FORM: IRB Proposal - Standard Submission	
NUMBER	VERSION DATE
HRP-UT901	04/29/2021

GENERAL STUDY INFORMATION

Use for greater than minimal risk studies and minimal risk studies that fit into one or more expedited categories (see Section 5.3 of our Policies & Procedures for details regarding expedited research).

Do NOT submit this form if the study will qualify for exempt review, instead submit HRP-UT902 IRB Proposal – Exempt Submission Form found in the document Library.

If you are only using secondary data that will not be initially collected solely for this research project, use HRP-UT903 Template IRB Proposal Secondary Use form instead.

For studies following a multi-center or sponsor protocol, please use this guidance to assist in your completion of this form.

For questions regarding definitions, policies, or terms referenced below see the policies and procedures manual.

Please note, Word online does not support Word checkboxes. Please download the file and use your desktop version of Microsoft Word.

1 Review Type (Choose one)

*Click on the check box (or double click and type an "X" if using Google Docs) the **one** review type that applies.*

Please note: Expedited Review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by ORHP. If you would like help determining which type of review is most appropriate for your study please contact the Office of Research Support and Compliance: https://research.utexas.edu/ors/about-ors/contact-us/.

a ☐ **Full Board Review – Greater than Minimal Risk Research**

b ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypothesis

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The primary specific aims of the study are to:
Aim 1 (Year 1): Conduct community-engaged formative studies to transform the existing family-focused intervention (FI) into two unique delivery methods: in-person (FI-IP) and remote technology (FI-RT) for use in a subsequent randomized controlled trial in a rural Latino community.

Aim 2 (Years 2-5): Conduct a randomized controlled trial to evaluate the comparative effectiveness of two parallel delivery methods of family-focused intervention (FI-IP and FI-RT) to address weight loss (primary outcome) and energy balance behaviors (secondary outcomes) among overweight / obese, rural, primarily Latino (≥ 70%) adults compared with adult participants in control group at immediate post intervention (3 months), again after a 3-month maintenance program (6 months post randomization) and a 6-month follow-up (12 months post randomization). A secondary aim is to examine the impact of FI-IP and FI-RT on children's weight and energy balance behaviors.

Hypothesis #1: We hypothesize that adult participants randomized to either FI-IP or FI-RT will achieve greater weight loss and improved energy balance behaviors compared with adult participants in the control group immediate post intervention (3 months post randomization), after a 3-month maintenance program (6 months post randomization) and a 6-month follow-up (12 months post randomization).

Hypothesis #2: We hypothesize that child participants randomized to either FI-IP or FI-RT will have better weight outcomes and improved energy balance behaviors compared with child participants in the control group immediate post intervention (3 months post randomization), after a 3-month maintenance program (6 months post randomization) and a 6-month follow-up (12 months post randomization).

3 Study Background

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Obesity is a significant health threat in South Texas, a largely Latino region with one of the most underserved, at-risk populations in the nation. Obesity can start in early childhood and persist lifelong, setting the stage for disease. Because obesity impairs health-related quality of life and billions are spent to manage obesity-related diseases, interventions to help obesity-affected families to adopt and maintain a healthier lifestyle and achieve a healthy weight can have great individual and public health benefits.

Much has been learned about the efficacy and effectiveness of comprehensive healthy lifestyle interventions to reduce obesity, but few studies have been translated into rural settings or among Latinos. Healthy Frio, modeled after Y Living, is an evidence-based family-focused intervention (FI) designed for urban Latino families by PI Dr. Deborah Parra-Medina and her South Texas-based research team. The FI is a 12-week behavioral modification program grounded in the social cognitive theory of behavior change

designed to engage the whole family in lifestyle changes by developing knowledge and skills in physical activity and healthy eating, building skills in goal-setting and self-monitoring, and creating a supportive environment at home. Researchers will engage community partners in formative research to adapt the current FI for rural Latino families.

Two parallel delivery methods of the FI will be developed (Aim 1) and tested (Aim 2): 1) in-person group setting at a community center (FI-IP) and 2) home-based delivered remotely with technology (FI-RT). While both will be designed to address the unique social, cultural and environmental factors facing rural Latino families, the latter takes advantage of innovative modern technology and e-Learning to increase program availability, accessibility and program participation in rural settings. Aim 1 will be conducted in Year 1 and Aim 2 in Years 2-5. Aim 1 consists of community-engaged formative studies to transform Y Living, the existing family-focused intervention (FI), into two new forms: 1) in-person sessions with rural families (FI-IP) and 2) a remote technology-based intervention (FI-RT) that will be used in a subsequent randomized controlled trial (RCT). Aim 2 consists of a 3-arm RCT to evaluate the effectiveness of the two family-focused interventions on weight loss and energy balance behaviors among obese Latino adults.

4 Design and Methodology

Provide information regarding study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

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Aim 1 activities, which take place in Year 1, are community-engaged formative studies conducted to transform an existing community-based program into two forms that are appropriate in a rural setting. We will recruit 15 parent-child dyads to participate in a pilot FI-IP (n=10) or FI-RT program (n=5) and provide feedback to refine the program through written evaluation and focus groups. These studies will take place in Frio County.

Aim 2 (Years 2-5) activities consists of a 3-arm randomized controlled trial (RCT) to evaluate the effectiveness of two family-focused interventions on weight loss (FI-IP and FI-RT). For the RCT, we will recruit 270 overweight / obese, primarily Latino (≥ 70%) adults, with a child (ages 8-17) from 3 rural primary care practices and various community sites and events in Frio and surrounding counties (i.e., Atascosa, Karnes, La Salle, Maverick, Medina, and Wilson).

5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

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Descriptive statistics will be used to summarize demographic data collected at baseline. Differences among the three arms will be evaluated using Fisher's exact test or Chi-square test for categorical variables and Kruskal-Wallis test or ANOVA F test for continuous variables. Variables that are significantly different across the three groups at baseline will be adjusted in the multivariate regression analysis. To determine the effect of the intervention on weight loss and energy balance behavior, the research team will use summary statistics to evaluate these outcomes (by FI-IP vs. control and FI-RT vs control) at 3-month post-intervention using Bonferroni adjustment. For continuous outcomes (Aim 2), we will use the t-test or Mann-Whitney U test, depending on the distributions of the outcomes. A GLMM modeling will be fitted to account for potential confounding variables at baseline (e.g., participants' demographics). In addition, based on GLMM modeling, the differences among the three arms will be evaluated simultaneously adjusted for confounding variables. Intention-to-treat analysis will be applied where multiple imputation with chained equations (MICE) approach will be used to handle missing data when needed. Models will be derived separately for adults (Aim 2) and children (secondary aim) although similar descriptive analysis and model fitting will be conducted. More specifically, to examine the intervention effect on improving body composition and behavior in children, in GLMM modeling, we will take into account the effects of parenting strategies and changes in home environment.

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Click on the check box (or double click and type an "X" if using Google Docs) each procedure included in your study.

A full description of all study procedures should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☐	**Bio-specimens**	☐	**Biometrics**	☐	**Registry or Repository**
☒	**Focus Group**	☐	**Genetic Analysis**	☐	**Genomic Data Sharing**

☐	International Research	☒	Interview/Survey	☐	MRI
☐	Protected Health Information	☐	Observation	☐	Radioactive Material/PET/Nuc. Med
☐	Record Review	☒	Sensors (Externally Placed)	☐	Sensors (Inserted)
☒	Video/Audio Recording	☐	X-Ray/CT		

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.

A full description of all study interventions should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☒	Behavioral	☐	Device	☐	Drug/Biologic

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Click on the check box (or double click and type an "X" if using Google Docs) each activity that requires oversight from additional UT committees.

☐	Energy introduced to the subject (electrical, magnetic, light)	☐	Human embryonic, human induced pluripotent, or human totipotent stem cells;	☐	Radiation exposure without direct clinical benefit

	or human gametes or embryos	

☐ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus IBC approval is needed.

a ☐ **Biological samples collected will not be stored on UT sites and another agency has responsibility for biospecimen safety.**

b **IBC Protocol Number**

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10 **Alternatives to Participation in This Study**

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STUDY PROCEDURE DESCRIPTION

11 **Procedure Description**

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- Provide a description of all research procedures being performed and when they are performed, in sequential order.
- All research measures/tests that will be used and state if questions or measures are standardized or published (upload copies of all surveys, scripts and data collection forms)
- Secondary data or specimens that will be obtained, how they will be collected, and how they will be used
- Where each activity will take place, the duration of each, and who will perform each activity
- Include time commitment of participants

To input text, click in the light grey area below.

Aim 1 activities which take place in Year 1 are community-engaged formative studies conducted to transform an existing community-based program into two forms that are

appropriate in a rural setting. Program activities and focus groups will take place at community sites in Frio County, Texas. The YMCA of Greater San Antonio will deliver the existing Y Living program in Frio County at community sites (e.g., Frio County cooperative extension office) selected by the Frio County Translational Advisory Board (Frio TAB) with support from the South Central Area Health Education Center.

Aim 2 (Years 2-5) activities consists of a 3-arm RCT to evaluate the effectiveness of two family-focused intervention on weight loss (FI-IP and FI-RT). For the RCT, we will recruit 270 overweight / obese, primarily Latino (≥ 70%) adults, with a child (ages 8-17) from 3 rural primary care practices and various community sites and events in Frio and surrounding counties. Research staff trained in human subjects research will recruit study participants in several ways as detailed in the Recruitment section below. Research staff will share a study recruitment flyer with prospective participants and assess eligibility using the eligibility screening form. Upon completion of baseline assessments, adult participants will undergo a 1-week run-in period, in which participants will be asked to complete several tasks that are similar to the FI-RT components (i.e., log food and beverage intake for 7 days in online diary, complete one online lesson) to ensure program compliance. If adult participants meet run-in criteria (i.e., log food and beverage for at least 4 of 7 days, complete online lesson), then we will randomize parent-child pairs to FI-IP (n=90), FI-RT (n=90), or Control (n=90). The primary outcome, weight loss in adults, will be assessed by measurements at baseline, 3, 6, and 12 months. Secondary outcomes, energy balance behaviors (PA and dietary intake), will be assessed at the same time points. We will also assess children at baseline, 3, 6, and 12 months to determine the impact of participation on primary and secondary outcomes. The study will be conducted in six cohorts (45 parent/child index pairs) to make group size more conducive to education, facilitate active participation, and allow efficient use of staff resources. Each cohort will be divided evenly across the three study arms:

1. In-person sessions with rural families (FI-IP)
   Parent-child pairs assigned to the FI-IP will participate in 24 health education sessions, 24 exercise sessions, 3 Wellness Consultations (WC), and 3 special events delivered by trained YMCA staff during the 12-week intervention and a 3-month maintenance period. The program will be delivered at a community site (e.g., Frio County cooperative extension office). The parent participant's initial weight loss goal will be 5% of baseline weight during the 12-week intervention. Energy balance behavioral goals include meeting the physical activity (PA) guidelines (150 minutes/week of moderate to vigorous physical activity (MVPA)) and decreasing caloric intake (≥500 kcal/day). The child participant's goal is to meet the energy balance behavior guidelines of "5-2-1-

0": 5 servings of fruits and vegetables per day, <2 hours per day of TV, 1 hour of PA each day, and zero sugar-sweetened beverages. Children will not have a weight loss goal.

2. Remote technology-based intervention (FI-RT)
   FI-RT is designed as a parallel form of the FI-IP and will be delivered by a health educator (HE) using technology-based delivery methods (tablet computers, Internet, and smartphones).
3. Control Group
   Parent-child pairs assigned to the control condition will attend an orientation session with the practice facilitator at the community program site. The practice facilitator will: 1) disclose randomization status; 2) provide standard health education materials (e.g., MyPlate and other nutritional guidelines), a community resource guide, and encourage the adult participant to follow-up with their primary care provider for office-based counseling; 3) review the assessment schedule; and, 4) register on MessageSpace so they can receive texts. Primary care providers may choose to work with the adult participant per their usual care practices. In order to retain control participants, they will receive weekly general health awareness texts that are aligned with national public health observances as well as texts to remind them of upcoming assessments.

COVID-19 Restrictions:
During the time-period where limitations are placed on in-person interactions, participants will only be randomized to the remote technology and control arms. The in-person intervention will not take place while university COVID-19-related restrictions are in effect. After the university releases restrictions on in-person research activities, researchers may resume in-person activities and/or continue optional telepresence interactions. All research activities can be conducted remotely.

Data Collection
Measurement takes place at several community sites in Frio County, including the AgriLife Community Center in Pearsall, the Pearsall Public Library, and the Frio County Regional Hospital. Measurements at baseline, 3-month, 6-month, and 12-month include 2 to 3 visits (at each time point) to be completed within a 2 to 3 week period. Visits will be scheduled on a day/time of the participants' choosing. Total time will be approximately 3 hours. If participants are unable to complete assessments in-person, data collectors will conduct assessments with participants via phone call.

The visits will consist of:

Visit 1: Review and sign informed consent, parent permission form, and child assent form. In this visit, data collection will consist of a brief questionnaire on parent demographics, parenting strategies, home and neighborhood environment, quality of life, height, weight, waist circumference measurements for parent and child, and instructions on wearing of accelerometers (both parent and child) for at least 12 hours over a period of 7 days. This visit will take 90 minutes.

Visit 2: Study staff will collect the accelerometer. If the parent or child does not have enough wear-time on their accelerometer, we will ask them to wear the monitor another week, to try and collect sufficient data for analysis. Food Frequency Questionnaire (FFQ; diet), and questionnaires about physical activity, sleep and sedentary behaviors will be administered to both parent and child. This visit will take 60 minutes.

Visit 3 (if needed): Parents and/or children that needed to wear the accelerometer an additional week return the monitor. During this visit, parents and/or children can also complete surveys they were unable to at their last visit. This visit will take up to 30 minutes.

In-person assessments. Participants will be provided a tablet so they may self-administer the surveys (located on REDCap, a secure electronic database), with the exception of the FFQ, which will be interviewer-administered by research staff.

Assessments by phone. Research staff will call participants on a predetermined day/time. While on the phone with the research staff, participants will be emailed a link to the surveys on REDCap, with the exception of the FFQ, which will still be interviewer-administered by research staff. Research staff will remain on the phone while participants complete the survey for that visit in case the participant has any questions or runs into technical issues.

Temporary procedures during COVID-19 social distancing policies:
During this period, participants will complete all assessments by telephone or Zoom interviews. We do not anticipate the total time to complete assessments to change. Accelerometers will be mailed to participants after the first telephone interview with instructions on how to wear it and how to assist their child in wearing it. We will provide return postage and advise parents to return them after two weeks of wear. Time for assessments by phone will be flexible based on the needs of parents. If they prefer to divide the first 2 hour visit into two 1 hour visits, we will accommodate that. However, the amount of incentives will remain the same. We propose to resume the

previously approved procedures once social distancing policies are lifted and UT IRB approves face-to-face protocols for any new participants after that point.

During the time-period where limitations are placed on in-person interactions, researchers will conduct all recruitment, consent, data collection, and intervention activities with participants using the remote procedures described throughout the protocol rather than any procedure described that would require in-person interaction. After the university releases restrictions on in-person research activities, researchers may resume in-person activities and/or continue optional telepresence interactions. All research activities can be conducted remotely.

Measures

a. Weight

Weight will be measured to the nearest 0.1 kg and body fat percentage will be measured by bioelectrical impedance analysis (BIA) using the foot-to-foot pressure contact electrode BIA technique using a portable Tanita Body Composition Analyzer following standard protocol. Weight will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

b. Height

Height will be measured to the nearest 0.5 cm and will be obtained using a stadiometer. Participants will be asked to remove their shoes and heavy clothes prior to both measurements. BMI will be calculated as weight (kg)/height squared (m2) for adults and BMI percentile for age and gender for children. BMI in combination with waist circumference is considered a reliable measure of obesity and visceral fat. BMI will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

c. Waist circumference

Waist circumference (minimum waist girth) will be measured to the nearest 0.1 cm using a retractable, tension-controlled metal tape measure at the midway between the right iliac crests and the lower ribs when the subject is standing erect with feet together. All measures will be conducted twice, if there is not agreement with in 0.5 cm, a third measurement will be done and the average of the two closest measures will be used. Waist circumference will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

d. Physical Activity (Objectively Measured)

Accelerometry has been shown to provide reliable and valid PA estimates for adults and children. Parent and child PA level will be assessed using the Actigraph

accelerometers worn for 7 consecutive days recording in 15-second blocks. Participants must wear the accelerometer for at least 12 hours per day and on at least 4, including on weekend days, of the 7 days for reliable measurement of activity. Total minutes per day in MVPA and sedentary activity will be computed with MeterPlus Software. Monitored physical activity will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

e. Physical Activity (Self-report)

To characterize adult participants' type, pattern, nature, and amount of PA, a comprehensive self-report measure will be administered called the Community Health Activities Model Program for Seniors (CHAMPS). The CHAMPS is a 41-item self-report measure of PA originally developed for older adults that has been used with the general adult population. Age-specific items will be modified to be more age-neutral (e.g., replacing "visit a senior center" with "visit a community center"). CHAMPS measures total average energy expenditure per week and minutes per week of moderate and vigorous activities. For children, we will use the Block Kids Physical Activity Screener for school-age children and adolescents. The screener asks about frequency and duration of activities in the past 7 days with 9 items about leisure and school activities, chores and part-time jobs. It also asks about sedentary behavior (time spent with TV, video games, and Internet). Perceived physical activity will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

f. Dietary Intake

We will use a validated Block Food Frequency Questionnaire (FFQ) for adults and children (2014 FFQ for Adults and 2004 FFQ for Kids ages 8-17) (see https://nutritionquest.com/assessment/list-of-questionnaires-and-screeners/). The correlation between the FFQ and 24-hr recalls for energy intake (0.5) and nutrients (≥ 0.4) are statistically tolerable. The FFQ is interviewer-administered using a visual portion-size graphic to facilitate accurate estimation of quantities consumed. This questionnaire estimates usual and customary intake of a wide array of nutrients and food groups. Dietary intake will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

g. Quality of Life

The 12-Item Short Form Health Survey (SF-12) will be used to measure general quality of life. The SF-12 replicates the physical and mental summary scales of the SF-36, explaining over 90% of the fluctuations in each. The SF-12 survey will be administered at baseline, month 3, month 6 and month 12 for adults only.

h. Home Environment

This validated survey measures availability, accessibility, parental role modeling, and parental policies related to PA, fruits, vegetables, and sugary drinks and snacks. This instrument has been validated for use with Latino families. The Home Environment survey will be administered at baseline, month 3, month 6 and month 12 for adults only.

i. Parenting Strategies

We will use the Parenting Strategies for Eating and Activity Scale to assess parenting strategies associated with children's dietary and activity-related behaviors in the home (i.e., limiting time child spends watching TV, tracking high-fat foods, rewarding good behavior with sweets). This survey has been validated in multiple samples of Latina mothers, and has been found to be valid and reliable in measuring Latino parenting strategies related to children's dietary and activity-related behaviors. A modified version has been developed to be answered by children 7 years and older. Parents will assist in completion of the questionnaire for younger children. The Parenting Strategies survey will be administered at baseline, month 3, month 6 and month 12 for adults and children.

j. Family Readiness

This survey will be administered to parents at baseline to assess readiness to commit to a healthy lifestyle change (i.e., likelihood that family could support a weight-maintenance program for child and the estimated length of time parent and child could commit to a healthy lifestyle change). The Family Readiness survey will be administered at baseline for adults only.

k. Demographics

This survey collects data from the parent on parent acculturation (i.e., four-item Acculturation scale, country of birth, and years in the U.S.), socioeconomic status (i.e., parent education, income, employment, health insurance, and food insecurity), health literacy (Short Test of Functional Health Literacy in Adults (S-TOHFLA)) and family's medical history of co-morbidities (i.e., diabetes, high blood pressure, heart disease). The demographic survey will be administered at baseline for adults only.

l. Perceived Stress

The PSS-10 scale examines the degree to which specific situations are deemed as stressful in the past week. The PSS-10 is well validated and has been used in many studies examining the association between stress and health. The Home Environment survey will be administered at baseline, month 3, month 6 and month 12 for adults only.

m. Depression

The 10-item Center for Epidemiological Studies Depression Scale (CES-D is a self-report scale designed to measure depressive symptomatology in the general population. The CES-D has been found to have high internal consistency, moderate test-retest reliability, and strong construct validity across samples from the general population with a wide variety of demographic characteristics. Depression will be measured at baseline, month 3, month 6 and month 12 for adults only.

n. Self Efficacy

Adult and child participants will self-report self-efficacy for physical activity and diet. Adults will complete the self-efficacy scale for exercise behaviors (12 items) and the eating habits confidence scale (20 items), which have been widely used and have strong psychometric properties, with acceptable test-retest reliability, internal consistency, and demonstrated criterion-related validity. Children will complete an adapted version of the physical activity self-efficacy scale (8 items) and the diet self-efficacy (9-items), where they will rate how sure they are that they could eat healthy in various social, emotional, or normal situations. These surveys have also demonstrated acceptable reliability, internal consistency, and validity. Physical activity and diet self-efficacy will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

o. Social Support

Adult and child participants will self-report social support for physical activity and diet. The social support for physical activity scale (13 items), is a self-report scale where adult participants will rate the extent to which family and friends are supportive of physical activity changes. Children's perceptions of family and friend social support for physical activity will be assessed with 7 items where they will rate how often, during a typical week, a family member or friend supports various physical activities. Adults will rate how supportive their family and friends are of healthy eating behaviors using the social support and eating habits survey (10 items). Children will also complete a 5-item support for healthy eating survey where they rate the extent to which family (4 items) and friends (1 item) support healthy eating. All measures have shown acceptable test-retest reliability, internal consistency, and concurrent criterion-related validity. Physical activity and diet social support will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

p. Benefits and Barriers.

The Decisional Balance Scale for Physical Activity assesses perceived benefits (pros) and perceived barriers (cons) of PA. Decisional balance will be measured at baseline, month 3, month 6 and month 12 for adults only.

q. Self-Regulation
Adult and child participants will self-report self-regulation for physical activity and diet. The self-regulation for healthy eating survey includes two subscales, one for regulating calories and fat (15 items) and another for regulating fiber fruits, and vegetables (13 items). Children will complete an adapted version of this survey (13 items). Adult self-regulation for physical activity will be assessed with a 14-item scale that measures exercise planning, monitoring, and goal setting. Children's self-regulation for physical activity will be measured with a 6-item scale. These surveys have been shown to be reliable, internally consistent, and valid. Self-regulation for physical activity and diet will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

r. Sleep
Adult sleep habits, problems, and quality over the past month will be assessed using the Pittsburgh Sleep Quality Index (9 items). Child sleep habits will be assessed with 4 items. Surveys have shown good reliability, internal consistency, and validity. Sleep will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

s. Sedentary Behavior
Adult sedentary behavior will be assessed via 20 items that capture the typical amount of time adults spend engaging in various sedentary activities (e.g., watching T.V.) on a typical weekday and weekend. Child sedentary behavior on the weekend or weekday as well as their access to TV and computers will be assessed with 4 items. All measures have demonstrated acceptable internal consistency and good criterion validity. Sedentary behavior will be measured at baseline, month 3, month 6 and month 12 for both adults and children.

SUBJECT POPULATION

12 **Protected Subject Populations**

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐	**Active military personnel**	☒	**Children**	☐	**Decisionally impaired adults**

☐	Emancipated minors	☐	Fetuses	☐	Individuals with limited English proficiency
☐	Neonates	☐	Pregnant Woman	☐	Prisoners
☐	UT Students	☐	UT or Seton Staff/Employees		

13* Research Participant Information

Describe the research population.

**For multiple research populations (e.g., teachers, students, and parents), copy this section as necessary to describe your population.*

a Participant Group Name

To input text, click in the light grey area below.

Adults

b Minimum Age

To input text, click in the light grey area below.

21

c Maximum Age

To input text, click in the light grey area below.

65

d Inclusion Criteria

To input text, click in the light grey area below.

Aim 1: Adult is obese (BMI 30-39.0), self-identifies as Latino, and has/cares for one child (ages 8-17 years)

Aim 2: Adult is eligible if a) overweight/obese (BMI 25.0-60.0kg/m2); b) not currently enrolled in a formal weight loss program or taking weight loss medications; c) no restriction for physical activity (i.e., no significant physical disability, does not require assistance to walk); d) has a smartphone; e) speak and read English; f) one child aged 8-17 (with no regard to obesity status) residing with the parent full-time and willing to participate; and, g) resides in Frio, Medina, Atascosa, Wilson, Karnes, or La Salle Counties.

e Exclusion Criteria

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Adult is pregnant or plans to become pregnant in the next year or those who have contradictions identified by the Physical Activity Readiness Questionnaire (PAR-Q) and do not receive clearance from their physician.

f Additional Population Information

To input text, click in the light grey area below.

As we are interested in the impact of the intervention on Latino adults' weight and energy balance-related behaviors, this study will be conducted in counties that have a large percentage of Latino residents (i.e., ≥40%).

13* Research Participant Information

Describe the research population.

**For multiple research populations (e.g., teachers, students, and parents), copy this section as necessary to describe your population.*

a Participant Group Name

To input text, click in the light grey area below.

Children

b Minimum Age

To input text, click in the light grey area below.

8

c Maximum Age

To input text, click in the light grey area below.

17

d Inclusion Criteria

To input text, click in the light grey area below.

Child included in the study if the adults meets inclusion criteria

e Exclusion Criteria

To input text, click in the light grey area below.

Child only excluded if adult excluded from the study

f Additional Population Information

To input text, click in the light grey area below.

14 Total Sample Size

To input text, click in the light grey area below.

Aim 1: N = 30 (15 adults, 15 children)

Aim 2: N = 540 (270 adults, 270 children)

15 Sample size rationale

To input text, click in the light grey area below.

Our sample size calculation is based on the primary comparison for the primary outcome (i.e., Hypothesis from Aim 2: adult participants randomized to either FI-IP or FI-RT will achieve greater weight loss at 3-month post-intervention compared with adults in control group) after adjustment for two pre-planned comparisons (FI-IP vs. control; FI-RT vs. control). Based on our previous single-arm Y Living study, for those adult participants from the families with at least one adult and one child, the baseline average weight was 200 lbs and the average weight loss was 2.3 lbs (SD=6.7). With 60 adults in each arm (i.e., 180 in total), there is 95% power to detect a 5-lb difference in weight loss between FI-IP and control with a significance level of 0.025 using a two-sided two sample t-test with SD=7. Under the assumption that the weight loss is 0 in the control group, a 5-lb difference in weight loss between FI-IP and control means that this study is powered to detect a 2.5% difference in weight (200 lbs at baseline × 2.5% = 5 lbs weight loss) in the FI-IP arm, hence this study is more than adequate to detect a 5% intervention weight loss goal. For secondary outcomes such as physical activity (PA), we assume that the PA will remain the same at 3-month post-intervention in the control arm. Based on findings from a previous study (Y-Living), PA increased by an average of 50 minutes/wk in the FI-IP group (SD=100). With 60 adults in each arm, there is 68% power to detect a difference of 50 in PA change between FI-IP and control groups with a significance level of 0.025 using a two-sided two-sample t-test. The final sample size is inflated to 90 adults per arm (i.e., 270 parent-child pairs in total) to accommodate an attrition rate as large as 33%. In this study, randomization will be stratified by clinic. In the analysis plan, we will address the clinic effect by using a generalized linear mixed model (GLMM).

SCREENING AND RECRUITMENT

16 Identification and Screening

Click on the check box (or double click and type an "X" if using Google Docs) if true.

☒ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**

1. Oral or written communication with the prospective subject or LAR

2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 Research staff will use an Eligibility Screening Form (ESF), a multi-component form to identify prospective participants who meet eligibility criteria. Staff will administer ESF in person on tablets with internet access or remotely over the phone. Research staff will thank and dismiss those who refuse screening or do not meet eligibility criteria. Prospective participants who are referred to the study website (e.g., by a friend, family member, or the recruitment flyer) can click on a link that takes them to the ESF (housed on REDCap), which they can self-administer, or they can provide their contact information (i.e., name, telephone number, email address) in the study interest form. Research staff will call individuals who fill out the study interest form and administer the ESF over the phone. The ESF includes a physical activity readiness questionnaire (PAR-Q) to identify participants in the high-risk strata according to American College of Sports Medicine Guidelines for Exercise Testing and Prescription. Research staff will record names, telephone numbers, and email addresses for participants who meet eligibility criteria but require physician approval. Research staff will provide a letter to each participant's primary care provider (PCP) that identifies the medical condition indicated by the prospective participant during the eligibility screening as well as a Physical Activity Readiness MedX (PAR MedX) form. Based on their clinical judgment and their understanding of the study's physical activity requirements, PCP will complete the PAR MedX form to indicate approval for their patient to participate in the study. PCP-approved patients will receive a personalized letter signed by the PCP and a study brochure. The letter will describe the benefits of program participation to the patient, briefly introduce the study, and inform them that research staff will contact them by phone and/or email to discuss participation. Research staff will send a letter to non-approved patients explaining the reason for their ineligibility and invite them to participate in the Frio TAB, the local community advisory board that promotes health in Frio County. During the in-person or telephone screening session, research staff will ask the parent if they are willing to discuss with their child the possibility of that child joining the Healthy Frio project. If the parent replies, "No," the parent will not be eligible for the program. If the subject replies, "Yes," and meets the minimum eligibility to enter the study, research staff will schedule the participant-child baseline assessments. Research staff will contact eligible individuals who completed the screener via the study website to provide them with more information about the study and ask if they are interested in participating. If the subject replies, "Yes", then research staff will schedule the participant-child baseline assessments.

18 **Recruitment Overview**

Click on the check box (or double click and type an "X" if using Google Docs) all recruitment methods utilized for this research.

☒	E-mail	☒	Flyer
☒	In-Person	☒	Letter
☒	Social Media	☐	Research Pool
☒	Telephone/Text	☒	Snowball Sampling
☒	Web-post	☒	Word of Mouth

19 **Describe the recruitment process, including where recruitment will take place.**

Describe the recruitment procedures below.
To input text, click in the light grey area below.

This study was developed in collaboration with the Frio County Translational Advisory Board (TAB). For Aim 1 (Year 1) activities, the Frio TAB will recruit 15 parent-child pairs (15 parents, 15 children) through in-person interactions with their well-established network of local families in Frio County.

For Aim 2 (Year 2-5) activities, research staff will recruit in clinic and community settings and through social media.

i. Clinic Settings: Clinic providers and research staff have identified several recruitment approaches appropriate for this setting, as outlined below. NOTE: Clinic staff already have access to electronic medical records (EMR) through their role as clinic employees and will not gain special access to EMRs for the purpose of screening for this study. Further, clinic staff do not have roles as researchers for this study.

1. *Staff in Waiting Room*. On days when research staff are on-site at the clinic, clinic staff will use electronic medical records to conduct an informal pre-screening of the day's scheduled patients to identify patients who may be eligible for the study based on BMI and age. When a patient checks in for their scheduled appointment, clinic staff will inform the patient about the study in which the patient may be interested, distribute a recruitment flyer, and point out the research staff in the clinic who is conducting eligibility screenings. If the patient would like more information about the study, they may talk with research staff on-site and may undergo eligibility screening at

that time. Research staff will also approach individuals in the waiting room to ascertain if they would like to participate in a research study first by presenting a study recruitment flyer. The prospective participant does not need to have an appointment. If the prospective participant is interested in joining the study, research staff will initiate the eligibility screening protocol.

2. Contact Information Obtained by Clinic Staff. Clinic staff will identify and flag patients using electronic medical records to conduct an informal pre-screening. When a patient checks in for their scheduled appointment, clinic staff will inform the patient about the study, distribute a recruitment flyer, and, if the patient is interested, invite the patient to add their name and contact information (i.e. telephone number, email address) to a HIPAA-compliant form (each form is on a removable sticker; clinic staff will remove the sticker from the clipboard and place the sticker on a separate form stored in a private location). Clinic staff will verbally inform the patient that by adding their name to the form they are agreeing that the research staff may contact them by telephone and/or email. Clinic staff will provide the day's list of signups to the research staff using a secure email or give the information directly to the research staff the next time they are on-site at the clinic. Research staff will contact participants on the list by telephone and/or email to answer questions about the study and, upon agreement by the participant, begin the eligibility screening process.

3. Letter from Providers. Clinic staff will conduct an informal prescreening to identify and flag all eligible patients based on age criteria using electronic medical records. Clinic staff will send research staff an Excel sheet that includes names and addresses of flagged patients through a secure link to a password protected folder on UT Box. To minimize burden to clinic, research staff will send the recruitment letter that includes research staff contact information to all flagged patients.

ii. Community settings

1. Community Events
    a. The Frio TAB will identify community events (e.g., health fairs, market days, community awareness events) and provide a list of events to the study's Recruitment Coordinator quarterly.
    b. Research staff will set up a table at the community event, distribute the recruitment flyer and screen for eligibility. If the prospective participant does not have time to complete the eligibility screening in-person, the research staff will gather contact information (i.e. telephone number,

email address, mailing address) in order to conduct eligibility screening by phone at a later date.

c. If research staff are unable to reach prospective participants by phone (i.e. individual does not respond to phone calls or text messages from research staff), then an email will be sent to prospective participants that includes the study flyer and research staff contact information. Finally, if the prospective participant is unresponsive to email, a letter will be mailed to prospective participants that includes the study flyer, research staff contact information, and an insert encouraging individuals to participate in the study.

1. Referrals from past participants
   a. Research staff will ask current Healthy Frio participants to refer prospective participants (aged 21-65 years, with children aged 8-17 years) to the study by sharing the recruitment flyer, Facebook page, or study website, with family and friends who meet this criteria. Participants will be informed that the people they invite should be a relative or friend who lives within the geographic boundaries of the study (i.e., Frio, Maverick, Medina, Atascosa, La Salle, Wilson or Karnes Counties). The participant will receive an 8-week workout program developed by Healthy Rural Texas and $25 for each person (up to 3 people) that they recruit and who enrolls in the study, for a maximum of $75. Participants who refer an individual who is not eligible or does not enroll in the study will still receive the 8-week workout plan. To confirm that an individual was referred by a participant, the eligibility screening form will include questions asking: 1) how they heard about us, and 2) the name of the participant that referred them.
2. Newsletters and bulletins
   a. *Bulletins.* The Frio TAB will assist research staff in identifying community bulletins (e.g., churches, schools) in which the Healthy Frio study can be advertised to community members. Frio TAB members will: 1) reach out to community contacts via phone or email or 2) provide research staff with contact information (email or phone). TAB members and/or research staff will ask the community contacts to include a short advertisement about the Healthy Frio study (see Healthy Frio News Ad).
   b. *Community Newspaper*. The Frio TAB will assist research staff in placing an ad about the study in the Frio-Nueces Current, a local newspaper serving both Frio and La Salle counties. The study ad will contain information about participation in the study as well as contact

information (see Healthy Frio News Ad). The ad will run for approximately 4 weeks, twice a year during recruitment periods.

3. Community Engagement Database
    a. Research staff will reach out to community members who registered with the Community Health Topic Survey and Research Registry (CHaTs) Area Health Education Centers (AHEC) database.
    b. The CHaTS AHEC database is used to recruit adults who are interested in participating in research studies.
    c. Website for more information about the CHaTS AHEC database: https://stahec.uthscsa.edu/projects/south-texas-area-health-education-center%E2%80%99s-community-health-topic-survey-and-research
4. Healthy Rural Texas Website
    a. The study website (www.healthyruraltx.com) contains study information, testimonials from participants who have completed the study, photos of intervention activities, a link to our eligibility screener, and a study interest form.
    b. The website link will be shared with community partners and currently enrolled study participants so that they, in turn, share the website with family and friends via text message, email, and/or social media.
    c. Research staff will encourage potential participants that do not have time to complete the eligibility screening to visit the study website and hand them the recruitment flyer, which has a QR code linked to the study website.

ii. Social Media
1. Facebook Page
    a. The study Facebook page () contans study information, staff contact information, and a link to our study website and eligibility screenng form.
    b. Research staff will share the Facebook page with community partners and currently enrolled study participants so that they, in turn, share the Facebook page with family and friends via text message, email, and/or other social media.

20 Consent Overview

Click on the check box (or double click and type an "X" if using Google Docs) all applicable items.

☒	Obtaining Written Informed Consent	☒	Requesting a Waiver of Documentation of Informed Consent
☐	Requesting a Waiver of Informed Consent	☐	Requesting an Alteration of the Required Elements of Informed Consent
☒	Obtaining Child Assent	☐	Obtain Consent Using a Short Form with a Witness

21 Consent and Assent Processes

Provide a detailed description of the consent process including who will obtain consent, where, and when consent will occur in such a manner that participants have sufficient time for adequate consideration.

To input text, click in the light grey area below.

For Aim 1, research staff will provide information sheets and a verbal explanation of Aim 1 activities to participants. Two information sheets were uploaded to IRB Access: 1) FI-IP (questionnaires and focus groups), 2) FI-RT (meetings). Research staff will distribute information sheets to adult participants. Signatures from adult participants will not be required. However, child participation will require a parent/guardian signature as well as a signature from the child on a child assent form. All signed documents will be securely stored in a locked filing cabinet in the Project Coordinator's office (GWB 2.316)

For Aim 2, research staff will obtain informed consent at the start of the baseline assessment appointment before administering any baseline assessments. There may be time between eligibility screening and obtaining consent. Staff will obtain consent/assent from the parent-child pair prior to conducting baseline assessments. The consent/assent forms describe the study and associated risks and benefits according to UT IRB protocols. The consent forms are self-explanatory and written at an appropriate literacy level for the study population. Research staff will inform participants that their participation is voluntary in nature, they may cease participation at any time, and refusal to participate in the research study will not affect their relationship with UT Austin or their provider. Parents and children will have an opportunity to ask questions.

i. In-Person: If the parent and child both agree to participate, staff will ask them to sign the forms. We will capture all signatures electronically on a tablet computer in REDCap in order to immediately secure the record and enhance protection of participant privacy by avoiding the instance of a signed paper document. The parent will sign two forms: Consent for Adult Participation in Research and Parental Consent for Child Participation in Research; the child will sign the Assent for Participation in Research form. Research staff obtaining consent will then sign the forms. The parent will receive a copy of all three forms for reference. Immediately after the consent/assent forms are signed, baseline assessments will commence.

ii. Remote (During COVID-19 pandemic): Research staff will obtain verbal consent from both the parent and the child over the phone. Verbal consent will be documented in REDCap, and research staff will sign a statement stating that parent and child verbally consented and assented to participating in the study.

22 Consent and Translation

Click on the check box (or double click and type an "X" if using Google Docs) to indicate that consent will be translated.

☐ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the translation process, either 21 or 22.

23 ☐ **The consent documents will be translated by a certified translator.**

24 ☐ **A non-certified translator will translate the consent documents.**

If selected, complete the next two questions below.

i Describe the translator's qualifications

To input text, click in the light grey area below.

ii ☐ **Another individual will confirm that the translation is accurate and appropriate.**

Waiver of Documentation of Informed Consent

To approve a waiver of documentation of informed consent, one of the following options below must be justified by the researcher.

Only complete the sections below if requesting a waiver of documentation of informed consent. *If not requesting a waiver of documentation of consent, skip to 27.*

Please choose one waiver option and provide additional information as prompted. The Office of Research Support and Compliance recommends using Waiver Option 2 in most cases.

25 Waiver Option 1

Provide confirmation for the following criteria and follow the additional instructions.

Additional Instructions:
1. Include this choice in the informed consent form.
2. Articulate the destruction process for signed consent forms in the privacy and confidentiality section.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The only record linking the subject and the research would be the consent document.**

b ☐ **The principal risk would be potential harm resulting from a breach of confidentiality.**

c ☐ **Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.**

26 Waiver Option 2

Provide confirmation for the following criteria and follow the additional instructions.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☒ **The study is minimal risk.**

b ☐ **Written consent would not be required outside the research context.**

27 Waiver Option 3

Provide confirmation for the following criteria and provide additional information as requested.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

b **Describe the cultural group or community.**

To input text, click in the light grey area below

c ☐ **The research presents no more than minimal risk of harm to subjects.**

d ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

e **Describe mechanism for documenting that informed consent was obtained**

To input text, click in the light grey area below

Waiver or Alteration of Informed Consent

To approve a waiver or alteration of informed consent all of the following criteria below must be justified by the researcher.

Only complete the sections below if requesting a waiver of informed consent. *If not requesting a waiver or alteration of consent, skip to 31.*

28 **The research involves no more than minimal risk to the subjects.**

To input text, click in the light grey area below

29 **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

To input text, click in the light grey area below

30 **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent).**

To input text, click in the light grey area below

31 **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

To input text, click in the light grey area below.

Deception and Debriefing

Only complete the sections below if requesting an alteration of informed consent that involves deceiving research participants. *If this study does not involve deception, skip to 35.*

See IRB Policies and Procedures Section 15 for a description of deception.

Click on the check box (or double click and type an "X" if using Google Docs).

32 ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive to subject to the nature of the study).**

33 ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

34 **Describe the nature of deception and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

35 **Describe debriefing procedures.**

To input text, click in the light grey area below.

BENEFITS

36 **Benefits to Society**

Describe the scientific and societal benefit(s) below.

To input text, click in the light grey area below.

Latino and rural populations are disproportionately impacted by obesity. While there are no direct benefits from participation, we hope that participants will learn about healthy eating and how to be more physically active with the health education they receive. We hope the information learned from this study will benefit other people in the future and will help develop innovative healthy lifestyle programs that are culturally appropriate for rural Latinos and address weight and energy balance-related behaviors such as physical activity and diet.

Benefits to Participants

Click on the applicable check box (or double click and type an "X" if using Google Docs).

37 ☒ **There is no anticipated direct benefit to participants.**

38 ☐ **There are anticipated benefits to participants.**

39 **If applicable, describe the potential direct benefits to participants.**

To input text, click in the light grey area below.

RISKS

40 **Describe the risks associated with each activity in this research**

To input text, click in the light grey area below.

Participants will be subject to minimal risks throughout this study. Potential risks are:

1. Loss of privacy during focus groups (Aim 1) in which participants provide feedback about the program to researchers in a group setting. Researchers cannot guarantee that participants of the group will not reveal each other's contributions to the group discussion once it ends.
2. Loss of confidentiality of data collected on brief written session evaluations and transcripts of group meetings (Aim 1) or data collected (e.g., weight, height, ethnicity, date of birth) for Aim 2.
3. Loss of time due to assessments and intervention activities (primarily for the parent).
4. Medical complications resulting from physical activity (PA). The major risks of exercise are orthopedic, primarily of the overuse category and can usually be treated by rest and change in the mode of PA. Minor problems may occur, including temporary soreness or irritation of muscles, tendons, and joints. The risks of a moderate intensity PA program are minimal.

41 **Describe how each risk is mitigated/minimized.**

To input text, click in the light grey area below.

1. Extra measures will be taken to protect each participant's privacy. The researcher will begin the focus group by asking participants to verbally agree to keep everything discussed in the room confidential and will remind them at the end of the group not to discuss the material outside. Only researchers will have access to the data collected. Written program session evaluations and any transcripts of the focus group will be destroyed at the end of the study.

2. Several steps will be taken to protect confidentiality, including: coding potential identifiers, storing written materials in a locked file cabinet, collecting the majority of information via electronic database, storing master list of participant names separate from numerical identifiers, etc. A detailed description is outline in the Privacy and Confidentiality section.
3. Research staff will communicate to participants the time estimates and schedules of study activities for assessments and intervention activities.
4. We will carefully exclude participants in the high-risk strata according to American College of Sports Medicine Guidelines for Exercise Testing and Prescription. ACSM does not recommend exercise testing for those in low or moderate CHD risk strata. We will have regular contact with intervention participants and will monitor safety at these contacts.

Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.

Click on the check box (or double click and type an "X" if using Google Docs).

42 ☒ **This study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

43 ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan/policy to monitor for safety.**

Complete Data Safety Monitoring Details (44-51).

44 ☐ **This study has a Data Safety Monitoring Board (DSMB).**

Complete Data Safety Monitoring Details (44-51) or upload this study's Data Safety Monitoring Board's charter.

Data Safety Monitoring (Details)

45 **How is safety information collected?**

To input text, click in the light grey area below.

46 **When will safety data collection start (for each participant or for the whole study, as applicable)?**

To input text, click in the light grey area below.

47 **How frequently will safety data be collected?**

To input text, click in the light grey area below.

48 **Who will review the data for safety?**

To input text, click in the light grey area below.

49 **How frequently will data be monitored for safety concerns?**

To input text, click in the light grey area below.

50 **What data will be reviewed?**

To input text, click in the light grey area below.

51 **State the frequency or periodicity of the review of cumulative data?**

To input text, click in the light grey area below.

52 **State any conditions that would trigger an immediate suspension of the research.**

To input text, click in the light grey area below.

Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to 56.*

Include this information in your consent form.

53 **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

To input text, click in the light grey area below.

Participants can withdraw from the study at any time for any reason. Participants will also be withdrawn if they become pregnant or move out of state during the study period. Because the study is minimal risk it is unlikely we would withdraw a participant from the study for safety purposes.

54 **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

55 **Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

To input text, click in the light grey area below.

REQUIRED DISCLOSURES

Required Consent Disclosures

Identify each element below that may require additional information to be disclosed in the consent form.

Click on the check box (or double click and type an "X" if using Google Docs).

56 ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**

57 ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

58 ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

59 **Articulate methods for addressing and reporting incidental findings, if applicable.**

To input text, click in the light grey area below.

PRIVACY AND CONFIDENTIALITY

60 Privacy

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants.

Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.

To input text, click in the light grey area below.

Research team trained in human subjects research and ethics will protect participants' privacy by 1) Removing personally identifiable information from study records (using unique identification number for each participant for all paperwork instead of his/her name). 2) Any written material will not use names or other information that identifies participants unless we obtain participant's written permission. 3) Participants in focus groups (FI-IP) and meetings with researchers (FI-RT) will be advised to maintain keep any private information learned during group meetings confidential.

Confidentiality and Data Security Plan

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the confidentiality and data security plan and provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.

61 ☒ Identifiers will be coded to protect confidentiality.

61a If true, state how data is coded and where identifiers are stored.

To input text, click in the light grey area below.

For Aim 1 (Year 1), the only data is qualitative data collected through brief written session evaluations and group meetings designed to elicit participant and TAB (community) feedback on the program. We will take notes at group meetings; notes will not contain personally identifiable information about individual participants. Participants will not be asked to include any personally identifying information in their written evaluations.

For Aim 2 (Year 2-5), both quantitative and qualitative data will be collected through surveys, questionnaires, and various anthropologic measurements. Most of the data will be recorded using electronic databases. Some written material, such as; consent forms, assent forms, sign in sheets, compensation forms, and BMI printouts will be protected by being securely stored in a locked filing cabinet in the Measurement Coordinator's office (University Health Systems, Robert B. Green Historical Building, A423).

Although a loss of confidentiality would likely not compromise the subject's privacy, the following steps will minimize loss of confidentiality for this study's subjects: 1) research staff collecting data will be trained and certified risk in human subjects research and ethics; 2) participants' names will not appear on measurement materials; instead, a unique numerical identifier will be assigned to each participant and used on electronic and written materials; 3) measurement staff will also be given a unique numerical identifier to track proper confidentiality practices; 4) all paper records will be stored in a locked file cabinet; 5) a master list that links participants' names to numerical identifiers will be stored in a separate locked cabinet; 6) electronic records will be stored on a password-protected database and backed up on a secured server, and 7) we will perform weekly data checks and quality control reports.

62 ☒ **Identifiable data will be destroyed.**

62a If true, describe destruction plan and timeline

To input text, click in the light grey area below.

The master list will be destroyed 3 years after completion of the study at which time the paper record will be shredded. Study data that does not contain personal identifying information about individual participants will be retained by the PI indefinitely to allow for review and reanalysis of data. Record retention and destruction will take place in compliance with NIH policies governing record maintenance, retention and applicable regulations.

63 ☐ **Identifiable data will not be destroyed.**

63a If true, provide rationale for retaining identifiable data indefinitely.

To input text, click in the light grey area below.

64 Data Access

Click on the check box (or double click and type an "X" if using Google Docs) for each group of individuals that will have access to study data.

If you plan on creating a repository, complete the repository form as well.

☒ Study Team Members	☐ External Collaborators	☐ Data coordinating center
☐ Sponsor	☒ Future Sharing with other researchers	

☐ **Others**

Describe below. To input text, click in the light grey area below.

65 **Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data**

To input text, click in the light grey area below.

Our funder endorses the sharing of final research data to support the timely release and sharing of final research data from NIH-supported studies for use by other researchers in an effort to ensure effective dissemination of findings and lessons learned. This study will be registered on the clinicaltrials.gov website, and our de-identified data will be available for research educational purposes upon request, once the data have been analyzed to investigate study aims.

Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.

If a Certificate of Confidentiality is not applicable for this study, skip to 68.

66 ☐ **The study requires a Certificate of Confidentiality.**

67 ☐ **NIH has issued a Certificate of Confidentiality for this study.**

68 ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

COMPENSATION AND COSTS

Compensation

Click on the check box (or double click and type an "X" if using Google Docs).

69 ☒ **Subjects receive compensation.**

70 ☐ **Subject will not receive compensation.**

Skip to question 74 if subjects will not receive compensation.

71 **Total Amount of Compensation**

To input text, click in the light grey area below.

Aim 1: Up to $180 (participants in FI-IP); Up to $360 (participants in FI-RT)
Aim 2: Up to $365

72 **Type of Compensation**

Click on the check box (or double click and type an "X" if using Google Docs) for each form of compensation that will be provided.

☒	Cash	☐	Check	☒	Gift Card
☐	Course Credit	☐	ClinCard	☒	Tango Card

☒ **Other**

Describe, To input text, click in the light grey area below.

Secure mobile payment system (e.g., Venmo or Paypal)

73 **Proration Schedule**

To input text, click in the light grey area below.

Families participating in Aim 1 FI-IP activities will complete questionnaires and participate in 3 focus groups to provide feedback on program implementation and suggest revisions. Each participating family will receive $60 per focus group. Families participating in Aim 1 FI-RT activities will test and inform development of the intervention's remote technology components in 6 meetings with researchers. Each participating family will receive $60 per meeting.

For Aim 2, incentives will be distributed as standardized assessments are completed. Upon completing assessments at baseline, each parent-child dyad will receive a $50 incentive. Incentive amount will increase with each subsequent assessment completed. Each parent-child dyad will receive $60 for completion of 3-month assessments, $80 for completion of 6-month assessments, and $100 for completion of 12-month assessments. Participants may receive an additional $75 for referring 3 individuals who screen eligible and enroll in the program.

74 ☒ **Amount of compensation and its form is reasonable for this population for the activities requested of them.**

75 **Costs**

Click on the check box (or double click and type an "X" if using Google Docs) each applicable item regarding costs.

☒	Participants will have no costs associated with this study		
☐	Standard of care procedures contributing to study data	☐	Research procedures not associated with standard of care
☐	Administration of drugs / devices	☐	Study drugs or devices
☐	Transportation and parking		

76 **Describe all costs below.**

To input text, click in the light grey area below.