Study Protocol and Statistical Analysis Plan

Title: "Insulin Superheroes Club: Diabetes Prevention Program in Youth (12-month Supplement to the CDC DPP for Adults)"

NCT: 03042936

Date: 03/08/2017

UTHSC IRB Memphis Form 1: Study/Project Application (Version 1.21)

1.0 General Information

***Please enter the full title of your study.**
The UTHSC IRB (Memphis) may add to your title using brackets; please do not amend the information within the brackets.

Insulin Superheroes Club

***Please enter a working title up to 15 characters.**

Insulin Superheroes Club
Working Title

2.0 Add Department(s)

2.1 * List all departments and affiliate institutions associated with this study/project, and always mark the Principal Investigator's UTHSC department as the primary department. If any of your study/project activities are being conducted at the following sites, list these organizations as well: Methodist and/or Le Bonheur, Regional One Health, Clinical Research Center (CRC), Office of Clinical Research, UTMG, Graduate School of Medicine, University Health System, University of Tennessee, Knoxville, Oak Ridge National Laboratories, University Family Physicians, UT Genetics Center, etc.

Primary Dept?	Department Name
○	**LeBonheur** - LeBonheur Children's Hospital
◆	**UTHSC** - *COM* - Peds - General Pediatrics

3.0 Assign key study personnel(KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

Mantilla, Chantis, Ph.D.

Select if applicable

☐ Student ☐ Department Chair
☐ Resident ☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Han, Joan C, MD
Co-Investigator
Hare, Marion Elizabeth, MD, MS
Co-Investigator

Jones, Tamekia, PhD
Co-Investigator
Smith, Webb A, PhD
Co-Investigator

B) Research Support Staff

Alshibli, Noor
Research Staff
Chow, Christopher R
Research Staff
Cole, Shelby, MS
Research Staff
Cunningham, Christopher
Research Staff
Cutshall, Michael Bartley
Research Staff
DECKER, KRISTINA, MS
Research Assistant
Gray, Emily, MSN
Research Nurse
HARRELL, CAMDEN
Data Clerk
Harlan, Matthew Shea
Research Staff
Kiley, Shannon
Research Staff
Mack, Raquel T, BSN, CCRP
Research Nurse
Morrison, Annie Ruth
Research Staff
Parvathareddy, Rohith
Research Staff
Pulusani, Srinidhi Reddy
Research Staff

3.3 *Please add a Study Contact:

Kiley, Shannon
Mantilla, Chantis, Ph.D.

The Study/Project Contact(s) will receive all important system notifications. (The study/project contact(s) are typically the Study Coordinator(s) and the Principal Investigator).

3.4 If applicable, please add a Faculty Advisor:

3.5 If applicable, please select the Designated Department Approval(s):

McCullers, Jon, M.D.
Department Chair

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g., the Department Review Chair, Dean, and/or Division Chief).

3.6 If applicable, please select the Research Administrative Specialist(s): Add the appropriate Research Administrative Specialist if any of the following activities will occur at the institutions listed below: identification of subjects through review of their medical records; recruitment of subjects; consent of subjects; performance of screening procedures; interventions or interactions with subjects; follow-up visits; or collection of private information about subjects. If none of the activities described will occur at any of these locations, you do not need to complete this section of the application.

- **Le Bonheur Children's Hospital - Ashley Thompson, MHA, CCRP**
- **Regional One Health/UT Regional One Physicians (UTROP) - Amira Wohabrebbi, PhD, BSN, RN**

☐ Sentiff, Lisa, MPH, CCRC

4.0 (415) Key Project Personnel Contact Information

4.1 * For the Principal Investigator and all Study Contacts (as listed in sections 3.1 & 3.3 above), answer ALL questions asked below. All OTHER key study personnel (as listed in sections 3.2A & B) must be added below ONLY if they will obtain consent or have access to research records; however, you do not have to complete any other questions for those persons (i.e., just the last 2 questions).

Note: All iMedRIS correspondence will be sent automatically to the Study Contacts' UT email account. You may contact the HELP Desk at (901) 448-2222 to have your UT email forwarded to another account at Methodist, yahoo, gmail, etc.
revised 12/05/2016

Entry 1

Name	Mantilla, Chantis, Ph.D.
Office Address	50 North Dunlap Street RM 477R
Office Phone Number	(901) 287-6867
Cell Number	3057932552
Pager	
E-mail Address	cmantill@uthsc.edu
Degree	PhD
Rank	Assistant Professor
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 2

Name	Mack, Raquel T, BSN, CCRP
Office Address	50 North Dunlap Street, Room 367R Memphis, TN 38103
Office Phone Number	

	(901) 287-6869
Cell Number	
Pager	
E-mail Address	rmack7@uthsc.edu
Degree	BSN
Rank	Staff
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 3

Name	Han, Joan C, MD
Office Address	50 North Dunlap Street RM 476R
Office Phone Number	(901) 287-6408
Cell Number	
Pager	
E-mail Address	jhan14@uthsc.edu
Degree	MD
Rank	Associate Professor
Will obtain informed consent	NA
Access to research records /specimens	Yes

Entry 4

Name	Smith, Webb A, PhD
Office Address	50 North Dunlap Street RM 447R
Office Phone Number	901 287 6878
Cell Number	
Pager	
E-mail Address	wsmith74@uthsc.edu
Degree	PhD
Rank	Assistant Professor
Will obtain informed consent	No
Access to research records /specimens	Yes

Entry 5

Name	DECKER, KRISTINA, MS
Office Address	50 North Dunlap Street RM 308R
Office Phone Number	(901) 287-6399
Cell Number	6184096093
Pager	
E-mail Address	kdecker2@uthsc.edu
Degree	M.S.
Rank	Staff
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 6

Name	Jones, Tamekia, PhD
Office Address	50 North Dunlap Street RM R
Office Phone Number	(901) 287-5355
Cell Number	
Pager	
E-mail Address	tjone100@uthsc.edu
Degree	PhD
Rank	Assistant Professor
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 7

Name	Gray, Emily, MSN
Office Address	49 N. Dunlap Room 137, Memphis, TN 38104
Office Phone Number	901-287-7494
Cell Number	
Pager	
E-mail Address	egray22@uthsc.edu
Degree	

	MSN
Rank	Staff
Will obtain informed consent	No
Access to research records /specimens	Yes

Entry 8

Name	Kiley, Shannon, BS
Office Address	50 North Dunlap St RM 448R
Office Phone Number	901-287-6876
Cell Number	
Pager	
E-mail Address	skiley@uthsc.edu
Degree	BS
Rank	Staff
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 9

Name	Cole, Shelby, MS
Office Address	50 N. Dunlap, Rm 367R Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	scole28@uthsc.edu
Degree	MS
Rank	Staff
Will obtain informed consent	Yes
Access to research records /specimens	No

Entry 10

Name	Parvathareddy, Rohith
Office Address	50 N. Dunlap, Rm 367R Memphis, TN 38103

Office Phone Number	
Cell Number	
Pager	
E-mail Address	rparvath@uthsc.edu
Degree	BS
Rank	Staff
Will obtain informed consent	No
Access to research records /specimens	Yes

Entry 11

Name	Morrison, Annie Ruth
Office Address	50 N. Dunlap, Rm 367R Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	amorri49@uthsc.edu
Degree	
Rank	Student
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 12

Name	Alshibli, Noor
Office Address	50 N. Dunlap, Rm 367R Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	nalshibl@uthsc.edu
Degree	
Rank	Student
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 13

Name	Pulusani, Srinidhi Reddy
Office Address	50 N. Dunlap, Rm 367R Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	spulusan@uthsc.edu
Degree	
Rank	Student
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 14

Name	Chow, Christopher R
Office Address	50 N. Dunlap Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	cchow@uthsc.edu
Degree	
Rank	Student
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 15

Name	Cunningham, Christopher
Office Address	50 N. Dunlap Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	CCUNNI25@uthsc.edu
Degree	
Rank	

	Student
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 16

Name	Harlan, Matthew Shea
Office Address	50 N. Dunlap Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	mharlan4@uthsc.edu
Degree	
Rank	Student
Will obtain informed consent	Yes
Access to research records /specimens	Yes

Entry 17

Name	HARRELL, CAMDEN
Office Address	50 N. Dunlap Memphis, TN 38103
Office Phone Number	
Cell Number	
Pager	
E-mail Address	charre15@uthsc.edu
Degree	
Rank	Staff
Will obtain informed consent	No
Access to research records /specimens	Yes

Entry 18

Name	Hare, Marion Elizabeth, MD, MS
Office Address	Doctors Office Building 66 North Pauline Street Memphis, TN
Office Phone Number	901-448-3752

Cell Number	
Pager	
E-mail Address	mhare@uthsc.edu
Degree	
Rank	Associate Professor
Will obtain informed consent	No
Access to research records /specimens	Yes

5.0 (418) IRB Submission

5.1 * Please indicate the correct status of this submission:

Note: If you are submitting a Form 2 for revision, DO NOT change your answer in this section.

- (●) I am requesting initial approval for research.
- ( ) I am registering the use of an anonymized human cell line purchased or acquired from commercial vendors, IRB approved repositories or government tissue banks.
- ( ) I am registering research that was originally approved on paper by the UTHSC IRB before 2009.
- ( ) I am submitting my research in accord with the St. Jude Cooperative Agreement where the St. Jude IRB has already approved it.
- ( ) I am submitting my research in accord with an IRB Authorization Agreement where another IRB has already approved it.
- ( ) I am registering a research study that was approved by the NCI CIRB.
- ( ) I am requesting initial approval for the use of a Humanitarian Use Device (HUD).
- ( ) I am notifying the IRB regarding the emergency use of an investigational device.
- ( ) I am notifying the IRB regarding the emergency use of an investigational drug, or biologic.
- ( ) I am requesting approval for compassionate use of an unapproved medical device.
- ( ) I am requesting approval for the treatment use of an unapproved medical device.
- ( ) I am requesting approval for the treatment use of an unapproved drug or biologic.
- ( ) I am requesting waiver of the HIPAA authorization preparatory to research.

6.0 (420) Other Committees Should be Consulted

6.1 * Does this research project involve any of the following?

Radiation Safety Committee (RSC)

1. Exposure to X-rays and other machine-produced ionizing radiation for purposes other than providing or guiding the treatment of individual subjects

( ) Yes (●) No

2. Exposure to non-FDA approved radioisotopes solely for purposes other than providing or guiding the treatment of individual subjects

( ) Yes (●) No

3. Exposure to FDA approved radioisotopes solely for purposes other than providing or guiding the treatment of individual subjects

○ Yes ◉ No

Note: If the answer to any of the 3 items above is "Yes", add **Vivian Loveless**, Pharm.D. as a Research Administrative Specialist in section 3.6 of this application.

Also note: If you have any dosimetry questions related to machine-produced ionizing radiation or radioisotopes used solely for research purposes, please contact **Thad Wilson**, Ph.D. at (901) 448-8323 or at **tawilson@uthsc.edu**.

Institutional Biosafety Committee (IBC)

1. Recombinant/ Synthetic nucleic acids (DNA/RNA)

○ Yes ◉ No

2. *In vivo* experiments that involve introduction of human-derived cells/ tissues/ products (e.g., introduction of human tumor cells into mice)

○ Yes ◉ No

3. *In vivo* experiments that involve infectious agents (bacterial, viral, fungal, or parasite) that require BSL-2 or BSL-3 containment practices

○ Yes ◉ No

4. Select agents or toxins (see this website for a list: **http://www.selectagents.gov/SelectAgentsandToxinsList.html**)

○ Yes ◉ No

Note: If the answer to any of the 4 items above is "Yes", you will need to have an approved IBC protocol before initiation of this project. For information, please visit the IBC website (**https://www.uthsc.edu/research/compliance/ibc/**) or contact the IBC Coordinator via email at **IBC@uthsc.edu** or via telephone at (901) 448-2164.

Institutional Animal Care and Use Committee (IACUC)

1. Live Animals

○ Yes ◉ No

Note: If the answer to the above question is "Yes", you will need to have an approved IACUC protocol before initiation of this project. For information, please visit the IACUC website (**https://www.uthsc.edu/research/compliance/iacuc/**) or contact the IACUC Coordinator via email at **IACUC@uthsc.edu** or via telephone at (901) 448-3904.

7.0 (468) Funding Source/Sponsor

7.1 * Is there a funding source associated with the study/project? This includes a source that will provide study drug/biologic /device at no cost.

○ Yes
◉ No

8.0 (485) Study/Project Information

8.1 * **Are you requesting Full Board, Expedited, Exempt or NHSR review by the IRB?**

- ○ Full Board
- ◉ Expedited
- ○ Exempt or NHSR (Not Human Subjects Research)
- ○ Not sure

8.2 * **Please indicate the type of study/project:**

Studies/Projects that merely observe outcomes in patients who receive a drug/biologic or device as part of their standard care, but do not involve administration of the drug/biologic or device as part of study/project procedures, should be checked "No drug/biologic or device."

- ○ A drug/biologic is being administered and evaluated as part of the study/project procedures.
- ○ A device is being administered and evaluated as part of the study/project procedures.
- ○ A drug/biologic AND a device is being administered and evaluated as part of the study/project procedures.
- ◉ No drug/biologic or device is being administered and evaluated as part of study/project procedures.

9.0 (495) Multi-Site, Externally Sponsored Protocol

9.1 * **Is this a multi-site, externally sponsored study for which a master protocol has been written by a commercial entity, cooperative study group, non-profit foundation, or NIH grantee?**
Note: For a local investigator-initiated study, you must answer "no" to this question. Your application serves as the protocol and it is not necessary to attach any additional protocol document. However, if this local investigator-initiated study is funded through a grant, then the relevant sections of the grant describing study procedures should be attached.

- ○ Yes. There is a multi-site master protocol written by an external sponsor of this study/project.
- ◉ No. There is NOT a multi-site master protocol written by an external sponsor of this study/project.

10.0 (701) Define "Expedited" and Minimal Risk

10.1 **"Expedited Review" is a speedier process than "Full Board Review." Proposals that may qualify for Expedited Review include: Research activities that**

1) present no more than minimal risk to human subjects
AND
2) involve only procedures listed in one or more of seven Expedited Review Categories.
By answering the following questions, you will assist the IRB in determining if your proposal will be granted an Expedited Review. Please hit "Save and continue..." in the upper right corner.

10.2 * **Do the research activities present no more than minimal risk to human subjects?**

For a definition of "no more than minimal risk" please click on the Question Mark in the right margin.

- ◉ Yes. The research activities present no more than minimal risk to human subjects.
- ○ No. The research activities DO present more than minimal risk to human subjects.

10.3 * **Would identification of the subjects and/or identification of their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing?**

- ○ Yes. Identification of subject or subject responses could place the subject at risk.
- ◉ No. Identification of subject or subject responses would not place subject at risk.

11.0 (706) Classified Research

11.1 * Is this project considered to be "classified" research?

For a discussion of the definition of "classified," please mouse over the question mark in the right margin and click on "Definition of Classified Research."

- ○ Yes. This research is considered classified.
- ◉ No. This research is NOT considered classified.

12.0 (720) Category 2: Blood Collection

12.1 * Does this research involve the collection of blood?

- ◉ Yes. This study/project does involve the collection of blood.
- ○ No. This study/project DOES NOT involve the collection of blood.

13.0 (722) Mode of Blood Collection

13.1 * Will the collection of blood samples be solely by finger stick, heel stick, ear stick, and/or venipuncture?

- ◉ Yes. Blood will be collected ONLY by the methods listed above.
- ○ No. Blood may be collected by other methods that do not meet requirements for expedited review.

14.0 (723) Study/Project Population

14.1 * Does the study/project population include the following? Check all that apply.

- ☐ Healthy, NON-pregnant adults who weigh at least 110 pounds
- ☑ Unhealthy adults, pregnant females, children, AND/OR persons who weigh less than 110 pounds (Click on the question mark in the right margin to review the definition of 'Children.'')

15.0 (726) Vulnerable Population Blood Collection

15.1 * Please check the amount of blood that will be collected from the unhealthy adults, pregnant women, children, and persons who weigh less than 110 pounds:

- ◉ NO MORE than the lesser of: [50 ml] OR [3-ml-per-kg] of blood will be collected in an 8 week period.
- ○ MORE than the lesser of: [50 ml] OR [3-ml-per-kg] of blood will be collected in an 8 week period.

15.2 * Please check the frequency of blood collection for the unhealthy adults, pregnant women, children, and persons who weigh less than 110 pounds:

- ◉ Blood will be collected NO MORE than 2 times per week.
- ○ Blood may be collected MORE THAN 2 times per week.

16.0 (730) Category 3: Prospective Biological Specimen Collection for Research Purposes

16.1 * Does this research entail prospective biological specimen collection other than blood for research purposes? Prospective specimen collection means the specimens will be collected AFTER this research application is submitted and approved.

- ○ Yes. This research includes prospective biological specimen collection other than blood for research purposes.

- (●) No. This research DOES NOT include prospective biological specimen collection other than blood for research purposes.

17.0 (740) Category 4: Non-Invasive Procedures

17.1 * If this study/project involves physical diagnostic and/or monitoring procedures, is it true that ALL are NON-INVASIVE and do not include general anesthesia, sedation, x-rays or microwaves?

For a definition of "Non-invasive Procedures" as defined in the Federal Register, please click on the Question Mark in the right margin.

- (●) Yes. The study/project involves physical diagnostic and/or monitoring procedures, all of which are non-invasive and do not include general anesthesia, sedation, x-rays or microwaves.
- ( ) No. The study/project involves physical diagnostic and/or monitoring procedures, some of which are invasive or include general anesthesia, sedation, x-rays or microwaves.
- ( ) Not applicable. The study/project does not involve physical diagnostic and/or monitoring procedures.

18.0 (750) Category 5: Use of Retrospective and Prospective Non-Research Materials

18.1 * Does this proposal involve using materials (data, documents, records, or specimens) that have been or will be collected solely for CLINICAL CARE PURPOSES?

- ( ) Yes. This proposal involves using materials (data, documents, records, or specimens) that have been or will be collected solely for CLINICAL CARE PURPOSES.
- (●) No. This proposal does not involve using materials (data, documents, records, or specimens) that have been or will be collected solely for CLINICAL CARE PURPOSES.

19.0 (760) Category 6: Recordings

19.1 * Does this proposal involve the collection of data from voice, video, digital or image recordings made for research purposes?

- (●) Yes. This proposal does involve data from recordings as noted above.
- ( ) No. This proposal does NOT involve data from recordings as noted above.

20.0 (770) Category 7: Characteristic, Behavioral, Methodology Research

20.1 * Is this research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior)
or
research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies?

- (●) Yes. This research is on characteristics, behaviors and/or involves one of the specified methodologies.
- ( ) No. This research does not fall into the behavior, characteristic or methodology categories above.

21.0 (925) Study/Project Synopsis

21.1 * Click on the gray bar below and provide a synopsis of the research study/project addressing the following SIX items USING these numbered subheadings:

1. Purpose,

2. Rationale,

3. Study/Project Population,

4. Research Design,

5. Study/Project Procedures, and

6. Outcome Measures.

Title: Memphis Superheroes Club

1. Purpose,

The primary purpose of this project is to develop and implement the culturally-tailored, comprehensive, and out-of-school program, Insulin Superheroes Club (ISC). This is a diabetes prevention program for youth based on the CDC curriculum designed for adults. This will be accomplished through collaborations with the University of Tennessee Health Science Center (UTHSC), Le Bonheur Children's Hospital (LBCH), and the YMCA. The goals are to improve participant health and prevent diabetes by improving metabolic parameters, physical fitness, and health habits.

2. Rationale, *Background and Significance:*

Engagement in regular physical activity is widely accepted as an effective preventative measure for a variety of health risk factors across all ages, genders, race/ethnicities, and socioeconomic groups (Janssen, 2010.) However, levels of physical activity remain low and obesity rates continue to rise (Odgen, 2014,) with significant disparities among Hispanic and African-American youth, nationally and specifically in Tennessee (Tennessee Department of Education, 2008.) The impact of obesity is evident in the worsening rates of metabolic functioning, especially among children who are experiencing greater rise in blood pressure (National Center for Chronic Disease Prevention and Health Promotion (NIHCM), 2008,) hyperlipidemia (NIHCM, 2008,) and increased prevalence of type 2 diabetes (Sinha, 2002.)

Type 2 diabetes occurs when there is an imbalance between insulin secretion and insulin resistance. Among youth populations, the prevalence of developing type 2 diabetes increases during puberty due to the natural transient state of insulin resistance (Caprio, 1989.) Type 2 diabetes in youth when compared that in adults has particular characteristics; the transition from glucose deregulation to overt diabetes occurs at a faster rate. In adults, the transition from pre-diabetic to a diabetic state takes about 10 years with a 7% reduction of beta cell function per year (Kahn, 2001, Matthews, 1998.) In pre-diabetic youth, the mean transition period is significantly reduced to about 2.5 years with a 15% reduction of beta cell function per year (Gungor, 2004.)

Along with decrease beta-cell function, youth with type 2 diabetes become resistance to pharmacological mono-therapy (metformin or rosiglitazone) and lifestyle intervention such as change in diet and physical activity. Due to these limiting factors, once a pre-diabetic child or adolescent develops type 2 diabetes, it is considered irreversible (Zeitler et al, 2012.) Given this, the focus is on early prevention of on-set pre-diabetes or type 2 diabetes among the obese youth population. Early lifestyle prevention and intervention programs consist of changing diet, physical activity and lifestyle habits (i.e taking the stairs instead of the elevator) through education. A number research study-programs have shown promising results in regards to diabetes prevention such as: 42% reduction of whole body insulin sensitivity, a two- fold greater change in body fat than body weight, increase lean body mass, and normalized fasting, two-hour plasma blood glucose levels, and decrease LDL cholesterol levels (Shaw, 2009, Wadden, 2012.)

In addition to the physical and metabolic impact of obesity, research supports the relationship between obesity, mental health, and health behaviors. Generally, overweight and obese youth have increased mental health concerns compared to their normal weight peers (Sinha, 2002.) Specifically, obesity has been linked to presence of depression, anxiety, attention deficit hyperactivity disorder, and conduct disorder among children (Halfon, 2013, Puder, 2010.) Difficulty coping with stress and decreased self-esteem are also associated with obesity (BeLue, 2009.) Studies have also shown that individuals, adults and youth, with type 2 diabetes have decreased cognitive functioning including mental processing speed, flexibility, memory, and learning (Puder, 2010.) Physical activity participation has been linked with improved academic performance, mental health, and cognitive function (Hillman, 2008.) Despite these findings, the best treatment or weight management for childhood obesity is still uncertain. A few studies have examined the cumulative impact of improving physical activity, fitness, nutrition, and overall health behaviors in children.

The specific aims of this research project are to:

1) Examine the change of health status of youth participants over time as a result of the 12-month (16 weekly, 3 biweekly, and 6-monthly session) ISC intervention through the evaluation of metabolic, physical fitness, and health habit parameters

2) Examine the change of health status of parent participants over time as a result of the 12-month (16 weekly, 3 biweekly, and 6-monthly session) DPP adult sessions through the evaluation of metabolic, physical fitness, and health habit parameters.

3. Study/Project Population,

Potential subjects and their parents will be informed of the study through flyers, community events, and physician referrals. Flyers will be distributed/posted at all YMCA sites and physician offices and clinics, throughout Memphis.
Inclusion criteria for youth participants will include:
1) Between 7-15 years-old
2) Hemoglobin A1C 5.7-6.4% or BMI ≥ 85th percentile, parent **or** grandparent with pre/type II Diabetes
3) Able to participate in physical activity
4) Parent or caregiver participation
Exclusion criteria for youth participants will include:
1) Pregnant females
2) Those with mental health illness (e.g. depression, ADHD, etc.)
3) Medications that would interfere with testing results (e.g. metformin, insulin)
Inclusion criteria for parent participants will include:
1) ≥18 years-old
2) At least one child enrolled in ISC
3) Able to participate in physical activity
Exclusion criteria for parent participants will include:
1) Those with mental health illness (e.g. depression, ADHD, etc.)
2) Medications that would interfere with testing results (e.g. metformin, insulin).
Inclusion and exclusion criteria will be assessed via parent and child self/physician referral form. The UTHSC/LBCH subcommittee will approve all procedures for the Use and Protection of Human Subjects. ISC and control group participants will be assigned on a fist come first serve basis.
Consenting and Questionnaires:
On the day of registration, parents or guardians will receive project information packets from the trained research team. The packets will include a parent/guardian consent form, a child assent form, and detailed participation requirements, benefits, and incentives. Once the researcher consents the parent and assents the child face-to-face, the child and parent will be asked to sit with the researcher to complete the study questionnaires. The parent will complete the Healthy Habits Questionnaire (parent version), the child and parent will complete the Healthy Habits Questionnaire (child version), and the child (child version) and parent (parent version) will complete the mental health questionnaire separately. Trained research team members will complete all face-to-face consenting and surveys/questionnaires. Upon consenting the family (parent and child/children) will be assigned, to either the ISC. Once completed the participant will return the following week to complete their pre-evaluation assessment.
The parents will be encouraged to contact the research team if they should have any questions regarding the study procedures. All questionnaires, consents, and assent forms must be completed prior to the data collection days with the assistance of a research team member. The research staff will review all materials and assign a study id prior to the child's participation in data collection. Following completion of the project parents or guardians of all children enrolled in the project will receive a report of their health behaviors, physical fitness, and mental health performance with strategies to improve/maintain their outcomes. The research team member will also inform the parent and child that video recording and pictures of the educational sessions, physical activity sessions, and evaluation sessions (only physical fitness measures) will be taken by a research team member for the use of dissemination and presentations regarding the findings. If parents do not wish to consent and child does not wish to assent to video recordings or photography of this nature the research team will make a note and respect the participants' wishes.

4. Research Design,
This project will employ a quasi-experimental non-control group design with an intervention group (ISC). The intervention group will receive the ISC curriculum, which promotes healthier physical activity, nutrition, sleep, and stress coping practices. The intervention phase will consist of 12-months: registration, six evaluation sessions (2-3 hours per evaluation: Week 1, 8, and 16, 6-month, 9-month, and 12-month), and 16-weekly, 3-bi weekly, 6-monthly educational and physical activity sessions (1.5 hours per session: 45-minutes of health education and 45-minutes of physical activity).
Youth between the ages of 7-15 throughout Shelby County will be recruited to participate in this study. Recruitment, data collection, and program implementation will be accomplished through a community-academic partnership between UTHSC/LBCH and the YMCA. Upon obtaining parental consent and child assent, all data collection will occur at the Gaisman Community Center site under the supervision of UTHSC/LBCH staff.
Incentives
Pre, post, and follow-up evaluations: $50 gift card for participant
Programs sessions: attendance raffle: participants will be provided with a raffle ticket for attending sessions and will be able to select a n item for a prize box (water bottles, t-shirts, jump ropes, hand sanitizer, myPlates, etc.)

5. Study/Project Procedures
Research and Program Setting. The YMCA of Memphis & the Mid-South's mission is to put faith-based principles into practice through programs that build healthy spirit, mind, and body while strengthening communities. The YMCA is the largest provider of before/after school services serving children in the Shelby County, Tennessee and Desoto County, Mississippi School Districts, and selected schools in the

Marion School District in Marion, Arkansas; thus being a major provider of after school care in the Mid-South.
All data collection and program activities with youth and their families will be located at the Gaisman Community Center. All tests and program activities will be under the supervision of UTHSC/LBCH and YMCA staff by trained researchers and staff.
The YMCA will collaborate and commit to the following throughout this study: 1) assist the research team to identify the cohort of children, 2) identify the staff members who will be trained to deliver the weekly lessons, 3) make the arrangements for staff training and development, and 4) provide administrative and financial oversight support to site directors and study staff. This collaboration is a mutually agreeable effort as it will result in gained scientific knowledge about factors that influence youth well being in Memphis. The expansive footprint of the YMCA and its own involvements with various populations in the community provides many opportunities for community translation of the research findings. Nationally, YMCAs are forging relationships and seeking ways to engage underrepresented racial and ethnic populations with close relations established with the Hispanic and African-American communities.
The Department of Human Services licenses all facilities of the YMCA; most program sites are located in school cafeterias and have access to outdoor playgrounds, computer laboratories, and school classrooms. The staff ratio is maintained at 1 staff: 12 participants, with two staff members present at all times. Annually, staff members are provided 20-25 hours of in-service training to include: first aid, CPR/blood borne pathogens, child abuse prevention, stewards of children, and sexual harassment. Through the study collaboration staff will receive an additional 40-50 hours of training and continued education.
All data collection and program activities will occur on YMCA sites under the supervision of UTHSC/LBCH. In total, **1-2 hours** will be required to complete all measures during the evaluation sessions. Youth will be provided with healthy snacks and beverages throughout the testing period, and will be encouraged to take breaks as needed. Each curriculum session will last **1.5 hours** and lessons will be taught by the YMCA trained Life Coaches under the supervision of a research team member.

Data Collection Evaluation Days.

Prior to the initial pre-evaluation a registration/consent day will be offered. Research staff will consent parents, assent children, and sit face-to-face with the parent and child to complete the Healthy Habits and mental health questionnaire. On evaluation days the participants will rotate through stations to complete all the measures collected by the research team members.

Questionnaires:

Health Behaviors. A Healthy Habits Questionnaire (HHQ) will be used to measure knowledge and behaviors toward developing a healthier lifestyle. The Healthy Habits questionnaire will take approximately 30 minutes to complete and will be administered by a research team member. These questions will be completed by the child and parent and includes questions about: demographics (i.e. age, race/ethnicity, SES, home environment); child's academic status; family health history; weight perception, and frequency and range of typically consumed foods, exercise, sleep, and healthy-living behaviors. To obtain a valid measure, questions from previously published school-based intervention studies will be selected (Prochaska, 1994; Perry, 1998; Stevens, 1999) and reviewed by our team of experts. The parent-child relationship will be assessed with measures of parent involvement (BeLue 2009) parent monitoring (O'Donnell, 2002) and family cohesion (Resnick, 1997.)

Evaluation Measures:

Physical Activity. An accelerometer (Computer Science and Applications, Inc., Shalimar, FL), will be used to assess physical activity (Epistein, 1996; Sallis 1990) The child will be asked to wear the accelerometer for 7-days. To ensure good reliability of devices use the children and parents will be taught how to use the accelerometers during a home visit and reminded of wear via a phone call. The PI and a research team member will schedule and conduct the home visits (pick-up and drop-off) with the parent and child. The home visits will provide an opportunity for detailed instruction and demonstration of device use as well as provide accountability of the device. The home visits will take approximately 30 minutes to complete.
*Metabolic Parameters***.** The metabolic parameters will take approximately 30 minutes to complete and will be administered by a trained health specialist under supervision of a medical director. The Inbody-570 multi-frequency bioimpedance analyzer (Biospace, Beverly Hills, CA), will be used to assess body composition (Inbody 570, 2006.) Information recorded will include: body weight, percent body fat, and BMI. Height (centimeters) will be measured using a Weigh Beam Eye-Level physicians' scale in cm (DETECTO, Webb City, MO, USA). A portable anthropometer (Lafayette Instrument Company, Lafayette, IN) will be used to measure sagittal abdominal height (SAH), as a predictor of visceral abdominal fat(Sampaio, 2007.) A Gulick spring loaded measuring tape (Dunlee, Aurora, IL) will be used to indicate central obesity (Center of Disease and Control, 2012.) Systolic and diastolic blood pressure (SBP and DBP respectively) will be taken using a manual sphygmomanometer (blood pressure cuff) with a child's cuff placed over the brachial artery (Tycos Instruments Inc., Arden, NC) using standard procedures (Kirkenale, 1967.) Resting heart rate will be measured manually after five minutes of seated rest through palpating radial pulse over 60 seconds and will be recorded as beats per minute (American Heart Association, 1996.) A1C will be assessed from a fingerstick capillary whole-blood sample using an A1CNow device (John & Edwards, 1994) (PTS Diagnostics, Indianapolis, IN). Lipid profile will measure total cholesterol, triglycerides, and LDL and HDL levels using Cholestech LDX (Alere, San Diego, CA.)
Physical Fitness. The physical fitness assessments will take approximately 1 hour to complete and will be administered by a trained research staff under supervision of an exercise physiologist. The National Institute of Health's (NIH) two-minute walk test will be used to measure aerobic endurance (NIH, 2012). A Jamar plus handgrip dynamometer (Sammons Preston, Bolingbrook, IL) will used to measure grip

strength with the elbow bent at a 90-degree angle (National Institute of Health, 2012.) Components of the Bruininks-Oseretsky Test of Motor Proficiency, Second Edition (BOT-2), an array of goal-directed activities, will be used to measure fine and gross motor control skills, balance, abdominal, and upper body strength (Bruinimks, 2005). The wall squat test was used to assess lower body strength and endurance, specifically for the quadriceps muscle group (Welk, 2008). The vertical jump test data were used to estimate average power (watts) according to the Lewis formula (Fox, 1974): Average Power (Watts) = √4. 9 x mass (kg) x √VJ (m) x 9.81. A sit-and-reach box (Flexer-tester, Novel Product Inc., USA) was used to assess lower back and hamstrings flexibility.
ISC Educational and Physical Activity Sessions:

- **Education Curriculum Overview:** The lesson portion will include health education session (e.g. nutrition, exercise, etc.) and session activity. This will take about 45 minutes to complete in each session.
- **Physical Activity Curriculum Overview:** All physical activities will include low to moderate intensity (body weight only) exercises such as: push-ups, dancing, jumping jacks, curl-ups, squats, skipping, stretching, brisk walking, and jogging/marching in place. Sports and games will also be offered such as: basketball, badminton, volleyball, tag, jump rope, and scavenger hunts. Th is will take about 45 minutes to complete in each session.

Intervention Session and Evaluation Timeline and Dates:
Visit 1: Consent, register participants, questionnaire completion

- The first visit will be for program registration and consenting at the Gaisman Community Center. Research staff will consent parents, assent children, and sit face-to-face with the parent and child to complete the Healthy Habits and mental health questionnaire. This will take about 1-2 hours to complete.

Visit 2: Pre-Evaluation

- All physical activity, physical fitness, and health measures described will be collected at the Gaisman Community Center. This will take about 1-2 hours to complete. The drop-off/pick-up home visit appointments will also be scheduled in order to collect physical activity data described in the health behaviors measures. The child will be asked to wear the activity monitor for 7-days hours. The drop-off home will take 30 minutes. The pick-up home visit will take 30 minutes. Both home visits will add up to 60 minutes to complete.

Visit 3: Session 1: Welcome to the YMCA's Insulin Superheroes Club
Visit 4: Session 2: Nutrition Basics
Visit 5: Session 3: Physical Activity
Visit 6: Session 4: Label Reading
Visit 7: Session 5: Stronger Muscles and Bones
Visit 8: Session 6: Sweetness Without Sacrifice
Visit 9: Session 7: Aerobic Exercise
Visit 10: Session 8: Vitamins
Visit 11: Mid-Evaluation

- All physical activity, physical fitness, and health measures (except the blood glucose and cholesterol) described above will be collected at the Gaisman Community Center. This will take about 2 hours to complete.

Visit 12: Session 9: De-stress and Motivation
Visit 13: Session 10: Grains
Visit 14: Session 11: Fats
Visit 15: Session 12: Protein
Visit 16: Session 13: Shopping Healthier Options
Visit 17: Session 14: Keeping Track
Visit 18: Session 15: Goal Setting
Visit 19: Session 16: Jeopardy
Visit 20: Post-Evaluation

- Research staff will sit face-to-face with the parent and child to complete the Healthy Habits and mental health questionnaire. All physical activity, physical fitness, and health measures described above will be collected. This will take about 1-2 hours to complete at the Gaisman Community Center. The drop-off/pick-up home visit appointments will also be scheduled in order to collect physical activity data described in the health behaviors measures. The child will be asked to wear the activity monitor for 7-days. The drop-off home will take 30 minutes. The pick-up home visit will take 30 minutes. Both home visits will add up to 60 minutes to complete.

Visit 21: Wrap-up Celebration

- This visit will be the wrap-up/celebration party where subjects will enjoy a healthy potluck and dancing at the Gaisman Community Center.

Visit 22: Session 17: Mindful Eating
Visit 23: Session 18: Rethink Your Drink
Visit 24: Session 19: FITT Brain
Visit 25: Evaluation

- All physical activity, physical fitness, and health measures described above will be collected at the Gaisman Community Center. This will take about 1-2 hours to complete. The drop-off/pick-up home visit appointments will also be scheduled in order to collect physical activity data described in the health behaviors measures. The child will be asked to wear the activity monitor for 7-dasy. The drop-off home will take 30 minutes. The pick-up home visit will take 30 minutes. Both home visits will add up to 60 minutes to complete.

Visit 26: Session 20: Brain Food
Visit 27: Session 21: Practicing Self-Love
Visit 28: Session 22: Flexibility and Stretching
Visit 29: Evaluation

- All physical activity, physical fitness, and health measures described above will be collected at the Gaisman Community Center. This will take about 1-2 hours to complete. The drop-off/pick-up home visit appointments will also be scheduled in order to collect physical activity data described in the health behaviors measures. The child will be asked to wear the activity monitor for 7-days. The drop-off home will take 30 minutes. The pick-up home visit will take 30 minutes. Both home visits will add up to 60 minutes to complete.

Visit 30: Session 23: Healthy Holidays & Fit Solutions
Visit 31: Session 24: Label Reading & Shop Smart
Visit 32: Session 25: Healthier Life: Goals & Keeping Track
Visit 33: Final Evaluation and Farewell Celebration (Pot-luck and a dance party)

- Research staff will sit face-to-face with the parent and child to complete the Healthy Habits and mental health questionnaire. All physical activity, physical fitness, and health measures described above will be collected. This will take about 1-2 hours to complete at the Gaisman Community Center. This visit will also be the wrap-up/celebration party where subjects will enjoy a healthy potluck and dancing. The drop-off/pick-up home visit appointments will also be scheduled in order to collect physical activity data described in the health behaviors measures. The child will be asked to wear the activity monitor for 7-days. The drop-off home will take 30 minutes. The pick-up home visit will take 30 minutes. Both home visits will add up to 60 minutes to complete.

6. Outcome Measures.
Research methods:
Outcome Measures:
Primary Predictors:
Physical Activity: An accelerometer (Computer Science and Applications, Inc., Shalimar, FL), will be used to assess physical activity. To ensure good reliability of devices used, children and parents will be taught how to use the accelerometers and reminded to wear them via a phone call. Self-report measures of physical activity and sedentary habits will also be obtained.
Physical fitness (cardiorespiratory, muscular strength and endurance, and motor skills): The fitness battery will include the NIH two-minute walk test (aerobic fitness), handgrip strength, wall-sit (lower body strength), push-ups (upper body strength), curl-ups (abdominal strength), unilateral balance, 50-foot shuttle run (agility), and sit-and-reach box (lower body flexibility).
Metabolic Parameters (total and central adiposity, blood pressure, physiological stress): These measures include the Inbody-570 multi-frequency bioimpedance analyzer (body composition), Weigh Beam Eye-Level physicians' scale (height), anthropometer (sagittal abdominal height), Gulick spring loaded measuring tape (central obesity), sphygmomanometer (systolic and diastolic blood pressure), radial pulse (resting heart rate), A1C (blood glucose levels) and lipid profile (total cholesterol, triglycerides, and LDL and HDL levels.)
Health Habits (physical activity, nutrition, self-efficacy): Self-report measures will include knowledge, physical activity, sedentary habits, nutrition, and stress management.
Mediators: A parent- and child-report healthy habits questionnaire (adapted from previous research) will be used to assess demographics (i.e. age, race/ethnicity, SES, home environment), child's academic status, family health history, weight perception, and frequency and range of typically consumed foods, exercise, sleep, and healthy-lifestyle behaviors.
Analysis: We will use mixed repeated measures ANOVA model time as the outcome and physical fitness, metabolic parameters, and health habits as our predictor variables. We will also include possible covariates (race, ethnicity, SES, age, and BMI-Z) in the models.

22.0 (1075) Background & Current Status of Work in the Field

22.1 * Provide a discussion of the background and current status of work in the field.

* This section must provide a justification and rationale for conducting the study/project.

Engagement in regular physical activity is widely accepted as an effective preventative measure for a variety of health risk factors across all ages, genders, race/ethnicities, and socioeconomic groups (Janssen, 2010.) However, levels of physical activity remain low and obesity rates continue to rise (Odgen, 2014,) with significant disparities among Hispanic and African-American youth, nationally and specifically in Tennessee (Tennessee Department of Education, 2008.) The impact of obesity is evident in the worsening rates of metabolic functioning, especially among children who are experiencing greater rise in blood pressure (National Center for Chronic Disease Prevention and Health Promotion (NIHCM), 2008,) hyperlipidemia (NIHCM, 2008,) and increased prevalence of type 2 diabetes (Sinha, 2002.)

Type 2 diabetes occurs when there is an imbalance between insulin secretion and insulin resistance. Among youth populations, the prevalence of developing type 2 diabetes increases during puberty due to the natural transient state of insulin resistance (Caprio, 1989.) Type 2 diabetes in youth when compared that in adults has particular characteristics; the transition from glucose deregulation to overt diabetes occurs at a faster rate. In adults, the transition from pre-diabetic to a diabetic state takes about 10 years with a 7% reduction of beta cell function per year (Kahn, 2001, Matthews, 1998.) In pre-diabetic youth, the mean transition period is significantly reduced to about 2.5 years with a 15% reduction of beta cell function per year (Gungor, 2004.)

Along with decrease beta-cell function, youth with type 2 diabetes become resistance to pharmacological mono-therapy (metformin or rosiglitazone) and lifestyle intervention such as change in diet and physical activity. Due to these limiting factors, once a pre-diabetic child or adolescent develops type 2 diabetes, it is considered irreversible (Zeitler et al, 2012.) Given this, the focus is on early prevention of on-set pre-diabetes or type 2 diabetes among the obese youth population. Early lifestyle prevention and intervention programs consist of changing diet, physical activity and lifestyle habits (i.e taking the stairs instead of the elevator) through education. A number research study-programs have shown promising results in regards to diabetes prevention such as: 42% reduction of whole body insulin sensitivity, a two- fold greater change in body fat than body weight, increase lean body mass, and normalized fasting, two-hour plasma blood glucose levels, and decrease LDL cholesterol levels (Shaw, 2009, Wadden, 2012.)

In addition to the physical and metabolic impact of obesity, research supports the relationship between obesity, mental health, and health behaviors. Generally, overweight and obese youth have increased mental health concerns compared to their normal weight peers (Sinha, 2002.) Specifically, obesity has been linked to presence of depression, anxiety, attention deficit hyperactivity disorder, and conduct disorder among children (Halfon, 2013, Puder, 2010.) Difficulty coping with stress and decreased self-esteem are also associated with obesity (BeLue, 2009.) Studies have also shown that individuals, adults and youth, with type 2 diabetes have decreased cognitive functioning including mental processing speed, flexibility, memory, and learning (Puder, 2010.) Physical activity participation has been linked with improved academic performance, mental health, and cognitive function (Hillman, 2008.) Despite these findings, the best treatment or weight management for childhood obesity is still uncertain. A few studies have examined the cumulative impact of improving physical activity, fitness, nutrition, and overall health behaviors in children. The specific aims of this research project are to:

1) Examine the change of health status of youth participants over time as a result of the 12-month (16 weekly, 3 biweekly, and 6-monthly session) ISC intervention through the evaluation of metabolic, physical fitness, and health habit parameters
2) Examine the change of health status of parent participants over time as a result of the 12-month (16 weekly, 3 biweekly, and 6-monthly session) DPP adult sessions through the evaluation of metabolic, physical fitness, and health habit parameters.
3) Examine the differences over time in metabolic, physical fitness, and health habit parameters among participants in the ISC group versus those in educational control group.

23.0 (1200) Site and Research Procedure Information

23.1 * Please list all sites and research procedures that will occur at each site. Research Site(s): If any of the following activities are being done, then include the site(s) below: identification of participants through review of their medical records; recruitment of participants; consent of participants; performance of screening procedures; interventions or interactions with participants; follow-up visits; collection of private information about participants; specimen storage; etc. Note: If any

activities are being conducted at any of the following: CRC, Methodist/Le Bonheur, Regional One Health, or University Clinical Health, review the corresponding institution's guidelines prior to submitting your application. The website listing the institution's point of contact is posted under the "Question Mark" icon to the right.

Site Name and Address	Additional Site Information include suite #	Procedure(s) at this location
Institution: Other	YMCA 245 Madison Avenue, Memphis, TN 38103	Program staff training will be conducted at this site.
Institution: University of Tennessee - Health Science Center	CFRI-50 North Dunlap Street RM 477R	All consenting, data collection, data storage, data input and analysis will be at this site.
	Gaisman Community Center, 4221 Macon Rd, Memphis, TN	ISC and WSC programs will be in held at this site.

23.2 * Is this a multicenter study/project (one that is conducted across many institutions in the U.S. or in the world and usually run by one sponsor)? Select "Not Applicable" if you are using a HUD, or engaging in treatment use of an unapproved drug/biologic or device, emergency use of an unapproved drug/biologic or device, or compassionate use of an unapproved device.

- ○ Yes. This is a multicenter study/project.
- ◉ No. This is NOT a multicenter study/project.
- ○ Not Applicable.

23.3 * Please state the intended number of multicenter sites in aggregate; state "0" if this is not a multicenter study (one that is conducted across many institutions in the U.S. or in the world and usually run by one sponsor).

0

24.0 (1400) Subject Population

24.1 Please state the anticipated number and age range of the subjects to be studied.

* Number of subjects to be accrued locally [This is the total number of subjects you expect to accrue (consent), including anticipated screen failures and withdrawals. For studies with pregnant women where information will be collected about both the mother and fetus/baby, both should be counted as subjects. For studies that are requesting an alteration or waiver of consent, subjects are considered accrued at the time ANY study interventions are performed, including medical record abstraction.]:

100

Overall number of subjects for sponsored multi-center studies [This is the total number of subjects that the protocol states will participate in the study across all centers.]:

* Age range of subjects to be accrued locally:

7-15 and 18+

25.0 (1488) Vulnerable Subjects

25.1 * Does your study require the inclusion of (i.e., are you targeting) any of the following categories of vulnerable subjects?

Check all that apply.

- [ ] Children (0-17 years) Who Are Not Wards of the State
- [ ] Children (0-17 years) Who Are Wards of the State
- [ ] Pregnant Females and Their Fetuses
- [ ] Neonates Who Are Nonviable or of Uncertain Viability
- [ ] Prisoners
- [ ] Developmentally Disabled Persons (Who Are Not Institutionalized)
- [ ] Developmentally Disabled Persons Who Are Institutionalized
- [ ] Persons Who Are Mentally Ill (But Who Are Not Institutionalized as Mentally Ill)
- [ ] Persons Who Are Institutionalized as Mentally Ill
- [ ] Students of a School Associated With This Project
- [ ] Employees of an Institution/Agency Associated With This Project
- [ ] Other Vulnerable Population Not Identified Above
- [x] Not Applicable Subjects Not Classified as Vulnerable

25.2 Might any of the following categories of vulnerable subjects be incidentally included in your study, even though their inclusion is not necessary? Check all that apply.

- [x] Children (0-17 years) Who Are Not Wards of the State
- [x] Children (0-17 years) Who Are Wards of the State
- [ ] Pregnant Females and Their Fetuses
- [ ] Neonates Who Are Nonviable or of Uncertain Viability
- [ ] Prisoners
- [ ] Developmentally Disabled Persons (who are not institutionalized)
- [ ] Developmentally Disabled Persons Who Are Institutionalized
- [ ] Persons Who Are Mentally Ill (but who are not institutionalized as mentally ill)
- [ ] Persons Who Are Institutionalized as Mentally Ill
- [ ] Students of a School Associated with this Project
- [ ] Employees of an Institution/Agency Associated with this Project

Please explain how a certain category of vulnerable subjects might be incidentally included:

26.0 (1494) Study/Project Duration

26.1 * What is the anticipated duration of a single subject's participation in the study/project?

1 year

26.2 * How long will the entire study last locally, including time for data analysis?

5 years

27.0 (1500) Inclusion Exclusion Criteria

27.1 Identify inclusion criteria.

Order Number	Criteria
1	1) Ages 7-15
	Parent Inclusion Criteria: 18 and older

1	
2	2) Prediabetes-A1C 5.7-6.4% **or** BMI of an 85th percentile or above **or** a grandparent /parent with diabetes
2	Parent Inclusion Criteria: at least one child enrolled in ISC
3	3) Able to participate in physical activity
3	Parent Inclusion Criteria: Able to do physical activity
4	4) Parent enrolls in the adult DPP

27.2 Identify exclusion criteria.

Order Number	Criteria
1	1) pregnant females
1	Parent Exclusion Criteria: those with mental disorder (e.g. depression, ADHD, etc.) and/or severe mental illness which requires immediate treatment (e.g., active psychotic episode)
2	2) those with mental disorder (e.g. depression, ADHD, etc.) and/or severe mental illness which requires immediate treatment (e.g., active psychotic episode)
3	3) medications that would interfere with testing results (eg. metformin, insulin)
3	Parent Exclusion Criteria: medications that would interfere with testing results (eg. metformin, insulin)

28.0 (1600) Subject Selection and Recruitment

28.1 * How will subjects be selected?

* Subjects identified through medical record screening

(•) Yes ( ) No

* Contact by investigator with his/her patients in the clinical setting

(•) Yes ( ) No

* Referral from non-investigator practitioner

(•) Yes ( ) No

* Subjects recruited from among students and/or employees

( ) Yes (•) No

* Telephone pre-screening

(•) Yes ( ) No

* Website pre-screening

( ) Yes (•) No

* Advertising

(•) Yes ( ) No

* Other

( ) Yes (•) No

28.2 * Recruitment Materials

At the end of this application, you are required to attach all recruitment materials which you intend to use for this study /project.

( ) No recruitment materials will be used in this research.
(•) Recruitment materials to be used in this research will be attached at the end of this application.
( ) Recruitment materials will be submitted at a later date.

* Describe how/where EACH of your recruitment materials (by name) will be used, in the text box below; e.g., on a website, sent to an email list, posted on campus, in a newspaper, etc.

Flyers and project information that will be posted on campus and throughout the community.

29.0 (1710) Study/Project Procedures

29.1 * Describe the procedures that will be performed to determine whether prospective subjects satisfy inclusion /exclusion criteria for study/project participation.

* Medical Record Review should be included as a procedure if it is used to determine whether prospective subjects satisfy the criteria for study/project participation.

Prospective subjects will be screened by a research staff personnel or screened by a health professional that is referring the participant. They will determine whether they qualify for the program if they meet the inclusion/exclusion criteria.

29.2 * Do the study/project procedures involve administration of a drug, device or other intervention to determine its efficacy, safety, and/or tolerability for treatment purposes?

( ) Yes. The study/project procedures involve administration of a drug, device or other intervention to determine its efficacy, safety, and/or tolerability for treatment purposes.
(•) No. The study/project procedures DO NOT involve administration of a drug, device or other intervention to determine its efficacy, safety, and/or tolerability for treatment purposes.

30.0 (1730) Procedures other than Treatments

30.1 * Describe all procedures, other than treatments, that will be performed.

For studies/projects that involve multiple study/project visits, specify the timing of each visit, and in chronological order, list what will be done at each visit.

Click on "Add a new row" to list each procedure of each visit.

If you do not wish to use the table, click on the Text Editor and type in the information (specify the timing of each visit and list in chronological order, using bullet points, what will be done at each visit).

Also use the Text Editor to further describe any procedures that are not self-explanatory.

Visit Name	Visit Timing	Procedure
Consent, registration	1-2 hours	Consenting
Pre-evaluation	1-2 hours	Pre-evaluation-- see below for details
Mid-evaluation	1-2 hours	Mid-evaluation--see below for details
post-evaluation (3 month)	1-2 hours	post-evaluation--see below for details

Consent, register participants, questionnaire completion

- The first visit will be for program registration and consenting at the Gaisman Community Center. Research staff will consent parents, assent children, and sit face-to-face with the parent and child to complete the Healthy Habits and mental health questionnaire. This will take about 1-2 hours to complete.

Pre-Evaluation

- All physical activity, physical fitness, and health measures described will be collected at the Gaisman Community Center. This will take about 1-2 hours to complete. The drop-off/pick-up home visit appointments will also be scheduled in order to collect physical activity data described in the health behaviors measures. The child will be asked to wear the activity monitor for 7-days hours. The drop-off home will take 30 minutes. The pick-up home visit will take 30 minutes. Both home visits will add up to 60 minutes to complete.

Mid-Evaluation

- All physical activity, physical fitness, and health measures (except the blood glucose and cholesterol) described above will be collected at the Gaisman Community Center. This will take about 2 hours to complete.

Post-Evaluation

- Research staff will sit face-to-face with the parent and child to complete the Healthy Habits and mental health questionnaire. All physical activity, physical fitness, and health measures described above will be collected. This will take about 1-2 hours to complete at the Gaisman Community Center. The drop-off/pick-up home visit appointments will also be scheduled in order to collect physical activity data described in the health behaviors measures. The child will be asked to wear the activity monitor for 7-days. The drop-off home will take 30 minutes. The pick-up home visit will take 30 minutes. Both home visits will add up to 60 minutes to complete.

31.0 (1731) Incidental Findings

31.1 * How will abnormal incidental findings be handled?

- (•) The subject will be referred for follow-up to his/her primary care physician.
- ( ) The study doctor will provide follow up for the abnormal finding.
- ( ) Other
- ( ) Not Applicable; incidental findings are not expected in this project.

32.0 (1733) Creation of Specimen & Data Repositories/Registries

32.1 * Does this study include creating a specimen repository or a data registry/repository? A repository is being established when there is a plan to make stored data and/or specimens available for later use in other research studies.

- ○ Yes
- ◉ No

33.0 (1734) Use of Other Data/Specimen Repositories

33.1 * Will this project/study involve using data/specimens from other repositories?

- ○ Yes
- ◉ No

34.0 (1735) Discontinuation, Endpoints, Analyses

34.1 * Describe the criteria for discontinuation of treatment and withdrawal of the subject from the study/project.

N/A

34.2 * Describe the endpoints or outcomes being assessed in the study/project, such as efficacy and safety endpoints.

Outcome Measures:
Change Over Time: Intervention
Baseline (Time: 0) by changes over time (mid-intervention (Time: 1), and post-intervention (Time: 2))

Change Over Time: Maintenance
Baseline (Time: 0) by changes over time (3-months out (Time: 3), 6 months out (Time: 4), 9 months out (Time: 5), 12 months out (Time: 6)

Post-intervention (Time: 2) by changes over time (3-months out (Time: 3), 6 months out (Time: 4), 9 months out (Time: 5), 12 months out (Time: 6))

34.3 * Describe the statistical analysis that will be used.

Primary Predictors:
Physical Activity: An accelerometer (Computer Science and Applications, Inc., Shalimar, FL), will be used to assess physical activity. To ensure good reliability of devices used, children and parents will be taught how to use the accelerometers and reminded to wear them via a phone call. Self-report measures of physical activity and sedentary habits will also be obtained.

Physical fitness (cardiorespiratory, muscular strength and endurance, and motor skills): The fitness battery will include the American Thoracic Society six-minute Walk Endurance Test (aerobic fitness) while monitoring pulse oximeter (blood oxygen), Jamar plus handgrip dynamometer (grip strength), MicroFET-2 handheld dynamometer (maximal isometric strength), sit-and-reach box (lower body flexibility), 30-foot shuttle run (agility), and Bruininks-Oseretsky Test of Motor Proficiency (fine and gross motor control skills, abdominal, and upper body strength).

Metabolic Parameters (total and central adiposity, blood pressure, physiological stress): These measures include the Inbody-570 multi-frequency bioimpedance analyzer (body composition), Weigh Beam Eye-Level physicians' scale (height), anthropometer (sagittal abdominal height), Gulick spring loaded measuring tape (central obesity), sphygmomanometer (systolic and diastolic blood pressure), radial pulse (resting heart rate), salivary cortisol collected using Oragene (physiological stress), HbA1c (blood glucose levels) and lipid profile (total cholesterol, triglycerides, and LDL and HDL levels.)

Cognition and Mental Health (self-efficacy, quality of life, brief general intellectual functioning, overall cognitive functioning,): General cognitive ability will be assessed using the Wechsler Abbreviated Scale of

Intelligence-II and the NIH toolbox computer-based cognitive battery will be used to measure specific cognitive abilities. Self-report measures will include the PedsQL a measure of health-related quality of life33; knowledge and self-efficacy about physical activity, sedentary habits, nutrition, and stress management.

Mediators: A parent- and child-report healthy habits questionnaire (adapted from previous research) will be used to assess demographics (i.e. age, sex, race/ethnicity, SES, home environment), child's academic status, family health history, weight perception, and frequency and range of typically consumed foods, exercise, sleep, and healthy-lifestyle behaviors.

Specific Statistical Analysis: We will use mixed repeated measures ANOVA model time as the outcome and health habits, physical fitness, and metabolic parameters as our predictor variables. We will also include possible mediators (e.g., parent-child relationship, family health history, weight perception), and covariates (race, ethnicity, SES, age, and grade) in the models.

35.0 (2000) Risks

35.1 *** Please click on "Add a new row" to list the name of the study/project document and the pages in that document where the risks of this research are discussed.**

For example:
Study/Project Protocol 33-37
Investigators Brochure 90-101 and 105-128

- (•) There are no other documents in which the risks of the study/project are discussed.
- ( ) Study/Project risks are also discussed in the attached documents listed below.

35.2 *** Please utilize the following table to describe the risks associated with participation in this research. Include physical, psychological, social, legal, and any other risks.**

Column 1: Type in the name of the procedure.

Columns 2-6: Identify the risks and their rate of occurrence in the appropriate column.

NOTE: If the study/project literature or the sponsor cannot provide the rate of occurrence of a risk, make an educated guess as to its rate of occurrence and type the word "Estimated:" before typing in the description of the risk.

	Procedure	Very Common: occurs >50 times out of every 100	Common: occurs 21-50 times out of every 100	Occasional: occurs 6-20 times out of every 100	Rare: occurs 1-5 times out of every 100	Very Rare: occurs less than 1 time out of every 100
						Estimated: Risks are expected to be minimal. There is a small risk that during the physical fitness measures and sessions, a student may fall, but will be no greater risk than that seen during normal

	Physical Activity	None	None	None	None	physical activity and outdoor play. All steps will be taken to prevent injury to your child and reduce risk. Water and first aid kits will be available. All personnel will also be First Aid /CPR certified. Furthermore, both the YMCA and UTHSC personnel will be chaperoning all students. The UTHSC staff will follow the YMCA emergency procedures. UTHSC personnel will be present to oversee and evaluate educational and physical activity curriculum implementation, which will be conducted by YMCA staff.	
	Questionnaire and	None	None	None	None	Estimated: Completion of the health questionnaire may make you feel uncomfortable or cause troublesome feelings or	

	Surveys					emotions. You may refuse to answer any of the questions and you may take a break at any time during the study.
	Videotaping, Photography and Audio recording	None	None	None	None	Estimated: Having your photograph taken, your voice recorded, and being videotaped may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who views your video and photographer listens to your audio recording of the educational, physical activity, and evaluation sessions might identify you.
						Estimated: With wearing the activity monitors, if irritation of the skin occurs due to wearing the device,

	Activity Monitor	None	None	None	None	discontinue wearing the device and consult a doctor for treatment. Although the Polycarbonate and Polyvinyl Chloride materials are not known to be irritating to the skin, some irritation to people with sensitive skin may occur. If this happens, consult your doctor for treatment and stop wearing the device. Also, notify a research team member that gave you the activity monitor that you have taken the device off since data collection will be effected.		
	Health Measures	None	None	None	None	Estimated: Possible risk of infection and bruising may occur with the finger stick procedure done to collect blood glucose and cholesterol levels, even if rare. Also, there is		

						possible risk of being uncomfortable while the health measures are performed.

If some risks noted above require further discussion by the PI in order for the IRB to review this research, please discuss those risks here:

N/A

36.0 (2210) AE's and Data Monitoring

36.1 * Has an independent data and safety monitoring board (DSMB) been established for the conduct of the study/project?

- ○ Yes. An independent data and safety monitoring board (DSMB) HAS been established for the conduct of the study/project.
- ◉ No. An independent data and safety monitoring board (DSMB) HAS NOT been established for the conduct of the study/project.

* Please explain so that the IRB understands the data and safety monitoring arrangements that are in place for this research, or indicate that it is explained in the sponsor protocol:

The research team leverage the strengths of the collaboration between CFRI Biomedical Informatics Core (BMIC) and the Pediatric Obesity Program of the University of Tennessee Health Science Center (UTHSC) /Le Bonheur Children's Hospital (LBCH) to facilitate many aspects of statistical design, data storage, and analysis. Such strengths include infrastructure support from the UTHSC Information Technology Services (ITS) computer center and skilled personnel with expertise in diverse fields of clinical data management, clinical trials, registries, specific analytics, and well-resourced database technologies. The UTHSC network and computing facilities are owned and managed by UTHSC and all database instances are physically housed in the UTHSC ITS department computer center.

CFRI Biomedical Informatics Core (BMIC)
The Biomedical Informatics Core (BMIC) provides best-in-class informatics support to CFRI's operation and administration. This capability includes research information databases and web sites to provide information and foster communication among CFRI clinical and translational investigators. Vanderbilt University (VU), with collaboration from the Clinical & Translational Award (CTSA) consortium of institutional partners, has developed the Research Electronic Data Capture (REDCap™) for electronic collection and management of research and clinical trial data. The REDCap™ system provides secure, web-based applications that comprise intuitive interfaces for users to enter data. REDCap™ is flexible for various research areas. With planning assistance from BMIC informatics team, all members of the research team use a study-specific data dictionary, adaptive logic, and real time validation rules (features in REDCap™) which results in well-planned data collection strategy for individual research studies. Because REDCap™ is web- based, users with appropriate permissions can access the system from anywhere in the world with via an Internet connection.
REDCap™ also provides a standard export mechanism to various types of common statistical packages (SPSS, SAS, Stata, R/S-Plus). This allows the Principal Investigator (PI) to generate data that are truly independent of the data entry method, thereby generating usable, collaborative datasets for outcome analysis. REDCap™ was designed specifically to comply with HIPAA security and privacy guidelines. BMIC REDCap™ servers are housed in a HIPAA-class server room with key card and passcode access protection. All web- based information transmission is encrypted and uses Secure Hypertext Transfer Protocol (HTTPS) employing SSL (Secure Sockets Layer) encryption technology. SSL creates the secure connection, and HTTPS transmits the data securely. REDCap™ currently supports over 240 academic and non-profit consortium partners with over 26,000 research end-users (www.project-redcap.org).

UTHSC Information Technology Services (ITS)
UTHSC owns and manages its network and computing facilities. All REDCap™ instances are physically housed in the UTHSC ITS department computer center. This center has electric power conditioning, battery backup for short-term outages, and a backup diesel generator for long-term outages. The

computer center also has fire suppression, temperature and humidity control, card key controlled access and video monitoring. The UTHSC police force monitors the building which has after-hour access controls. Networking equipment across the campus is housed in dedicated and locked wiring closets with battery backups; access is limited to UTHSC network services personnel.
A 100-MB switched network with fully redundant network cores provides connections to both the Internet and Internet 2. Network traffic crossing the UTHSC network boundary is examined by a Cisco firewall against its Access Control Lists. A Cisco intrusion prevention system has been deployed to further examine traffic indicative of known exploits, and traffic is shunned or trapped as appropriate. Access from outside the UTHSC network for public data is to known web server ports and services. VPN (Virtual Private Network) access is available to authorized users by personalized NetID. No device may have network connectivity until its owner registers it; registration requires a University NetID and agreement with the UTHSC policy on acceptable use of computer resources. Systems at UTHSC are required to run current anti-virus software. All UTHSC systems are required to maintain current software patch levels.

Data security
The CFRI BMIC follows and implements all required information security standards. All deployed web applications use the standard industry practice of a dual server, consisting of a "front-end" web server accessible to the general Internet and a "back-end" database server accessible only to connections from the private network (and not from the public internet). All servers reside behind the UTHSC ITS unified threat management system, which is actively monitored. To provide greater data security and performance, the web server and database server are separated and do not reside on the same computer. To enable compliance with Good Clinical Practice (GCP) and regulatory guideline 21 CFR Part 11/45 CFR 164, user-controlled privileges are implemented in our central registry database.
To satisfy the NIST SP 800-44 requirement, the BMIC corporate information infrastructure includes an integrated firewall and intrusion detection system, backed up by continuous monitoring and automatic detection and alerts. The corporate network is divided into physical segments and logical zones. Network traffic crossing segments and zone boundaries is monitored and controlled. Access to and from the internet is limited to particular ports and firewall zones. Access to the host Web Server requires users to log in through Secure Hypertext Transfer Protocol (HTTPS) connections.
To maintain HIPAA compliance across our system, all Personal Identifiable Information (PII) and Limited Data Set are encrypted by FIPS 140-2 compliance encryption standard for the NIST. All communications use HTTPS, which employs state-of-the-art Transport Layer Security (TLS) protocol and SSL (Secure Sockets Layer) encryption technology. SSL creates the secure connection and HTTPS transmits the data securely.
Additionally, the CFRI BMIC recently participated in the Web Application Security Consortium (WASC) and Open Web Application Security Project (OWASP) community mailing list, wiki, and blog. The WASC and OWASP are 501(c)3 not-for-profit worldwide groups of experts focused on improving the security of application software and the best-practice security standards for the World Wide Web. Furthermore, CFRI's BMIC informatics architecture separates database and application functionality across servers. All servers are protected by UTHSC firewalls. Development/staging environments are separate from production environments. All coding design and implementation in REDCapTM are implemented through the development environment and source control. Security is considered in all phases of the system development life cycle and is treated as an integral part of the system development and implementation process, including system modifications. CFRI's BMIC development team leader ensures that adequate and effective management, operational and technical control mechanisms are integrated into the system development lifecycle.

Secure data access
REDCap™ has the ability to strictly control access to the data using role-based control. Granted access is based on the role of individual user. Examples include a general user or a privileged user such as an administrator, regular user, principal investigator, co-investigator, etc. Audit records include date and time of the event, subject identity, and success or failure of the event. The database can be queried through the web- based interface with an appropriate control access through Virtual Private Network (VPN) and login authentication. We will provide a unique assigned username and password, which will be required for authentication.
Our database (REDCap™) uses system authentication to connect to the application. The application enforces rights limitations and information flow control. Connectivity between application and database, and between users and applications, is limited by VPN, firewall filtering and service/application access control. Passwords for all user accounts expire every 90 days as part of our Standard Operating Procedures (SOPs). Users will be warned that their passwords are about to expire, beginning at least 14 days prior to the expiration date. User are notified via Rules of Behavior (RoB) that they must not share password with others and to report lost or compromised password immediately to the CFRI BMIC. The user session is dropped after 20 minutes of navigation inactivity. Because these applications are browser-based, user session is terminated. To continue, a user must log in to the application and establish a new session.

Data storage
Data are stored on a MySQL database server that is housed in UTHSC ITS HIPAA-class server room and protected by the UTHSC firewall. Access to the server room is protected by the use of key cards and personal security passcode access protection. The server uses a Redundant Array of Independent Disks

(RAIDs) configuration on the hard drives available in the event of a drive failure so drives can be replaced immediately. All data is moved to a backup server nightly. A tape backup is made of the two most recent full backups. These tapes are encrypted and stored in the server room before entering the rotation again. To militate data loss in the event of the disaster, CFRI's BMIC follows the UTHSC Disaster Recovery Plan (DRP) and Business Continuity Plan (BCP).

Vulnerability scan
The CFRI BMIC actively monitors for vulnerabilities in our security plan. This monitoring takes place at various levels of granularity. The top-level review is our internal Risk Assessment Retreat. This is quarterly meeting engages all developers, supervisors, and data managers as well as the systems, network, and database administrators to discuss perceived risks to our system. Attendees are invited to spend a number of hours preparing through the use of system reviews, log analysis, feasibility analysis, and white hat analysis. Internal CFRI BMIC policy dictates that a risk assessment be performed when configuration changes are made. This includes any creation or modifications of firewall rules, backup plan, database, roles, and internal user access. This ongoing review aims to identify possible problems or attacks on our servers early on. There could be unexpected utilization of the central processing unit (CPU), a large number of refused connections, or a drastic increase in web server traffic.

37.0 (2730) If Subjects Were Not to Participate

37.1 * List all of the procedures (including those such as medical record abstraction or survey administration) that will be performed ONLY because the subject is in this study/project. This means even listing how many additional blood draws, visits, etc., would occur beyond the number of standard of care blood draws, visits, etc. If all procedures are being performed solely for research purposes, you may simply state this.

All procedures are being performed solely for research purposes.

38.0 (2748) Privacy

38.1 * Confirm that ALL of the following are true:

- **the collection of private information will be limited to the minimum necessary to meet the objectives of the study; AND**
- **the number of key study personnel (KSP) who have access to private information will be limited to the minimum number necessary to meet the objectives of the study; AND**
- **research records will be kept separate from other records, such as medical or educational records, unless the information is useful for the welfare of the subject, or unless the clinic /hospital's policy is to include research consent forms in the patient's medical record.**

- (●) Yes, all of the above statements are true.
- ( ) No, one or more of the above statements are not true.

38.2 * Check off all of the following approaches that will be used to assure that prospective subjects are screened, recruited, and /or invited to participate in a way that protects them from being witnessed, overheard, or viewed in a manner that violates their privacy.

- [ ] Patients will initially be approached for participation by their physician, not a stranger to the patient, unless there is documented permission from the physician to approach the patient.
- [ ] Recruitment letters will only be sent by the patient's physician, or will state that the researcher obtained permission from the patient's physician.
- [x] Recruitment letters will only be addressed to the prospective subject or their legally authorized representative, as appropriate.
- [x] Recruitment will not be conducted in an open area or in a group setting when medical conditions, sensitive topics (such as criminal behavior; sexual practices; alcohol and drug use; physical, emotional, or sexual abuse; etc.), or other private matters are being studied.
- [ ] Screening will not be conducted in an open area or in a group setting when medical conditions, sensitive topics (such as criminal behavior; sexual practices; alcohol and drug use; physical, emotional, or sexual abuse; etc.), or other private matters are being studied.
- [ ] If screening requires the prospective subject to disrobe partially or completely, the prospective subject will do so in a private room and will have a gown or proper cover to put on while he/she waits in the

room.

- [ ] Other
- [ ] Not applicable. This study does not involve screening or recruitment.

38.3 * Check off all of the following approaches that will be used to assure that interventions and interactions with subjects provide protections against them being witnessed, overheard, or viewed in a manner that would violate their privacy.

- [x] Interventions and interactions with subjects will not be conducted in an open area or in a group setting when medical conditions, sensitive topics (such as criminal behavior; sexual practices; alcohol and drug use; physical, emotional, or sexual abuse; etc.), or other private matters are being studied.
- [ ] If interventions require the subject to disrobe partially or completely, the subject will do so in a private room and will have a gown or proper cover to put on while he/she waits in the room.
- [ ] If photographs, voice recording, or video recording will be performed, the subject is aware of this fact and informed about who will be viewing them and/or receiving them, and the subject has given written permission for these procedures.
- [ ] Other

38.4 * Check off all of the following ways in which tracking non-compliant subjects or subjects lost to follow-up will assure that their medical condition and/or participation in the research is not disclosed to persons outside the research.

- [ ] Written permission will be secured from subjects regarding all of the methods that may be utilized to track them.
- [x] The subject's phone number(s) will be called, and if the subject is not the person who answers, the researcher will not divulge the title of the study or the fact that the subject is/was participating in a study.
- [ ] Certified mail will be sent to the subject.
- [ ] The return address nor any markings on the envelope of a letter to the subject will not identify the title of the study or the fact that the subject is/was participating in a study.
- [ ] Any letter sent to subjects will not reveal the topic of the study if a medical condition and/or sensitive issue is being studied (such as criminal behavior; sexual practices; alcohol and drug use; physical, emotional, or sexual abuse; etc.).
- [ ] The topic of the study or the fact of the subject's participation will not be disclosed to any person outside the study who is contacted to determine the whereabouts of subjects.
- [ ] Other
- [ ] Not Applicable. We will not attempt to track non-compliant subjects or subjects lost to follow-up.

39.0 (2750) Confidentiality 1a

39.1 * Will you collect, for screening purposes, individually identifiable, private information (including health information) about prospective subjects? (This includes information that you abstract from the medical record or information you collect via telephone, mobile app, or website for screening purposes prior to obtaining written informed consent.) (Consult the question mark icon for definitions.)

- (•) Yes
- ( ) No

40.0 (2755) Confidentiality 1b

40.1 * Explain what will be done with the individually identifiable, private information (including health information) that you collect about prospective subjects who fail screening or who do not agree to participate (consult the question mark icon for definitions):

- (•) The information will be destroyed; e.g., shredded or properly deleted from a computer.
- ( ) Items of individually identifiable, private information such as names, contact information, and health information will be maintained by the local investigator (either locked and stored if on paper; computer

password protected and accessible only to research personnel, or stored in an encrypted fashion on a thumb drive, laptop, or desktop computer).

- ○ Information will be forwarded to sponsor/CRO using an encrypted method and then destroyed at the local site.
- ○ Other

41.0 (2800) Confidentiality 2

41.1 * Will all paper research records containing identifiable, private information (including the original signed consent form) from individual subjects be locked and stored and be accessible only to research personnel? (Consult the question mark icon for definitions.)

- ◉ Yes. All paper research records containing identifiable, private information from individual subjects (including the original signed consent form) will be locked and stored and will be accessible only to research personnel.
- ○ No. Not all paper research records containing identifiable, private information from individual subjects (including the original signed consent form) will be locked and stored and will be accessible only to research personnel.
- ○ Not applicable. There will be no paper research records containing identifiable, private information from individual subjects.

41.2 * Check off all of the following items that apply regarding the electronic storage of identifiable, private information collected in this project (consult the question mark icon for definitions.):

- ☑ All electronic research records containing identifiable, private information from individual subjects will be computer password protected and accessible only to research personnel.
- ☐ All electronic research records containing identifiable, private information from individual subjects will be stored in an encrypted fashion (e.g., on an encrypted, password protected thumb drive; on an encrypted laptop; on an encrypted desktop computer; in an encrypted, password protected file on a laptop/computer; etc.).
- ☐ Other or additional methods of secure storage (e.g., data will have inter-file linkage, error inoculation, top coding, bracketing, data brokering, etc.)
- ☐ Not applicable. Electronic research records will NOT contain identifiable, private information from individual subjects.
- ☐ Not applicable. There will be NO electronic research records.

41.3 * Select the following item that applies regarding the electronic transmission (either locally or externally) of identifiable, private information collected in this project (consult the question mark icon for definitions):

- ◉ All electronic research records containing identifiable, private data from individual subjects will be transmitted electronically via an encrypted method (e.g., UT Vault, Xythos, a federal or industry-sponsor cleared web-based portal, etc.).
- ○ All electronic research records containing identifiable, private data from individual subjects will be coded before transmitted electronically, and the master key will be maintained at the local site.
- ○ Other or additional methods of secure electronic transmission
- ○ Not applicable. NO electronic transmission of identifiable, private data will occur.

42.0 (2805) Biological Specimens

42.1 * Will biological specimens be collected in this study/project?

- ○ Yes. Biological specimens will be collected in this study/project.
- ◉ No. Biological specimens will NOT be collected in this study/project.

43.0 (2820) Confidentiality 3

43.1 * **Will information obtained from procedures performed only for research purposes be placed in the medical record of subjects?**

- ○ Yes. Information obtained from procedures performed only for research purposes MAY BE placed in the medical record of subjects.
- ○ No. Information obtained from procedures performed only for research purposes WILL NOT BE placed in the medical record of subjects.
- ○ Not applicable: There will be no procedures performed only for research purposes.
- ◉ Not applicable: This project does not include access to or use of the medical record of the subjects.

43.2 * **Will documentation of the participation of the subject in the research study, such as a copy of the consent form or other notation, be placed in the medical record of the subject?**

- ○ Yes. Documentation of the participation of the subject in the research study, such as a copy of the consent form or other notation, MAY BE placed in the medical record of the subject.
- ○ No. Documentation of the participation of the subject in the research study, such as a copy of the consent form or other notation, WILL NOT BE placed in the medical record of the subject.
- ◉ Not applicable: This project does not include access to or use of the medical record of the subjects.

44.0 (2825) Confidentiality 4

44.1 * **Will a federal Certificate of Confidentiality be obtained for this study/project (http://www.uthsc.edu/research/compliance/irb/researchers/documents/certificates-confidentiality.pdf)?**

- ○ Yes. A federal Certificate of Confidentiality WILL be obtained for this study/project.
- ◉ No. A federal Certificate of Confidentiality WILL NOT be obtained for this study/project.

45.0 (3045) Payment

45.1 * **Will any type of payment (money, gift card, or other item) be provided to the subject for participation?**

- ◉ Yes ○ No

46.0 (3050) Describe Payment

46.1 * **Indicate the AMOUNT of money to be paid (including reimbursement pay) per visit AND total maximum payment, the TYPE of payment (check, cash, gift card and value), as well as the monetary worth of any OTHER tangible item provided as payment for study/project participation.**

For each data collection session the child attends they will receive an incentive of their choice (ex. food log, water bottle, jump rope, exercise band, label reading guides, pedometer, etc.). After the completion of the pre-evaluation the participant and parent will be provided with a YMCA gym family membership for 3 months (value: $75 for family registration, $32 per family member monthly, and tax; therefore the value for a family of four would be approximated $240 for a 3 month membership). After the post-evaluation the participant and parent will be given an additional 3 month YMCA gym family membership. This amount is based on previous incentives provided for similar YMCA programs. Also, at the end of the study you and your child will receive a full report with all the information collected and an explanation that can help you and your child with health and fitness goals.
Incentives:
Pre, post, and follow-up evaluations: $50 gift card (from Kroger or Walmart) for participant
Programs sessions: attendance raffle: participants will be provided with a raffle ticket for attending sessions and will be able to select a n item for a prize box (water bottles, t-shirts, jump ropes, hand sanitizer, myPlates, etc.)

46.2 * **To whom will the payment [money, gift certificate, other items] be paid/given?**

- ○ The subject
- ○ The subject's legally authorized representative
- ◉ Mixed arrangement, depending on the age or health of subjects

* Please explain:

Child: incentive of their choice (ex. food log, water bottle, jump rope, exercise band, label reading guides, pedometer, etc.)
Parent/Child: YMCA memberships, $50 gift cards (from Kroger or Walmart) for the family each data collection section

46.3 * How will the actual amount of money received by the subjects or their legally authorized representative be determined?

- ○ Lump sum payment will be made at completion of the study/project (Note: if paying per visit, the payment must not be held until the end of the study because of potential undue inducement; the same applies if a rather large sum of money will be paid only at the end of the study.)
- ◉ Prorated payments will be processed or issued at the time specific visits and/or procedures are completed
- ○ Prorated payments will be processed or issued at the time specific visits and/or procedures are completed, plus a bonus will be paid for completing the entire study/project
- ○ Not applicable; no money will be paid to the subjects

* If your answer is the second option, "Prorated payments for...procedures," please describe the schedule of payments for specific visits and/or procedures.
* If your answer is the third option, "Prorated payments... plus a bonus for completing the entire study," describe the schedule of payment for specific visits and/or procedures, as well as the bonus for completing the entire study/project.

The payment (YMCA membership) will be prorated based on the completion on evaluation session. At consenting/registration the parent/child will be given a 3 month YMCA family membership. At the completion of the intervention portion or the program and post evaluation the parent/child will be given an additional 3 month YMCA family membership. Therefore 2 payment amounts will be given.

47.0 (3100) Financial Obligations

47.1 * Will any drug/biologic, device or intervention being administered and evaluated as a diagnostic, monitoring or treatment procedure in this study/project be provided free of charge?

- ◉ Not Applicable. No drug/biologic, device or other intervention is being evaluated as treatment in the study/project.
- ○ Yes. The drug/biologic, device or other intervention being evaluated as treatment WILL be provided free of charge.
- ○ No. The drug/biologic, device or other intervention being evaluated as treatment WILL NOT be provided free of charge.

47.2 * With respect to study/project procedures other than any treatments being evaluated in the study/project, will there be any costs to the subject as a result of research procedures that exceed what would be incurred with standard treatment (e. g., additional diagnostic tests, monitoring procedures, hospitalization, etc.)?

- ◉ Not applicable. The procedures of this research do not correlate to any standard treatment.
- ○ No costs will exceed what would be incurred with standard treatment.
- ○ Costs to exceed what would be incurred with standard treatment.

48.0 (3200) Research Injuries

48.1 * Does the research include procedures that have the potential to cause physical injury to the subjects?

- (●) Yes. The research includes procedures that have the potential to cause physical injury to the subjects.
- ( ) No. The research DOES NOT include procedures that have the potential to cause physical injury to the subjects.

49.0 (3210) Potential Injury

49.1 * Who will be responsible for the costs of treating research-related physical injuries?

Write "the subject & his/her insurance" or "the subject & his/her insurance, and the sponsor" below, regarding who will be responsible for the costs of treating research-related physical injuries, or specify any other arrangements.

the subject & his/her insurance

49.2 * Will research personnel provide treatment or referral for research-related physical injuries as needed or requested by the subject?

- ( ) Research personnel will provide acute care for research-related physical injuries.
- (●) Research personnel will refer subjects for appropriate care for research-related physical injuries.
- ( ) Research personnel will provide acute care for research-related physical injuries and will refer subjects for appropriate care.
- ( ) Other.

49.3 * Will compensation be available to subjects for any ancillary expenses incurred as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.?

- ( ) Yes. Compensation will be available to subjects for any ancillary expenses incurred as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.
- (●) No. Compensation will NOT be available to subjects for any ancillary expenses incurred as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

50.0 (3230) Compensation for Non-Physical Injuries

50.1 * Will compensation be available to subjects for any non-physical injuries that may be incurred as a result of research participation, such as exposure to criminal or civil liability, or damage to their reputation, financial standing, or employability?

- ( ) Yes. Compensation will be available to subjects for any non-physical injuries that may be incurred as a result of research participation, such as exposure to criminal or civil liability, or damage to their reputation, financial standing, or employability.
- (●) No. Compensation will NOT be available to subjects for any non-physical injuries that may be incurred as a result of research participation, such as exposure to criminal or civil liability, or damage to their reputation, financial standing, or employability.

51.0 (3300) Conflict of Interest

51.1 * For any publically traded entity whose monetary worth may be directly affected by the results of this research study, have any individuals among the key research personnel listed in section 3.0 above [including their spouses (whether or not they commingle assets), parents, and children (both dependent and non-dependent, and including stepchildren and foster children)] received salary for services or any other payments (e.g., consulting fees, honoraria, paid authorship) from that entity during the previous 12 months, and/or hold an equity interest in that entity, such that the combined value, when aggregated, exceeds $5,000?

- ( ) Yes. Key study personnel (or their spouses, parents, or children as defined above) have received

remuneration and/or possess equity interests which, when aggregated, exceed $5,000.

- ○ No. Key study personnel (or their spouses, parents, or children as defined above) have NOT received remuneration and/or possess equity interests which, when aggregated, exceed $5,000.
- ◉ Not Applicable. There is no publicly traded entity whose monetary worth may be directly affected by the results of this research.

51.2 * **For any non-publically traded entity whose monetary worth may be directly affected by the results of this research study, have any individuals among the key research personnel listed in section 3.0 above [including their spouses (whether or not they commingle assets), parents, and children (both dependent and non-dependent, and including stepchildren and foster children)] received salary for services or any other payments (e.g., consulting fees, honoraria, paid authorship) from that entity during the previous 12 months which exceeds $5,000, or hold any equity interest in that entity?**

- ○ Yes. Key study personnel (or their spouses, parents, or children as defined above) have received remuneration from the entity which, when aggregated exceeds $5,000, or hold some equity interest in the entity.
- ○ No. Key study personnel (or their spouses, parents, or children as defined above) have received NOT remuneration from the entity which, when aggregated exceeds $5,000, and do NOT hold any equity interest in the entity.
- ◉ Not Applicable. There is no non-publicly traded entity whose monetary worth may be directly affected by the results of this research.

51.3 * **Do any individuals among the key research personnel listed in section 3.0 above [including their spouses (whether or not they commingle assets), parents, and children (both dependent and non-dependent, and including stepchildren and foster children)] have intellectual property rights (patents, trademarks, licensing agreements or copyrights) in any test article being evaluated in the research and have already received income related to such rights and interests?**

- ○ Yes. Key study personnel (or their spouses, parents, or children as defined above) have intellectual property rights related to the test article being evaluated and have already received income related to such rights and interests.
- ○ No. Key study personnel (or their spouses, parents, or children as defined above) do not have intellectual property rights related to the test article being evaluated or have not received income related to such rights and interests.
- ◉ Not Applicable. No test article involving intellectual property rights is being evaluated in this study.

52.0 (3329) Informed Consent

52.1 * **Check each of the following that apply to your study/project:**

- ☑ Informed consent will be secured from adult subjects who are able to consent for themselves.
- ☐ Informed consent will be secured from legally authorized representatives for adult subjects who are not able to consent for themselves.
- ☑ Permission will be secured from legally authorized representatives for children who are subjects.
- ☑ Assent will be secured from child subjects 8-17 years of age and/or from adult subjects who do not have the capacity to consent.
- ☐ A request is being made to waive or alter consent for some or all of the subjects. (Note: Informed consent normally requires the use of a consent form prepared according to the IRB format and the conduct of an individual in-person interview with the prospective subject. WAIVER of consent is a request to forego consent entirely. ALTERATION of consent is a request to alter the normal process, e. g., by using a shorter consent statement or conducting consent over the phone.)
- ☐ Consent will be secured from the subjects, but a request is being made to NOT obtain a signed consent form for some or all of the subjects. (For example, you are conducting an online survey study.)
- ☐ A request is being made to waive informed consent under the emergency medicine research provisions of the FDA regulations.
- ☐ Non-English speaking subjects will be included in the study population.

53.0 (3440) Consent & Assent Process

53.1 * **Briefly explain when and where informed consent of the subject or Legally Authorized Representative (LAR), assent of the subject (if applicable), and permission from parents (if applicable) will be sought. Explain whether you will obtain consent (not assent) when a child subject turns 18 while still in the study (if applicable). If consent is provided by a Legally Authorized Representative when a subject is temporarily not capable of consenting or assenting, explain whether you will obtain consent or assent from the subject when he/she becomes capable of consenting while still in the study.**

On the day of registration, parents or guardians will receive project information packets from the trained research team. The packets will include a parent/guardian consent form, a child assent form, and detailed participation requirements, benefits, and incentives. Once the researcher consents the parent and assents the child face-to-face, the child and parent will be asked to sit with the researcher to complete the study questionnaires. The parent will complete the Healthy Habits Questionnaire (parent version), the child and parent will complete the Healthy Habits Questionnaire (child version), and the child (child version) and parent (parent version) will complete the mental health questionnaire separately. Trained research team members will complete all face-to-face consenting and surveys/questionnaires.

Once completed the participant will return the following week to complete their pre-evaluation assessment.
The parents will be encouraged to contact the research team if they should have any questions regarding the study procedures. All questionnaires, consents, and assent forms must be completed prior to the data collection days with the assistance of a research team member. The research staff will review all materials and assign a study id prior to the child's participation in data collection. Following completion of the project parents or guardians of all children enrolled in the project will receive a report of their health behaviors, physical fitness, and mental health performance with strategies to improve/maintain their outcomes.

54.0 (3450) HIPAA

54.1 * **In order to conduct this research, or to identify or recruit potential subjects, are you requesting to use SOURCE DOCUMENTS or SOURCE MATERIALS that contain the Protected Health Information of persons without their authorization (or with their limited authorization) AND/OR are you obtaining Protected Health Information of persons without their authorization (or with their limited authorization), such as through telephone screening?**
Note: Source documents/materials are documents/materials from which you are going to abstract information in order to conduct this research or to identify or recruit potential subjects, for example, a patient's medical record.

- (●) Yes. I am requesting to use source documents/materials that contain Protected Health Information (PHI) of persons (living or dead) without their authorization (or with limited or altered authorization) to conduct the study, or to identify or recruit potential subjects.
- ( ) No. I am not requesting to use source documents/materials that contain Protected Health Information (PHI) of persons (living or dead) without their authorization (or with limited or altered authorization) to conduct the study, or to identify or recruit potential subjects.

55.0 (3455) HIPAA Type of Waiver Requested

55.1 * **Please identify the regulatory category under which the request is being made to view, record, and/or retain Protected Health Information (PHI) without subject authorization.**

- [x] Waiver of subject authorization is being requested because some or all of the PHI is being viewed, recorded, and/or retained without the subject (or potential subject) signing a HIPAA authorization.
- [ ] Some or all Protected Health Information (PHI) to be viewed, recorded, and/or retained is from individuals who were deceased prior to the date this research proposal was submitted.
- [ ] Some or all Protected Health Information (PHI) to be viewed, recorded, and/or retained is a limited data set. A limited data set is a medical record, database, or other source document being accessed for this research which does NOT contain 16 of the 18 HIPAA-specified identifiers. (The 16 identifiers can be found by clicking on the question mark to the right of this section.)
- [ ] Some or all Protected Health Information (PHI) to be viewed, recorded, and/or retained is de-identified data. De-identified data is a medical record, database, or other source document being accessed for this research which does NOT contain ANY of the 18 HIPAA-specified identifiers. (The 18 identifiers can be found by clicking on the question mark to the right of this section.)

56.0 (3460) Section A: PHI

56.1 * **Briefly describe the Protected Health Information (PHI) to be used in the research activity. If this study involves a review of records for which all the records will be in existence and completed at the time that the study is initiated, then specify the beginning and ending dates of those records.**

A referring non-investigative M.D. may provide a potential subject's name, date of birth, telephone number, Hemoglobin A1c, BMI. Research staff will need the telephone number to contact the subject and /or the parent/legal guardian as well as the potential subject's name to be able to identify the subject during a telephone contact to inquire.

56.2 * **If Protected Health Information (PHI) will be disclosed to the investigator by another covered entity or entities, briefly describe these entities.**

N/A

56.3 * **Briefly explain who will receive and use the Protected Health Information (PHI) and where it will be stored.**

Primary investigator, co-investigators, and research staff will receive the PHI to contact potential subjects who contacted the study coordinator or were referred by a non-investigator MD. PHI will be stored on a spreadsheet that is password protected. The spreadsheet will be stored on a password protected computer. The computer will be stored in a locked office to which only designated research staff will have access to. PHI will be stored in electronic form and only accessible by appointed study personnel.

57.0 (3462) Section B: Use of PHI Under the Waiver

57.1 * **Protected Health Information (PHI) will be used without a signed consent form containing a HIPAA authorization:**

- [x] to identify potential subjects for recruitment (e.g., where a chart review will be conducted before asking the potential subject to sign a consent form containing the HIPAA authorization).
- [x] to contact potential subjects regarding study participation (e.g., obtaining a phone number from the medical record in order to call potential subjects to conduct a survey).
- [ ] for the collection of data for the study (e.g., a retrospective chart review).

58.0 (3466) HIPAA Waiver or Alteration

58.1 * **Briefly describe the plan to protect the Protected Health Information (PHI) - health information with identifiers.**

PHI will be stored on a password protected database. The database will be stored on a password protected computer. The computer and any paper PHI will be stored in a locked office to which only designated research staff will have access.

58.2 * **Briefly describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. If there is a justification for retaining the identifiers or such retention is otherwise required by law, this should be explained.**

PHI identifiers will be removed and assigned a unique identification code. Subject identifiers will be destroyed at the earliest opportunity consistent with the conduct of research.

58.3 * **Will the Protected Health Information (PHI) - health information with identifiers - be reused or disclosed to any other person or entity than those listed in (415) and (470)?**

- ( ) Yes
- (•) No

58.4 * **Is it true that the Protected Health Information (PHI) will not be reused or disclosed to any other person or entity EXCEPT as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI is approved by the IRB?**

- (●) True. PHI will not be reused or disclosed unless as excepted above.
- ( ) Not true. PHI may be reused or disclosed.

58.5 * Briefly explain why you must have access to the PHI in order to complete your research.

PHI is needed to identify and recruit potential participants for study project.

59.0 (3468) HIPAA Waiver Practicality

59.1 * Why can the research not be practicably carried out without the waiver of the authorization requirement?

- [x] Funds and personnel do not exist to contact all potential subjects to secure their authorization.
- [ ] Failure to include all potential subjects might result in skewed analysis of the results of the study.
- [ ] Other reason.

60.0 (5000) References

60.1 * Please list all literature references in support of this research.

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61.0 Save and Attach Documents

61.1 **The following text box is provided in the event that you need to share additional information with the Review Board.**

Kristina Decker is a UT graduate assistant.

61.2 **After clicking the "Save and Continue" button, you will advance to the routing form in order to attach any supporting documents (such as consent forms) and to send the submission to the necessary personnel for their signatures.**

CLICK on "Save and continue..."