, and attend at least 12 treatment sessions if your family is in the group receiving FBT.

What happens if my child does not want to be in this research?
Your child's participation in this pilot research study is voluntary. You or your child may choose not to enroll in this study. There are no other research alternatives other than to participate in this study.

What happens if my child and I say yes, but change our mind later?
Your child can leave the pilot research at any time. It will not be held against him/her. Your child does not have to answer every question and may refuse to answer any questions that he/she does not want to answer.

If your child decides to leave the pilot research, you may not be able to find this kind of family treatment in your area outside of this research study. Other types of treatment may be available in your community, in which case we will provide a list of these and how to find them if you prefer this option. You and/or your insurance company would be responsible for any costs associated with these options. You also may not receive full compensation for your participation if your child decides to leave the research. Contact the investigator at the contact information included below if your child decides to leave the study. If your child stops being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your child's routine medical care.

Is there any way being in this study could be bad for my child?
There are certain risks and discomforts that may be associated with this research.

They include:

Likely

- Your child might feel hungry when dieting or sore after exercising.

Less Likely

- Your child may find some of the questions embarrassing or be uncomfortable having his/her height and weight measured.
- There may be some family disagreements as issues of family functioning, communication, and discipline are discussed.
- Your child may be inconvenienced at times by having to miss school activities, meetings, etc., to attend assessments and family sessions.

Rare

- There is a risk of audio recordings being lost. All recordings will be immediately stored in a locked drawer or saved to a password-protected computer in the research office after the individual family and group weight loss and maintenance sessions. Your family name will not be on these recordings, which will be identified only by a study ID number.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.
- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.

Other Risks

- In this study your child will be given a physical activity goal. Given that some people may have medical risks associated with increasing their physical activity, these recommendations for your child will be given in consultation with his/her doctor.

Will being in this study help my child in any way?
We cannot promise any benefits to you, your child, or others from your taking part in this research. However, possible benefits could include your child losing weight, becoming more physically active, and eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to better relationships and better mood. However, we cannot guarantee your child will receive any benefits from this study. This study may provide information that will help other children inside and outside your household to lose weight and keep it off.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your child's personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your child's information include the IRB and other representatives of this organization. Information related to your child will be treated in strict confidence to the extent provided by law. Your child's identity will be coded and will not be associated with any published results. Your child's code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your child's participation in this study and the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal Investigator until the end of the study, at which point they will be destroyed. If your child withdraws from the study, no further data will be collected, but any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your child's identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your child's medical records and related health information. These are described in the HIPAA section of this document.

Can my child be removed from the research without our OK?

The principal investigator of the study can remove your child from the research study without you or your child's approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons. We will tell you about any new information that may affect your child's health, welfare, or choice to stay in the research.

What else do my child and I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).

If your child needs medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury. If your child agrees to take part in this research study, we will pay your family up to $30 for your time and effort. The amount you are paid depends upon your attendance to visits in the study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about your child and about your child's health that will be obtained by the researchers when your child participates in the research study. Health information is considered "protected health information" when it may directly identify your child as an individual. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about your child as part of this research study?

__√__ Information from your child's full medical records.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your child's protected health information be shared?

Your child's health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in your child's care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institutes (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your child's information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your child's information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your child's individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your child's protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about your child unless you revoke this authorization in writing.

__√__ Your child's protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about your child will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care your child receives at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you and your child will not be able to participate in the research study.

Signature Block for Parental Permission

Signature documents your permission for the named child to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Printed name of child	
Signature of parent or individual legally authorized to consent to the child's general medical care	Date
Printed name of parent or individual legally authorized to consent to the child's general medical care	❑ Parent ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Assent Process

- ❑ Child is birth-6 yrs. old - Assent is not required
- ❑ Child is 7-17 yrs. old – A separate Assent Document is to be signed by the child
- ❑ Assent will be obtained Verbally
- ❑ Assent has been waived by the IRB

I certify that the nature and purpose, the potential benefits and possible risks associated with participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent	Date
Printed name of person obtaining consent	

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

PILOT Parent Adult Consent to Participate in a Research Study

Version Date: 07-18-2018

Investigators: Leonard H. Epstein, Ph.D.

Why am I being invited to take part in a research study?
You and your child are being invited to take part in a pilot research study because:

- You are an adult able to read the English language. You have reported no current learning disabilities, medical problems, or psychiatric problems.
- You have a child between the ages of 7 and 12 years old that falls into the overweight or obese weight category (defined as at or above the 85th percentile for age and sex), and you are interested in weight loss and participating in the study.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein**.** You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu

If:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this pilot study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care.

How long will the research last?
We expect that you will be in this treatment and research study for 3 months.

How many people will be studied?
We expect about 6 families will be in the pilot phase of this research study.

What happens if I say yes, I want to be in this research?
To determine if your family is eligible to participate, you and your child will be asked to complete an eligibility assessment at an orientation session about this study. You and your child's height and weight will be measured, and standard questions regarding medical and psychological history will be asked by a trained interviewer to determine eligibility.

If your family is eligible for this research study and agrees to participate, you and your child will be asked to come to your pediatric office to complete a baseline assessment (detailed below). After the baseline assessment, your family will be enrolled. You will meet with a PLAN coach weekly.

Group
At the start of the study, your family will be assigned to receive family-based behavioral treatment for weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment, tracking eating and physical activity, setting goals, problem solving, setting up a reward

system, incentives for behavior change and weight loss, finding substitutes for unhealthy foods, and improving positive parenting. FBT also involves making changes in the home. So that weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

Treatment Schedule
Every family will receive FBT and will complete at least 12 sessions with the FBT PLAN coach during the 3 months of the study.

Assessments, Interviews, Questionnaires
Attendance will be taken and both you and your child will be weighed at every session. In addition, there will be two major assessments throughout the entire 3 months of the pilot study:

- 1 Baseline assessment upon starting study (0 months)
- 1 Follow-up assessment at end of study (3 months)

Both major assessments will take approximately 30-90 minutes to complete at your child's pediatric office, or a home visit can be arranged. Height and weight will be taken on you and your child. Your height will be taken at the beginning of the study, and your child's height will be taken at each major assessment. At your baseline and follow-up appointment, we will ask you to do a computer task that asks you to make choices between different amounts of money.

Audio Recording
Your interviews and individual family will be audiotaped or digitally recorded for research purposes, but you will not be identified on the recording and the recordings will not be labeled with your name. Recording the sessions is the best way to make sure we collect accurate information. It also helps us make sure that all our staff delivers the study to participants in the same way. The recordings will be stored on password-protected computers with restricted access within the University at Buffalo, and then transferred to Washington University School of Medicine. The recordings will be labeled only with your study ID, date, and session number. The Principal Investigator and research staff may use these recordings for purposes of evaluation, treatment, research, and training related to this study. Recordings may also be used to train staff implementing these or similar interventions at other sites. The recordings will be destroyed at the end of the study when all data analysis is complete. You do not have to agree to be audio recorded in order to participate in this study.

Please check and initial below if you agree or do not agree to give permission for you and your child to be audio recorded during your sessions with the PLAN coach.

___YES _____, Yes, I give my permission to be audio recorded during sessions with a PLAN coach

____NO_____, No, **I do not** give my permission to be audio recorded during sessions with a PLAN coach

Parent INITIAL_____ Date: _____

What are my responsibilities if I take part in this research?
If you take part in this pilot research, you will be responsible to attend the baseline assessment, 3 month follow-up assessment, and attend at least 12 treatment sessions.

What happens if I do not want to be in this research?
Your participation in this pilot research study is voluntary. You may choose not to enroll in this study. There are no other research alternatives other than to participate in this study.

What happens if I say yes, but I change my mind later?
You can leave the pilot research at any time. It will not be held against you. You do not have to answer every question. You may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not be able to find this kind of family treatment in your area outside of this research study. Other types of treatment may be available in your community. In which case we will provide a list of these and how to find them if you prefer this option. However, you and/or your insurance company would be responsible for any costs associated with these options. You also may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included below. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way being in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You might feel hungry when dieting or sore after exercising.

Less Likely

- You may find some of the questions embarrassing or be uncomfortable having your height and weight measured.
- There may be some family disagreements as issues of family functioning, communication, and discipline are discussed.
- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments and family sessions.

Rare

- There is a risk of audio recordings being lost. All recordings will be immediately stored in a locked drawer or saved to a password-protected computer in the research office after the individual family and group weight loss and maintenance sessions. Your family name will not be on these recordings, which will be identified only by a study ID number.

- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.
- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.

Other Risks

- In this study you will be given a physical activity goal. Given that some people may have medical risks associated with increasing their physical activity, these recommendations for your child will be given in consultation with his/her doctor. As an adult, you may consider getting approval from your doctor for setting physical activity goals. Adult participants will be responsible for consulting their doctor for approval.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits could include you and your child losing weight, becoming more physically active, and eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to better relationships and better mood. However, we cannot guarantee that you or your child will receive any benefits from this study. This study may also provide information that will help other children inside and outside your household to lose weight and keep it off.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal Investigator until the end of the study. At which point they will be destroyed. If you withdraw from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?

The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.

What else do I need to know?

This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institutes (NHLBI). If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury. If you agree to take part in this research study, we will pay you up to $30 for your time and effort. The amount you are paid depends upon your attendance to visits in the study.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form, you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__√__ Specific information from your full medical records related to your height, weight, dietary restrictions, and physical activity restrictions.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in you and your child's care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institutes (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

___√__ Other medical investigators/centers/institutions participating in this research study.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring

Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√__ Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.
Signature of subject Date
Printed name of subject
Signature of person obtaining consent Date
Printed name of person obtaining consent

THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Participating Child Assent to be in a Research Study (for Children 7-13 yrs. of age)

Version Date: 6.25.19

Investigators: Leonard H. Epstein, PhD.

Who are we?
My name is Dr. Leonard H. Epstein and I am a researcher at the University at Buffalo. I work in the Department of Pediatrics.

Why are we meeting with you?
You have aged into a different age group of 7-13 year olds. We need you to assent to continue participating in this weight loss program for kids.

Why are we doing this study?
We want to look at a certain kind of weight loss program for kids. We want to know if it will work at a doctor's office.

What will happen to you if you continue to participate in the study?
You will continue to come to the doctor's office like before, nothing has changed. You will keep coming in to get your height and weight measured and fill out surveys.

You and your parent will continue to be a part of one of two groups:

- If you are in one group, you follow the recommendations of your doctor.
- If you are in the other group, you come to your doctor's office once a week for 2 years. This happens for at least 26 visits. At the visits you meet with someone from the study. Your weight is taken and you learn about healthy food. We teach you fun ways to exercise.

Every 6 months we ask you some questions about yourself. We continue to measure your height and weight. At your 12-month and follow-up appointments, we ask you to do a computer task that asks you to make choices between different amounts of money.

You do not have to answer any questions that you do not want to answer. You do not have to do any activities that you do not want to do.

What are the good things and bad things that may happen to you if you continue to be a part of the study?

Most Likely: You can have fun learning about healthy food and exercise. You could become healthy.

Maybe: You could become hungry when trying to eat healthy. Your muscles could feel sore from exercise. That will go away once you are used to exercising. You might experience common exercise injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

Do you have to continue to be in the study?
No you don't. No one will get angry or upset with you if you don't want to do this. Just tell us if you don't want to continue to be in the study. Also, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: *Leonard H. Epstein, Ph.D.* Phone Number: *(716) 829-3400*

Signature Block for Assent of Child

Your signature documents your permission to continue to take part in this research.		
Signature of subject		Date
Printed name of subject		
I certify that the nature and purpose, the potential benefits and possible risks associated with continued participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

(*This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19*)**.**

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Targeted Child Ages 14-17 Assent to Participate in a Research Study

Version Date: 7.8.19

Investigators: Leonard H. Epstein, PhD.

Why am I being asked to continue in this research study?
You are being asked to assent to continue in this research study because:

- You have aged into a different age group of 14-17 years.

This research study is supported by a grant through the National Heart Lung and Blood Institute (NHLBI). Research studies only include individuals who choose to take part in them. Your decision to continue in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to continue to participate. You may also take home an unsigned copy of this consent form to think about continuing to participate or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you continue is up to you.
- You can choose not to continue.
- You can agree to continue and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care.

How long will the research last?
We expect that you will be in this treatment and research study for 24 months from your original start of the study.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location. Out of 528 families in the entire study nationally.

What happens if I say yes, I want to continue to be in this research?
You will continue your participation as before and no components of the research study have changed. As a reminder, you will continue to be asked to come to your pediatric office to complete assessment appointments (detailed below).

Groups

Your family has been assigned to one of two groups. Participants in one group receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group receive family-based behavioral treatment for weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family is in/the treatment you receive was chosen by chance. Like flipping a coin. Neither you nor your doctor chose what treatment your family is receiving.

Treatment Schedule

Every family will follow their pediatrician's recommended schedule of appointments for weight management to have at least 4 visits with their child's doctor over the course of the 24 months of the study. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT PLAN Coach during the 24 months of the study. The amount of sessions completed within this range will be based on progress through the program and will vary for each family.

Assessments, Interviews, Questionnaires

Attendance will be taken and you will continue to be weighed at every session. In addition, there are five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Treatment assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of the study (24 months)

Each major assessment takes approximately 30-90 minutes to complete at your pediatric office, or a home visit can be arranged. Height and weight is taken on you as well as the identified other family members (if applicable). Your height was taken at the beginning of the study and will be taken at each major assessment. You will also complete short questionnaires. You as well as the identified other family members will be asked questions about parenting behaviors and the home food and activity environment. At your baseline, 12-month, and follow-up appointments, you will be asked to complete a computer task. Throughout the study, you will have access to a website that contains study materials and interactive tools.

Audio Recording

Your interviews and individual family will be audiotaped or digitally recorded for research purposes, but you will not be identified on the recording and the recordings will not be labeled with your name. Recording the sessions is the best way to make sure we collect accurate information. It also helps us make sure that all our staff delivers the study to participants in the same way. The recordings will be stored on password-protected computers with restricted access within the University at Buffalo, and then transferred to Washington University School of Medicine. The recordings will be labeled only with your study ID, date, and session number. The Principal Investigator and research staff may use these recordings for purposes of evaluation, treatment, research, and training related to this study. Recordings may also be used to train staff implementing these or similar interventions at other sites. The recordings will be destroyed at the end of the study when all data analysis is complete.

What are my responsibilities if I continue to take part in this research?
If you continue to take part in this research, you will be responsible to attend all treatment assessments, at least 26 treatment sessions if your family is in the group receiving FBT, and the follow-up assessment.

What happens if I do not want to continue to be in this research?
Your participation in this research study is voluntary. You may choose not to continue in this study. There are no other research alternatives other than to participate in this study.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. It will not be held against you. You do not have to answer every question and may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not be able to find this kind of family treatment in your area outside of this research study. Other types of treatment may be available in your community. In which case we will provide a list of these and how to find them if you prefer this option. However, you and/or your insurance company would be responsible for any costs associated with these options. You also may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included above. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way continuing to be in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You might feel hungry when dieting, sore after exercising, or experience common exercise injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

Less Likely

- You may find some of the questions embarrassing or be uncomfortable having your height and weight measured.
- There may be some family disagreements as issues of family functioning; communication; and discipline are discussed.
- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments and family sessions.

Rare

- There is a risk of audio recordings being lost. All recordings will be immediately stored in a locked drawer or saved to a password-protected computer in the research office after the individual family and group weight loss and maintenance sessions. Your family name will not be on these recordings, which will be identified only by a study ID number.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security measures and carry their own risks if your family chooses to use them to supplement your participation in this study.
- In addition, although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.

Other Risks

- In this study you will be given a physical activity goal. Given that some people may have medical risks associated with increasing their physical activity, these recommendations will be given in consultation with your doctor. Participants will be responsible for consulting their doctor for approval.

Will continuing to be in this study help me in any way?

We cannot promise any benefits to you or others from your continuing to take part in this research. However, possible benefits could include you losing weight, becoming more physically active, and eating more healthfully as a result of participation. In addition, maintaining weight loss may lead to better relationships and better mood. However, we cannot guarantee that you will receive any benefits from this study. This study may also provide information that will help other children inside and outside your household to lose weight and keep it off.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. All recordings of the sessions will be kept in a locked file of the Principal Investigator until the end of the study. At which point they will be destroyed. If you withdraw from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your medical records and related health information.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institutes (NHLBI). If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury. If you agree to continue to take part in this research study, we will pay your parents up to $175 for your family's time and effort. The amount your parents are paid depends upon your attendance to visits in the study.

Signature Block for 14-17 year-old

Your signature documents your permission to continue to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject		Date
Printed name of subject		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

(*This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19*)**.**

THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Sibling Assent to be in a Research Study - (for Children 7-13 years of age)

Version Date: 6.25.19

Investigators: Leonard H. Epstein, PhD.

Who are we?
My name is Dr. Leonard H. Epstein and I am a researcher at the UB. I work in the Department of Pediatrics.

Why are we meeting with you?
You have aged into a different age group of 7-13 year olds. We need you to assent to continue participating in this weight loss program for kids.

Why are we doing this study?
We want to look at siblings of kids participating in a study through your doctor's office.

What will happen to you if you continue to participate in the study?
You will continue to come to the doctor's office like before, nothing has changed. You will keep coming in for a total of 5 times over 2 years so we can measure your height and weight. This will be done in private. Only your parent, your sibling, and the study member will be with you. You do not have to answer any questions if you don't want to. You do not have to do any activities you do not want to do.

What are the good things and bad things that may happen to you if you continue to be a part of the study?
Most Likely:

Good: You can learn how you are growing.

Maybe:

Good: You could learn what is like to be in a research study. You might lose weight.

Bad: You might not like getting your height and weight taken. You might feel hungry when dieting, sore after exercising, or experience common exercise injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

Do you have to continue to be in the study?
No you don't. No one will get angry or upset with you if you don't want to do this. If you do not want to be in the study at any time, it will not affect your family being in the study. Just tell us if you don't want

to be in the study. And remember, you can change your mind later if you decide you don't want to be in the study anymore.

Do you have any questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can call:

Name of contact person on the study: *Leonard H. Epstein, Ph.D.*
Phone Number: *(716) 829-3400*

Signature Block for Sibling Assent of Child

Your signature documents your permission to continue to take part in this research.		
Signature of subject		Date
Printed Name of Subject		

I certify that the nature and purpose, the potential benefits and possible risks associated with continued participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.

Signature of person obtaining consent		Date
Printed name of person obtaining consent		

(*This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19*)**.**

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Sibling Assent of a 14-17-year-old to Participate in a Research Study

Version Date: 7.8.19

Investigators: Leonard H. Epstein, PhD.

Why am I being invited to take part in a research study?
You are being asked to assent to continue in this research study because:

- You have aged into a different age group of 14-17 years.

This research study is supported by a grant through the National Heart Blood and Lung Institutes (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully and ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you continue is up to you.
- You can choose not to continue.
- You can agree to continue and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity, but there is still much to learn about how the treatment should be incorporated into various medical settings, such as primary care and how it effects siblings living with participating parents and children.

How long will the research last?
We expect that you will be in this treatment and research study for 24 months from your original start of the study.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location, out of 528 families in the entire study nationally.

What happens if I say yes, I want to continue to be in this research?
You will continue your participation as before and no components of the research study have changed. As a reminder, you will continue to be asked to come to your pediatric office to complete assessment appointments (detailed below).

Groups
Your family has been assigned to one of two groups. Participants in one group receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group receive family-based behavioral treatment for weight management (FBT). FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family is in/the treatment you receive was chosen by chance. Like flipping a coin. Neither you nor your doctor chose what treatment your family is receiving.

Treatment Schedule
Every family will follow their pediatricians recommended schedule of appointments for weight management. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT interventionist during the 24 months of the study. The amount of session completed within this range will be based on progress through the program and will vary for each family. You will not attend the sessions with the PLAN coach.

Assessments, Interviews, Questionnaires
You will continue to attend five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Measurement assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment takes approximately 30-90 minutes to complete at your sibling's pediatric office, or a home visit can be arranged. Your height and weight will continue to be taken at each major assessment.

What are my responsibilities if I continue to take part in this research?
If you continue to take part in this research, you will be responsible to attend all measurement assessments and the follow-up assessment. Your continued participation in any other meetings with your family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

What happens if I do not want to continue to be in this research?
Your continued participation in this research study is voluntary. You may choose not to continue in this study, it will not affect your family being in the study. ***There are no other research alternatives other than to participate in this study.***

What happens if I say yes, but I change my mind later?
You can leave the research at any time, it will not be held against you. You do not have to answer every question and may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included below. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way continuing to be in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments.
- You might feel hungry when dieting, sore after exercising, or experience common exercise injuries (i.e., sprains, shin splints, tendonitis, muscle pulls, strains, etc).

Less Likely

- You may find having your height and weight measured uncomfortable.

Rare

- Although this treatment usually prevents the development of eating disorder problems, in rare cases it may increase them.
- The use of online platforms is associated with risks involving breaches of confidentiality. We implement many layers of security to limit these risks as much as possible within our website and REDCap database. Outside platforms (i.e., MyFitnessPal) are subject to their own security

measures and carry their own risks if your family chooses to use them to supplement your participation in this study.

Will continuing to participate in this study help me in any way?
We cannot promise any benefits to you or others from your continuing to take part in this research. This study may provide information that will help you to lose weight and keep it off. However, we cannot guarantee that you will receive any benefits from this study.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. If you withdraw from the study, no further data will be collected, but any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.

What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).
If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

Signature Block for Assent of Child

Your signature documents your permission to continue to take part in this research. By signing this form, you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.	
Signature of subject	Date

Printed name of subject	
I certify that the nature and purpose, the potential benefits and possible risks associated with continued participation in this research study have been explained to the above individual and that any questions about this information have been answered. A copy of this document will be given to the subject.	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

(*This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19*)**.**

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federal wide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Sibling Adult Consent to Participate in a Research Study

Version Date: 6.25.19

Investigators: Leonard H. Epstein, PhD.

Why am I being invited to continue in this research study?
You are being asked to assent to continue in this research study because:

- You have aged into a different age group of 14-17 years.

This research study is supported by a grant through the National Heart Blood and Lung Institute (NHBLI). Research studies only include individuals who choose to take part in them. Your decision to take part in this study is entirely voluntary. Please read this information carefully. Ask questions about anything you do not understand before deciding whether or not to participate. You may also take home an unsigned copy of this consent form to think about participating or if you wish to discuss this matter with your family or your personal doctor. Please take your time to make your decision. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you continue is up to you.
- You can choose not to continue.
- You can agree to continue and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team by telephone at 716-829-3400 for Dr. Leonard Epstein. You may also contact the PLAN coach at your child's doctor's office. You can also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

- You have questions about your rights as a participant in this research
- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You want to talk to someone besides the research team.
- You want to get information or provide input about this research.

Why is this research being done?
The goal of this study is to determine whether a specific kind of weight loss treatment called family-based behavioral treatment (FBT) for children, delivered by a PLAN coach, can be included in the primary care setting. Extensive information has been gathered by our research team about the treatment of childhood overweight and obesity. But there is still much to learn about how the treatment should be incorporated into various medical settings. Such as primary care and how it effects siblings living with participating parents and children.

How long will the research last?
We expect that you will be in this treatment and research study for 24 months from your original start of the study.

How many people will be studied?
We expect about 132 families will be in this research study in your geographical location. Out of 528 families in the entire study nationally.

What happens if I say yes, I want to continue to be in this research?
You will continue your participation as before and no components of the research study have changed. As a reminder, you will continue to be asked to come to your pediatric office to complete assessment appointments (detailed below).

Groups

Your family has been assigned to one of two groups. Participants in one group receive the current standard of care offered by their physician for the treatment of childhood weight management. Participants in the second group receive family-based behavioral treatment for weight management (FBT).

FBT is a behavioral weight-control intervention that aims to make weight changes in both a child and their participating parent. FBT is a well-tested treatment that targets diet, activity, behavioral techniques, parenting, and social facilitation in children and their parents. The treatment includes: 1) The Traffic Light Eating Plan uses RED; YELLOW; and GREEN labels for food to guide families toward the goal of eating nutritious foods. 2) The Traffic Light Activity Program, also uses RED; YELLOW; and GREEN labels for different levels of exercise to increase physical activity and reducing inactive behaviors. 3) a variety of behavioral techniques including changing and controlling your environment; tracking eating and physical activity; setting goals; problem solving; setting up a reward system; incentives for behavior change and weight loss; finding substitutes for unhealthy foods; and improving positive parenting. FBT also involves making changes in the home. So weight loss or prevention of weight gain may extend to members of the family who are not regularly attending treatment sessions (e.g., siblings and spouse).

The group that your family is in/the treatment you receive was chosen by chance. Like flipping a coin. Neither you nor your doctor chose what treatment your family is receiving.

Treatment Schedule
Every family will follow their pediatrician recommended schedule of appointments for weight management. Families in the group receiving FBT will additionally complete at least 26 sessions with the FBT PLAN Coach during the 24 months of the study. The amount of sessions completed within this range

will be based on progress through the program. The amount will vary for each family. You will not attend the sessions with the PLAN Coach.

Assessments, Interviews, Questionnaires
You will attend five major assessments throughout the entire 2 years of the study:

- 1 Baseline assessment upon starting study (0 months)
- 3 Measurement assessments during the study (6, 12, and 18 months)
- 1 Follow-up assessment at end of study (24 months)

Each major assessment will take approximately 30-90 minutes to complete at your pediatric office, or a home visit can be arranged. Height and weight measurements will be taken at each major assessment.

What are my responsibilities if I continue to take part in this research?
If you take part in this research, you will be responsible to attend all measurement assessments and the follow-up assessment. Your participation in any other meetings with your family are voluntary. Weight measurements at these times are also voluntary and can be used as data.

What happens if I do not want to continue to be in this research?
Your participation in this research study is voluntary. You may choose not to continue in this study. There are no other research alternatives other than to participate in this study.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. It will not be held against you, or affect your family's participation in the study. You do not have to answer every question. You may refuse to answer any questions that you do not want to answer.

If you decide to leave the research, you may not receive full compensation for your participation. If you decide to leave the research, contact the investigator at the contact information included below. If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.

Is there any way continuing to be in this study could be bad for me?
There are certain risks and discomforts that may be associated with this research. They include:

Likely

- You may be inconvenienced at times by having to miss work, school activities, meetings, etc., to attend assessments.

Less Likely

- You may find having your height and weight measured uncomfortable.

Will continuing to be in this study help me in any way?
We cannot promise any benefits to you or others from your continued participation in this research. This study may provide information that will help you to lose weight and keep it off. However, we cannot guarantee that you will receive any benefits from this study.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We

cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be coded and will not be associated with any published results. Your code number and identity will be kept in a locked file of the Principal Investigator. The only connection between your participation in this study and the study itself will be this signed consent form. If you withdraw from the study, no further data will be collected. Any information that has been provided may be retained by the researchers and analyzed. In order to monitor this research study, representatives from the Institutional Review Board (IRB) and other federal agencies such as NIH (National Institutes of Health) and OHRP (Office of Human Research Protection) may inspect the research records which may reveal your identity. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time. Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include need for hospitalization for physical or psychological reasons.
What else do I need to know?
This research is being funded by the National Institutes of Health, specifically the National Heart, Lung and Blood Institute (NHLBI).
If you need medical care because of taking part in this research study, contact the investigator and/or speak with your doctor and medical care will be made available. Generally, this care will be billed to you, your insurance or other third party. The University at Buffalo has no program to pay for medical care for research-related injury.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__√__ Information from your full medical records (height, weight, dietary restrictions and physical activity restrictions.

__√__ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__√__ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__√__ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment.

__√__ The sponsor of this research study ***(National Heart, Lung and Blood Institutes (NHLBI)*** cooperative group, etc., or its agents.

__√__ The organization(s) responsible for administering this research (e.g., Research Foundation of SUNY, University at Buffalo, Washington University, Nationwide Children's Hospital, University of Rochester).

__√__ Other medical investigators/centers/institutions participating in this research study.

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

__√__ This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

__√__ Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Leonard H. Epstein, Ph.D.
University at Buffalo Department of Pediatrics
Division of Behavioral Medicine
3435 Main Street
G56 Farber Hall
Buffalo, NY 14214
Phone: 716-829-3400

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to continue to participate in the research study.

Signature Block for Capable Adult

Your signature documents your permission to continue to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.		
Signature of subject		Date
Printed name of subject		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

(*This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda, 10.25.19*)**.**

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Addendum: Parental Permission for Targeted Child to Participate in a Research Study

Version Date: 9.6.19

Investigators: Leonard H. Epstein, PhD, Denise Wilfley, PhD, Stephen Cook, MD, MPH, Ihuoma Eneli, MD, MS, FAAP

Change of Assessment Compensation:

In the initial consent form that you signed, we indicated that 'If your child agrees to take part in this research study, we will pay your family up to $175 for your time and effort. The amount you are paid depends upon your attendance to visits in the study'. However, the compensation for the 24-month assessment has increased from $50 to $100. This brings total potential compensation to $225. The amount you are paid depends upon your attendance to visits in the study.

In addition, each participating site will give participants tickets when they attend an assessment. Each participant will have a chance of accumulating up to 4 tickets depending on the number of assessments they attend (i.e., 6, 12, 18, & 24 month appointments). The number of winning tickets will be proportional to the number of families randomized at each site. Each winning ticket is worth $50.00. Please let the PLAN staff member know if you have any questions.

To ensure that each family is aware of this change to the consent form, please sign where indicated below:

Signature Block for Capable Adult

Your signature documents your permission to continue to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.		
Signature of subject		Date
Printed name of subject		
Signature of person obtaining consent		Date
Printed name of person obtaining consent		

(DSMB approved protocol addenda, 10.25.19).

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Title of research study: THE EFFECTIVENESS OF FAMILY-BASED WEIGHT LOSS TREATMENT IMPLEMENTED IN PRIMARY CARE

Addendum: Assessment Protocol in Response to Coronavirus Pandemic (COVID-19)

Date: 4.14.2020

Investigators: Leonard H. Epstein, PhD, Denise Wilfley, PhD, Stephen Cook, MD, MPH, Ihuoma Eneli, MD, MS, FAAP

Change of Assessment Protocol:
Due to the recent Coronavirus Disease (COVID-19) pandemic, we have modified our assessment protocols to adhere to public health guidelines as recommended by the Center for Disease Control and Prevention. In the initial consent form that you signed, we indicated "Each major assessment takes approximately 30-90 minutes to complete at your pediatric office, or a home visit can be arranged." Assessments will now take place at your home using scales, measuring tapes, and household objects to gather height and weight measurements that you will complete. Any materials that you may need as described in our protocol, but you do not currently possess, will be sent to your home by a PLAN With Families vendor (ie. Amazon) via postal mail at no cost to you. A subset of 10 families from each site, will be asked to complete a second height measurement one to two weeks after completing a remote assessment for quality control for an additional payment of $10.00.

During the assessment, a PLAN staff member will call or video conference with you to guide you through the measurement protocol to assist you through the process, and record your height and weight data. Additionally, you will be sent online questionnaires to complete using your personal computer, tablet, or smartphone, including a new questionnaire to assess your family's well-being during the current pandemic.

Upon the lifting of social distancing recommendations, we will meet with your family at your pediatric practice to gather your height and weight measurements based on our usual standardized lab protocol. You will be compensated 50% of the normal assessment payment for your self-conducted home measurement, and paid the remaining 50% at the in-person portion of the assessment.

Signature Block for Capable Adult

Your signature documents your permission to continue to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

(DSMB approved protocol addenda, 5.7.20).

C. Screening Measures

INITIAL ELIGIBILITY SURVEY SCRIPT

Introduce yourself and the PLAN program:

"Hello, my name is (name), this research is being conducted by the National Institutes of Health to encourage healthy eating habits and promote healthy *lifestyles* ***changes*** *for* ***families.*** *Our study is for families with a 6-12-year-old child and a parent, both of whom are overweight or obese. Additionally, overweight siblings and non-participating parents that are interested in the program will have the opportunity to participate as well.*

Would you be interested in learning more about the study?

IF NO → *Thank you for your time and consideration.* **END SCREEN.**

IF YES → ***Do you have a few minutes right now*** *for me to* ***tell you more about the program and ask you a few questions to see if this program would be a good fit for your family?"***

If NO:
Schedule a follow-up call, verify phone number. Document contact in the tracking database:

"Would there be a day/time that works better for you to talk more about the program? I can give you a call at a time that works best for you. What is your phone number? Or I could send you an email with a link to more information about the program. What is your email address?"

If YES:
Describe the study:

"Great! I want to let you know that specific personal questions will be asked during this phone screen and recorded into a private database maintained by Washington University in St. Louis, MO. This database will include your contact information and your answers to any specific eligibility criteria discussed during this phone screen."

"Just to review, our program is called PLAN with Families. That stands for Primary care pediatrics, Learning, Activity, and Nutrition. The goal of the program is for you and your child to learn ways to become healthier and stay healthy."

"In this study, we require that one child and one parent participate. The study will last about 2 years. To help us and you see what progress you make during your participation, you will complete some questionnaires, a short computer task, and have your height and weight taken 5 times over the 2 years. Since we think learning to be healthier is important for the whole family, you can include any other children you may have and your child's other parent in the study, too, but you don't have to. If one of your child's siblings is involved in the study, he or

she will only be asked to attend appointments every 6 months for height and weight measurements."

"All of the program meetings will be held here at your child's doctor's office. Your family will have an opportunity to participate in one of two groups. The first group is a Family Based Treatment (FBT) group where your family would meet regularly with a trained PLAN coach to learn new information and skills related to health topics, such as calorie intake and physical activity. The second group is called a Usual Care (UC) group where your family would continue to receive the most up to date health information from working closely with your child's pediatrician."

"If your family is interested and you decide this study would be a good fit for you, you and your child will be asked to come here to [practice name] to complete an orientation session. After the orientation meeting, if you join the program, you will learn which group you and your child will participate in.

"Does this sound like a study you might be interested in for you and your family?"

If NO:
Thank them for their time, share your contact information:

"Thank you for your time. Here's my contact information in case you change your mind or have any questions."

"Here is a postcard from the program. On this card is our website, http://planwithfamilies.com , ***where you can learn more about our program"***

If MAYBE:
If the family would rather think about if the study is the right fit for them or if they seem hesitant:

"If you would like to take some time to think about if the PLAN program is the right fit for you and your family, that's okay. I can follow-up with you in a few days. Would that be ok?"

"Here is a postcard from the program. Please provide a contact number and a preferred time to be reached. You can also check out the website http://planwithfamilies.com ***that is listed on the card."***

If YES:
Begin Initial Eligibility Survey

"Great! In order to get started I need to ask you some questions first. Do you have a few minutes to answer some questions?"

INITIAL ELIGIBILITY SURVEY INTRODUCTION

This survey is the first step in determining if the PLAN program is right for your family. This survey is brief and should only take approximately 10 minutes.

Your participation in this survey is voluntary and you may stop the survey at any time. Any information related to you and your household will be kept confidential and will be stored in a secure database that is only accessible to the PLAN team.
If you have questions at any time, please stop me and I will answer them for you. If you have questions in the future, feel free to contact me at (PLAN coach's cell phone number). I will be happy to answer any questions or concerns that you or your family may have about our program! Do you have any questions at this time?"

PARENT INFORMATION

The following questions must be answered by the parent or adult interested in enrolling in the PLAN program. If there are any questions that you do not wish to answer, please let me know and will move onto the next question.
Q: What is your first name? (*Ask for spelling if necessary*) _____

Q: What is your last name? (*Ask for spelling if necessary*) _____

Q: What is your address?
Street Address: _____
Street Address, continued: _____
City: _____
State: _____
Zip Code: _____

Q: What is the best number at which to contact you? _____

Q: What is the best email address to use to contact you? _____

Q: Is your family planning to move from the area in the next two years?
- ***No***
- ***Yes***
- ***Refuse to answer***

Q: What is your date of birth? (select from Calendar MM/DD/YYYY)
Q: What is your sex? Choose from dropdown menu:
- ***Male***
- ***Female***
- ***Other***
- ***Refuse***

Q: What is your race?
- ***American Indian or Alaskan Native***
- ***Asian***
- ***Native Hawaiian or Other Pacific Islander***
- ***Black or African American, not of Hispanic Origin***
- ***White or Caucasian, not of Hispanic Origin***

- ***Hispanic or Latina/o***
- ***Other, please specify:***
    - ***Other, please describe: _____***

Q: What is your height, in inches? _____

Q: What is your weight? _____

BMI Parent: _____

Q: When was your weight last taken? (Estimated if necessary MM/YYYY or YYYY)

_____

Q: Are you able to complete, at minimum, a brisk 5-10-minute walk?

- ***Yes***
- ***No***
- ***Refuse to answer***

Q: Have you had a concussion in the last 3 months?

- ***No***
- ***Yes,***
    - ***Date of concussion: _____***
    - ***Please describe: (description, effects) _____***

Q: How many children do you have? _____

Q: Do you have a child between the ages of 6-12 that you would like to enroll in this study?

- ***Yes***
- ***No***

If family is ineligible:

"Thank you for your interest and answering these questions. A requirement of this program is that the adult is joined by one of their children between the ages of 6-12 years old. Because you do not have a child between these ages that you would like to enroll, the PLAN program is not a good fit for your family. However, may we keep your information and contact you with future projects for which you or your family may be a good match?"

- ***No***
- ***Yes***

If family is eligible:

"Thank you for answering the survey questions about yourself. Next we will ask you to answer some general information questions about your child."

CHILD INFORMATION

"The following questions pertain to the child between the ages of 6-12 who you would like to enroll in the PLAN program."

If family has two or more children between the ages of 6-12 years old:
"It is great that your children are interested in participating! Unfortunately, we can only enroll once child as the participating child. We typically encourage the enrollment of the oldest sibling because s/he will serve as a role model for the younger sibling. However, we leave it up to our parents to decide which child would best fit our program."

"If there are any questions that you do not wish to answer, please let me know."

Q: What is the first name of the child you wish to enroll in the study? (*Ask for spelling if necessary*) _____

Q: What is the last name of the child you wish to enroll in the study? (*Ask for spelling if necessary*) _____

Q: Is this child:

- ***Biological child***
- ***Adopted child***
- ***Step child***
- ***Foster child***
- ***Other relative***
    - ***If other relative, please describe: _____***

Q: What is the name of your child's primary care physician? _____

Q: What is this _____'s date of birth? (select from Calendar MM/DD/YYYY)

Q: Child's age: (will automatically populate) _____

Q: What is _____'s sex? Choose from dropdown menu:

- ***Male***
- ***Female***
- ***Other***
- ***Refuse***

Q: What is your child's race?

- ***American Indian or Alaskan Native***
- ***Asian***
- ***Native Hawaiian or Other Pacific Islander***
- ***Black or African American, not of Hispanic Origin***
- ***White or Caucasian, not of Hispanic Origin***
- ***Hispanic or Latina/o***
- ***Other, please specify:***
    - ***Other, please describe: _____***

Q: How much does this child weigh? _____

Q: When was his/her weight last measured? (Estimated if necessary MM/YYYY or YYYY)
_____

Q: What is _____'s height in inches? _____

Participating child's BMI: _____

Q: Has this child had a concussion in the last 3 months?

- ***Yes***
  - ***If yes, date of concussion: (M-D-Y) _____***
  - ***Please explain (description, effects): _____***
- ***No***
- ***Refused***

Q: Is _____ able to complete, at minimum, a brisk 5-10-minute walk?

- ***Yes***
- ***No***
- ***Refused***

If family is ineligible because there are no children between the ages of 6-12 in the household:
Thank you for your interest and your willingness to answer these questions. A requirement of this program is that the adult is joined by one of their children between the ages of 6-12 years' old who meets certain criteria. Because you do not have a child between these ages that meets our criteria, the PLAN program is not a good fit for your family. However, may we keep your information and contact you with future projects for which you or your family may be a good match?

- ***No***
- ***Yes***

If child has had a concussion in the last three months:
"One of our requirements is that the participating child has not had a concussion in the last three months. This is because your child's performance on one of our program tasks may be affected by concussion symptoms. Therefore, I would like to wait until ____ more months have passed before continuing the screening process. Would that be okay with you?"

If YES: Coach will schedule a call back date/time.
If NO: Thank them for their time.

If family is eligible: The coach will proceed to asking questions regarding additional siblings.

ADDITIONAL SIBLING INFORMATION

"We want the entire family to benefit from the program. Therefore, we offer an opportunity for your child's siblings to participate, as well. The sibling(s) would have their height and weight taken with you and your child at the 5 time points, as well as have access to the information on healthy lifestyle that we provide."

Do you have another child, who also meets the criteria for overweight/obesity, in your family between the ages of 2-18 that you would like to enroll in this program as well?

If YES***: "How many additional children would you like to enroll? You may enroll up to four additional children in the program."***

If YES: Move on INCLUDING all parts about participating sibling and collect the following information.

If NO: Move onto the "Wrapping Up" section below.

The coach will ask the following questions for all non-participating siblings.
Q: What is the first name of the second/third/fourth child you would like to enroll in the study? (*Ask for spelling if necessary*) _____

Q: What is the last name of the second/third/fourth child you wish to enroll in the study? (*Ask for spelling if necessary*) _____

Q: Is _____ your:
- ***Biological child***
- ***Adopted child***
- ***Step child***
- ***Foster child***
- ***Other relative***
    - ***If other relative, please describe: _____***

Q: What is the name of _____'s primary care physician? _____

Q: What is this _____'s date of birth? (select from Calendar MM/DD/YYYY)

Q: Age: (will automatically populate) _____

Q: What is this child's sex? Choose from dropdown menu:
- ***Male***
- ***Female***
- ***Other***
- ***Refuse***

Q: How much does _____ weigh? _____

Q: When was his/her weight last measured? (Estimated if necessary MM/YYYY or YYYY)
_____

Q: What is _____'s height in inches? _____

Q: Non Participating Child's BMI: (Automatically calculated) _____

Q: Has _____ had a concussion in the last 3 months?

- ***Yes***
  - ***If yes, date of concussion: (M-D-Y) _____***
  - ***Please explain (description, effects): _____***
- ***No***
- ***Refused***

Q: Is _____ able to complete, at minimum, a brisk 5-10-minute walk?

- ***Yes***
- ***No***
- ***Refused***

READING LEVEL INFORMATION

The coach will ask this question about the participating child and any non-participating siblings:

Q: Can _____ read and comprehend at a first grade level?

- ***Yes***
- ***No***

WRAPPING UP

The coach will then wrap up the Initial Eligibility Survey:

"Thank you for answering the questions on the Initial Eligibility Survey. Next we will ask you to answer additional questions about you and your child's medical and psychiatric histories on the Eligibility Survey. This survey usually takes between 15-20 minutes to complete. Do you have time for us to complete this survey right now?"

If NO:

Schedule a follow-up call, verify phone number. Document contact in the tracking database:

"Would there be a day/time that works better for you to talk more about the program? I can give you a call at a time that works best for you, or we could schedule another time to meet here at the office."

If YES: Schedule a call (verify phone number) or in person meeting at the practice. Document contact in the database.

If NO: Thank them for their time.

If YES:

Begin Eligibility Phone Screen.

ELIGIBILITY PHONE SCREEN SCRIPT

"Just to review, our program is called Primary care pediatrics, Learning, Activity, and Nutrition, or PLAN for short. The goal of our program is for you and your child to learn ways to become healthier and stay healthy. In this program, we require that one child and one parent participate. The study will last about 2 years. During your participation in the program, we will look at your progress by asking you to complete some questionnaires, a short computer task, and have your height and weight taken 5 times over the 2 years.

All of the meetings will be held here at your child's doctor's office. If interested, you and your family, including the participating child and parent, non-participating parent, and participating sibling/s will be asked to come to your child's physician's office to meet with the PLAN coach to complete an orientation, height and weight measurements, and an assessment,

Your family will have an opportunity to participate in one of two groups: A Family Based Treatment group (FBT) where your family meets regularly with a trained health coach at the practice, or the usual care group where your child will continue to receive standard care from their doctor.

Families are randomly selected into each group. Those in the group receiving Family Based Treatment, or FBT, will additionally complete at least 26 sessions with the health coach during the 24 months of the study. The amount of sessions completed within this range will be based on progress through the program and will vary for each family. Participating siblings, as well as the non-participating parent, will be asked to attend appointments every 6 months for height and weight measurements.

"Does this sound like a program you might be interested in for your family?"

If NO: Thank them for their time
If YES: Continue to *Eligibility Phone Screen.*

ELIGIBILITY PHONE SCREEN

"Next, there are a few more questions to answer in order to determine your full eligibility for this study. Some of these questions are a little repetitive from the questions that I asked you during the Initial Eligibility Survey because I want to make sure all of the information that I gather about your family is correct. Do you have any questions?"

Q: We ask that one overweight parent attends and participates with the child in the program. What is the first name of the parent interested in participating? _____

Q: What is the participating parent's last name? _____

Q: Is [parent's first name] willing to attend all treatment sessions and assessments with the child over the next two years?

- ***Yes***
- ***No***

Q: Parent BMI is _____ (answer is automatically generated)

Q: Is the parent able to continue with the screen based on BMI?

- ***Yes***
    - ***If yes, continue with screening.***

- ***No***
    - ***If no, follow the procedure listed below.***

If the preferred participating parent is not overweight based on the reported height and weight from the Initial Eligibility Survey:
We require that the participating parent meets specific weight criteria. Unfortunately, your answers indicate that you do not meet these criteria. Is there another parent who meets the overweight criteria that would be interested in participating?

If NO: Thank them for their time
If YES: Continue on with Eligibility Phone Screen by gathering information about the parent who is eligible.

Q: What is the name of your/_____'s current physician? _____

Q: What is the physician's practice name? _____

Q: What is the practice address?
Practice address: _____
Practice address continued, if necessary: _____
City, State, Zip: _____

Q: Practice phone number: _____

Q: We want the entire family to benefit from the program. Therefore, we offer an opportunity for your child's siblings to participate as well. The sibling would have his/her height and weight taken with you and your child at the 5 time points, as well as have access to the information on healthy lifestyles that we provide.
Do you have another child (a sibling of the child participating) that would be interested in participating?

- ***Yes***
- ***No***

Q: What are the ages of the children who would like to participate?

- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***
- ***12***
- ***13***

- ***14***
- ***15***
- ***16***
- ***17***
- ***18***
- ***Over 18***

If age is < 2 or > 18:
"Unfortunately your child (participating sibling) does not meet the age criteria to participate in this study; however, this does not affect you and your other child's ability to participate."

- ***Move on with script EXCLUDING all parts about participating sibling.***
- ***This is not an exclusionary criterion for the primary participating child and parent.***

If age is 2-18:
"Would he/she be interested in participating in this study?"

- ***If yes, move on to INCLUDING all parts about participating sibling.***
    - ***If family has two children ages 6-12 years old, we will be encouraging that the older sibling be the primary participant, as it is more likely the older sibling will serve as a role-model for the younger sibling.***
    - ***In families where more than one eligible sibling is available, we will enroll the sibling whose age is closest to that of the study child.***
- ***If no, move on EXCLUDING all parts about participating sibling.***

"Next, there are a few more questions related to your family's medical and psychiatric histories. I will ask you specific personal questions. Your participation in this survey is voluntary and you may stop the survey at any time. Any information related to you and your household will be kept confidential and will be stored in a secure database that is only accessible to the PLAN team. Do you have any questions?"

"I will start by asking you questions about the child that would like to participate in the program."

Q: What is your child's first name? _____

Q: Does _____ have any medical conditions or is s/he undergoing any medical treatment?"

- ***Yes***
    - ***If yes, can you describe the treatment?*** _____
- ***No***

Q: Does _____ take any medications?

- ***Yes***
- ***No***

Q: How many medications?

- ***1***

- *2*
- *3*
- *4*
- *5*

Q: Name of first medication: _____

Q: Dose: _____

Q: How often does your child take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: Years taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
- *12*
- *13*
- *14*
- *15*
- *16*
- *17*
- *18*

Q: Number of months [medication]?

- *0*
- *1*
- *2*

- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*

Q: Name of second medication: _____

Q: Dose: _____

Q: How often does your child take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: Years taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
- *12*
- *13*
- *14*
- *15*
- *16*
- *17*
- *18*

Q: Number of months [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***

Q: Name of third medication: _____

Q: Dose: _____

Q: How often does your child take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: Years taking [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***
- ***12***
- ***13***

- ***14***
- ***15***
- ***16***
- ***17***
- ***18***

Q: Number of months [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***

Q: Name of fourth medication: _____

Q: Dose: _____

Q: How often does your child take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: Years taking [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***

- *9*
- *10*
- *11*
- *12*
- *13*
- *14*
- *15*
- *16*
- *17*
- *18*

Q: Number of months [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*

Q: Name of fifth medication: _____

Q: Dose: _____

Q: How often does your child take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: Years taking [medication]?

- *0*
- *1*
- *2*
- *3*

- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
- *12*
- *13*
- *14*
- *15*
- *16*
- *17*
- *18*

Q: Number of months [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*

***Q: Does your child have any condition that would make him/her unable to exercise or limit the amount* of exercise?"**

- *Yes*

- *No*

Q: Has _____ever had weight-related surgery such as gastric bypass?

- *Yes*
- *No*

Q: Is your child currently participating in a weight loss or weight management program?

- *Yes*
- *No*

Q: Does _____ have any food allergies or dietary restrictions?

- ***Yes***
    - ***If yes, please list restrictions and/or allergies: _____***
- ***No***

Q: Has this child undergone any psychological treatment and/or counseling?"

- ***Yes***
    - ***If yes, please describe condition: _____***
- ***No***

Q: Has _____ ever been diagnosed with a psychiatric condition like depression or anxiety?

- ***Yes***
- ***No***

Q: Has your child ever been diagnosed with a developmental delay, intellectual disability, or Autism Spectrum Disorder?

- ***Yes***
- ***No***

Q: Is _____ able to speak and comprehend English at the first grade level?

- ***Yes***
- ***No***

PARENT QUESTIONS

"Now I am going to ask you some questions about yourself."

Q: Are you _____'s biological, adoptive parent, or legal guardian?

- ***Yes***
- ***No***

Q: Do you and your child live together full time?

- ***Yes***
- ***No***
    - ***If no, how often does _____ live with you? (closest percentage)***
        - ***0***
        - ***10***
        - ***20***
        - ***30***
        - ***40***
        - ***50***
        - ***60***

        - ***70***
        - ***80***
        - ***90***
        - ***100***

Q: Please obtain detailed notes on family situation: _____

Q: Who does _____ live with? List all in home, and their relationship to the participating child: _____

Q: Do you have another child or children [sibling(s) of the child participating] that would be interested in participating?

- ***Yes***
- ***No***

Q: If yes, how many children who are between the ages of 2-18 would like to participate?

- ***1***
- ***2***
- ***3***
- ***4***

PARTICIPATING PARENT HEALTH

Q: Do you have any medical conditions or are you undergoing any medical treatment?

- ***Yes***
    - ***Notes: _____***
- ***No***

Q: Do you take any medications?

- ***Yes***
    - ***Q: How many medications do you currently take? (Select answer from dropdown)***
        - ***1***
        - ***2***
        - ***3***
        - ***4***
        - ***5***
        - ***6***
        - ***7***
- ***No***

Q: Name of first medication: _____

Q: What is your dose of [medication]? _____

Q: How often do you take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: How many years have you been taking [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***
- ***12***
- ***13***
- ***14***
- ***15***
- ***16***
- ***17***
- ***18***
- ***19***
- ***20***
- ***21***
- ***22***
- ***23***
- ***24***
- ***25***
- ***26***
- ***27***
- ***28***
- ***29***
- ***30***
- ***31***
- ***32***
- ***33***
- ***34***
- ***35***
- ***36***
- ***37***
- ***38***
- ***39***
- ***40***
- ***41***
- ***42***
- ***43***
- ***44***
- ***45***
- ***46***
- ***47***
- ***48***
- ***49***
- ***50***

Q: How many months have you been taking [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***

- *10*
- *11*

Q: Name of second medication: _____

Q: What is your dose of [medication]? _____

Q: How often do you take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: How many years have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
- *12*
- *13*
- *14*
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- *16*
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- *31*
- *32*
- *33*
- *34*
- *35*
- *36*
- *37*
- *38*
- *39*
- *40*
- *41*
- *42*
- *43*
- *44*
- *45*
- *46*
- *47*
- *48*
- *49*
- *50*

Q: How many months have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*

- *7*
- *8*
- *9*
- *10*
- *11*

Q: Name of third medication: _____

Q: What is your dose of [medication]? _____

Q: How often do you take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: How many years have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
- *12*
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- *37*
- *38*
- *39*
- *40*
- *41*
- *42*
- *43*
- *44*
- *45*
- *46*
- *47*
- *48*
- *49*
- *50*

Q: How many months have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*

- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*

Q: Name of fourth medication: _____

Q: What is your dose of [medication]? _____

Q: How often do you take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: How many years have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
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- *41*
- *42*
- *43*
- *44*
- *45*
- *46*
- *47*
- *48*
- *49*
- *50*

Q: How many months have you been taking [medication]?

- *0*

- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*

Q: Name of fifth medication: _____

Q: What is your dose of [medication]? _____

Q: How often do you take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: How many years have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
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- *43*
- *44*
- *45*
- *46*
- *47*
- *48*
- *49*
- *50*

Q: How many months have you been taking [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***

Q: Name of sixth medication: _____

Q: What is your dose of [medication]? _____

Q: How often do you take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: How many years have you been taking [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***
- ***12***
- ***13***
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- *42*
- *43*
- *44*
- *45*
- *46*
- *47*
- *48*
- *49*
- *50*

Q: How many months have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*

Q: Name of seventh medication: _____

Q: What is your dose of [medication]? _____

Q: How often do you take [medication]?

- ***Once per day***
- ***Twice per day***
- ***Three times per day***
- ***Four times per day***
- ***As needed***
- ***Every other day***
- ***Weekly***
- ***Bi-weekly***
- ***Monthly***
- ***Only during the school week***

Q: How many years have you been taking [medication]?

- *0*
- *1*
- *2*
- *3*
- *4*
- *5*
- *6*
- *7*
- *8*
- *9*
- *10*
- *11*
- *12*
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- ***33***
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- ***41***
- ***42***
- ***43***
- ***44***
- ***45***
- ***46***
- ***47***
- ***48***
- ***49***
- ***50***

Q: How many months have you been taking [medication]?

- ***0***
- ***1***
- ***2***
- ***3***
- ***4***
- ***5***
- ***6***
- ***7***
- ***8***
- ***9***
- ***10***
- ***11***

Q: Do you have a condition that would make you unable to exercise or limit the amount of exercise?

- ***Yes***
- ***No***

Q: Have you ever had weight-related surgery *such as gastric bypass?*

- ***Yes***
- ***No***

Q: Are you or any other immediate family members currently participating in a weight loss or weight management program?

- ***Yes***
  - ***Please describe:*** _____
- ***No***

Q: Would you or your family member be willing to stop their program if accepted into our program? (This is necessary to participate in the study.)

- ***Yes***
- ***No***

Q: Do you have any food allergies or food restrictions?

- ***Yes***
  - ***Please list food allergies and/or restrictions:*** _____
- ***No***

Q: Have you ever participated in any psychological treatment and/or counseling?

- ***Yes***
- ***No***

Q: Have you ever been diagnosed with a psychiatric condition such as depression or anxiety?

- ***Yes***
- ***No***

Q: Are you currently pregnant or plan to become pregnant in the next 2 years?

- ***Yes***
- ***No***

"Thank you for your willingness to answer all of these questions. We want to make sure your family has a great experience in our program. Let's look at your eligibility status."

PLAN EXCLUSIONARY CRITERIA

- The participating parent is pregnant or planning on becoming pregnant during the 2-year study period.
- Participation to any degree in a weight management or weight loss program.
- Weight-related surgeries (e.g., gastric bypass) *if within the last 2 years.*
    - *Please note that the patient must be weight stable or gaining weight (cannot be losing weight) (DSMB approved protocol addenda, 11.2.18).*
- Medical condition altering the nutritional status or intestinal absorption (e.g., inflammatory bowel disease, diabetes).
- Medical condition that affects growth (e.g., genetic or metabolic disease/syndrome that is associated with obesity).
- Chronic medical condition, including: Type 1 diabetes, heart disease/failure, HIV/AIDS, muscular dystrophy, renal diseases, hypothyroidism (if untreated or treated with medication for less than 6 months).
- Severe restriction of that would inhibit family from reasonably following the Traffic Light Eating Plan.
- Significant developmental delays, intellectual disabilities, or Autism Spectrum Disorder.
- Unmanaged/active psychiatric conditions (e.g., binge eating disorder, schizophrenia) with impairing clinical symptoms (e.g., suicidality).
    - Further assessed in Pre-Orientation Surveys and follow-up clinical interviews
- Disability that prevents performance of physical activity at the level of a brisk walk.
    - Further assessed via PCP Medical Clearance Form
- Exclusionary medications:
    - Orlistat (Xenical), Phentermine, Sibutramine (Meridia), and Topirimate (Topama) are exclusionary at all doses and durations
    - All other weight/growth-affecting medications should be noted (name, dose,

frequency, and duration) and brought to the attention of onsite physician

Q: Does exclusionary criteria exist?

- ***Yes***
    - ***The following script can be used for these exclusionary issues: Unfortunately, it does not look like your family is eligible to participate in the study at this time. Because we are a research-based program, we must adhere to certain criteria and are not able to accept families where the parent or child (insert exclusionary criteria). However, I would like to continue to gather information from you so that we can keep your family in our database. This way, when we run another study that you or your child does qualify for, we can contact you to see if you are interested in participating. Would you like to proceed with the screening so that you will be in our database to contact for other studies your child may be eligible for?"***
        - ***Yes***
            - ***Continue to collect household information according to site specific rules.***
        - ***No***
            - ***Thank them for their time. END CALL.***
- ***No***

Q: Is the family eligible to participate?

- ***Yes***
    - Family creates website profile and coach collects household information.
- ***No***
    - ***Thank them for their time.***
- ***Unsure (see below)***: If coach is unsure about whether or not the family is eligible/eligible, s/he should follow-up with their project coordinator for clarification and use the following script: ***Thank you for taking the time to answer all of these questions. At the moment, I have all of the information that I need. The next step is for me to review your responses in order to determine your eligibility status. I will follow-up with you within the next few days.***

If YES/ELIGIBLE:

"It appears your family is initially eligible for our study so the next step is for you and your child to complete a few online questionnaires. I will send you an e-mail link to these questionnaires after our phone call. The first three questionnaires will be for you to complete about you and your child. The final questionnaire should be completed by your child. Please be sure to complete these questionnaires at your earliest convenience. Also, there is the

possibility that you may need to complete a brief interview following these questionnaires. If so, I will call you to schedule that interview, which can be done over the phone."

Q: Is your email address [automatically generated]?

- ***Yes***
- ***No***
    - ***What is your email?*** _____

"In the meantime, I would like to schedule you and your family for an orientation appointment here at the office, which will last for approximately two hours. During the orientation, you will be given a presentation on the study goals and procedures. You will have an opportunity to ask questions and then decide if the study is right for you and your child. If you decide you are not interested, your appointment will end. If you decide that you are interested in participating after the orientation, you will complete several assessments and schedule upcoming study appointments.

Both the participating parent and participating child need to attend in order to enroll in the program. We will also need to collect measurements from any non-participating siblings and non-participating parents. We do offer the option to have them attend the orientation session as well. However, we recommend that they schedule an appointment separate from the orientation session due to the length of the session. If these individuals do attend the session, we recommend that they have a mode of transportation that is separate from the participating child's and participating parent's."

Q: Is the participant able to schedule at this time?

- ***Yes***
    - ***If yes, when is the orientation appointment?*** _____
- ***No***

"We will call you and send you an e-mail reminder two days prior to the orientation session, scheduled on (MM/DD/YYY) at (HH:MM) at (pediatric office name). Do you have any questions?"

If non-participating parent cannot come in with family:
If the non-participating parent is not able to come in at the same time as the rest of the family, they are able to come in at any time (based on health coach hours) to have their height and weight taken and ask questions/get information from the health coach about the program.

Q: Would the non-participating parent like to be contacted about the program and times when they can come in?

- ***Yes***
- ***No***

Q: What is the best phone number to reach them? _____

Q: What is the best email address to reach them? _____

"Thank you for your time, and we look forward to seeing you soon!" END CALL.

Table 1. Exclusionary Medications

Criteria	Medication	
Exclusionary at all doses and durations	Orlistat (Xenical) Phentermine Sibutramine (Meridia) Topirimate (Topamax)	
Exclusionary if at current dose for <6 months	Adderall (ADHD) Amourthyroid (hypothyroid) Carbamazepine (Tegretol) Celexa Clonidine (ADHD) Clozapine (Clozaril) Cyproheptadine (Periactin) Diethylproprion (Tenuate) Elavil Gabapentin Haloperidol Insulin Lithium Metformin Mirtazapine Neurotin Nortriptyline	Olanzapine (Zyprexa) Paroxetine Perphenazine Prozac Quetiapine (Seroquel) Risperidone (Risperdal) Sertraline Steroids (non-inhalant) Trazadone Tofranil Tricyclics Trileptal Valproate Valproic acid (Depakote/Depakene/Depacon) Ziprasidone (Geodon) Zyprexa
Exclusionary if started within past 6 months	Synthroid (hypothyroid)	

Patient Health Questionnaire (PHQ)

This questionnaire is an important part of providing you with the best health care possible. Your answers will help in understanding problems that you may have. Please answer every question to the best of your ability unless you are requested to skip over a question.

1. During the last 4 weeks, how much have you been bothered by any of the following problems?	**Not bothered**	**hered a little**	**thered a lot**	
a. Stomach pain				
b. Back pain				
c. Pain in your arms, legs, or joins (knees, hips, etc.)				
d. Menstrual cramps or other problems with your periods				
e. Pain or problems during sexual intercourse				
f. Headaches				
g. Chest pain				
h. Dizziness				
i. Fainting spells				
j. Feeling your heart pound or race				
k. Shortness of breath				
l. Constipation, loose bowels, or diarrhea				
m. Nausea, gas, or indigestion				
2. Over the last 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**ral days**	**than half the days**	**every day**
a. Little interest or pleasure in doing things				
b. Feeling down, depressed, or hopeless				
c. Trouble falling or staying asleep, or sleeping too much				
d. Feeling tired or having little energy				
e. Poor appetite or overeating				
f. Feeling bad about yourself – or that you are a failure or have let yourself or your family down				
g. Trouble concentration on things, such as reading the newspaper or watching television				
h. Moving or speaking so slowly that other people could have noticed? Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual				
i. Thoughts that you would be better off dead or of hurting yourself in some way				
3. Questions about anxiety.	**No**		**Yes**	

a. In the last 4 weeks, have you had an anxiety attack – suddenly feeling fear or panic?			
If “No”, go to question 5.			
b. Has this ever happened before?			
c. Do some of these attacks come suddenly out of the blue- that is, in situations where you don’t expect to be nervous or uncomfortable?			
d. Do these attacks bother you a lot or are you worried about having another attack?			
4. Think about your last bad anxiety attack.			
a. Were you short of breath?			
b. Did your heart race, pound, or skip?			
c. Did you have chest pain or pressure?			
d. Did you sweat?			
e. Did you feel as if you were choking?			
f. Did you have hot flashes or chills?			
g. Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhea?			
h. Did you feel dizzy, unsteady, or faint?			
i. Did you have tingling or numbness in parts of your body?			
j. Did you tremble or shake?			
k. Were you afraid you were dying?			
5. Over the last 4 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**veral days**	**e than half the days**
a. Feeling nervous, anxious, on edge, or worrying about a lot of different things.			
If “Not at all”, go to questions 6.			
b. Feeling restless so that it is hard to sit still.			
c. Getting very tired easily.			
d. Muscle tension, aches, or soreness.			
e. Trouble falling asleep or staying asleep.			
f. Trouble concentrating on things, such as reading a book or watching TV.			
g. Becoming easily annoyed or irritable.			
6. Questions about eating.	**No**	**Yes**	
a. Do you often feel that you can’t control what or how much you eat?			
b. Do you often eat, within any 2-hour period, what most people would regard as an unusually large amount of food?			

If "No" to either a. or b., go to questions 9.				
c. Has this been as often, on average, as twice a week for the last 3 months?				
7. In the last 3 months, have you often done any of the following in order to avoid gaining weight?				
a. Made yourself vomit?				
b. Took more than twice the recommended dose of laxatives?				
c. Fasted – not eaten anything at all for at least 24 hours?				
d. Exercised for more than an hour specifically to avoid gaining weight after binge eating?				
8. If you checked "Yes" to any of these ways to avoid gaining weight, were any as often, on average, as twice a week?				
9. Do you ever drink alcohol (including beer or wine)?				
If "No", go to question 11.				
10. Have any of the following happened to you more than once in the last 6 months?				
a. You drank alcohol even though a doctor suggested that you stop drinking because of a problem with your health.				
b. You drank alcohol, were high from alcohol, or hung over while you were working, going to school, or taking care of children or other responsibilities.				
c. You missed or were late for work, school, or other activities because you were drinking or hung over.				
d. You had a problem getting along with other people while you were drinking.				
e. You drove a car after having several drinks or after drinking too much?				
11. If you checked off any problems on this questionnaire, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	**difficult at all**	**newhat difficult**	**y difficult**	**tremely difficult**

Pediatric Symptom Checklist

Emotional and physical health go together in children. Because parents are often the first to notice a problem with their child's behavior, emotions or learning, you may help your child get the best care possible by answering these questions. Please mark under the heading that best fits your child.

	Never (0)	Sometimes (1)	Often (2)
1. Complains of aches/pains			
2. Spends more time alone			
3. Tires easily, has little energy			
4. Fidgety, unable to sit still			
5. Has trouble with a teacher			
6. Less interested in school			
7. Acts as if driven by a motor			
8. Daydreams too much			
9. Distracted easily			
10. Is afraid of new situations			
11. Feels sad, unhappy			
12. Is irritable, angry			
13. Feels hopeless			
14. Has trouble concentrating			
15. Less interest in friends			
16. Fights with others			
17. Absent from school			
18. School grades dropping			
19. Is down on him or herself			
20. Visits doctor with doctor finding nothing wrong			
21. Has trouble sleeping			
22. Worries a lot			
23. Wants to be with you more than before			
24. Feels he or she is bad			
25. Takes unnecessary risks			
26. Gets hurt frequently			
27. Seems to be having less fun			
28. Acts younger than children his or her age			
29. Does not listen to rules			
30. Does not show feelings			
31. Does not understand other people's feelings			
32. Teases others			
33. Blames others for his or her troubles			
34. Takes things that do not belong to him or her			
35. Refuses to share			
Total Score			
	No		**Yes**

Does your child have any emotional or behavioral problems for which she/he needs help?		
Are there any services that you would like your child to receive for these problems?		
If yes, what services?		

QUESTIONNAIRE ON EATING AND WEIGHT PATTERNS-5 - Parent

(QEWP-5-Parent)

Marian Tanofsky-Kraff, Susan Z. Yanovski, and Jack A. Yanovski

1. During the past **three** months, did your child ever eat what most people, like their friends, would think was a REALLY BIG amount of food?

   YES NO IF NO, SKIP TO QUESTION 18

2. When your child ate a REALLY BIG amount of food, was it ever within a short time (2 hours or less)?

   YES NO IF NO, SKIP TO QUESTION 18

3. When your child ate a REALLY BIG amount of food, did you ever feel your child could not stop eating or control what or how much they were eating?

   YES NO IF NO, SKIP TO QUESTION 18

4. During the past **three** months, how often did your child eat like this--ate a REALLY BIG amount of food along with the feeling that their eating was out of control? There may have been some weeks where this did not happen—just give your best guess.

   ____ Less than 1 time a week
   ____ 1 time a week
   ____ 2 or 3 times a week
   ____ 4 to 7 times a week
   ____ 8 to 13 times a week
   ____ 14 or more times a week

5. When your child ate a REALLY BIG amount of food and felt like they could not control their eating, did they usually:

   YES NO Eat very fast?
   YES NO Eat until their stomach hurt or they felt sick to their stomach?
   YES NO Eat REALLY BIG amounts of food even when they were not hungry?
   YES NO Eat by themselves because they did not want anyone to see how much they ate?
   YES NO Feel REALLY BAD about themselves because of what or how much they were eating?

6. Think about a usual time when your child ate a REALLY BIG amount of food and felt they could not control their eating:

   a. During that time, when did they start eating?
      ____ (8 AM to 12 Noon)
      ____ (12 Noon to 4 PM)
      ____ (4 PM to 8 PM)
      ____ (8 PM to 12 Midnight)
      ____ (12 Midnight to 8 AM)

   b. For how long did they eat during this time?
      ____ hours
      ____ minutes

c. As best as you can remember, please list **everything** your child ate or drank during this time. Be specific - include brand names where possible, and amounts as best you can guess.

_____
_____
_____
_____
_____
_____

d. At the time they started eating, how long had it been since your child had last eaten a meal or snack?
____ hours
____ minutes

7. During the past **three** months, how bad did your child feel when they ate a REALLY BIG amount of food and felt their eating was out of control?
____ Not bad at all
____ Just a little bad
____ Pretty bad
____ Very bad
____ Very, very bad

8. During the past **three** months, did your child ever make themselves vomit, throw up, or get sick in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?
YES NO

IF YES: How often, **in general**, did your child do that?
____ Less than 1 time a week
____ 1 time a week
____ 2 to 3 times a week
____ 4 to 7 times a week
____ 8 to 13 times a week
____ 14 or more times a week

9. During the past **three** months, did your child ever take medicine to make them poop or have a bowel movement (laxatives) in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?
YES NO IF NO, SKIP TO QUESTION 11

10. Did your child take more medicine than the directions on the box or bottle say to take?
YES NO

IF YES: How often, **in general**, was that?
____ Less than 1 time a week
____ 1 time a week

____ 2 to 3 times a week
____ 4 to 5 times a week
____ 6 to 7 times a week
____ 8 or more times a week

11. During the past **three** months, has your child ever taken medicine to make them pee or urinate (diuretics or water pills) in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?
    YES NO IF NO, SKIP TO QUESTION 13

12. Did your child take more medicine than the directions on the box or bottle say to take?
    YES NO

    IF YES: How often, **in general**, was that?
    ____ Less than 1 time a week
    ____ 1 time a week
    ____ 2 to 3 times a week
    ____ 4 to 5 times a week
    ____ 6 to 7 times a week
    ____ 8 or more times a week

13. During the past **three** months, did your child ever eat nothing at all for at least 24 hours (a full day) in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?
    YES NO

    IF YES: How often, **in general**, was that?
    ____ Less than 1 day a week
    ____ 1 day a week
    ____ 2 days a week
    ____ 3 days a week
    ____ 4 to 5 days a week
    ____ More than 5 days a week

14. During the past **three** months, did your child ever exercise too much (for example, even though they were hurt or sick or it kept them from doing important things) MAINLY in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?
    YES NO

    IF YES: How often **in general**, was that?
    ____ Less than 1 time a week
    ____ 1 time a week
    ____ 2 to 3 times a week
    ____ 4 to 7 times a week
    ____ 8 to 13 times a week
    ____ 14 or more times a week

15. During the past **three** months, did your child ever take diet pills in order to keep from gaining weight after eating like you described (when your child ate a REALLY BIG amount of food and felt their eating was out of control)?

    YES NO IF NO, SKIP TO QUESTION 17

16. Did your child take more medicine than the directions on the box or bottle say to take?

    YES NO

    IF YES: How often, **in general**, was that?

    ____ Less than 1 time a week
    ____ 1 time a week
    ____ 2 to 3 times a week
    ____ 4 to 5 times a week
    ____ 6 to 7 times a week
    ____ 8 or more times a week

17. During the past **three** months, how important has your child's weight or shape been in how they feel about themselves as a person – as compared to other things in their life, such as their schoolwork, friends, sports, or getting along with their family?

    ____ Weight and shape were **not very important**
    ____ Weight and shape were **played a part** in how they felt about themselves
    ____ Weight and shape were **among the main things** that affected how they felt about themselves
    ____ Weight and shape were **the most important things** that affected how they felt about themselves

Continue here after completing question 17 *OR* if you skipped to question 18 from Question 1, 2, or 3

18. During the past **three** months, did your child ever have times when they felt that they could not stop eating or control what or how much they were eating, but when they did ***not*** eat a REALLY BIG amount of food?

    YES NO IF NO, SKIP TO QUESTION 32

19. During the past **three** months, how often did your child eat like this—felt that their eating was out of control, but they did ***not*** eat a REALLY BIG amount of food. There may have been some weeks where this did not happen—just give your best guess.

    ____ Less than 1 time a week
    ____ 1 time a week
    ____ 2 to 3 times a week
    ____ 4 to 7 times a week
    ____ 8 to 13 times a week
    ____ 14 or more times a week

20. When your child felt their eating was out of control but they did ***not*** eat a REALLY BIG amount of food, did they usually:

    YES NO Eat very fast?
    YES NO Eat until their stomach hurt or they felt sick to their stomach?

YES NO Eat REALLY BIG amounts of food even when they were not hungry?
YES NO Eat by themselves because they did not want anyone to see how much they ate?
YES NO Feel REALLY BAD about themselves because of what or how much they were eating?

21. Think about a usual time when your child felt they could not stop eating or control what or how much they were eating, but they did ***not*** eat a REALLY BIG amount of food:

    a. During that time, when did they start eating?
    ____ (8 AM to 12 Noon)
    ____ (12 Noon to 4 PM)
    ____ (4 PM to 8 PM)
    ____ (8 PM to 12 Midnight)
    ____ (12 Midnight to 8 AM)

    b. For how long did they eat during this time?
    ____ hours
    ____ minutes

    c. As best as you can remember, please list **everything** your child ate or drank during this time. Be specific - include brand names where possible, and amounts as best you can guess.
    _____
    _____
    _____
    _____
    _____
    _____

    d. At the time they started eating, how long had it been since your child had last eaten a meal or snack?
    ____ hours
    ____ minutes

22. During the past **three** months, how bad did your child feel that they could not stop eating or control what or how much they were eating even when they did ***not*** eat a REALLY BIG amount of food?
    ____ Not bad at all
    ____ Just a little bad
    ____ Pretty bad
    ____ Very bad
    ____ Very, very bad

23. During the past **three** months, did your child ever make themselves vomit, throw up, or get sick in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control but they did ***not*** eat a REALLY BIG amount of food)?
    YES
    NO

IF YES: How often, **in general**, did your child do that?
____ Less than 1 time a week
____ 1 time a week
____ 2 to 3 times a week
____ 4 to 7 times a week
____ 8 to 13 times a week
____ 14 or more times a week

24. During the past **three** months, did your child ever take medicine to make them poop or have a bowel movement (laxatives) in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did ***not*** eat a REALLY BIG amount of food)?
YES NO IF NO, SKIP TO QUESTION 26

25. Did your child take more medicine than the directions on the box or bottle say to take?
YES NO

IF YES: How often, **in general**, was that?
____ Less than 1 time a week
____ 1 time a week
____ 2 to 3 times a week
____ 4 to 5 times a week
____ 6 to 7 times a week
____ 8 or more times a week

26. During the past **three** months, has your child ever taken medicine to make them pee or urinate (diuretics or water pills) in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did ***not*** eat a REALLY BIG amount of food)?
YES NO IF NO, SKIP TO QUESTION 28

27. Did your child take more medicine than the directions on the box or bottle say to take?
YES NO

IF YES: How often, **in general**, was that?
____ Less than 1 time a week
____ 1 time a week
____ 2 to 3 times a week
____ 4 to 5 times a week
____ 6 to 7 times a week
____ 8 or more times a week

28. During the past **three** months, did your child ever eat nothing at all for at least 24 hours (a full day) in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did ***not*** eat a REALLY BIG amount of food)?
YES NO

IF YES: How often, **in general**, was that?

____ Less than 1 day a week
____ 1 day a week
____ 2 days a week
____ 3 days a week
____ 4 to 5 days a week
____ More than 5 days a week

29. During the past **three** months, did your child ever exercise too much (for example, even though they were hurt or sick or it kept them from doing important things) MAINLY in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did ***not*** eat a REALLY BIG amount of food)?
    YES NO

    IF YES: How often **in general**, was that?
    ____ Less than 1 time a week
    ____ 1 time a week
    ____ 2 to 3 times a week
    ____ 4 to 7 times a week
    ____ 8 to 13 times a week
    ____ 14 or more times a week

30. During the past 3 months, did your child ever take diet pills in order to keep from gaining weight after eating like you described (when your child felt their eating was out of control, but they did ***not*** eat a REALLY BIG amount of food)?
    YES NO IF NO, SKIP TO QUESTION 32

31. Did your child take more medicine than the directions on the box or bottle say to take?
    YES NO

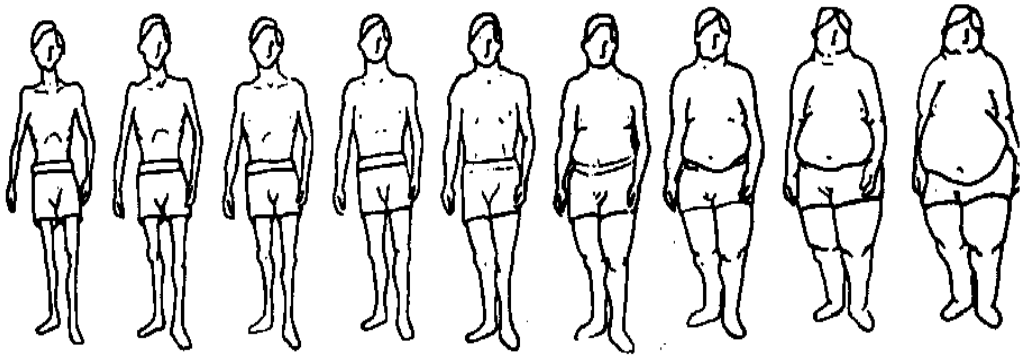
    IF YES: How often, **in general**, was that?
    ____ Less than 1 time a week
    ____ 1 time a week
    ____ 2 to 3 times a week
    ____ 4 to 5 times a week
    ____ 6 to 7 times a week
    ____ 8 or more times a week

Continue here after completing question 31 *OR* if you skipped to question 32 from Question 18

32. Please look at these drawings of people. Pick the person that matches your child's biological (birth) father's and mother's sizes. If you don't know their biological (birth) father or mother, don't pick anything for that parent.

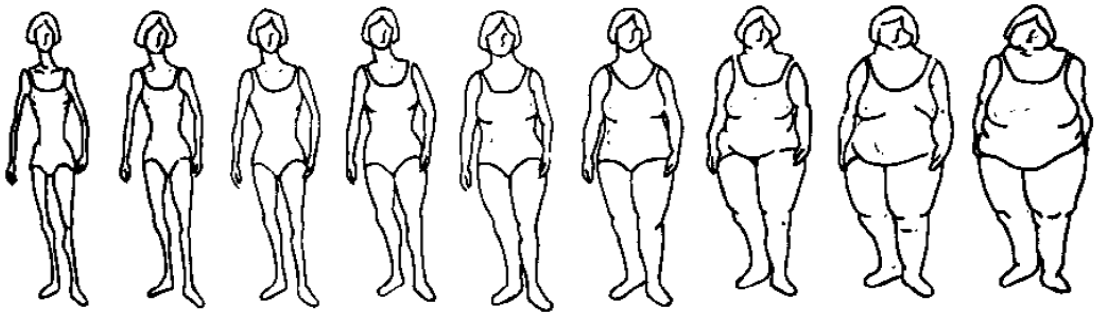
The QEWP-5-P is an adaptation of the QEWP-5. Yanovski SZ, Marcus MD, Wadden TA, Walsh BT. The Questionnaire on Eating and Weight Patterns-5: an updated screening instrument for binge eating

YOUR FATHER



1 2 3 4 5 6 7 8 9

YOUR MOTHER



1 2 3 4 5 6 7 8 9

disorder. Int J Eat Disord. 2015 Apr;48(3):259-61. doi: 10.1002/eat.22372. Epub 2014 Dec 26. Adapted with permission.

PLAN ELIGIBILITY TRACKING FORM

Initial Eligibility Survey **Date**

___/___/___

YES NO Child is between 6 and 12 years of age.

YES NO Child's BMI is above the 85th percentile for sex and age.

YES NO Parent's BMI is above 25kg/m^2.

YES NO Child and parent have not had a concussion in past 3 months.

YES NO Child and parent are able to complete a brisk 5-10 minute walk.

YES NO Family is not planning to move away within next 2 years.

Notes:

_____
_____
_____
_____

Eligibility Phone Screen **Date**

___/___/___

YES NO Parent agrees to attend all treatment meetings.

YES NO Child resides with targeted parent at least 50% of the time.

YES NO Parent is child's biological or adoptive parent or legal guardian.

YES NO Child and parent do not have any exclusionary medical conditions.

YES NO Child and parent are not taking any exclusionary medications.

YES NO Child and parent have not had any weight-related surgeries.

YES NO Child and parent are not in a weight management/weight-loss program.

YES NO Child and parent do not have severe restriction of diet.

YES NO Child and parent do not have any significant intellectual delays, disabilities, or ASD.

YES NO Child and parent do not have any unmanaged or active psychiatric conditions/symptoms (self-report).

YES NO Child and parent have no history of an eating disorder (self-report).

YES NO Child and parent are able to speak/comprehend English at a 1st grade level (self-report).

YES NO Parent is not pregnant or planning on becoming pregnant during study period.

Notes:

_____
_____
_____
_____
_____

Pre-Orientation Surveys (PHQ, PSC, QEWP-5 Parent and Child Report) **Date**

___/___/___

YES NO Child and parent do not have any unmanaged or active psychiatric conditions/symptoms.

YES NO Child and parent have no history of an eating disorder.

Notes:

_____
_____
_____
_____
_____

Follow-Up Interview (KSADS, SCID) **Date**

___/___/___

YES NO Did a PLAN Coach administer the KSADS for the child?

Modules:

_____
_____

YES NO Did a PLAN coach administer the SCID for the parent?

Modules:

_____
_____
_____

YES NO Child and parent do not have any unmanaged or active psychiatric conditions/symptoms.

YES NO Child and parent have no history of an eating disorder.

Notes:

_____
_____
_____
_____

Orientation

YES NO Child's BMI is above the 85th percentile for sex and age.

YES NO Parent's BMI is above 25kg/m^2.

YES NO Child and parent are able to speak/comprehend English at a 1st grade level (per the WRAT).

Notes:

_____
_____
_____
_____

Pre-Randomization

YES NO Child and parent received medical clearance from their PCPs.

YES NO Family is eligible for randomization.

Notes:

_____
_____
_____
_____

Assessment Measures
Height and Weight Measurement Checklist. (Primary Aim 1a & b and Secondary Aim 1)

General Information for Measurements:
HEIGHT RELIABILITY CRITERIA
Height measurements are to be within 0.3cm (3mm) of a reliable staff member. The above requirements are to be met for 10 different height measurements (i.e., 10 participants measured by a reliable staff member and the staff in training). If the reliable staff member and new staff member do not meet acceptable reliability criteria, additional participants should be measured by both staff members until adequate reliability is established.

- Reliability should be checked periodically throughout the study to assure that there is no measurement drift between height assessors.
- Height and weight will be monitored and rechecked randomly to ensure accuracy of the data.
- Calibration of the stadiometer and scale will occur every so often to ensure the accuracy of the equipment.

HEIGHT PROCEDURES FOR CHILDREN AGES ≥ 4 YEARS AND ADULTS

1. *The participant should be barefoot or in thin socks.*
2. *The PLAN coach will instruct the participant to stand up straight with his/her back against stadiometer board. The coach should make sure that the participant is not standing on his/her pants if long.*
3. *Ask the participant to stand with his/her heels together and toes pointing out to form a "V".*
4. *The participant should be looking straight ahead with his/her arms at his/her sides.*
5. *The PLAN coach should lightly rest headboard on top of the participant's head to be sure that it sits at the highest point of the head and then lift the head board out of the way.*
6. *The coach should instruct the participant to take a deep breath in and stretch upwards while s/he places both hands under the mastoid process of skull. The coach should then gently lift the participant's head, which will elongate the spine to ensure an accurate height reading.*
    a. *The mastoid process of the skull is the bony projection of the temporal bone and is located behind the ears.*
7. *The coach should make sure there is an imaginary line between the participant's eyes and ears that runs parallel with the floor while the participant's eyes gaze forward.*
8. *The coach should ensure that the participant's feet are firmly planted on the ground and that s/he is not standing on his/her toes.*
9. *The coach should take the height measurement.*
    a. *The headboard should rest on highest point of the participant's head and, if applicable, should compress the participant's hair.*
10. *The coach should then ask the participant to step away from the height board.*
11. *The coach will record the height on a hard copy of the "Height and Weight" REDCap form that s/he will print off prior to the appointment.*
12. *The coach will measure the height in millimeters. Then, the coach will read what this measurement is in centimeters to the nearest decimal place (i.e., 65.7). If the height falls in between two decimal places, the coach will record to the lower decimal place.*
13. *The coach should repeat the process two times to check validity.*
    a. *If the two height measurements are not within 0.3 centimeters of each other, the coach will take two additional measurements.*
    b. *The coach will repeat this process until s/he has two measurements that are within 0.3 centimeters of each other.*

c. *REDCap will take the mean of the last pair of measurements to determine the participant's BMI.*
    i. *All measurements will remain in REDCap so that the total measurements taken and the values of the measurements can be reviewed.*

14. *The coach will enter the two height measurements into the participant's file in REDCap on the "Height Tracking Form".*
15. *Coaches will use their REDCap username and password to log on to the PLAN study in REDCap via https://redcap.wustl.edu/redcap/srvrs/. They will then complete the following steps:*
    a. *Open the "Add/Edit Records" tab that is located on the left side of the screen.*
    b. *Select the appropriate Screening ID from the "Choose an existing Screening ID" dropdown menu, which will take the coach to the "Record Home Page" for the family.*
    c. *Double click on the appropriate "Height and Weight Tracking Form".*
    d. *Complete the height portion of the Height and Weight Tracking Form.*
    e. *The coach will select the appropriate form status based on whether or not s/he has to input more measurement data.*
    f. *The coach will click "Save & Exit Form".*
16. *The coach should wipe down the scale pre and post measurement with a Lysol wipe if the participant is bare footed.*

MANUAL CALIBRATION OF THE HEAD SLIDE

1. *All PLAN coaches will use 72 centimeter PVC pipes to calibrate their stadiometers.*
    a. *SR scales will cut 72 (+/- 0.3) centimeter PVC pipe sections with a laser cutter.*
    b. *The exact length of each pipe will be written on the pipe.*
    c. *A staff member from the University at Buffalo will retrieve the pipes and mail out them out to each site.*
2. *All PLAN coaches will take height measurements with their PVC pipes each time their stadiometer is used.*
    a. *The stadiometer should always measure the known height of the PVC pipe that was documented on the pipe.*
    b. *If the stadiometer measures the height of the PVC pipe as something different than the known height, the coach will document the discrepancy. The coach will then make arrangements to procure a new stadiometer*

HEIGHT MEASUREMENT REPORT

1. *The height measurements will be manually entered into REDCap for analysis of outcome measures as well as written on hard copy of height and weight form (pdf form from REDCap).*
2. *The reported height measurements will be exactly the same as the reading on the stadiometer, which will provide an unbiased report of the height measurements (This change was made on 9.18.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*

WEIGHT PROCEDURES

1. *To begin, the PLAN coach should plug the SR Scale into a wall outlet. The coach should then press the "Zero/Weigh" button that is located on the right side of the scale. The scale will be operational when the display reads 0.00. The coach should ensure that the scale is recording weight in pounds. If the scale is set to measure weight in kilograms, the coach will press the toggle button next to the "Zero/Weigh" button to switch the unit measurement from kilograms to pounds.*

2. *In order to ensure accurate measurement, the coach should instruct the participant to do the following:*
    a. *The participant should empty out his/her pockets, and remove shoes and any heavy clothing or accessories.*
    b. *The participant should always be weighed around the same time of the day.*
    c. *The participant should always use the bathroom prior to being weighed.*
    d. *The participant should follow similar eating and activity schedules.*
3. *The coach will ask the participant to stand in the middle of the scale and instruct the participant to do the following:*
    a. *The coach will ask the participant to remain still, have relaxed shoulders, and to have his/her hands at his/her sides.*
    b. *The coach will ask the participant to look straight ahead.*
    c. *The coach will tell the participant to stand with the same posture as on a balance beam scale.*
4. *The coach will wait for weight measurement to stabilize.*
    a. *While standing to the left of the scale, the coach will monitor the digital readout.*
5. *Once the measurement has stopped fluctuating, the coach will record the weight on a hard copy of the "Height and Weight" REDCap form that s/he will print off prior to the appointment.*
6. *The coach will repeat this procedure a second time.*
7. *The coach will instruct the participant to step off the scale.*
8. *The coach should wipe down the scale pre and post measurement with a Lysol wipe if the participant is bare footed.*

MANUAL CALIBRATION OF THE SCALE

1. *All PLAN coaches will use Pro-Form 15-pound kettle bells to calibrate their scales.*
    a. *A staff member from the University at Buffalo will perform weight measurements with all Pro-Form kettle bells on a calibrated scale.*
    b. *The staff member will document the exact weight of each kettle bell.*
    c. *The staff member will write the exact weight on a piece of painter's tape and tape it to the kettle bell.*
    d. *The staff member will mail out the kettle bells each site.*
2. *All PLAN coaches will take weight measurements with their kettle bells each time their scale is used.*
    a. *The scale should always measure the known weight of the kettle bell that was documented by the University at Buffalo on the painter's tape.*
    b. *If the scale measures the weight of the kettle bell as something different than the known weight, the coach will document the discrepancy. The coach will then make arrangements to send the scale to SR Scales for re-calibration.*

WEIGHT MEASUREMENT REPORT

1. *For analysis of outcome measures (see 11 in Weight Procedures above; (This change was made on 9.18.17 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18).*

Use of Weight App was discontinued (*DSMB approved change, 11.18.19*).*Hard copy height and weight measurement forms will be uploaded to the secure REDCap database to allow the CCC, DCC and TFC to check for transcription and/or unit of measurement errors.*

Remote assessments Protocol

Step 1: Coach Instructions for CONTACTING FAMILY

1. Schedule phone call with family to introduce the remote assessment, check for materials, review instructions, describe changes in payment, complete the AE survey, and to schedule an assessment date with a blinded measurement coach. *A random subset of families from each site will be asked to complete the height protocol for a second quality control measure of this remote height measurement.*
    a. See email script if they do not answer the phone:

    "Hello [Parent],

    Thank you for participating in the PLAN with Families Program! It is time for your family's [X] month assessment.

    Because of the current unexpected circumstances, we will be conducting your assessment virtually. This means we will supply you with measurement equipment and call you to walk you through measuring yourself and your children.

    You will receive payment for this assessment. Please call, text, or email me so we discuss the details and schedule a date.

    Thank you,

    [Name]

    [phone number]

    b. Introduction of remote assessment:
        i. *"Due to unforeseen circumstances, our assessments for the measurement procedures have changed for the time being. At this time, we are asking families to complete height and weight measurements at home using equipment that you have or can be sent to you. With your permission, we will call you during the assessment to walk you through the procedures."*
    c. Describe payment procedure:
        i. *"You will get the usual payment for this remote measurement."*
            1. Remote payment will be sent by each site's PC
                a. Within 2-3 days of completing the remote measurement
                b. UB checks, UR gift cards
                    i. Certified mail serves as receipt of payment
                c. WU e-gift cards and NCH ClinCard will be instantaneous
            2. In-person payment will be directly given to the family as normal protocol procedures.

d. Discuss consenting procedures: Electronic signature procedure through downloads or directly in REDCap)
    i. "I will email you an addendum document for the remote assessment and instructions for opening and signing the document. Can you please confirm your correct and working email address where I can send this form? [Confirm email address in REDCap]"
    ii. "To complete the consent form, you will need to open the email, download the document and open the form in your "downloads folder" on your computer. Open this file using the Adobe application, there will be blue squares and rectangles which are interactive. You can select a box to either consent, or do not consent. You will input the date, and then click the blue box below signature to sign the document. A window will appear asking about a digital ID, if you have a preset one with your correct name you may use it. If not, you can configure a new one according to the instructions that will be included in my email to you. Please contact me should you have any troubles or questions with any step of this consenting process."
    iii. "Please send me a confirmation email when you receive the instructions and consent form to your email."
        1. Follow-up with family 1 day after sending the email if you do not receive confirmation.
    iv. **REDCap consent procedure:**
        1. "You will receive an email from me in a few minutes. In it, there will be a link to the electronic consent form. Let me know when you have it open so I can go over it with you. [wait]"
        2. "This consent form is telling you about some updates to the study and is asking you to sign to agree to these changes."
            a. Addendum: "First, as you know we will be doing your assessment remotely, meaning you will take heights and weights for all the PLAN participants in the study. Second, we will be paying your regular payment for the remote assessment Third, we have changed the total payment for the 24 month assessment from $50 to $100. Last, we have started a lottery where you earn 1 chance to win an extra $50 for every in person assessment you attend."
            b. Reconsent: "I have sent a second email with another consent form for [child] to sign. Now that [child] has turned [age], they are old enough to sign a consent form for an older age group. This consent is just asking [child] to sign so we can keep doing the study just as we have in the past. There is nothing new in this consent form."
        3. "Please take your time and read over the form(s). If you have any questions, I can answer them. Whenever you are ready, you may scroll

to the bottom and "sign" your name with today's date. (For reconsent: Please make sure your child is the one to sign and not you.) I will stay on the line with you until you are ready."

e. Ask if they have:
    i. "In order to complete the measurement you will need the following pieces of equipment. Please let me know if any of the following are not available to you:
        1. PLAN Provided Weight Scale
            a. Is their mailing address correct?
        2. Carpenter's Square
        3. Metal Measuring Tape
        4. Computer or phone access to internet and web camera
            a. If they don't have these, ask if they have some form of camera to take a picture of the measurements. Pictures can be emailed to the measurement coach.
    ii. If these items are available:
        a. "Great. Please have these items ready at the time of your measurement, we will provide you with a PLAN weight scale through the mail. Please confirm your mailing address and any special delivery instructions for your residence."
    iii. If an item(s) is not available:
        a. "We will mail a standardized scale and [item(s)] to your address for the assessment. Please confirm your mailing address and any special delivery instructions for your residence."
        2. Contact PC to coordinate delivery of materials
f. Schedule the family's remote measurement
    i. "To allow time for materials to arrive for the measurement, we will schedule 2 weeks out from this call."
    ii. Give 2-3 possible days/times to schedule appointment.
g. Complete AE survey according to protocol
    i. "At this time I have a 5-10 minute survey to go through with you. Is now a good time to complete this?"
        1. If yes, complete AE survey.
        2. If no, "is there a convenient day/time where I can contact you to complete this survey?" or email it to the family
h. Notify family that necessary questionnaires will be emailed and should be completed before the measurement appointment through REDCap.
    i. If family does not have computer/phone access with internet:
        1. Surveys can be done over the phone BEFORE the appointment
            a. AEQ, DDs, FNPA, 24M Parent/Child
        2. Measurement instructions will be mailed to their address
    ii. Send reminder email 1 day before assessment if questionnaires are not complete

i. Check when family's next well child visit is to coordinate in person follow-up measurement at a convenient date and time
    i. "In addition to the remote measurement, we will also schedule a follow-up measurement at the pediatric office. Does your child have an existing well-visit appointment that would be convenient for you to schedule this follow-up?"
    ii. If not, schedule a follow-up appointment that will take place in the summer
j. Ending the phone call
    i. "Thank you so much for your time today, I will send you a 1 week and 1 day reminder prior to your assessment. Please contact me with any changes or questions in the meantime."

2. Record all assessment information into your site's specific tracking spreadsheet.
    a. Add date and time, and all other necessary information, (UB Assessments - Tracking, WU, NCH, UR)
    b. Include family's consent for audio/video recording
3. Contact a blinded measurement coach to run the assessment via video conference or phone.
    a. For 24 month assessments, both the blinded assessor and the PLAN Coach should be present
4. Send video conference email link to family and assessor using https://zoom.us/home?zcid=2478 or Webex
    a. Set the duration as 30 min, or 60 min for a 24 month assessment.
    b. Set a password.
    c. Attach Family Instructions for measurements
5. Email all the surveys to the family through REDCap (see next section)
6. Confirm assessment dates with family one week before and the day of the assessment
    a. Include the call-in information and instruction sheet again.

Step 2: PLAN Coach Instructions for FORMS AND PAPERWORK COMPLETION

NOTE: For 6, 12, and 18 month assessments, all surveys should be completed by families BEFORE the assessment.

For 24 month assessments, surveys should be completed by families BEFORE the assessment, AND the PLAN Coach should attend the assessment to give FBT materials and finish payment AFTER the blinded assessor leaves the call.

1. For families doing 12- and 24-month assessments, have them complete the online questionnaires.
    a. At 12 month assessments: Child DD Validation, Child DD, Parent DD.
    b. At 24 month assessments: Child DD Validation, Child DD, Parent DD, FN & PA, and 24 Month for both Child and Parent.
    c. For families with internet access, use REDCap to send the online surveys.

i. In the family's REDCap record, click the circle that corresponds to the questionnaire that needs to be sent
ii. Under the "Survey Options" drop down menu, select "Compose Survey Invitation"
iii. Fill out the invitation form
1. Send out immediately
2. Check the box to enable reminders and choose to resend every 3 days with recurrence up to 5 times
3. Make sure it is your email address the email will be from, and choose the participant's email address to where it will be sent
4. Type in subject line: "PLAN with Families 12/24 month survey"
5. Compose a message in the text box.
a. For example, "Hi [Name], Please click the link and complete the questionnaire, following the directions provided. If you have any questions, contact your PLAN coach at [phone number here]."
b. Be sure to clarify if that specific questionnaire needs to be filled out by the parent or the child
iv. Repeat for each questionnaire that needs to be completed

d. For families who don't have access to internet
i. DD tasks, FNPA, and 24 Month Surveys can be done over the phone BEFORE the assessment
ii. Contact PC about mailing paper forms if necessary

2. If the family needs a re-assent, re-consent, or an addendum:
a. These will become forms in REDCap
b. You will send them just like you send the surveys BEFORE the assessment
c. In the subject line, use: "PLAN with Families Consent form for [Name of participant]"
d. If they do not complete, the blinded assessor will have to go over them with the family during the assessment
i. They will have to send the REDCap form at beginning of assessment and check to see if it is finished before they end the call.

3. Payment
a. Site specific payment procedures
i. UB: PC will send a check via certified mail within 2-3 days of the assessment.
1. There will be a receipt mailed with the check, please have the family sign this receipt and text the PLAN or measurement coach a picture of their signature.
2. Follow-up with the family 1 week from the mailing date if a receipt picture has not been submitted.
ii. WU: PC will mail a VISA gift card or email an Amazon e-gift card within 2-3 days of the assessment
iii. UR: PC will mail gift cards or other site determined method.

iv. NCH: PP will be credited the money to the ClinCard within 2-3 days of the assessment.

b. 6 month measurements:
   i. At the end of the measurement, assure the participating parent that they earned $ 25
   ii. Inform family that they have earned the chance to be entered for a $50 raffle at the end of the study.

c. 12 and 18 month measurements:
   i. At the end of the measurement assure the participating parent that they earned $50
   ii. Inform family that they have earned the chance to be entered for a $50 raffle at the end of the study.

d. 24 month measurements:
   i. At the end of the measurement assure the participating parent that they earned $100
   ii. There will be a receipt mailed with the check, please have the family sign this receipt and text the PLAN or measurement coach a picture of their signature.
      1. Follow-up with the family 1 week from the mailing date if a receipt picture has not been submitted.
   iii. Measurement coach will need to contact site PC immediately following session to notify them if family has won lottery or not so that check can be prepared if needed

e. Height quality control measurement:
   i. Families that participate in the second measurement will receive $10.00 payment as specified above.

4. 24 Month-specific procedures
   a. Inform family that they have earned the chance to be entered for a $50 raffle.
      i. The blinded assessor will pull from the ticket bag via video conference for the family.
      ii. If the family wins the raffle, notify the Coach and the PC so they can adjust the payment.
   b. PLAN Coach sends the family the link to 24-month video to describe PLAN website and handouts.
      i. Sent during the assessment, but after the blinded assessor leaves the call
      ii. Sent via email
      iii. Include the PC's contact information

   Thank the family for their participation.

Step 3: Measurement Coach Instructions for HEIGHT MEASUREMENTS

1. Confirm with family and/or coach that measurement is set for the scheduled date

2. Contact family at the day and time of assessment
    a. If the family has a Webcam and Internet Access: use WebEx and/or Zoom
    b. If they do not have a WebCam and Internet access: use phone to call the family and ensure they have a camera
3. Guide family through height and weight procedure, giving them feedback, answering any questions, making notes, and voicing corrections if they are needed
    a. Assume the family has NOT read the instruction sheet and will need to be walked through the steps
    b. Have them e-sign consent forms if they need to (see previous section)
    c. Remind the family about which members need to be measured
    d. Reference "Measurement Coach Checklist" with all the necessary information
4. Have family report their measurements aloud, and write them on a blank paper
5. Measurement coach will confirm accurate values and write them down on "Height and Weight form"
6. After the assessment, enter these values into REDCap as per normal protocol

Family Instructions for HEIGHT MEASUREMENTS

NOTE: Only children who enrolled in PLAN as participants need to have their heights measured. Parents or legal guardians enrolled in PLAN should measure the children's heights.

Location: On a level, non-carpeted, flat surface (e.g. wood, concrete floor, tile) against a door

Materials Needed:

1. Carpenter's square https://www.homedepot.com/p/Empire-7-in-Polycast-Rafter-Square-296/100154430
2. Metal measuring tape
3. Tape
4. Object of known height (ie participating parent, adult, yardstick)
5. Pencil or Pen
6. Piece of paper
7. Stool (especially if your child is taller than you)
8. Computer or phone with a web cam and internet access
    1. If you do not have a web cam and/or internet access, have a camera present

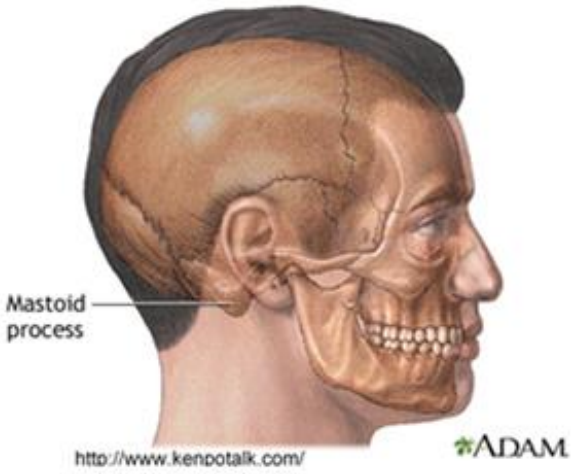
Procedure:

1. First, you will practice taking a height measurement with the carpenter's square and foldable yardstick.
    a. Tape the foldable yardstick against a door with the bottom on a level, flat floor and it standing straight.
    b. Place an object of known height against the foldable yardstick
    c. Place the carpenter's square on top of the person's head or object,
        i. Make sure one of the square's flat edges is directly touching the doorl

ii. Make sure the object is standing straight up and not leaning, compare to edge of door.

d. Check the height of the object with the bottom edge of the carpenter square
e. Remove the person or object
f. Tell your measurement coach the height of the object
g. Did your measurement match the known height of the object? if it did not to make some adjustments and recheck.

2. Now, you will measure your child. Make sure:
    a. Your child's hair is let down (if possible)
    b. Your child is not wearing shoes
3. Have your child stand with their back against the door.
4. Tape a piece of paper on the door behind the foldable yardstick, around the center of the top of their head.
5. Have them put their heels as close to the door as possible
6. Have them touch their heels together so they are standing in a V-shape
7. Have your child look straight ahead at you
8. Find your child's **mastoid process** (a bony knob behind their ears – see picture)
9. Place your pointer and middle fingers of both hands on your child's mastoid processes
10. Tell them, "On the count of three, take a deep breath, and I will lift your head up"
11. Count to three, and as they breath in, gently lift their head slightly upwards.
12. While they are holding their breath:
    a. Make sure they are NOT on their tiptoes
    b. Make sure their head is NOT tilted up or down
    c. Place the carpenter's speed square on top of your child's head with the right angle facing the wall and one flat side directly touching the wall
    d. Make a mark of their height on the paper
13. Tell your child they can let go of their breath and step away from the wall
14. Write the number "1" and your child's initials next to the mark
15. Report the height to the measurement coach
16. Repeat steps 2-15 to complete a second measurement
    a. Mark the line on the piece of paper with a "2" and the child's initials to differentiate from the first mark
    b. If measurements 1 and 2 differ by more than 0.3 centimeters, the measurement coach will ask you to take two more measurements.
17. Repeat steps 2-16 for additional siblings enrolled using a new piece of paper.



Family Instructions for WEIGHT MEASUREMENTS

NOTE: All participants who are enrolled in PLAN—parents and children—should measure their weight.

Location: On a level, non-carpeted, flat surface (e.g. wood, concrete floor)

Materials Needed:

1. PLAN weight scale

Procedure:

1. Before stepping on the scale, make sure:
    a. You remove shoes, any items in your pockets, and any heavy pieces of clothing or jewelry, such as belts, hoodies, etc.
    b. You use the restroom beforehand
2. Step on the scale
    a. Stand straight, in the middle of the scale, with feet shoulder-width apart, looking straight ahead
    b. Make sure your child does not move on the scale, as that can affect the accuracy of the measurement
3. Once the weight has stabilized, step off the scale and write down the weight.
4. Report the measurement to the measurement coach .
5. Repeat steps 2-5 to get a second weight
6. If measurements 1 and 2 differ by more than 0.25 pounds, your measurement coach will tell you to take two more weights.
7. Repeat steps 2-7 for every PLAN participant

Step 4: Wrapping up Assessment

1. PLAN Coach:
    a. Thank the family and praise their efforts.
    b. Identify families that will participate in the quality measurement of height to take a second measurement at a later date, confirm date and time. Follow protocol for remote height.
    c. Instruct family to make confirm they received payment
    d. Contact PC with payment amount and family address
    e. Update site-specific tracking forms
2. Measurement Coach:
    a. Enter data into REDCap
        i. Check email to see if you received the pictures of the measurements
    b. Contact PLAN Coach to notify that assessment was completed (or not completed)

Participant Instructions on Opening and Signing Consent Form

Steps:

1. Coach and participant will discuss how the consent form will be sent.
    a. I.e. Email
        i. Confirm email is correct and working
2. Coach will send the consent form to the participant and confirm that the participant has indeed received it.
3. Participant will open the email and download the document.
    a. Once the form is downloaded, participant will open the form
    b. The document will open up as a tab
    c. This tab CANNOT be used to sign the form
        i. Steps on how to sign the form will be below
4. Participant will close the tab and instead open the consent form manually from the 'Downloads' folder on the computer
5. To access the 'Downloads' folder:
    a. Open up 'Start' menu option
    b. Search for 'File Explorer'
        i. This icon looks like a vanilla folder
    c. Open the 'File Explorer'
    d. On the left hand side should be a tab labeled as 'Quick access'
        i. A drop down menu should be below 'Quick access'
    e. Select the 'Downloads' option
    f. You are now in the 'Downloads' folder
6. Once in the 'Downloads' folder
    a. Find the name of the consent form, labeled as '(INSERT CONSENT FORM NAME HERE)'
    b. Open the consent form, it should automatically open up with 'Adobe'

7. To complete the consent form:
    a. There will be blue squares and rectangles which are interactive
    b. Participant will click on the blue rectangle below 'Participant Name' and type their name
    c. Participant will then select a box on whether they consent or do not consent
        i. These boxes will pop-up a check mark when clicked on
    d. Participant will then 'Date' the form before signing it
        i. Just like the 'Name' section of the form, click the box and write the date in
        ii. Format the date in as MM/DD/YYYY
            1. Click the 'Enter' key on your keyboard
            2. The program will then change the format of the date, this is fine
    e. Participant will then sign the document by clicking on the blue box below 'Signature'
8. To sign the document is a little complicated to be sure to follow the steps below:
    a. Click on the blue box below 'Signature'
    b. Another window will appear on the form asking about a Digital ID
        i. If you already have one preset with your correct name, you may use it and and click the 'Continue' button
            1. Then click 'Sign' and move on to step 9
        ii. If you need to create a Digital ID, the steps are:
            1. There may be a button which says 'Configure New Digital ID' at the bottom of the window Click this button to go to a screen which asks you to 'Select the type of Digital ID'
                a. If there is no 'Configure New Digital ID' button, but instead asks you to 'Select the type of Digital ID' then this is the screen which you need to be on
            2. 'Select the type of Digital ID' window is what you want to see
                a. There should be a list of options
                b. Select the option which says 'Create a new Digital ID'
                c. Then click 'Continue'
            3. A new window will appear labeled 'Select the Destination of the New Digital ID'
                a. Two options will be there
                    i. First option will be to save your Digital ID to your computer
                    ii. Second option will be to save your Digital ID to the Windows Certificate Store
                b. Either option is fine, which ever the participant prefers
                    i. PLAN Recommends to save the Digital ID to a file on your computer
                    ii. However, it is up to the participant to decide which option is best for them
                c. Once the destination is selected, click 'Continue'
                d. 'Create a self-signed Digital ID' window will appear

i. This window will ask for your name
    1. First and Last is preferred
ii. The window will also ask for your email address
    1. Preferably the email address you have registered with PLAN
iii. These two pieces of information are the only ones that you need to provide, all else can be ignored
iv. Click 'Continue' once you have filled this window out

e. 'Save the self-signed Digital ID to a file' window will appear
    i. Here is where you would select a file on your computer where the Digital ID should be stored
    ii. Select the 'Browse Button'
    iii. And select a file
    iv. PLAN Recommends that you should select the 'Documents' file as for convenience purposes
        1. However, it is up to the participant to decide where the Digital ID should be stored
    v. Once you have selected the location of the file, you will have to give a password for security purposes of your Digital ID
        1. The participant is responsible for choosing the password and remembering this password
        2. PLAN recommends you choose a password that only the participant knows and keeps the password a secret
    vi. Once the password is written and rewritten on the second box, click 'Save'

4. You have now created your Digital ID and should see your Name on the window that pops up

c. Select the option which has your name on it
d. Then click 'Continue'
e. A new window will appear asking you for your password that you have previously made
    i. First review that all the information is correct on this screen
    ii. Then type the password in
    iii. Click 'Sign'
f. Once you have clicked the 'Sign' button a new window will appear asking you where the Consent Form should be saved to
    i. PLAN Recommends for the document to be saved in the 'Documents' tab which can be located on the left hand side of the window that pops up, for easy access
    ii. However, the participant is responsible to decide where the best location to save this document is
g. Once you have decide the location, click the 'Enter' key on your keyboard

    h. Once you have done this, your signature should appear on the document and the document is complete
9. The participant will now review the consent form to make sure everything is correct
10. The participant will then save the entire file once more by:
    a. Click the 'File' tab in the top left of the window
    b. A drop menu will appear
    c. Select the 'Save' option
    d. Your document is not saved once again
11. The participant will now email the consent form to their coach

If any problems arise during this process that the participant cannot solve, please contact your coach, who will then proceed to help and fix the issue. The coach can also reach out to the tech specialist if more assistance is needed. This process can be done through email or a phone call.

NEED TO ASSESS COSTS AND BUDGET

EQUIPMENT	**Equipment Cost**	**Shipping Cost**
Scale	25.00	TBD
Carpenters 90 degree Angle	8.00	TBD
Tape measure	5.00	TBD
Yard stick	10.00	TBD
Total	48.00	TBD

Delay of Gratification. (Delay Discounting: Secondary Aim 2)

The following items are representative of the type of questions a participant may be asked to answer in the delay of gratification computer task. The task is adaptive and adjusts the questions based on participant responses, thus each participant will receive different questions.

Instructions: For each of the following choices, please **choose** which reward you would prefer: the smaller reward at the time point listed, or the larger reward in the specified number of days. Please carefully consider each of the choices.

1. Would you prefer	**$49 today**	or	**$60 in 89 days**?
2. Would you prefer	**$47 today**	or	**$50 in 160 days**?
3. Would you prefer	**$54 today**	or	**$80 in 30 days**?
4. Would you prefer	**$27 today**	or	**$50 in 21 days**?
5. Would you prefer	**$41 today**	or	**$75 in 20 days**?

Parental Survey – Child Report. (Secondary Aim 3)

Instructions: Please circle the best answer for the questions below.

1. It happens that my parent/caregiver promises me a reward and then forgets about it.

Never or Very Rarely **Sometimes** **Often** **Always or Almost Always**

2. My parent/caregiver promises to get something for me, but then [s]he doesn't do it.

Never or Very Rarely **Sometimes** **Often** **Always or Almost Always**

3. It happens that my parent/caregiver announces something (e.g., a family excursion, a visit at the zoo), and then it falls through.

Never or Very Rarely **Sometimes** **Often** **Always or Almost Always**

Scoring: Items are scored from 1 (never or very rarely) to 4 (always or almost always) and summed to create a total score.

FAMILY NUTRITION & PHYSICAL ACTIVITY (FNPA)

Administered at Baseline, 12 month, and 24 month assessments (*DSMB approved protocol addenda, 9.29.19*).

For Each Question, please select the answer that best represents your child/family

Question	Almost Never	Sometimes	Usually	Almost Always
1. My child eats breakfast….				
2. Our family eats meals together…..				
3. Our family eats while watching TV…				
4. Our family eats fast food…				
5. Our family uses microwave or ready to eat foods…				
6. My child eats fruits and vegetables at meals or snacks…				
7. My child drinks soda pop or sugary drinks…				
8. My child drinks low fat milk at meals or snacks…				
9. Our family limits eating of chips, cookies, and candy…				
10. Our family uses candy as reward for good behavior…				
11. My child spends 2 hours on TV/games/computer per day or less…				

12. Our family limits the amount of TV our child watches…				
13. Our family allows our child to watch TV in their bedroom…				
14. Our family provides opportunities for physical activity…				
15. Our family encourages our child to be active every day…				
16. Our family finds ways to be physically active together…				
17. My child does physical activity during his/her free time…				
18. My child is enrolled in sports or activities with a coach or leader…				
19. Our family has a daily routine for our child's bedtime…				
20. My child gets 9 hours of sleep a night…				

Scoring: Add up scores for each scale (items should be scored 1, 2, 3, 4 from left to right except for items that are reverse coded (3, 4, 5, 7, 10, and 13), These should be scored 4, 3, 2, 1 from left to right. See back for Feedback.

Family Meal Patterns	Item 1	_____	+	Item 2	_____	=	_____
Family Eating Habits	Item 3	_____	+	Item 4	_____	=	_____
Food Choices	Item 5	_____	+	Item 6	_____	=	_____
Beverage Choices	Item 7	_____	+	Item 8	_____	=	_____
Restriction / Reward	Item 9	_____	+	Item 10	_____	=	_____
Screen time behavior and monitoring	Item 11	_____	+	Item 12	_____	=	_____
Healthy Environment	Item 13	_____	+	Item 14	_____	=	_____
Family Activity Involvement	Item 15	_____	+	Item 16	_____	=	_____
Child Activity Involvement	Item 17	_____	+	Item 18	_____	=	_____
Family Routine	Item 19	_____	+	Item 20	_____	=	_____

Total Score: _____

The FNPA Tool was developed at Iowa State University by Michelle Ihmels (mihmels@iastate.edu) and Greg Welk (gwelk@iastate.edu) in partnership with the American Dietetic Association.

Environmental Enrichment – Parent Report. (Secondary Aim 3)

Instructions: The following questions ask you about your home environment and the surrounding areas. Please read the instructions for each section and answer the corresponding questions.

About how long would it take to get from your home to the <u>nearest</u> businesses or facilities listed below if you <u>walked</u> to them? Please put only <u>one</u> check mark (√) for each business or facility.

	1–5 min	6-10 min	11-20 min	20-30 min	30+ min	Don't Know
Example: *gas station*			√			
Environment						
1. convenience/small grocery store						
2. supermarket						
3. hardware store						
4. fruit/vegetable market						
5. laundry/dry cleaners						
6. clothing store						
7. post office						
8. library						
9. elementary school						
10. other schools						
11. book store						
12. fast food restaurant						
13. coffee place						
14. bank/credit union						
15. non-fast food restaurant						
16. video store						
17. pharmacy/drug store						
18. salon/barber shop						
19. your job or school [check here _____ if not applicable]						
20. bus or train stop						
21. park						
22. recreation center						
23. gym or fitness facility						

For each of the following food types, please tell us whether they are RIGHT NOW in your home, immediately eatable, and about how much is there. (Answer yes if any of the items listed for each question is in your home.)

- *<u>In home</u>* = the food can be in the kitchen, pantry, bedrooms, basement, garage, or other rooms

- *Child can immediately eat* = Is the food in a package/container that the child is able to open, and/or does it require preparation that the child can do on her/his own? (Regardless of whether or what rules may be about your child accessing food by himself/herself)
- *How much* = *A little* (enough for up to 2 people to eat at a snack/meal), *Some* (enough for 3-8 people to eat at a snack/meal), *A lot* (more than a little or some)

FOOD	***In home?***	***Child can imme***
24. fresh bananas, oranges, pineapple, melons	*Yes No*	*Yes N*
25. fresh apples, grapes, celery, lettuce	*Yes No*	*Yes N*
26. potatoes, corn on the cob, whole tomato, frozen vegetables	*Yes No*	*Yes N*
27. "100% fruit juice"	*Yes No*	*Yes N*

For the following electronic devices, please write down the total number in each room that work, regardles

If an electronic device has multiple functions, please list each function in the appropriate spot UNLESS it is a DVD/CD under DVD. However, if you have a stereo that plays CDs, tapes, and the radio, count all three

General room categories are listed at the end for you to add rooms that are specific to your home that may have th additional bedrooms, dining room, etc.). BR stands for Bedroom.

Electronics	**Kitchen**	**Living Room**	**Parent's BR**	**Child's BR**	**BR #3:**	**BR #4:**	**Other Room: _____**
28. TVs							
29. VCR (not portable)							
30. DVD player (not portable)							
31. Digital TV recorders (e.g., TiVo, ReplayTV)							
32. Radio (not portable) can include alarm clock							
33. CD player (not portable)							
34. Tape Player (not portable)							
35. Desktop computer with internet access							
36. Desktop computer without internet access							
37. Video game player (e.g., Playstation, xbox)							
38. Telephone (non-cell phone)							
39. Portable CD player							
40. Portable Tape Player							
41. Portable Radio Player							
42. Portable MP3 player (ex: iPod)							
43. Portable DVD player							
44. Hand held videogame player (e.g., Game boy, Sony PSP etc.)							
45. Laptop or portable computer							
Total number of electronics in each room:							

Which of the following things are **available and in useable condition** in your home or yard/common area? Do not include things that are buried in boxes (except toy boxes), buried in a closet, or in storage. **Please circle either "Not Available" or "Available," and then indicate whether your child commonly uses the item(s)** If any of the items listed for each question is available, circle *available*.

Activities	**Not Available**	**Available**	**If available, does your child commonly use this item?**
46. bike	0	1	Yes No N/A
47. basketball hoop (includes child size or adult size)	0	1	Yes No N/A
48. jump rope	0	1	Yes No N/A
49. sports equipment (e.g., balls, racquets, bats, sticks)	0	1	Yes No N/A
50. swimming pool (including kiddie pool)	0	1	Yes No N/A
51. roller skates, skateboard, scooter	0	1	Yes No N/A
52. fixed play equipment (e.g., swing set, play house, jungle gym)	0	1	Yes No N/A
53. home aerobic equipment (e.g., treadmill, cycle, cross trainer, stepper, rower, workout video or audiotapes)	0	1	Yes No N/A
54. weight lifting equipment, toning devices (e.g., free weights, pull up bars, exercise balls, ankle weights, etc.)	0	1	Yes No N/A
55. water or snow equipment (e.g., skis, skates, canoe, row boat, surf board, boogie board, windsurf board, slip-n-slide, etc.)	0	1	Yes No N/A
56. yoga/exercise mats	0	1	Yes No N/A
57. exercise, play, or recreation room	0	1	Yes No N/A

58. trampoline	0	1	Yes No N/A

59. How many books are in the home that are approximately at your child's reading level and that he/she has access to? (please che ___ 0 books ___ 1 - 10 books ___ 11 - 20 books ___ 21 - 30 books ___ 31 - 40 books ___ 4			
Books	**Never**	**Rarely**	**Sometime**
60. How often does a parent or caregiver in the home read to your child?			
61. How often does your child read for pleasure?			
62. How often does your family receive magazines and/or newspapers?			
63. How often does a parent or caregiver take your child to a museum?			
64. How often does a parent or caregiver take your child to a show or performance?			

65. Are there any musical instruments in the home that your child has access to?	Yes	No
66. Does your child receive lessons for singing or playing a musical instrument?	Yes	No
67. Does your child engage in any other regular hobbies or activities? If YES, please specify: _____	Yes	No

Scoring for Environmental Enrichment:

1-23: Land-Use Mix Diversity
Responses (item scoring):
1-5 min (5) 6-10 min (4) 11-20 min (3) 20-30 min (2) 30+ min (1) don't know (1)
Additional scoring: Tally the number of items ≤20-minute walk (either a '3', '4' or '5' response) and call this 'tally of close facilities')

24-27: Fruit and Vegetable
Each food item can be given a total of up to 5 points (range: 0-5). Points are given – then summed to get the total points for that food item – based on (a) presence in the home, (b) the child being able to immediately eat the food, and (c) amount present:

"In home?" – Yes=1, No=0
"Child can immediately eat?" – Yes=1, No=0
"How much is there?" – A little=1, Some=2, A lot=3

28-45: Electronic Equipment
OVERALL TOTAL = The total number of electronics in the household: Sum the "total" row for all rooms (i.e., kitchen, living room, etc.), including the total for "in house (not always in 1 room)." If "total" for a given room is blank, code that room as 0.

46-58: Physical Activity

Each physical activity item can be given a total of 0, 1, or 2 points. Points are given – then summed to get the total points for that physical activity equipment item – based on availability and whether the child uses the item:

"Which of the following things are available and in usable condition in your home or yard/common area?"
Not available = 0, Available = 1

"If available, does your child commonly use this item?"
Yes = 1
No = 0
N/A = 0
Total score = sum of physical activity item points (items 41-53)

59-67: Cognitive Stimulation
A total of 0-28 points may be awarded based on the presence of cognitively-stimulating items in the child's home. These questions are scored on different scales, as follows:

Item 59 ("How many books…")
0 books = 0
1-10 books = 1
11-20 books = 2
21-30 books = 3
31-40 books = 4
41 or more books = 5

Items 60 – 64 ("How often does a parent…")
Never = 0
Rarely = 1
Sometimes = 2
Often = 3
Very Often = 4

Items 65 – 67
Yes = 1
No = 0
Total score = sum of points awarded for items 59-67

Summary Score for Environmental Enrichment Questionnaire: Sum all subscales to create a global score of non-snack food reinforcers available to the child.

Attitudes toward Evidence-Based Treatment. (Exploratory Aim)

The following questions ask about your feelings about using new types of therapy, interventions, or treatments. Manualized therapy, treatment, or intervention refers to any intervention that has specific guidelines and/or components that are outlined in a manual and/or that are to be followed in a structured or predetermined way. **Indicate the extent to which you agree with each item using the scale shown below.**

	0 Not at all	1 To a slight extent	3 To a moderate extent	4 To a great extent	5 To a very great extent
1. I like to use new types of therapy/interventions to help my clients.					
2. I am willing to try new types of therapy/interventions, even if I have to follow a treatment manual.					
3. I know better than academic researchers how to care for my clients.					
4. I am willing to use new and different types of therapy/interventions developed by researchers.					
5. Research-based treatments/interventions are not clinically useful.					
6. Clinical experience is more important than using manualized therapy/interventions.					
7. I would not use manualized therapy/interventions.					
8. I would try a new therapy/intervention, even if it were very different from what I am used to doing.					

For the following questions if you received training in a new therapy or intervention how likely would you be to adopt it if:

	0 Not at all	1 To a slight extent	3 To a moderate extent	4 To a great extent	5 To a very great extent
9. It was intuitively appealing?					
10. It made sense to you?					
11. It was required by your supervisor?					
12. It was required by the counseling center director?					
13. It was a state requirement?					
14. It was being used by colleagues who were happy with it?					
15. You felt you had enough training to use it correctly?					

Scoring guide for Attitudes Towards Evidence-Based Treatment

Scoring the Subscales
The score for each subscale is created by computing a total or mean score for the items that load on a given subscale. For example, Items 11, 12, and 13 constitute subscale 1.

Subscales
Requirements
Items: 11, 12, 13

Appeal
Items: 9, 10, 14, 15

Openness
Items: 1, 2, 4, 7

Divergence
Items: 3, 5, 6, 7

Computing the Total Scale Score
For the total score, all items from the Divergence subscale (Sub-scale 4) must be reverse scored before being used in computing the EBPAS total score.

Attributes of FBT. (Exploratory Aim)

Given your knowledge and understanding of FBT, please respond to the following questions.

1. Using FBT in the clinic was more effective than the clinic's existing treatment method.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

2. The content of FBT is compatible with my personal beliefs and values.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

3. FBT is useful.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

4. FBT is credible.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

5. FBT is easy to administer in the practice setting.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

6. The content of FBT is clear.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

7. The content of FBT is relevant to my work as a medical treatment provider.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

8. FBT can be experimented without requiring an extensive involvement.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

9. FBT can be adapted or modified to suit the needs of the interventionist.

1 **2** **3** **4** **5**

Strongly Agree *Strongly Disagree*

10. The benefits of using FBT with my patients are obvious/visible.

1	**2**	**3**	**4**	**5**
Strongly Agree				*Strongly Disagree*

11. The evidence regarding the impact of FBT is available.

1	**2**	**3**	**4**	**5**
Strongly Agree				*Strongly Disagree*

Scoring for Attributes of FBT:
The scale is composed of five subscales: Relative advantage (1), compatibility (2-4), complexity (5-7), trialability (e.g., the potential to experiment with an innovation before implementing; 8-9), and observability (10-11). If the subscale has more than one item, the subscale score is created by computing a total or mean score for the items that load on a given subscale.

Intended Adoption. (Exploratory Aim)

How likely is it that you will use this model of having a co-located interventionist to treat children who are overweight/obese as a result of your experiences with an FBT interventionist within your practice?

0%_____100%

Scoring: Physicians will place an X on the electronic line to signal their percentage likelihood.

Family Demographics. (Descriptor)

Please put an X in the appropriate box for your mother's, your father's, your spouse / partner's, and your level of school completed and occupation. If the exact occupation is not listed, please put an **X** by the category that most closely matches the individual's occupation, and if a parent is retired, please indicate their most recent occupation. If you grew up in a single parent home, mark only your one parent, and mark "N/A" for the other parent. If you are neither married nor partnered, mark "N/A" for Spouse/Partner.

A. Level of School completed	Mother	Father	Spouse/Partner	You
(N/A)				
Less than 7th grade				
Junior high / Middle school (up to 9th grade)				
Partial high school (10th or 11th grade)				
High school graduate				
Partial college (at least one year)				
College education				
Graduate degree				

B. Occupation	Mother	Father	Spouse/Partner	You
(N/A or stay-at-home parent)				
Day laborer, janitor, house cleaner, farm worker, food counter sales, food preparation worker, busboy.				
Garbage collector, short-order cook, cab driver, shoe sales, assembly line workers, masons, baggage porter.				
Painter, skilled construction trade, sales clerk, truck driver, cook, sales counter, or general office clerk.				
Automobile mechanic, typist, locksmith, farmer, carpenter, receptionist, construction laborer, hairdresser.				
Machinist, musician, bookkeeper, secretary, insurance sales, cabinet maker, personnel specialist, welder.				
Supervisor, librarian, aircraft mechanic, artist or artisan, electrician, administrator, military enlisted personnel, buyer.				
Nurse, skilled technician, medical technician, counselor, manager, police or fire personnel, financial manager, physical/occupational/speech therapist.				
Mechanical/nuclear/electrical engineer, educational administrator, veterinarian, military officer, elementary/high school/special education teacher.				
Physician, attorney, professor, chemical/aerospace engineer, judge, CEO, senior manager, public official, psychologist, pharmacist, accountant.				

C. Please indicate whether your current household income is derived from: (circle all that apply)

1. One income
2. Two incomes
3. Unemployment
4. Public assistance
5. Child support / alimony
6. Other: _____

D. Please circle your current annual household income:

1. Under $9,999
2. $10,000 - $19,999
3. $20,000 - $29,999
4. $30,000 - $39,999
5. $40,000 - $49,999
6. $50,000 - $59,999
7. $60,000 - $69,999
8. $70,000 - $79,999
9. $80,000 - $89,999
10. $90,000 - $99,999
11. $100,000 - $119,999
12. $120,000 - $129,999
13. $130,000 - $139,999
14. $140,000 - $149,999
15. $150,000 - $159,999
16. $160,000 - $169,999
17. $170,000 - $179,999
18. $180,000 - $189,999
19. $190,000 - $199,000
20. Over $200,000

E. Please circle the ethnic group(s) that YOU identify with (please circle all that apply):

1. American Indian or Alaskan Native
2. Asian
3. Native Hawaiian or Other Pacific Islander
4. Black or African American, not of Hispanic origin
5. White or Caucasian, not of Hispanic origin
6. Hispanic or Latino
7. Other (please specify): _____

F. Please circle the ethnic group(s) that your CHILD most identifies with (please circle all that apply):

1. American Indian or Alaskan Native
2. Asian
3. Native Hawaiian or Other Pacific Islander
4. Black or African American, not of Hispanic origin
5. White or Caucasian, not of Hispanic origin
6. Hispanic or Latino
7. Other (please specify): _____

G. Think of this ladder as representing where people stand in the United States.

At the **top** of the ladder are the people who are the best off—those who have the most money, the most education, and the most respected jobs. At the **bottom** are the people who are the worst off—who have the least money, least education, and the least respected jobs or no job. The higher up you are on this ladder, the closer you are to the people at the very top; the lower you are, the closer you are to the people at the very bottom.

Where would you place yourself on this ladder?

Please place a large “X” on the rung where you think you stand at this time in your life, relative to other people in the United States.

Scoring guide for Participant Demographics:

Parts A and B:
The parent indicates level of school completed by their Mother, their Father, their Spouse / Partner, and themselves. If the parent grew up in a single-parent home, they only provide information for their one parent. If the parent is not married and does not have a partner, they do not provide information on a spouse. If they are a full-time student, they only circle scores for their parents. Point values are assigned depending on the level of school completed for each person:

Level of School Completed	Mother	Father	Spouse	You
Less than 7th grade	3	3	3	3
Junior high / Middle school (9th grade)	6	6	6	6
Partial high school (10th or 11th grade)	9	9	9	9
High school graduate	12	12	12	12
Partial college (at least one year)	15	15	15	15
College education	18	18	18	18
Graduate degree	21	21	21	21

The parent indicates the occupation for their Mother, their Father, their Spouse / Partner, and themselves. If the parent grew up in a single-parent home, they only provide information for their one parent. If the parent is not married and does not have a partner, they do not provide information on a spouse. If they were a full-time student, they only circle scores for their parents. If a parent is retired, they use their most recent occupation. Point values are assigned depending on the occupation for each person:

Occupation	Mother	Father	Spouse	You
Day laborer, janitor, house cleaner, farm worker, food counter sales, food preparation worker, busboy.	5	5	5	5
Garbage collector, short-order cook, cab driver, shoe sales, assembly line workers, masons, baggage porter.	10	10	10	10
Painter, skilled construction trade, sales clerk, truck driver, cook, sales counter or general office clerk.	15	15	15	15
Automobile mechanic, typist, locksmith, farmer, carpenter, receptionist, construction laborer, hairdresser.	20	20	20	20
Machinist, musician, bookkeeper, secretary, insurance sales, cabinet maker, personnel specialist, welder.	25	25	25	25
Supervisor, librarian, aircraft mechanic, artist and artisan, electrician, administrator, military enlisted personnel, buyer.	30	30	30	30
Nurse, skilled technician, medical technician, counselor, manager, police and fire personnel, financial manager, physical, occupational, speech therapist.	35	35	35	35
Mechanical, nuclear, and electrical engineer, educational administrator, veterinarian, military officer, elementary, high school and special education teacher.	40	40	40	40
Physician, attorney, professor, chemical and aerospace engineer, judge, CEO, senior manager, public official, psychologist, pharmacist, accountant.	45	45	45	45

Level of School Completed

1	Parents' score: If they grew up with both parents, add "Mother" + "Father" and divide by 2. If they grew up with one parent, enter that score to the right.	
2	If they are married or partnered, add "Spouse" + "You" and divide by 2. If they live alone/are not married/do not have a partner, enter the "You" score to the right. If they are a full-time student, leave this blank.	
3	Double the score from line 2. If they are a full-time student, leave this blank.	
4	If they are a full-time student, enter only their parents' score. Otherwise, add line 1 and line 3, then divide by 3 (three) for a **TOTAL EDUCATION.** *Note: Score should be between 3 and 21*	

Occupation Scoring

1	If they grew up with both parents, add "Mother" + "Father" and divide by 2. If they grew up with one parent, enter that score to the right.	
2	If they are married or partnered, add "Spouse" + "You" and divide by 2. If they live alone/are not married/do not have a partner, enter the "You" score to the right. If they are a full-time student, leave this blank.	
3	Double the score from line 2. If they are a full-time student, leave this blank.	
4	If they are a full-time student, enter only their parents' score. Otherwise, add line 1 and line 3, then divide by 3 (three) for **TOTAL OCCUPATION.** *Note: Score should be between 5 and 45*	

TOTAL SES Score (A & B)
Add **TOTAL EDUCATION** + **TOTAL OCCUPATION.** *Note:* Score should be between 8 and 66

Parts C-F:
Individual stand-alone items

Part G:
The ladder contains 10 rungs and responses will be scored based on location of the "X." The bottom rung is given the score of 1 and each subsequent rung progresses in numerical order until the top rung, which is given the score of 10.

Participant Acceptability: Parent. (Descriptor)

We are interested in your honest opinions regarding the services you have received through the study, whether they are positive or negative. Please answer all questions.

1. How would you rate the quality of service you received?

4	3	2	1
Excellent	Good	Fair	Poor

2. Did you get the kind of service you wanted?

1	2	3	4
No, definitely not	No, not really	Yes, generally	Yes, definitely

3. To what extent has our program met your needs?

4	3	2	1
Almost all of my needs have been met	Most of my needs have been met	Only a few of my needs have been me	None of my needs have been met

4. If a friend were in need of similar help, would you recommend the treatment to him/her?

1	2	3	4
No, definitely not	No, not really	Yes, generally	Yes, definitely

5. How satisfied are you with the amount of help you received?

1	2	3	4
Quite dissatisfied	Indifferent or Mildly dissatisfied	Mostly satisfied	Very satisfied

6. Have the services you received helped you deal more effectively with your problems?

4	3	2	1
Yes, they helped a great deal	Yes, they helped somewhat	No, they really didn't help	No, they seemed to make things worse

7. In an overall, general sense, how satisfied are you with the service you received?

1	2	3	4
Very satisfied	Mostly satisfied	Indifferent or Mildly dissatisfied	Quite dissatisfied

8. If you were to seek help again, would you use the treatment you received again?

1	2	3	4
No, definitely not	No, not really	Yes, generally	Yes, definitely

9. I would follow through if my child was referred outside this clinic for childhood obesity treatment.

1	2	3	4	5
Strongly Agree				Strongly Disagree

10. I am comfortable having my child receive obesity treatment at the clinic.

1	2	3	4	5
Strongly Agree				Strongly Disagree

11. My child was treated the same as other people who get care at the clinic.

1	2	3	4	5
Strongly Agree				Strongly Disagree

12. I prefer my child to receive obesity treatment services at the location where he/she receives medical care.

1	2	3	4	5
Strongly Agree				Strongly Disagree

Participant Acceptability: Child. (Descriptor)

What do you think about the care we gave you? Was it good or bad? Tell us by answering all of the questions below. Please be honest!

1. Did you like the care we gave you?

4	3	2	1
Very Good	Good	Bad	Very Bad

2. Did you get the kind of care you wanted?

1	2	3	4
No, not at all	No, not really	Yes, sort of	Yes, I really did

3. Did we help with all the things you wanted?

4	3	2	1
All of the things I wanted	Most of the things I wanted	Some of the things I wanted	None of the things I wanted

4. If a friend needed care like you did, would you tell them to see us?

1	2	3	4
No, not at all	No, not really	Yes, sort of	Yes, I would

5. Were you happy with all of the kinds of help we gave you?

1	2	3	4
Very Happy	Happy	Kind of happy	Kind of unhappy

6. Has the care we gave you helped with your problems?

4	3	2	1
Yes, it helped a lot	Yes, it helped a little	No, it didn't help	No, it made it worse

7. How happy are you with the care we gave you?

1	2	3	4
Very Happy	Happy	Kind of happy	Kind of unhappy

8. Would you want us to help you again if you needed it?

1	2	3	4
No, not at all	No, not really	Yes, sort of	Yes, I would

Provider Demographics. (Descriptor)

Please respond to the following questions. For the questions with space to mark your answer (e.g., place an "X"), please mark all that apply. For any responses that you mark as "Other," please write in your response.

1. What is your age? _____ years

2. What is your race? (Check all that apply.)
__ American Indian or Alaskan
__ Asian or Asian American
__ African American or Black
__ Caucasian or White
__ Native Hawaiian or Pacific Islander
__ Other: _____

3. What is your ethnicity?
__ Hispanic
__ Non-Hispanic

4. What is your gender?
__ Male
__ Female
__ Other: _____

5. What is your highest degree?
__ MD
__ NP
__ PA
__ DO
__ Other: _____

6. What is your job title? _____

7. How many years have you worked at the clinic? _____

8. How many years have you been in practice? _____

9. What is your specialty? _____

10. Before your enrollment in this study:

a) Were you aware of the American Academy of Pediatrics Guidelines for Assessing Obesity?
Yes No

If yes, how did you learn about these guidelines?

b) Were you aware of Family-based Behavioral Weight Loss Treatment for Children with Obesity?

Yes No

If yes, how did you learn about this treatment?

11. Have you had experience(s) with **weight-related counseling for obesity or behavioral intervention for obesity (including weight control/weight management)**? If yes, what type of experience(s)? (Check all that apply.)

__ I have not had any experience with weight-related counseling or behavioral interventions for obesity

__Yes, I have observed weight-related counseling or behavioral interventions for obesity

__Yes, I have delivered weight-related counseling or behavioral interventions for obesity

__Yes, I have received weight-related counseling or behavioral interventions for obesity

__Yes, other: _____

_____

12. Have you had experience(s) with **other counseling or behavioral interventions (i.e., not related to weight or obesity)**? If yes, what type of experience(s)? (Check all that apply.)

__ I have not had any experience with counseling interventions or behavioral interventions

__Yes, I have observed counseling interventions or behavioral interventions for: _____

_____

__Yes, I have delivered counseling interventions or behavioral interventions for: _____

_____

__Yes, I have received counseling interventions or behavioral interventions for: _____

_____

__Yes, other: _____

_____

Provider Usual Care Survey. (Descriptor)

	At well child visits, I *(check all that apply)*:
	Accurately measure height and weight of child
	○ Calculate BMI ○ Plot BMI on BMI growth chart ○ Make a weight category diagnosis using BMI percentile
	Define BMI and explain consequences of high BMI to families
	Perform a thorough physical examination
	○ Measure blood pressure ○ Order lab tests
	Take a family history, including:
	○ Obesity ○ Type 2 diabetes ○ Cardiovascular disease ○ Early deaths from heart disease or stroke
	Assess diet and physical activity behaviors
	○ Sugar-sweetened beverages ○ Servings of fruits and vegetables per day ○ Daily eating patterns (e.g., consumption of breakfast, portion sizes, family meals) ○ Frequency of fast food or restaurant eating ○ Amount of moderate to vigorous physical activity per day ○ Screen time
	Provide positive feedback for behavior(s) in optimal range
	○ Elicit response to feedback ○ Reflect/probe
	Provide neutral feedback for behavior(s) not in optimal range
	○ Elicit response to feedback ○ Reflect/probe
	Query which, if any, of the behaviors the family may be interested in changing or which might be easiest to change
	Agree on a target behavior
	Assess readiness to change
	Assess self-efficacy to change
	Collaborate possible next steps to change
	Develop and write a plan for change
	Summarize change plan and provide positive feedback

	Offer referral to a more intensive behavioral weight management intervention if necessary
	Agree to follow up within a certain amount of time (e.g., 6 months from today)

24 Month Survey – Parent (*DSMB approved protocol addenda, 9.29.19*).

Date:_____

1. Which site are you at*? *this is required for branching logic for the next question**
    a. Buffalo
    b. Rochester
    c. Columbus
    d. St. Louis
2. Who was your most recent Coach? ** list of each site's Coaches will appear with a "Don't Know" option **
3. Were you ever assigned another Coach?
    a. Yes
    b. No
4. Who else was your Coach? ** list of each site's Coaches will appear with a "Don't Know" option **

For the following questions, please CIRCLE the number that matches how much you agree with each statement.

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
5. This program changed the healthy habits of my family members who were not enrolled.	1	2	3	4	5
6. If a friend were in need of similar help, I would recommend this program to him/her.	1	2	3	4	5
7. This program has met my needs.	1	2	3	4	5

Some people have made the following statements about their food situation. Please answer whether the statements were OFTEN, SOMETIMES, or NEVER true for you and your household <u>in the last 12 months</u>.

8. Within the past 12 months, you worried that your food would run out before you got money to buy more.
    - Often true
    - Sometimes true
    - Never true
    - Don't know, Refuse

9. Within the past 12 months, the food you bought just didn't last and you didn't have money to get more.
    - Often true
    - Sometimes true
    - Never true
    - Don't know, Refuse

The following are behaviors that people may or may not use to support their healthy lifestyle. For each of the following behaviors:

Please choose how often **<u>YOU</u> use them on a scale from Never to Daily:**

<u>Never</u>	**<u>Yearly</u>**	**<u>Monthly</u>**	**<u>Weekly</u>**	**<u>Daily</u>**
0	1	2	3	4

Please choose how helpful **<u>YOU</u> find them on a scale from Slightly Helpful to Very Helpful:**

N/A	Slightly Helpful	Somewhat Helpful	Moderately Helpful	Very Helpful
0	1	2	3	4

If you do not use the behavior, you may write "0" for N/A in the helpfulness column.

	How Often?	How
10. Using a food journal or food diary (Habit Book)		
11. Tracking the number of Calories you eat		
12. Increasing the number of low-calorie, green, leafy foods you eat, like spinach or kale (GREEN foods)		
13. Decreasing the number of high-calorie, low-nutrient foods you eat, like candy or pizza (RED foods)		
14. Decreasing the number of high-calorie, low-nutrient drinks you drink, like soda (RED drinks)		
15. Increasing your moderate to intense physical activity, like walking or biking (GREEN physical activity)		
16. Weighing yourself		
17. Praising your child		
18. Planning meals ahead of time		
19. Having a Daily Check-In with your child about what they are eating		
20. Decreasing recreational screen time		
21. Sleeping for 7-9 hours a night		
22. Using a rewards or points system to encourage healthy behaviors (Reinforcement System)		
23. Engaging in physical activity with your family		
24. Engaging in healthy eating with your friends		
25. Engaging in physical activity with your friends		
26. Accessing community healthy eating resources, like a farmer's market		
27. Accessing community physical activity resources, like a fun run or walk		
28. How helpful were the PLAN sessions for you?		
29. How helpful was the entire PLAN program for you?		

For each of the following questions, please circle the best answer.

30. Avocados, marshmallows, and black olives are a part of which food group?
    a. Proteins
    b. Fats, Oils, Sweets & Others
    a. Condiments, Dressings, & Other Ingredients
31. Which of the following are examples of the lowest calorie foods with the most nutrition (GREEN foods)?
    a. Green (non-starchy) vegetables
    b. Fruit
    c. Dairy
    d. Beans/legumes
32. Why is a food journal (Habit Book) important for weight loss and making healthy food choices?
    a. It helps you to be more aware about what you are eating
    b. It helps you to be more accountable about what you are eating
    c. It is not really that important for weight loss or healthy food choices
    d. A and B

33. The benefits of planning meals ahead of time include:
    a. Allowing time for food preparation and cooking
    b. Budgeting for groceries
    c. Knowing the number of calories in meals
    d. All of the above
34. Aerobic exercises (moderate to intense physical activity) does not burn a lot of calories and is not good for weight loss.
    a. True
    b. False
35. Once your child has learned a new behavior, you can slowly decrease the amount of praise for that behavior.
    a. True
    b. False
36. Which of the following methods can be used to remove distractions when eating?
    a. Eat when sitting down
    b. Eat in the same place
    c. Turn the television and laptop off
    d. All of the above
37. When you give children a choice about an activity, they are more likely to enjoy that activity.
    a. True
    b. False
38. Which of the following is a way to shop healthy on a budget?
    a. Meal planning
    b. Making a grocery list
    c. Using leftovers
    d. All of the above
39. Which of the following are examples of activities that only burn limited calories (RED activities)?
    a. Sending text messages
    b. Watching a movie on your tablet
    c. Sitting and playing a video game
    d. All of the above
40. A good sleeping area includes all of the following EXCEPT:
    a. Comfort
    b. Low noise level
    c. Bright room lights
    d. No distractions
41. The portion sizes in many restaurants will make up two or more meals.
    a. True
    b. False
42. How can you decrease the chance of relatives giving your child high-calorie, low-nutrient foods like candy (RED foods)?
    a. Give your child high-calorie, low-nutrient foods before they go over to a relative's house
    b. Threaten to ground your child if they accept any high-calorie, low-nutrient foods
    c. Give your relatives examples of non-food items that they can give your child
    d. Tell your child it's okay for them to eat high-calorie, low-nutrient foods because it is like they're on vacation
43. Which of the following will increase the chance of a person staying committed to a physical activity?
    a. Paying for an exercise class
    b. Buying new exercise clothes

c. Buying new workout music
d. Doing it with a buddy

44. Parents can increase their child's concern about body shape by doing which of the following?
    a. Talking about their own concerns about their body shape in front of their children.
    b. Ignoring any concerns about their body shape they might have in front of their children.
    c. Downplaying their own concerns about their body shape in front of their children.
    d. All of the above.

Is there anything about the program that you really liked or you thought worked really well for your family?

_____

_____

_____

_____

_

_____

_____

Is there anything about the program that you would change or would recommend for future programs that would make

it work better for your family?

_____

_____

_____

24 Month Survey – Child (*DSMB approved protocol addenda, 9.29.19*).

Date:_____

For these questions, please CIRCLE how much you agree with the sentence:

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Stron Agre
45. This program helped my family members (like your other parent or your brother or sister) who were not a part of the program.	1	2	3	4	5
46. If a friend needed the same help as me, I would tell them to try the PLAN program.	1	2	3	4	5
47. This program helped me.	1	2	3	4	5

For each of the following questions, please circle the best answer.

48. Avocados, marshmallows, and black olives are a part of which food group?
    a. Proteins.
    b. Fats, Oils, and Sweets.
    c. Condiments and Dressings.
49. Which of the following are examples of the lowest calorie foods with the most nutrition (GREEN foods)?
    a. Green (non-starchy) vegetables.
    b. Fruit.
    c. Dairy.
    d. Beans/legumes.
50. Why is a food journal (Habit Book) important for weight loss and making healthy food choices?
    a. It helps you really think about what you are eating.
    b. It helps you to track the foods you are having throughout the day.
    c. It is not really that important for weight loss or healthy food choices.
    d. A and B.
51. A good thing about planning ahead for meals is:
    a. Allowing time for you and your parent to prepare food.
    b. Having healthy meals already chosen.
    c. Knowing the calorie content of meals.
    d. All of the above.
52. Aerobic exercises (medium to intense activity) do not burn a lot of calories and are not good for weight loss.
    a. True
    b. False
53. The best rewards or reinforcers are:
    a. Something you want.
    b. Not food, money, or sitting activities.
    c. Special.
54. All of the above. When you are eating, you should:
    a. Watch television.
    b. Play on your tablet.
    c. Just eat.
    d. None of the above.
    e. All of the above.
55. You want to eat foods that are low in:
    a. Fat.
    b. Fiber.
    c. Protein.
    d. Color.
56. Instead of drinking soda, a healthier option is:
    a. Diet soda.
    b. Water with fruit.
    c. Juice.
    d. Iced tea.

57. Which of the following are examples of activities that only burn limited calories (RED activities)?
    a. Watching television.
    b. Watching a movie on your tablet.
    c. Playing a video game while sitting.
    d. All of the above
58. Why might fast food restaurants be unhealthy?
    a. Fast food is high in calories.
    b. Fast food is high in fat.
    c. Fast food restaurants usually do not offer a lot of healthy options.
    d. All of the above.
59. A bedtime routine could include which of the following?
    a. A bath.
    b. Reading a book.
    c. Brushing teeth.
    d. All of the above.
60. How could you tell your friends about your healthy habits?
    a. Give your friends examples of medium to intense activity (GREEN physical activity) that they can do with you.
    b. Give your friends examples of low-calorie foods (GREEN foods) that they can eat every day.
    c. Tell them that you can only eat high-calorie foods (RED foods) when you are playing at their houses.
    d. Both A and B.
61. Which of the following is a benefit of planning physical activities to do with your friends during get-togethers?
    a. You can strengthen friendships with your healthy friends.
    b. It helps you and your friend to feel good.
    c. It makes it easier to make healthy activity choices.
    d. All of the above.
62. If you have a positive body image, you think which of the following?
    a. That your body is good.
    b. That your body is valuable.
    c. That you feel proud of what your body can do.
    d. All of the above.

The following are behaviors that people may or may not use to support their healthy lifestyle. For each of the following behaviors:

Please choose how often **YOU use them on a scale from Never to Daily:**

Never	**Yearly**	**Monthly**	**Weekly**	**Daily**
0	1	2	3	4

Please choose how helpful **YOU find them on a scale from Slightly Helpful to Very Helpful:**

N/A	Slightly Helpful	Somewhat Helpful	Moderately Helpful	Very Helpful
0	1	2	3	4

If you do not use the behavior, you may write "0" for N/A in the helpfulness column.

	How Often?	Ho
63. Using a food journal where you write down what you ate every day (Habit Book)		
64. Writing down the number of Calories you eat		
65. Increasing the number of low-calorie, green, leafy foods you eat like spinach or kale (GREEN foods)		
66. Decreasing the number of high-calorie, low-nutrient foods you eat like candy or pizza (RED foods)		
67. Decreasing the number of high-calorie, low-nutrient drinks you drink like soda (RED drinks)		
68. Increasing your medium to intense physical activity like walking or biking (GREEN physical activite)		
69. Weighing yourself		
70. Getting praise from your parent		
71. Having a Daily Check-In with your parent about what you are eating		
72. Decreasing screen time		
73. Sleeping for 9-11 hours a night		
74. Getting rewards or points (reinforcers) for doing healthy behaviors		
75. Doing physical activity with your family		
76. Eating healthy with your friends		
77. Doing physical activity with your friends		
78. How helpful were the PLAN sessions for you?		
79. How helpful was the PLAN program for you?		

Is there anything about the program that you really liked or you thought worked really well for your family?

_____

_____

_____

_____

_____

_____

_____

Is there anything about the program that you would change, or would recommend for future programs that would make it work better for your family?

_____

_____

_____

Coach Demographics Survey *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*

Please complete the survey below. Thank you!

Which Site are you from?

- Buffalo
- Columbus
- Rochester
- St Louis

Which Coach are you, A,B,C?

- A
- B
- C

What is your age? _____

How would you describe your race?

- Native American Indian or Alaskan
- Asian or Asian American
- African American or Black
- Caucasian or White
- Native Hawaiian or Pacific Islander
- Other or Multi-racial:
- Refused

Please describe: _____

What is your ethnicity?

- Hispanic or Latina/o
- Non-Hispanic or Latina/o

What is your sex:

- Female
- Male
- Other
- Refused

What is your job title? _____

BEFORE YOUR ENROLLMENT AND PARTICIPATION IN THIS STUDY:

Were you aware of the American Academy of Pediatrics Guidelines for Assessing Obesity?

A. Yes
B. No

If yes, how did you learn about these guidelines? _____

Were you aware of Family-Based Behavioral Weight Loss Treatment for Children with Obesity?

- Yes
- No

If yes, how did you learn about this treatment? _____

Have you had experience(s) with weight-related counseling or behavioral intervention for obesity (including weight control or weight management)?

- Yes
- No

If yes, what type of experience(s)? Check all that apply.

- Yes, I have observed weight-related counseling or behavioral interventions for obesity.
- Yes, I have delivered weight-related counseling or behavioral interventions for obesity.
- Yes, I have received weight-related counseling or behavioral interventions for obesity.
- Yes, other, please describe:

Other, please describe:

_____

Have you had experience(s)with other counseling or behavioral interventions (i.e., not related to weight gain or obesity)?

- Yes
- No

What type of experience(s) have you had with other counseling or behavioral interventions (i.e., not related to weight gain or obesity)? Check all that apply:

- Yes, I have observed counseling interventions or behavioral interventions.
- Yes, I have delivered counseling interventions or behavioral interventions.
- Yes, I have received counseling interventions or behavioral interventions.
- Yes, Other, please describe.

Please describe the type of experience you have:

_____

Coach Treatment Knowledge *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*

Please complete the survey below. Thank you!

For a child, overweight is defined as ____ for age and sex.

A. Weight-for-height ratio >85th percentile
B. Weight-for-height ratio >99th percentile
C. Body mass index (BMI) percentile of 85th to 94th
D. BMI > 90th percentile

For a child, obesity is defined as _____ for age and sex.

A. Weight-for-height ratio >95th percentile
B. Weight-for-height ratio >99th percentile
C. BMI >99th percentile
D. BMI> 95th percentile

At what age should BMI begin being calculated, and how often should BMI be calculated?

A. At age 2, every year
B. At age 2, every well-child visit
C. Overweight or obese children, every other year
D. All children every other year

What are the maximum recommended weight loss targets for obese children and adolescents?

A. Weight loss should not exceed 1 lb. per month in children 2-11 years or 3 lbs. per week in older children and adolescents.
B. Weight loss not to exceed .5 lb. per month in children 2-11 years or 1 lb. per week in older children and adolescents
C. Weight loss not to exceed 1 lb. per month in children 2-11 years or 2 lbs. per week in older children and adolescents.
D. Weight loss not to exceed .5 lb. per month in children 2-11 or 2 lbs. per month in older children and adolescents.

23) There are several recommendations for assessing obesity. Calculating and plotting BMI is one of them. Which of the following are the other recommendations for assessing obesity?

I. Assess medical risk, including patient history, parental obesity, family history, and physical exam and review of systems.
II. Assess psychological risk, including depression, anxiety, and eating disorders
III. Assess behavior risk, including sedentary time, eating, physical activity, and home environment
IV. Assess attitudes, including family and patient concern, and motivation.

A. I, III, and IV
B. All four

C. I and III
D. I, II, and III

24) For children 2 and older, which of the following are appropriate recommendations for what children should be eating, drinking, and doing each day?

A. 5 or more fruits and vegetables, 1 hour or less or recreational screen time, 30 minutes or more of physical activity
B. 6 or more fruits and vegetables, 2 hours or less of recreational screen time, 90 minutes or more of physical activity, 0 sugary drinks
C. 5 or more fruits and vegetables, 2 hours or less of recreational screen time, 60 minutes or more of physical activity, 1 sugary drink or less
D. 6 or more fruits and vegetables, 1 hour or less of recreational screen time, 60 minutes or more of physical activity, 1 sugary drink or less.

25) Imagine you that you are working with a family of an overweight child and have recommended that the child lose a small amount of weight in the next few months (e.g., 4 pounds). If you only have time to set one goal, which of the following is the most likely to help the child to lose weight and establish healthy habits?

A. Identify healthy options the child can choose for lunch at school by discussing the menu (i.e., reviewing what is posted online by the child's school).
B. Determine which healthy foods the parents(s) will have available at home so that the home is a "healthy zone" and increase the amount of foods consumed from home.
C. Discuss physical activity options and increase walking to and from school or the bus stop.
D. Reduce the child's time spent watching movies or playing video games by determining an appropriate amount of time and having the parent(s) set a timer.

26) If you are setting a goal with the parent(s) and child about increasing exercise to 3 times in the next week, but they seem resistant to the goal (i.e., they are not "getting it"), what would you do?

A. Patiently describe the exercise goal and its importance in their larger goals for health, focusing on the goal you have defined (3 times in the next week).
B. Ask them what they are interested in setting as a goal for exercise, then encourage them to follow through with their identified goal.
C. Discuss their perceived barriers and collaboratively identify an appropriate goal that will address their exercise behaviors.
D. If they seem more willing to focus on a goal related to the child's eating patterns instead, identify a goal for the family that will address eating behaviors rather than activity behaviors.

Coach Attributes of Evidence Based Treatment *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*

Please complete the survey below. Thank you!
The following questions ask about your feelings about using new types of therapy, interventions or treatments. Manualized therapy, treatment, or intervention refers to any intervention that has specific guidelines and/or components that are outlined in a manual and/or that are to be followed in a structured or predetermined way.

Indicate to the extent to which you agree with each item using the scale shown below.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

I like to use new types of therapy or interventions to help my clients.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

I am willing to try new types of therapy or interventions, even if I have to follow a treatment manual.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

I know better than academic researchers how to care for my clients.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

I am willing to use new and different types of therapy or interventions developed by researchers.

1. Not at all
2. To a slight extent

3. To a moderate extent
4. To a great extent
5. To a very great extent

Research-based treatments/interventions are not clinically useful.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

Clinical experience is more important than using manualized interventions.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

I would not use manualized therapy/interventions.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

I would try a new therapy or intervention, even if it were very different from what I am used to doing.

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

For the following questions if you received training in a new therapy or intervention how likely would you be to adopt it if:

It was intuitively appealing?

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

It made sense to you?

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

It was required by your supervisor?

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

It was a state requirement?

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

It was being used by colleagues who were happy with it?

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

You felt you had enough training to use it correctly?

1. Not at all
2. To a slight extent
3. To a moderate extent
4. To a great extent
5. To a very great extent

Coach Attributes Family Based Treatment (FBT) *(This change was made on 7.25.19 prior to review and approval by the DSMB, DSMB approved protocol addenda on 9.29.19).*

Please complete the survey below. Thank you!

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

The content of FBT is compatible with my personal beliefs and values.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

FBT is useful.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

FBT is credible.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

FBT is easy to administer in the practice setting.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

The content of FBT is clear.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree

4. Disagree
5. Strongly Disagree

FBT can be implemented without requiring an extensive training.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

FBT can be adapted or modified to suit the needs of the interventionist.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

The benefits of using FBT with my clients are obvious/visible.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

The evidence regarding the impact of FBT is available.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

The content of FBT is relevant to my work as a clinical treatment provider.

1. Strongly Agree
2. Agree
3. Neither Agree or Disagree
4. Disagree
5. Strongly Disagree

Coach consent

Please upload the .pdf file of the signed Coach consent.

Indicate yes or no that Coach consent is uploaded.

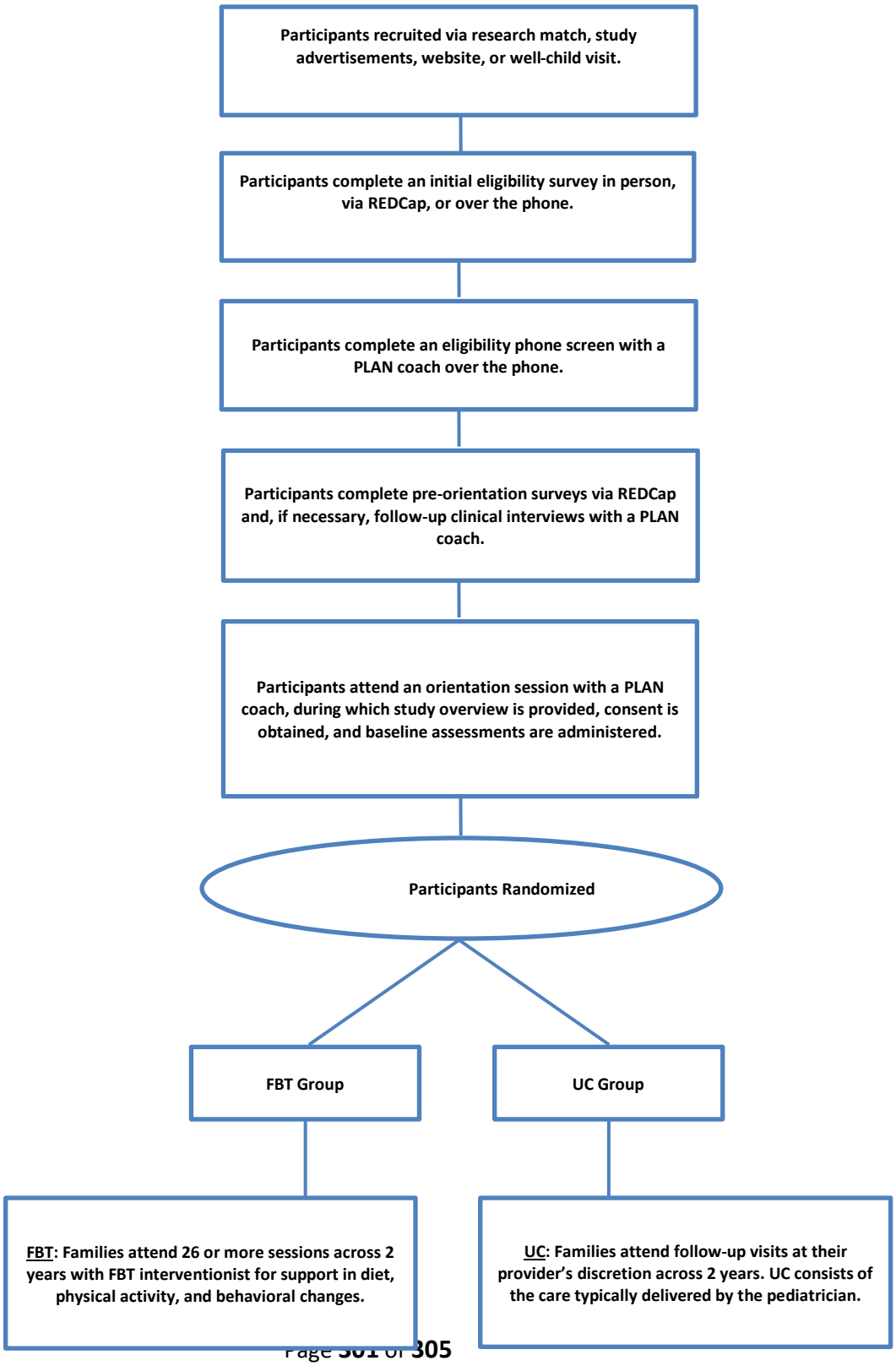
- No

- Yes

Why is the coach consent not uploaded? _____

D. Additional Forms

Figure 1. Study Flow Chart



PLAN Adverse Event Questionnaire

During the time since your last visit on *(insert date of last major assessment)*, have you or your child:

1. Been hospitalized overnight?
   YES NO

2. Been to the emergency room or an urgent care clinic?
   YES NO

3. Been treated by a medical provider for illness or injury?
   YES NO

4. Had any injuries (e.g., sprained ankle or broken bone)?
   YES NO

5. Started any new medications or receive a change in dosage of a current medication?
   YES NO

6. Experience increased symptoms of a current illness or injury (If applicable)?
   YES NO

7. Seen a new counselor, psychologist, or psychiatrist?
   YES NO

8. Gone long periods (8 waking hours or more) without eating to control your weight?
   YES NO

9. Felt like you have lost control over your eating?
   YES NO

10. Thrown up after eating?
    YES NO

11. Taken laxatives or diet pills?
    YES NO

12. Felt particularly nervous, worried, or anxious?
    YES NO

13. Felt very sad or down? Or lost interest in things that you normally enjoy doing?
    YES NO

(This change was made on 5.23.18 prior to review and approval by the DSMB, DSMB approved protocol addenda on 11.2.18)

ADVERSE EVENT FORM

The Effectiveness of Family-based Weight Loss Treatment Implemented in Primary	
Site: _____ Participant ID: _____	Has the participant had any adverse ev ☐ Yes (Please list all AEs below ☐ No

Severity	Relationship to Study Intervention	Action Taken Regarding Study Intervention	Outcome of AE
1. Mild 2. Moderate 3. Severe	1. Definitely related 2. Possibly related 3. Not related	1. None 2. Discontinued	1. Resolved 2. AE still present – no treatment 3. AE still present – being treated 4. Residual effects present – not treated 5. Residual effects present – treated 6. Death (complete SAE form) 7. Unknown

Adverse Event	Start Date	Stop Date	Severity	Relationship to Study Intervention	Action Taken	Outcom of AE

Signature of Clinical Site PI: **Date:**

SERIOUS ADVERSE EVENT FORM

The Effectiveness of Family-based Weight Loss Treatment Implemented in Primary Care
Site: _____ Participant ID: _____

1. SAE Onset Date: ____/____/_____

2. SAE Stop Date: ____/____/_____

3. Location of SAE:

4. Was this an unexpected adverse event? □ Yes □ No

5. Brief description of participant with no personal identifiers: □ Male □ Female
   Age_____

6. Brief description of SAE (attach description if more space needed):
   _____
_____
   _____
   _____
   _____
   _____

□Death
□ Life-threatening impairment
□ Hospitalization – initial or prolonged
□ Disability/incapacity
□ Congenital anomaly/birth defect
□ Required intervention to prevent permanent
□ Other:
_____

7. Intervention type:
   □ Medication or nutritional supplement
   □ Behavioral/lifestyle
   □ Device
   □ Surgery

8. Relationship of SAE to intervention:
   □ Unrelated (clearly not related to intervention)
   □ Possible (may be related to intervention)
   □ Definite (clearly related to intervention)

9. Was study intervention discontinued due to event? □ Yes □ No

10. What other steps were taken to treat SAE?
    _____
_____
    _____
    _____
    _____
    _____

Signature of Clinical Site PI: **Date:**