Family-Based Treatment for Type 1 Diabetes (FBT for T1D)

NCT05756361

Last Date of IRB Approval: November 12, 2025

Study Protocol and Statistical Analysis Plan

PROTOCOL TITLE:

Include the full protocol title.

Response:

Title: A Family-Based Approach to Treat Obesity and its Co-morbidities in Youth with Type 1 Diabetes and Their Parents

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

Response:

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VERSION NUMBER/DATE:

Include the version number and date of this protocol.

Response:

5.0

11.12.2025

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

FUNDING:

Indicate any funding for this proposal. This should match the Funding Sources page in Click IRB.

Response:

UB CTSI Translational Pilot Studies Program

Grant Number: PS-QUATTRIN under UL1TR001412

GRANT APPLICABILITY:

Indicate whether this protocol is funded by a grant (e.g. NIH, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.

NOTE: This question does not apply to studies funded by a sponsor contract.

Include a copy of the grant proposal with your submission.

Response:

UB CTSI Translational Pilot Studies Program

Grant Number: PS-QUATTRIN under UL1TR001412

RESEARCH REPOSITORY:

Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed.

Response:

Location: Room 6083

Address: CTRC, 875 Ellicott St. Buffalo, NY 14203

Department: Jacobs School of Medicine and Biomedical Sciences

Study Summary

Study Title	Title: A Family-Based Approach to Treat Obesity and its Co-morbidities in Youth with Type 1 Diabetes (T1D) and Their Parents Short Title: FBT for T1D Families
Study Design	We are proposing a 12-week (with optional 12 week extension) pilot study enrolling 20 patient-with T1D-parent dyads. Participating youth will be 6-17 years old with overweight/obesity. The parent will have overweight/obesity. This study will test the feasibility of delivering a family-based treatment (FBT) with a strong behavioral component to treat overweight in BOTH child (with T1D and overweight/obesity) and one parent (with overweight/obesity). The coaching sessions will be delivered

	both in person at the clinic and remotely via Zoom/Whatsapp/Facetime, adapting to include more remote sessions for families unable to travel to the center to enhance inclusivity and flexibility.
Primary Objective	The AIM of this pilot study is to test the hypothesis that Family Based Treatment (FBT) will lead to reduction of overweight/obesity in youth with T1D and reduction of overweight/obesity in their parents.
Secondary Objective(s)	The secondary AIMS will test the hypotheses that: 1. In the youth affected by T1D, reduction of obesity will lead to reduced insulin dosing, improved Hemoglobin A1c(HbA1c), a goal standard of diabetes metabolic control;
Research Intervention(s)/ Investigational Agent(s)	The intervention does not use a pharmacologic agent. It will include standard of care dietary and physical activity counseling and FBT already highly tested in specialized and primary care setting for treatment of overweight in youth and adults, this will be adapted for delivery to children with T1D children and their parents.
IND/IDE #	
Study Population	Participating youth will be 6-17 years old with overweight/obesity. The participating parent will have overweight/obesity.
Sample Size	20 youth with T1D and 20 (1/youth) participating parent
Study Duration for individual participants	3-6.5 months
Study Specific Abbreviations/ Definitions	Family-Based Treatment (FBT) Type 1 diabetes (T1D) Type 2 diabetes (T2D) HbA1c (Hemoglobin A1c) BMI (Body Mass Index) Physical activity (PA) Continuous Glucose Monitoring (CGM)

Objectives*

Describe the purpose, specific aims, or objectives of this research.

Response:

The primary AIM .of the proposed pilot study is to test the hypothesis that FBT will lead to reduction of obesity in youth with T1D as well as reduction of obesity in their parents.

The secondary AIMS will test the hypotheses that:

1. In the youth affected by T1D, reduction of obesity will lead to reduced insulin dosing, improved HbA1c;

State the hypotheses to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response:

The AIM of this pilot study is to test the hypothesis that Family Based Treatment (FBT) will lead to reduction of obesity in youth with T1D and reduction of obesity in their parents.

The secondary AIMS will test the hypotheses that:

1 The primary AIM .of the proposed pilot study is to test the hypothesis that FBT will lead to reduction of obesity in youth with T1D as well as reduction of obesity in their parents.

The secondary AIMS will test the hypotheses that:

1. In the youth affected by T1D, reduction of obesity will lead to reduced insulin dosing, improved HbA1c;

Scientific Endpoints*

3.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should ***not*** *be a date.*

Response:

The scientific endpoint is a reduction of overweight/obesity in both youth and parents. It is further described above that the secondary hypotheses are testing in youth improvement of parameters of T1D control (HbA1c, and insulin dosing) This study will use T1D standard of care dietary and physical activity guidelines while adding the delivery of FBT intervention, which is not ordinary part of standard of care. The importance of reducing overweight in persons with T1D is related to the fact that persons with T1D are living longer and heathier lives. Therefore, decreasing overweight can translate into reducing co-morbidities, such as hypertension, insulin resistance, hyperlipidemia etc. that may compound with the classic T1D complications, i.e. nephropathy, retinopathy, neuropathy, ect.

Background*

Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior research by the investigator.

Response:

Type 1 Diabetes (T1D) used to be characterized by underweight and undernutrition secondary to severe calorie wasting. However, with advances in insulin replacement therapy, malnutrition has ceased but the prevalence of obesity in T1D has dramatically increased, reflecting the trend in the general population (1, 2). In a historical cohort of patients with T1D followed over 18 years, overweight and obesity prevalence increased by 47% and 7-fold respectively compared to baseline. In adults with T1D, obesity has been reported in as many as 52.4% and recent surveys showed that over 1 in 3 adolescents with T1D are overweight/obese, with the highest rate of obesity in females and those of minority status (3). Obesity is a state of insulin resistance; therefore, individuals with T1D and obesity will develop insulin resistance to exogenous insulin making disease management more challenging. In addition, obesity causes poorer mental and quality of life outcomes, and increases the risk of hypertension and dyslipidemia (precursors for vascular disease).

Obesity has genetic and environmental etiologies. When a patient with T1D is obese, it is likely that one or both parents are obese (4). Nutrition is an essential component of diabetes management that needs to be culturally sensitive and tailored to individual food preferences (5). Dietary management and physical activity (PA) are not only key elements to optimize glycemic control, but also to prevent complications, such as hyperlipidemia and hypertension. Unfortunately, these preventative strategies are difficult to implement, especially when comorbidities run in the family, and health care professionals focus on the child rather than the family unit. We are proposing an innovative, cost-effective approach to the treatment of obesity in patients with T1D and their parents. Our preliminary data obtained via de-identified questionnaires from 50 parents of children with T1D show that 31 parents had overweight/obesity, 26 hypertension, 15 pre-diabetes or T2D, 17 hyperlipidemia and 32 had back/knee/hip problems. We have extensive experience in Family-Based Behavioral Treatment (FBT) in youth and adults with overweight and obesity (6). While FBT has been used in Type 2 diabetes (T2D), it has not been tested in T1D, largely because obesity is overlooked in this cohort. If successful, the benefit of this innovative program will extend well beyond Western New York because it will set a new paradigm for the management of obesity and T1D. Moreover, it will be cost effective since it will address obesity and in the parents and family (7).

Include complete citations or references.

Response:

1. Majumdar I, Bethin K, Quattrin T. Weight trajectory of youth with new-onset type 1 diabetes comparing standard and enhanced dietary education. Endocrine. 2015;49(1):155-62.

2. Conway B, Miller RG, Costacou T, Fried L, Kelsey S, Evans RW, et al. Temporal patterns in overweight and obesity in Type 1 diabetes. Diabet Med. 2010;27(4):398-404.

3. Minges KE, Whittemore R, Weinzimer SA, Irwin ML, Redeker NS, Grey M. Correlates of overweight and obesity in 5529 adolescents with type 1 diabetes: The T1D Exchange Clinic Registry. Diabetes Res Clin Pract. 2017;126:68-78.

4. Nielsen LA, Nielsen TR, Holm JC. The Impact of Familial Predisposition to Obesity and Cardiovascular Disease on Childhood Obesity. Obes Facts. 2015;8(5):319-28.

5. Rovner AJ, Nansel TR, Gellar L. The effect of a low-glycemic diet vs a standard diet on blood glucose levels and macronutrient intake in children with type 1 diabetes. J Am Diet Assoc. 2009;109(2):303-7.

6. Quattrin T, Roemmich JN, Paluch R, Yu J, Epstein LH, Ecker MA. Treatment outcomes of overweight children and parents in the medical home. Pediatrics. 2014;134(2):290-7.

7. Quattrin T, Cao Y, Paluch RA, Roemmich JN, Ecker MA, Epstein LH. Cost-effectiveness of FamilyBased Obesity Treatment. Pediatrics. 2017;140(3).

8. Epstein LH, Quattrin T. Ideas for Next-Generation Treatments of Adolescent Obesity. JAMA Pediatr. 2020;174(6):527-8.

9. Spoth R, Redmond C. Study of Participation Barriers in Family-Focused Prevention: Research Issues and Preliminary Results. Int Q Community Health Educ. 1993;13(4):365-88.

10. Epstein LH, Schechtman KB, Kilanowski C, Ramel M, Moursi NA, Quattrin T, et al. Implementing family-based behavioral treatment in the pediatric primary care setting: Design of the PLAN study. Contemp Clin Trials. 2021;109:106497.

11. Battelino T, Danne T, Bergenstal RM, Amiel SA, Beck R, Biester T, et al. Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations From the International Consensus on Time in Range. Diabetes Care. 2019;42(8):1593-603.

12. Tang TS, Funnell MM, Anderson RM. Group Education Strategies for Diabetes Self-Management. Diabetes Spectrum. 2006;19(2):99-105.

13. Vidgen HA, Gallegos D. Defining food literacy and its components. Appetite. 2014;76:50-9.

14. Paluch RA, Epstein LH, Roemmich JN. Comparison of methods to evaluate changes in relative body mass index in pediatric weight control. Am J Hum Biol. 2007;19(4):487-94.

15. Sharma AM, Kushner RF. A proposed clinical staging system for obesity. Int J Obes (Lond). 2009;33(3):289-95.

16. Mortensen HB, Hougaard P, Swift P, Hansen L, Holl RW, Hoey H, et al. New definition for the partial remission period in children and adolescents with type 1 diabetes. Diabetes Care. 2009;32(8):1384-90.

17. Kolotkin RL, Crosby RD, Kosloski KD, Williams GR. Development of a brief measure to assess quality of life in obesity. Obes Res. 2001;9(2):102-11.

18. Nadeau K, Kolotkin RL, Boex R, Witten T, McFann KK, Zeitler P, et al. Health-Related Quality of Life in Adolescents With Comorbidities Related to Obesity. J Adolesc Health. 2011;49(1):90-2.

19. Birkett MA, Day SJ. Internal pilot studies for estimating sample size. Stat Med. 1994;13(23-24):2455-63.

Study Design*

Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, observational).

Response:

Response:

We are proposing a 12 week (with optional 12 week extension) pilot study enrolling 20 patient-parent dyads. Patients are 6–17-year-old youth with T1D and overweight/obesity with a parent with overweight/obesity willing to participate in the program as well. We realize that the age range chosen encompasses different developmental ages and are prepared to make some adaptations based on the intellectual and developmental abilities of the youth. For example, young children react very well to games related to food choices.

Inclusion criteria:

- T1D duration $\geq$1 year (to exclude patients in the partial remission period)
- Overweight or obesity defined as a Body Mass Index (BMI) $\geq 85^{th}$ percentile for age and gender
- receive insulin therapy via pump.
- wear a continuous glucose monitor (CGM).
- Have one parent with overweight/obesity (BMI >27 Kg/Meter^2 willing to participate in the FBT)
- FBT is being added to standard of care dietary and Physical activity counseling. We will provide the participants with Body Trace Weight scales and instruct parents and youth to check their weight twice/week. The purpose of weight checking in-between in-person meetings is for the family coach to help the parent (and the child is old enough) relate weight changes to diet and activity habits/healthy behaviors and to develop plans to address weight gain relapse when

needed. The choice of the Body Trace Weight scale is because it is a cellular enabled scale that will work even if there is a lapse in Wi-Fi availability and is user friendly without complicated set up procedures. Moreover, we have already purchased them and will not need funding for them.

- The intensity of the proposed schedule is in keeping with the treatment dose recommended by the United States Preventive Task Force recommendations (8). The coaching sessions will occur weekly for nine weeks (week 0,1,2,3,4,5,6, 7, 8), followed by sessions every two weeks for one month (wks. 10,12,), with an optional extension for an additional 12 weeks (meeting at weeks 14,16,18, 22, and 26). The intensity of contact needs to be greater initially because this facilitates change in habits. However, "lack of time" is a major barrier to the acceptance of FBT programs for treatment of overweight and ultimately in the translation and dissemination of successful programs (9). Therefore, to overcome this barrier, we will adapt to include more remote sessions via Zoom/Whatsapp/Facetime when needed for families unable to travel to the center to enhance inclusivity and flexibility. Essentially, the only required in-person visits are week 0, 1, and 12, and week 26 (if extended), so that we can obtain important study data such as weight, height, blood glucose, and HbA1c, and the participating dyads are welcome to visit in-person or virtually via Zoom/Whatsapp/Facetime for the other sessions.
- The coordination of the sessions with the standard of care visit will also involve the patient's diabetologist in following the patient's progress, providing positive feedback and learning himself/herself from this program. We have experience with virtual delivery of FBT in the primary care setting during the COVID pandemic (10).
- Moreover, patients with T1D are accustomed to the use of digital health to upload their pump and sensors/glucose monitors (11). We have conducted a 4-week pilot on the use of Wi-Fi scales in ten children 2-8 years old and their mothers (6/10 overweight or obese) who were instructed to monitor their weight and the child's weight twice week for a total of 8 times. 8/10 mothers monitored their weight and that of their child 7/8 times.
- We have considered the possibility of group sessions which reinforce learning acquired during 1:1 sessions and peer support and are cost-effective. Group education has been adopted in the treatment of overweight and in adults with Type 2 diabetes (12). While we have conducted FBT group meetings in many instances in the past, they have been coupled with 1:1 meeting to tailor coaching to the particular needs of a participant and to "make up" missed group sessions. T1D is a chronic and very taxing disorder for patients and families. The coordination of group meetings imposes a "fixed day and time" regimen that cannot be met by many parents who need flexibility and tends to exclude single parents and those families who have health and socio-economic inequities, which could benefit the most from coaching. In the recently completed PLAN grant, a multicenter FBT implemented in the primary care setting we adopted a 1:1

strategy which has allowed us to recruit 43% of minority families and 17% with income at the poverty line or below.

- Our FBT curriculum, which has been delivered successfully in the specialty and primary care settings, has 3 components: 1. Meal planning including quality of carbohydrates and glycemic index for both parents and children while ensuring that youth have a balanced meal plan with adequate amounts of carbohydrates for optimal growth (5). Our FBT has a focus on "Food Literacy" including healthy food selection and sourcing of affordable healthy food, food preparation and preplanning, social engagement tailoring the meal plan to the needs to the family in socio cultural appropriate way and also feasibility based on logistics and economic aspects (13); 2. Physical activity (PA) component with shaping strategy to allow for a progressive shaping of easy PA starting, if needed, with as little as with 10 minutes of walking/day and strategies to incorporate PA in daily routines, family, and social activities; 3. Extensive behavioral component which has been shown to be very powerful in obesity treatment and will be tailored to the needs of the patient with T1D. The program will focus overall on strategies on energy reduction, increased PA, and behavioral techniques to develop and sustain heathy habits conducive to reach healthy weight while balancing glycemic targets.
- In the past, we have compared the FBT intervention in a randomized fashion to an Education Control arm, where parents (and children if old enough) would receive education regarding meal planning and physical activity pertaining ONLY to the child (targeting child only) without a behavioral component and without treating the parent. This modality of controls for attention and still provides some benefit but not the same degree of weight loss (6). However, for this proposal, we will deliver the treatment to 20 families without randomizing to a control arm because this is the first time we are adapting our successful evidence based FBT for treatment of obesity in the general population to treat patients with T1D and obesity and their parents with obesity. Moreover, it is also the first time that the protocol (not due to the pandemic constraints) includes a mix of in-person and virtual treatments. Therefore, with the limited time and funding, we feel that the first step in this adaptation is to demonstrate that FBT to a new population and the hybrid program do work. We will compare the FBT intervention to a standard of care control group of patients matched for gender, T1D duration, age and HbA1c to the participants in this study. The data abstracted are existing standard of care data and therefore we are asking for a HIPPA waiver for this component of the study. In other terms, the subjects acting as historical control will not be participants in the study. We acknowledge that the major limitation of this control group is the fact that there is not randomization and also that we will not be collecting parental data. Yet this, coupled with the change that each patient and parents will have compared to baseline, will give us some solid preliminary data to judge the effectiveness of the program and provide data for power calculations for extramural application supporting a randomized trial.
- In contrast to Type 2 diabetes, T1D is not more prevalent in Black, Indigenous and People of Color (BIPOC). However, the highest rate of obesity in patients with T1D is seen in patients with socio-economic disparities and minority status

(3) and we will prioritize enrollment of these patients. We are aware of the inequities caused by the digital divide. The choice of cellular scales that enable communication during internet lapses was made to assist families who may have socio economic difficulties. The majority of these families still have cellular phones which will allow virtual contact. Therefore, we will use some of the funds to help families with socio-economic disparities afford internet and a means to communicate electronically.

Study Intervention/Investigational Agent

6.1 Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.

Response:

We will collect preliminary data on the efficacy of an FBT intervention added to standard of care counseling for children with T1D and obesity and their parents with T1D and obesity.

Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.

If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., Research Pharmacy SOP for the Control of Investigational Drugs, etc.), please reference that SOP in this section.

Response:

N/A

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

Identify the holder of the IND/IDE/Abbreviated IDE.
Explain procedures followed to comply with sponsor requirements for FDA regulated research for the following:

	Applicable to:		
FDA Regulation	***IND Studies***	***IDE studies***	***Abbreviated IDE studies***
21 CFR 11	***X***	***X***	
21 CFR 54	***X***	***X***	
21 CFR 210	***X***		
21 CFR 211	***X***		
21 CFR 312	***X***		
21 CFR 812		***X***	***X***
21 CFR 820		***X***	

Response:

N/A

Local Number of Subjects

Indicate the total number of subjects that will be enrolled or records that will be reviewed locally.

Response:

We expect to recruit 20 participants (6–17-years old) who have T1D and overweight/obesity and at least one parent with overweight/obesity.

If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate).

Response:

We estimate that we will need to approach 150 patients with overweight to recruit 20 patient-parent dyads. Via electronic medical records (EHR), we will find 4-6 patients/half day outpatient session, with T1D and overweight/obesity among patients followed at our Diabetes Center at UBMD Pediatrics and Oishei Children's Hospital. These patients will be flagged in the EHR so that their Diabetologist will mention the program and perform a warm handoff to the research coordinators. Only patients with overweight/ obesity will be approached. Given the genetic nature of overweight, it is very likely that patient with T1D and overweight will have a parent with overweight/obesity.

Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?

Response:

The Diabetes Center at UBMD Pediatrics and Oishei Children's Hospital follows over 850 patients with T1D. Assuming conservatively that across ages 25-35% are overweight, we need to recruit less than 6% (20/340). Given that 1/3 adolescents have

overweight and prevalence of overweight is about 30% in younger children, we have a very vast pool for recruitment of 20 participants namely less than 10%. Moreover, these patients already have a doctor-patient relationship with the investigators and therefore are more likely to be comfortable enrolling.

Inclusion and Exclusion Criteria*

*Describe the criteria that define who will be **included** in your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Inclusion:

T1D of 12 or more months duration

Age 6–17-years

Presence of overweight/obesity

Youth uses a pump for insulin delivery and a continuous glucose monitoring device to monitor glycemic levels

Youth has one parent with overweight/obesity willing to participate in the program

*Describe the criteria that define who will be **excluded** from your final study sample.*

NOTE: This may be done in bullet point fashion.

Response:

Exclusion:

Child:

- Chronic conditions other than T1D
- Other autoimmune conditions other then T1D or autoimmune thyroiditis.
- Medications that can affects weight, such as medications used to treat Attention Deficit Disorder or high dose steroids used to treat asthma.
- Depression symptoms by standard of care Patient Health Questionnaire (PHQ) 9 in the child or parent
- Inability to perform at least mild physical activity such as walking
- Child with handicap (such as developmental delay or deafness) that would prevent him/her from benefitting from counseling in person and/or remotely

Participating parent with

- symptoms of depression assessed by standard of care PHQ
- autoimmune disorders other than T1D or autoimmune thyroiditis

- Participating parents with chronic disorder that is treated with medications that interfere with weight loss or are preventing him/her from performing at least mild physical activity
- Participating parent unwilling to use internet for remote sessions or unable to afford internet despite the $30/month subsidy provided by the duration of the study (6 months).
- Participating mother intending to become pregnant (but dad could be the participating parent

Indicate specifically whether you will include any of the following special populations in your study using the checkboxes below.

NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.

Response:

☐ Adults unable to consent

☒ Individuals who are not yet adults (infants, children, teenagers)

☐ Pregnant women

☐ Prisoners

Indicate whether you will include non-English speaking individuals in your study. ***Provide justification if you will exclude non-English speaking individuals.***

In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may ***not*** *be routinely excluded from research as a matter of convenience.*

In cases where the research is of therapeutic intent or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. However, there are studies in which it would be reasonable to limit subjects to those who speak English. Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit.

Response:

We will not include non-English speaking participants because this study uses teaching materials and assessments that are not translated in other languages. The inability to speak English in our patients with T1D and their parents is the absolute exception. However, the PI and RD employed at the Diabetes Center will ensure that non-English speaking families receive culturally appropriate standard of care dietary and physical activity counseling.

Vulnerable Populations*

If the research involves special populations that are considered vulnerable, ***describe the safeguards included to protect their rights and welfare.***

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

For research that involves ***pregnant women,*** *safeguards include:*
NOTE CHECKLIST: Pregnant Women (HRP-412)

Response:

☒ **N/A**: This research does not involve pregnant women.

For research that involves ***neonates of uncertain viability or non-viable neonates,*** *safeguards include:*
NOTE CHECKLISTS: Non-Viable Neonates (HRP-413), or Neonates of Uncertain Viability (HRP-414)

Response:

☒ **N/A:** This research does not involve non-viable neonates or neonates of uncertain viability.

For research that involves ***prisoners****, safeguards include:*
NOTE CHECKLIST: Prisoners (HRP-415)

Response:

☒ **N/A:** This research does not involve prisoners.

For research that involves ***persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children")****, safeguards include:*
NOTE CHECKLIST: Children (HRP-416)

Response:

This project is no greater than minimal risk. Children and their rights will be safeguarded by:

- Asking for their continued assent (and their parent's consent) throughout the study during the meetings with study personnel.
- Assuring the child that their information will be de-identified and that any information we take will be kept on a password-protected computer, and that any physical copies will be stored in a locked drawer in a locked room. Children will also be assured that all meetings will be private, whether in a private room at the Diabetes Center or via a password-protected online video call.

☐ **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures ("children").

*For research that involves **cognitively impaired adults**, safeguards include:*
NOTE CHECKLIST: Cognitively Impaired Adults (HRP-417)

Response:

☒ **N/A:** This research does not involve cognitively impaired adults.

Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. ***Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.***

Response:

NA

Eligibility Screening*

*Describe **screening procedures** for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.*

📎 *Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaire).*

Response:

Electronic Medical Records of eligible youth will be flagged before the outpatient visit usually occurring every 3 months. Flags will be placed if the child is 6–17-years old, has had T1D duration >12 months and had overweight/obesity at the prior visit. Additionally, the child is using a pump for insulin delivery and a continuous glucose monitoring device to monitor glycemic levels. The health care professional who follows the child routinely will mention the study and give a hand off to the study recruiter who will explain the study. Part of this procedure will be tactfully to explain that the FBT targets also the family – in particular a parent who needs to be overweight/obese.

Youth who have one parent with overweight/obesity willing to participate in the program.

☐ **N/A:** There is no screening as part of this protocol.

Recruitment Methods

☐ **N/A:** This is a records review only, and subjects will not be recruited.
NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections.

Describe when, where, and how potential subjects will be recruited.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.).

Response:

Recruitment occurs during standard of care visit in the outpatient UBMD Pediatric Diabetes Center. Similar to what we have done when we implemented FBT for obesity treatment in the primary care setting, we will flag the electronic medical record of potentially eligible patients (see above 10.0) with overweight/obesity so that our clinical staff can mention the study and the research staff can present the study. If the patient and parent are interested, Dr. Quattrin will further explain the study and commitment in more detail. The PI and study staff will provide informed consent/assent for the patient and family to review. Besides the hybrid nature of the program, another strategy to facilitate enrollment and retention is that we have the option of conducting the in-person sessions (other than those coordinated with standard of care) in urban or sub-urban settings we have already in place. Lastly, we plan to allocate some funds ($30/month) to offset some of the cell phone bill and to provide reimbursement for travel to the in-person sessions.

Describe how you will protect the privacy interests of prospective subjects during the recruitment process.

NOTE: Privacy refers to an individual's right to control access to him or herself.

Response:

All interactions between the study staff and the subject will be in a private space.

Identify any materials that will be used to recruit subjects.

NOTE: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.

For advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB-required revisions, provided the IRB also reviews and approves the final version.

Response:

N/A

Procedures Involved*

*Provide a description of **all research procedures or activities** being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible.*

NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response.

Response:

Participants and their family members will undergo our 3-to-6-month FBT curriculum, using 3 components: 1. Meal planning including quality of carbohydrates and glycemic index for both parents and children while ensuring that youth have a balanced meal plan with adequate amounts of carbohydrates for optimal growth (5). Our FBT has a focus on "Food Literacy" including healthy food selection and sourcing of affordable healthy food, food preparation and preplanning, social engagement tailoring the meal plan to the needs to the family in socio cultural appropriate way and also feasibility based on logistics and economic aspects (13); 2. Physical activity (PA) component with shaping strategy to allow for a progressive shaping of easy PA starting, if needed, with as little as with 10 minutes of walking/day and strategies to incorporate PA in daily routines, family, and social activities; 3. Extensive behavioral component which has been shown to be very powerful in FBT for obesity and will be tailored to the needs of the patient with T1D. The program will focus on energy reduction, increased PA, and behavioral techniques to develop and sustain heathy habits conducive to reach healthy weight while balancing glycemic targets.

The intensity of the schedule is in keeping with the treatment dose recommended by the United States Preventive Task Force recommendations (8). The coaching sessions will occur weekly for nine weeks (week 0,1,2,3,4,5,6, 7, 8), followed by sessions every two weeks for one month (wks. 10,12,), with an optional extension for an additional 12 weeks (meeting at weeks 14,16,18, 22, and 26). Participants will be afforded the option to participate in-person or virtually. Essentially, the only required in-person visits are week 0, 1, and 12, and week 26 (if extended), so that we can obtain important study data such as weight, height, blood glucose, and HbA1c, and the participating dyads are welcome to visit in-person or virtually via Zoom/Whatsapp/Facetime for the other sessions.Moreover, we will coordinate the standard of care diabetes follow-ups (needed every 10-12 weeks) at the same time of the coaching sessions (IP + clinic at week 0-12 and 26 if extended).

The coordination of the sessions with the standard of care visit will also involve the patient's diabetologist in following the patient's progress, providing positive feedback and learning himself/herself from this program. We have experience with virtual delivery of FBT in the primary care setting during the COVID pandemic (10).

Change in weight is the primary outcome. Therefore, youth and parents' weight will be checked with standardized procedure at in-person meetings and obtained via Body Trace Weight scale twice/week throughout the program. After recruitment, participants will be provided a Body Trace Weight scale. The choice of the Body Trace Weight scale is because it is a cellular enabled scale that will work even if there is a lapse in Wi-Fi availability and is user friendly without complicated set up procedures. Weight self-monitoring linking it to behaviors is extremely important for weight management and sustaining healthy habits.

Patients and parents will also be asked to record their intake. We will give options of recording with a smart phone application such as Myfitnesspal or manually if preferred. Standard of care for patients with T1D and families is to learn Carbohydrate counting. The patient enters the number CHO in the pump which is preprogrammed to deliver a preset insulin dose based on CHO. However, we need to make sure that throughout the

study the kind and quality of CHO are monitored as well as protein and fat. This is because we need to be able to establish total Energy Intake and decrease it as tolerated to control weight increase (in youth who are still growing in height) or induce weight loss in those who completed their growth and in parents. Decreasing an average of 500 Kilocalories/day leads to a pound of weight loss per week. Our program aims for this modest goal, but often the goal is exceeded because cutting 500 Kilocalories /day is not difficult and accomplished possibly by cutting a beverage like a soda or coffee.

As mentioned above patients and parents will also be asked to perform physical activity and record it. This is because calories expenditure is just as relevant as calories intake.

Describe what data will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response:

Assessments will take place at baseline, 3 and 6 months (if extended) and will include:

The primary measure in youth and parents is a reduction of overweight/obesity. In children this will be assessed by monitoring Percent Over the 50th percentile of BMI. In growing children, BMI has percentiles similar to the percentiles for height and weight. Percent BMI over the 50th percentile allows to measure weight changes in relation to height changes in the growing child. For parents we will record the BMI changes (because their height does not change). HbA1c and Insulin dose are secondary measures. HbA1c will be measured at baseline, 3 and 6 months. The 3- and 6-month sessions will be coordinated with standard of care and it is standard of care to measure HbA1c every 3 months.

List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form). Include copies of these documents with your submission.

Response:

Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records).

Response:

We will be using patients' medical charts at the Diabetes Center.

*Indicate whether or not **individual** subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.*

Response:

The primary care physician of the child and parent will be informed of the participation in the study. We routinely send a note to the pediatrician at the time of the standard of care visit and that note will detail the progress of the child including those in the study. For parents, we will share with their primary care physicians that they are entering the study. We will collect a medication history at baseline and make sure that we communicate with the primary care physician potential changes in medications suggested by the Endocrinologist on the team. Of course, in compliance with HIPPAA regulations, the parent will have to sign a release of records.

Patients are able to see their own blood sugar and insulin records along with weight records and HbA1c. The data are important in order to empower them to actively participate in their T1D and weight management.

*Indicate whether or not **study** results will be shared with subjects or others, and if so, describe how these will be shared.*

Response:

Any publications in peer-reviewed journals will contained aggregated, de-identified data only.

Study Timelines*

Describe the anticipated duration needed to enroll all study subjects.

Response:

Enrollment will commence as soon as IRB approval is obtained and extend until 20 dyads have been enrolled.

Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response:

The program lasts 3-6 months. The first 4 visits will take 45 minutes with following sessions lasting approximately 30 minutes.

Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response:

All data will be collected within the 12 months – However we may conduct additional sub analyses also for 12 months following the study.

Setting

Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

NOTE: Examples of acceptable response may be: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access," or, "Community Center meeting hall."

Response:

The in-person sessions of the FBT curriculum will be implemented at the Diabetes Center at Conventus or in the suburban outpatient office. There is ample private and comfortable space in both locations to conduct the sessions in both locations. The 3- and 6-month visits will be coordinated with standard of care visits and will need also standardized weight measurements for the assessments.

For research conducted outside of UB and its affiliates, describe:

- *Site-specific regulations or customs affecting the research*
- *Local scientific and ethical review structure*

NOTE: This question is referring to UB affiliated research taking place outside UB, i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.

Response:

☒ **N/A:** This study is not conducted outside of UB or its affiliates.

Community-Based Participatory Research

Describe involvement of the community in the design and conduct of the research.

NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Response:

☒ **N/A:** This study does not utilize CBPR.

Describe the composition and involvement of a community advisory board.

Response:

☒ **N/A:** This study does not have a community advisory board.

Resources and Qualifications

*Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of the Principal Investigator **and** staff to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles.

Response:

Principal Investigator:

Teresa Quattrin, MD, UB Distinguished Professor and Associate Dean for Research Integration at the Jacobs School of Medicine and Biomedical Sciences at the University at Buffalo is also Director of the Special Population Core of the Clinical and Translational Research Award. She has had over 30 years of experience in clinical research and clinical trials. This project is part of the CTSA pilot studies

Our Multidisciplinary Team includes:

Lucy D. Mastrandrea, MD, PhD, Pediatric Endocrinologist and Professor and Division Chief, JR Oishei Diabetes Center Director; Leonard H. Epstein, PhD, SUNY Distinguished Professor and Division Chief, Behavioral Medicine; Greg Wilding, PhD, Chair and Professor, Department of Biostatistics, School of Public Health and Health Professions, UB CTSI Biostatistics, Epidemiology and Research Design Core.

Additional Project Staff Include:

Andrew Strohmeier, Integrating Special Populations Coordinator: Master's degree, experience in survey creation and administration, meeting coordination, community and corporate outreach.

Colleen Kilanowski, Project Coordinator

Katelyn Carr, Postdoctoral Fellow

All research staff have current CITI training and GCP training.

Describe other resources available to conduct the research.

Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.

NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research.

Response:

It is estimated that the PI will devote 0.5 FTE during the recruitment phase and coordination of the project (4-6 month). This effort will decrease to 0.35 in the second 6 months of the study. Integrating Special Populations Coordinator will dedicate about .25 of 1.0 FTE to coordinating this project.

We will also have the additional personnel supported by the study:

- Colleen Kilanowski (13 hours of supervision per participant x 10 participants and 80 hours for materials adaptation)
- Project Coordinator & Recruiter: 50% effort x 6 months
- Coaches ($28 x 50 hours x 10 participants)

Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.

NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression.

Response:

N/A As outlined above, this study carries no greater than minimal risk (if any) – in fact FBT in itself provides psychological support and can only help patients and families.

Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

Response:

Weekly meetings will be conducted to review project goals, updates, and progress, with the Coordinator, and Assistant providing updates to the co-PIs when prudent. There will be also weekly meetings the coordinator and PI will conduct with the coaches. All team members have CITI training.

Other Approvals

Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).

Response:

☒ **N/A:** This study does not require any other approvals.

Provisions to Protect the Privacy Interests of Subjects

Describe how you will protect subjects' privacy interests during the course of this research.

NOTE: Privacy refers to an individual's right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a classroom setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response:

Study staff will administer the curriculum in a private room in the clinic or on-line via Zoom/Whatsapp/Facetime with password protected rooms. These interactions will be between only the staff and the participants and family with no other persons in attendance. The participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.

Indicate how the research team is permitted to access any sources of information about the subjects.

NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question ***does apply*** *to records reviews.*

Response:

The study uses a HIPAA waiver and consent/assent form.

Data Management and Analysis*

Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response:

Primary outcome measures for both parents and children are anthropometric parameters to be collected in standardized way at 0, 3, and 6 months. Height will be measured with calibrated stadiometers, and weight using calibrated scales to calculate BMI (kg/m2). BMI and absolute weight loss and percent weight loss will be calculated for parents. For children weight changes will be assessed by measuring changes in % Over BMI over the 50th percentile for age and gender (% OBMI) (6). Percent OBMI is defined as [(child's BMI − 50th percentile BMI)/50th percentile BMI] * 100 (13). HbA1c will be measured using Alere Affinition AS100 point of care device. These measures will be collected by "assessors" who will not perform any coaching.

Secondary measures are: In youth we will measure HbA1c, Insulin dose adjusted A1c [A1c% + 4 x insulin dose (units/kg per 24 hours)] (15), absolute insulin. Evaluating the absolute insulin dose is important because insulin dose is calculated as U/Kg/Day. Therefore, the denominator (kg) will decrease with weight loss and therefore may not

adequately demonstrate a decrease in insulin dose indicating likely improvement in insulin sensitivity.

Measured outcome variables will be summarized overall and by relevant demographic and baseline variables. Descriptive statistics such as frequencies and relative frequencies will be computed for all categorical variables. Numeric variables will be summarized using simple descriptive statistics such as the mean, standard deviation and range. The amount and nature of missing data for collected study variables will be characterized and no method of imputation will be used for missing data for primary analyses. A summary of missing data will be provided according to the number of participants in tabular form. We acknowledge the possibility of informative missingness, that is, the probability of a particular observation being missing may be related to participant-specific characteristics, and therefore analyses will be interpreted with caution.

Analyses will be performed with a focus on estimation of specific clinically important parameters for use in the planning of a subsequent comparative trial designed to fully assess efficacy. To describe the observed variability in the data and test for differences between time points, a multivariate linear model will be fit to each considered outcome with the numeric outcome modeled as a function of time, treated as a fixed effect. To account for the within-subject dependence structure, the model will assume that the distribution of the error terms for each subject to be multivariate normal with zero mean and a first-order autoregressive covariance structure. Once the model is fit, a linear contrast based on the estimated model parameters will be constructed and used to test hypotheses of interest using an approximate F-test as implemented by SAS PROC MIXED. Point estimates and corresponding confidence intervals to quantify time effects will be provided. Reporting on results will proceed according to established guidelines. There will be no formal interim statistical analysis. All tests will be two-sided and tested at a 0.05 nominal significance level. Standard diagnostic plots will be used to assess model fit and transformations of variables may be considered in order to meet statistical assumptions. All statistical tests will be carried out using SAS version 9.4 (or higher) statistical software (Cary, NC).

The information from this study will be used to derive informed power calculations associated with future work, and thus sample size is primarily based on accurate assessment of study parameters. The sample size is that recommended for pilot studies (18). Timepoint-specific outcome means will be estimated in the proposed study with an associated confidence interval width of approximately 0.94 standard deviations.

If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response:

N/A This is a pilot study and we have not developed a power analysis.

Describe any procedures that will be used for quality control of collected data.

Response:

There will be checks in the data entered periodically and ability to refer back to the data in source document. Data will be reviewed for completeness during weekly meetings with study team.

Confidentiality*

A. Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality of **study data and any records that will be reviewed for data collection**.*

*A. Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) **and** electronic files.*

Response:

Electronic files will be stored in a password-protected, computer file. Any physical copies of notes will be stored in a locked file cabinet in the Clinical and Translational Research Center.

A. How long will the data be stored?

Response:

Data will be stored for 3 years after study closure.

A. Who will have access to the data?

Response:

All individuals listed in the protocol will have access to the data.

A. Who is responsible for receipt or transmission of the data?

Response:

Individuals listed in this protocol.

A. How will the data be transported?

Response:

Data will be collected by members of the research team (listed in this protocol) and transported to the Clinical and Translational Research Center. The data will be de-identified.

B. Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of **study specimens**.*

☒ **N/A:** No specimens will be collected or analyzed in this research.
(Skip to Section 21.0)

B. Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

B. How long will the specimens be stored?

Response:

B. Who will have access to the specimens?

Response:

B. Who is responsible for receipt or transmission of the specimens?

Response:

B. How will the specimens be transported?

Response:

Provisions to Monitor the Data to Ensure the Safety of Subjects*

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Response:

Data safety and monitoring for individual participant safety will not be necessary because there is no anticipated risk of harm or unique risks to subjects that require monitoring.

Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response:

N/A (See above, 21.1)

Describe any safety endpoints.

Response:

N/A (See above, 21.1)

Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response:

N/A (See above, 21.1)

Describe the frequency of safety data collection.

Response:

N/A (See above, 21.1)

Describe who will review the safety data.

Response:

N/A (See above, 21.1)

Describe the frequency or periodicity of review of cumulative safety data.

Response:

N/A (See above, 21.1)

Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response:

N/A (See above, 21.1)

Describe any conditions that trigger an immediate suspension of the research.

Response:

N/A (See above, 21.1)

Withdrawal of Subjects*

☐ **N/A:** This study is not enrolling subjects. This section does not apply.

*Describe **anticipated** circumstances under which subjects may be withdrawn from the research without their consent.*

Response:

N/A (participants will not be withdrawn without their consent)

Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response:

N/A (there will not be termination)

Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response:

If the participant decides to withdraw from the program, we will still see the participant for standard of care, which will not be affected at all.

Risks to Subjects*

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response:

There are no reasonably foreseeable risks or discomforts to participation in this project.

Data and Assessments will be de-identified.

Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response:

Data will not contain identifiable data.

*If applicable, indicate **which procedures** may have risks to the subjects that are currently unforeseeable.*

Response:

There are no known unforeseeable risks to participation.

If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant.

Response:

N/A Participation in this program does not pose any risk to the fetus. In fact, fertility is enhanced by weight loss. We ask is a participating Mom intends to be pregnant because obviously we cannot reliably measure weight changes due to the program. We have had mothers who have had unplanned pregnancies in similar FBT programs and we have had healthy babies.

If applicable, describe risks to others who are not subjects.

Response:

N/A There are no foreseeable risks to others who are not subjects.

Potential Benefits to Subjects*

Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.

*NOTE: Compensation **cannot** be stated as a benefit.*

Response:

Participants may benefit by having access to FBT and increased monitoring of their pump/sensor and weight data.

Compensation for Research-Related Injury

☒ **N/A:** The research procedures for this study do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

If the research procedures carry a risk of research related injury, *describe the available compensation to subjects in the event that such injury should occur.*

Response:

Provide a copy of contract language, if any, relevant to compensation for research related injury.

NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with ***different language regarding research related injury****, you must modify your response here and submit an amendment to the IRB for review and approval.*

Response:

Economic Burden to Subjects

Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response:

N/A There are no foreseeable costs to subjects. Compensation to offset gas/transportation/parking and cell phone/internet payments are budgeted.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

Compensation for Participation

27.1 Describe the amount and timing of any compensation to subjects, including monetary, course credit, or gift card compensation.

Response:

We will pay for parking at Conventus for the in-person sessions. Participating parents will be given two $25 gift cards (one intended for the parent and one intended for the child) for each in-person session and two $15 gift cards (one intended for the parent and one intended for the child) for each virtual session. Including the screening session, participants will attend 11 sessions. These gift cards will be distributed at each in-person session or mailed to the participating family.

☐ **N/A:** This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

☐ **N/A:** There is no compensation for participation. This section does not apply.

Consent Process

Indicate whether you will be obtaining consent.

NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study. Consent documentation is addressed in Section 29.0.

☒ ***Yes*** *(If yes, Provide responses to each question in this Section)*
☐ ***No*** *(If no, Skip to Section 29.0)*

Describe where the consent process will take place. Include steps to maximize subjects' privacy.

Response:

Consent will occur in a private room at the Diabetes Center.

Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.

NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See "SOP: Informed Consent Process for Research (HRP-090)" Sections 5.5 and 5.6.

Response:

Potential participants will have ample time to read the consent, ask questions and understand the commitment involved. A consent will be given if the patient and parent interested during the outpatient visit. Time will be given after the issuance of the consent and Dr. Quattrin will call the participants to make sure they don't have any questions and explain the schedule of events and commitment. Giving time for patient and family to consider participation is in our experience key to the smooth implantation of the program and facilitates retention in the study.

Describe any process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.

Response:

They will be reminded that they can stop participating at any time.

Indicate whether you will be following "SOP: Informed Consent Process for Research (HRP-090)." Pay particular attention to Sections 5.4-5.9. If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:

The role of the individuals listed in the application who are involved in the consent process

The time that will be devoted to the consent discussion

Steps that will be taken to minimize the possibility of coercion or undue influence

Steps that will be taken to ensure the subjects' understanding

Response:

☒ We have reviewed and will be following "SOP: Informed Consent Process for Research (HRP-090)."

Non-English Speaking Subjects

☒ **N/A:** This study will not enroll Non-English speaking subjects.
(Skip to Section 28.8)

Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

NOTE: The response to this Section should correspond with your response to Section 8.4 of this protocol.

Response:

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language, how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study, and any process to ensure ongoing consent. Indicate the language that will be used by those obtaining consent.

NOTE: Guidance is provided on "SOP: Informed Consent Process for Research (HRP-090)."

Response:

Cognitively Impaired Adults

☒ **N/A**: This study will not enroll cognitively impaired adults.
(Skip to Section 28.9)

Describe the process to determine whether an individual is capable of consent.

Response:

Adults Unable to Consent

☒ **N/A**: This study will not enroll adults unable to consent.
(*Skip to Section 28.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 28.9 and 28.10) ***and, where possible, assent of the individual should also be solicited*** *(Sections 28.11 and 28.12).*

Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" for research in New York State.

NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.

Response:

☐ We have reviewed and will be following "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."

For research conducted outside of New York State*, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

Describe the process for ***assent of the adults****:*

Indicate whether assent will be obtained from all, some, or none of the subjects. ***If some, indicate which adults will be required to assent and which will not.***

Response:

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Response:

Describe whether ***assent of the adult*** *subjects will be documented and the process to document assent.*

NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the "Template Consent Document (HRP-502)" Signature Block for Assent of Adults who are Legally Unable to Consent.

Response:

Subjects who are not yet Adults (Infants, Children, and Teenagers)

☐ **N/A**: This study will not enroll subjects who are not yet adults.
(Skip to Section 29.0)

*Describe the criteria that will be used to determine **whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NYS, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children."*

NOTE: Examples of acceptable responses include: verification via electronic medical record, driver's license or state-issued ID, screening questionnaire.

Response:

This study is enrolling children. Medical records will be used to recruit the children and will therefore be used to determine whether a prospective subject has not attained the legal age for consent.

***For research conducted outside of New York State**, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)."*

Response:

Describe whether parental permission will be obtained from:

Response:

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

☐ Parent permission will not be obtained. A waiver of parent permission is being requested.

NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the "CHECKLIST: Children (HRP-416)."

*Describe whether permission will be obtained from individuals **other than parents**, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual's authority to consent to the child's general medical care.*

Response:

*Indicate whether assent will be obtained from all, some, or none of the **children**. If assent will be obtained from some children, indicate which children will be required to assent.*

Response:

Yes, assent will be obtained for any participant age 6 or above. It is very important that the youth wants to be involved since the program requires his/her active participation.

When assent of children is obtained, describe how it will be documented.

Response:

Assent will be obtained through the attached assent form.

Waiver or Alteration of Consent Process

Consent will not be obtained, required information will not be disclosed, or the research involves deception.

☒ **N/A:** A waiver or alteration of consent is not being requested.

If the research involves a waiver or alteration of the consent process, please review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.

NOTE: For records review studies, the first set of criteria on the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" applies.

Response:

If the research involves a waiver of the consent process for planned emergency research, please review the "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)" to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here:

Response:

Process to Document Consent

☐ **N/A:** A Waiver of Consent is being requested.
(Skip to Section 31.0)

Indicate whether you will be following "SOP: Written Documentation of Consent (HRP-091)." If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as 'verbal consent.' Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information.

📎 *If you will document consent in writing, attach a consent document with your submission. You may use "TEMPLATE CONSENT DOCUMENT (HRP-502)". If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. consent script or Information Sheet).*

Response:

Consent/assent will be documented in writing.

☒ We will be following "SOP: Written Documentation of Consent" (HRP-091).

Multi-Site Research (Multisite/Multicenter Only)*

☒ **N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites.

Response:

*If this is a multi-site study **where you are the lead investigator**, describe the processes to ensure communication among sites, such as the following.*

All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.

All required approvals have been obtained at each site (including approval by the site's IRB of record).

All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.

All engaged participating sites will safeguard data as required by local information security policies.

All local site investigators conduct the study appropriately in accordance with applicable federal regulations and local laws.

All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.

Response:

Describe the method for communicating to engaged participating sites.

Problems (inclusive of reportable events)

Interim results

Study closure

Response:

*If this is a multicenter study **where you are a participating site/investigator**, describe the local procedures for maintenance of confidentiality.*

Where and how data or specimens will be stored locally?

How long the data or specimens will be stored locally?

Who will have access to the data or specimens locally?

Who is responsible for receipt or transmission of the data or specimens locally?

How data and specimens will be transported locally?

Response:

If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described elsewhere in the protocol.

Describe when, where, and how potential subjects will be recruited.

Describe the methods that will be used to identify potential subjects.

Describe materials that will be used to recruit subjects. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)

Response:

Banking Data or Specimens for Future Use*

☒ **N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

*If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.*

NOTE: Your response here must be consistent with your response at the "What happens if I say yes, I want to be in this research?" Section of the Template Consent Document (HRP-502).

NOTE: If the UBIRB has approved this study to bank data and/or specimens for potential future use outside the scope of this research study, any future use or disclosure of the data that is not described within the approved study must be submitted for review to the UBIRB.

Response:

List the data to be stored or associated with each specimen.

Response:

Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: