# IRB-HSR PROTOCOL

## Investigator Agreement

BY SIGNING THIS DOCUMENT, THE INVESTIGATOR CONFIRMS:

1. I am not currently debarred by the US FDA from involvement in clinical research studies.
2. I am not involved in any regulatory or misconduct litigation or investigation by the FDA.
3. That if this study involves any funding or resources from an outside source, or if you will be sharing data outside of UVA prior to publication that you will contact the Dean's office regarding the need for a contract and letter of indemnification. If it is determined that either a contract or letter of indemnification is needed, subjects cannot be enrolled until these documents are complete.
4. The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the IRB including any modifications, amendments or addendums submitted and approved by the IRB throughout the life of the protocol.
5. That no personnel will be allowed to work on this protocol until they have completed the IRB-HSR On-line training and the IRB-HSR has been notified.
6. That all personnel working on this protocol will follow all IRB-HSR Policies and Procedures as stated on the IRB-HSR Website http://www.virginia.edu/vprgs/irb/ and on the School of Medicine Clinical Trials Office Website: http://knowledgelink.healthsystem.virginia.edu/intranet/hes/cto/sops/sop_index.cfm
7. I will ensure that all those delegated tasks relating to this study, whether explicitly or implicitly, are capable through expertise, training , experience or credentialing to undertake those tasks.
8. I confirm that the implications of the study have been discussed with all Departments that might be affected by it and have obtained their agreement for the study to take place.
9. That no subjects will be recruited or entered under the protocol until the Investigator has received the signed IRB-HSR Approval form stating the protocol is open to enrollment
10. That any materials used to recruit subjects will be approved by the IRB-HSR prior to use.
11. That all subjects will sign a copy of the most current consent form that has a non-expired IRB-HSR approval stamp.
12. That any modifications of the protocol or consent form will not be initiated without prior written approval from the IRB-HSR, except when necessary to eliminate immediate hazards to the subjects.

13. Any significant findings that become known in the course of the research that might affect the willingness of subjects to enroll or to continue to take part, will be promptly reported to the IRB.
14. I will report immediately to the IRB any unanticipated problems involving risk to subjects or to others including adverse reactions to biologics, drugs or medical devices.
15. That any serious deviation from the protocol will be reported promptly to the Board in writing.
16. That any data breach will be reported to the IRB, the UVa Corporate Compliance and Privacy Office , UVa Police as applicable.
17. That the continuation status report for this protocol will be completed and returned within the time limit stated on the form.
18. That the IRB-HSR office will be notified within 30 days of a change in the Principal Investigator or of the closure of this study.
19. That a new PI will be assigned if the current PI will not be at UVA for an extended period of time. If the current PI is leaving UVa permanently, a new PI will be assigned PRIOR to the departure of the current PI.
20. All study team members will have access to the current protocol and other applicable documents such as the IRB-HSR Application, consent forms and Investigator Brochures.
21. Signed consent forms and other research records will be retained in a confidential manner. Records will be kept at least 6 years after completion of the study.
22. No data/specimens may be taken from UVa without a signed Material Transfer Agreement between OSP/SOM Grants and Contracts Office and the new institution. Original study files are considered institutional records and may not be transferred to another institution. I will notify my department administration regarding where the originals will be kept at UVa. The material transfer agreement will delineate what copies of data, health information and/or specimens may be taken outside of UVa. It will also approve which HIPAA identifiers may be taken outside of UVa with the health information or specimens.
23. If any member of study team leaves UVa, they are STRONGLY ENCOURAGED to use Exit Checklist found on IRB-HSR website at http://www.virginia.edu/provost/facultyexit.pdf.

<u>The IRB reserves the right to terminate this study at any time if, in its opinion, (1) the risks of further experimentation are prohibitive, or (2) the above agreement is breached.</u>

**<u>Investigators' Experience</u>**

Dr. Zoellner is an associate professor who has been conducting human subjects research, similar to this application, for over 12 years. She has specifically been working with this study population on obesity-related research initiatives for over 7 years. She was MPI of the prior NIH grant leading to this application and oversaw all IRB aspects of

that previous study. Dr. Zoellner has a reputable history of managing large scale, community-based, lifestyle trials that target nutrition and physical activity behaviors. She is also well-published on processes for building and evaluating community capacity.

## Signatures

**Principal Investigator**

| _____ | _____ | _____ |
|---|---|---|
| Principal Investigator Signature | Principal Investigator Name Printed | Date |

The Principal Investigator signature is ONLY required if this is a new protocol, a 5 year update or a modification changing the Principal Investigator.

**Department Chair**

BY SIGNING THIS DOCUMENT THE DEPARTMENT CHAIR AGREES:

1. To work with the investigator and with the board as needed, to maintain compliance with this agreement.
2. That the Principal Investigator is qualified to perform this study.
3. That the protocol is scientifically relevant and sound.

| _____ | _____ | _____ |
|---|---|---|
| Department Chair or Designee Signature | Department Chair or Designee Name Printed | Date |

The person signing as the Department Chair cannot be the Principal Investigator or a sub-investigator on this protocol.
The Department Chair or Designee signature is ONLY required if this is a new protocol or a modification changing the Principal Investigator.

## Brief Summary/Abstract

This is a single site study and all Co-Investigators and study staff will follow this same protocol. The **primary aim** of this comparative effectiveness study is to determine the relative effectiveness in child BMI z-scores at 3, 6, and 12-months post baseline of *i*Choose+ versus *Family Connections*. Both *i*Choose+ and *Family Connections* are evidence- and family-based obesity treatment programs that target nutrition and physical activity behaviors, but vary in program intensity and duration.

This research targets 174 parent/child dyad from the medically underserved Dan River Region. The primary end point is childhood BMI z-scores at 6-months. Families will be identified through medical chart review from the SOVAH Pediatrics (formerly Children's Health Care Center) and PATHS in Danville and Chatham, VA, as well as through responding through local advertisements or flyers. Inclusion criteria include a child between 5-12 years old with a BMI percentile that is 85% or greater for their age

and gender, live in the Dan River Region, are English speaking, and parents/caregivers ≥18 years of age who provide informed consent.

**Secondary aims** are to determine (1) reach/representativeness, fidelity, and implementation costs, (2) community capacity for implementation and sustainability, (3) relative impact on family eating/physical activity and parental weight, and (4) relative adherence and potential dose response relationships.

Related to the capacity aim, the Community Advisory Board (CAB) includes about 20 local Dan River Region health care and community partners and academic researchers. Some members of the CAB will be responsible for screening, recruit, enrollment/data collection, and program implementation and are included as study investigators. The Parent Advisory Team (PAT) includes about 15 parents who are past iChoose program participants who will serve in a similar role as a community health worker or patient navigator. They will be asked to assist in distributing recruitment materials for our open referral/enrollment process, help potential families understand both programs and timing of the intervention sessions, and ask to promote program adherence and provide a program 'safety net'. This will include contacting enrolled families and supporting their needs to successfully engage in the program. Both the PAT and CAB groups will meet monthly (e.g. using a mix of in-person and conference call meetings) and use a shared-decision making and participatory agenda meeting structure to guide all aspects of the study. As a part of this process, those who volunteer and sign informed consent will also participate in annual mixed-methods evaluation to assess capacity and engagement. Patient and stakeholder engagement and evaluation is a requirement of our funder.

To this end, we have 4 groups of participants who are in this protocol: 1) children, 2) parents of these children, 3) Community Advisory Board (CAB) members, and 4) Parent Advisory Team (PAT) members. Some members of the CAB and PAT, are both involved in the conducting the research and are research subjects who will be completing the mixed-methods evaluation as indicated in the CAB and PAT consent forms [NOTE: PAT members may NOT be simultaneously enrolled at participants in the childhood obesity treatment program].

## Background

**1. Provide the scientific background, rationale and relevance of this project.**

**A. Background**

**The Dan River Region (DRR): Obesity, Disparities, & Community Action.** Obesity prevalence is a public health concern that is a national priority.[1-3] The outcomes of sustained obesity include diabetes, cardiovascular disease, and some forms of cancer.[1-4] Increased rates of obesity in children are related to 'adult' diseases such as type 2 diabetes and hypertension presenting during childhood.[4] Of particular concern is the persistence of disparities related to obesity for children from low income, minority, and geographically dispersed groups in the population.[5,6] The DRR, located in south central Virginia and north central North Carolina, characterizes these disparities. The DRR is a

confluence of social determinants of health that includes low socio-economic status, a high proportion of racial minorities, and small regional cities that lack resources to address obesity. The DRR includes the city of Danville, Pittsylvania, Henry and Caswell Counties and is a federally designated, medically underserved area burdened with educational, economic, and health disparities.[7-12] Regional unemployment rates are nearly double the state and national averages,[13] and 27% of residents are black, 16.5% live below the Federal Poverty Level, and only 9% have obtained a bachelor's degree.[8,9] Furthermore, rates of low literacy levels exceed state averages by nearly 20%.[7] Although childhood obesity data are limited, one local school district showed 17% of 1st graders were overweight and 19% were obese.[14] By 5th grade, this cohort increased prevalence to 19% overweight and 36% obese. This rate of obesity is 3 times higher than state averages (~11% of VA youth are obese). Prevalence of adult chronic diseases such as obesity (~35%) and type 2 diabetes (27-33%), are significantly higher than state averages (25% obesity; 19.5% diabetes) and further illustrate serious regional health concerns.[7,12,15]

**The Research-Practice Gap for Family-Based Childhood Obesity Treatment Programs (FBCO; RQ-1).** Due to the high prevalence rates, impact on child health, and potential chronic conditions that arise in adulthood,[1-4] there is a large body of literature and a number of systematic reviews documenting the efficacy of FBCO interventions.[16-18,19,20,21-23] In particular, family-based interventions that target the parent, or the parent and child, have efficaciously reduced and maintained child weight status . For example, Epstein and colleagues developed the Traffic Light model which first demonstrated efficacy over 30 years ago and includes an explicit method for reducing caloric intake, increasing the intake of more healthful foods, and decreasing the intake of less healthful foods.[17,18,24] Golan and colleagues developed a health centric approach that focused on changes to the home environment that a parent can make to improve the likelihood that a child will eat better and be more active.[21,22,25] In contrast to the Traffic Light program that includes contact with the parent and child, Golan's model is a parent-only program. Finally, Bright Bodies developed by Savoye and colleagues, provided a balanced program to support parents and overweight children in assessing energy intake and expenditure.[26-28] From a pragmatic perspective, each of these programs varies in implementation appeal, based on the number and duration of contacts, contact targets (i.e., parent and child vs. parent only), and associated implementation costs. Impressively, each of these programs includes data that demonstrates efficacy.[17,18,24 21,22,25-28]

Unfortunately, there is little evidence that any FBCO treatment has been systematically translated into regular practice or reaches a large number of families in health disparate regions.[29] Further, there are substantial gaps in the literature related to the features within clinical and community settings that could improve the translation of FBCO interventions into typical practice.[30] Systems-based approaches suggest the need to integrate research, practice, and patient perspectives to improve the movement of the evidence-base from the scientific domain and into the community domain. This approach highlights the importance of priorities, cultural norms, and context; tacit

practice-based knowledge; relationships within and across community and clinical organizations; and the strategic processes that influence decision-making.[31,32 33] These principles were used to create the partnership responsible for developing this proposal—the Partnering for Obesity Planning and Sustainability Community Advisory Board (POPS-CAB) and Parent Advisory Team (POPS-PAT). The POPS-CAB includes local organizational partners from health care (SOVAH Pediatrics-formerly known as the Children's Healthcare Center), public health, and recreation (City of Danville Parks & Recreation; Parks & Rec) that reach a broad and high-need cross-section of overweight/obese children, and includes both the staff that interact with families who would benefit from a childhood obesity program and the decision-makers who provide approval for effective strategies to be implemented and sustained. The POPS-PAT includes parents from 3 cohorts of participants in the iChoose FBCO intervention that was collaboratively identified and adapted from the Bright Bodies evidence-based intervention by the POPS-CAB for local implementation. Based on the current literature and our own data, *our community-based participatory research (CBPR) and systems-based proposed approach holds promise for the translation of efficacious FBCO interventions into practice and for improving the reach into health disparate regions such as the DRR.*

**The Challenge of Adherence and Maintenance (RQ1).** When examining FBCO interventions, those that include 26-75 contact hours or more are typically the most successful in reducing weight status.[34] However, programs that include a high number of contact hours over 6 months are associated with low adherence.[35] In healthcare-based pediatric weight management programs, it is typical to see 60 to 70% attrition over the course of a 6-month (or shorter) program.[35-39] Barlow and Ohlemeyer studied a clinically available weight management program and documented 60% attrition over the course of the program.[40] Through follow-up with families that had discontinued the program they found that nearly half indicated that it was too difficult to schedule or that the program was too far from home. These findings align with a review of childhood obesity treatment programs that found family difficulty in attending sessions due to competing time demands as the most prevalent reason for low adherence.[41] This lack of adherence is problematic given the consistent finding that higher adherence to treatment protocol is associated with higher likelihood of success.[42,43]

Compounding adherence issues is a trend for child weight status reductions to move towards baseline values, with a few exceptions,[21,24] once a FBCO intervention is completed.[29 44-47] As a result, several research teams have developed and tested FBCO maintenance interventions—with notable results. First, one study demonstrated that a 5 month FBCO intervention followed by 4 months of weekly family sessions using social facilitation practices sustained the initial reduction of ~0.20 in BMI z-score up to 18 months post maintenance intervention.[48] Another study, that included 15 family group sessions and 10 family counseling sessions over 2 years, found that parent led self-help groups were just as effective at maintaining child BMI z-score reductions at 24 months when compared to a therapist delivered intervention (~0.17 vs 0.18 reduction, respectively)[49]. Finally, when relapse prevention was addressed with only 3 monthly

telephone support calls following a 3-month intensive intervention of either parent-focused dietary change, child-focused physical activity, or a combination of the two, each demonstrated sustained BMI z-score reduction 6 months after maintenance intervention completion.[50,51] Conversely, FBCO interventions with maintenance interventions that are not effective seem to primarily continue behavioral strategies without a specific focus on changing the social environment around families or explicitly addressing relapse prevention.[52-54] There is also interplay between the maintenance intervention design and translational potential for typical community or clinical settings. In our work, some POPS-CAB and POPS-PAT members identified longer-duration programs as potentially problematic for program participants, recalling many of the same issues that influence adherence in programs that have high contact, while others identify the need to continue structured contacts to support families in maintenance of behaviors. Katzmarzyk and colleagues nicely summarizes the need for FBCO interventions to address both adherence and maintenance—"…research is needed to identify the effective components of family-based, comprehensive behavioral interventions that can be delivered at the lowest contact intensity to improve pediatric weight status of a magnitude that is clinically relevant" (page 892)[29]. In light of successful maintenance interventions that can be delivered in a short period of 3 to 4 months with as low intensity as 3 monthly support calls*, there is a need to test lower-contact hour interventions that focus on relapse prevention and social factors in typical community settings* where high-need audiences lack access to effective programming and local providers have limited resources for delivery.

**B. Significance**

**Participant and Stakeholder Engagement in Addressing Childhood Obesity in the DRR (PC-1).** The prevalence of childhood obesity has increased significantly over the previous 4 decades[1,55] with approximately 1 in 3 children being classified as obese[2] and, therefore at risk of developing type-2 diabetes and other chronic conditions while still in their youth.[4] The proposed project was developed to add to, and improve the quality of generalizable evidence that can be used to help small regional communities that experience disparities identify, implement, and sustain FBCO interventions using locally available resources. Participant and key stakeholders in the DRR have participated in formulating our research questions (including the need to develop methods to facilitate implementation for local youth serving organizations), defining our target population and selecting the comparator interventions to increase the likelihood that all families who agree to participate in the trial have the opportunity to benefit. Our preparatory work included having stakeholder involvement in identifying valued outcomes and outcome assessments, ongoing sharing of study progress and outcomes, and interpretation of our findings for future adaption or for sustained delivery. The basis for this project was generated by several comprehensive needs assessments in the DRR that identified high rates of obesity as a regional priority area and revealed challenges that included a low availability of weight loss resources and a lack of organized community health coalitions to address these issues.[15,32,56] In response, the Dan River Partnership for a Healthy Community (DRPHC) was formed using a CBPR approach.[57,58]

In brief, CBPR is an action-oriented research approach that aims to build equitable community-academic partnerships, encourages community participation in all aspects of the research, and promotes program sustainability.[59-62] In 2012, based on persistent stakeholder concerns of low access to FBCO programs and referrals of obese children to programs that are a 2-hour drive away, the DRPHC formed the Partnering for Obesity Planning and Sustainability Community Advisory Board (POPS-CAB). The POPS-CAB was awarded a NIH-NIMHHD R24 CBPR planning grant to address mounting regional childhood obesity problems and lack of locally available treatment programs. The primary aims of the planning grant were to build community capacity to develop, implement, and sustain a FBCO intervention in the DRR. In June of 2015, families who completed this FBCO program formed a Parent Health Advisory Team (POPS-PAT) that contributed to identifying additional strategies to help with recruitment of high need families, improve adherence to intervention components, and maintenance of healthful eating, physical activity, and weight control for the involved children.

**Parent Health Advisors and the Parental Advisory Team: Potential to improve FBCO adherence and maintenance (PC-1).** The POPS-PAT also identified the need for a participant 'safety-net' to support families that engage in the iChoose program over time. In addition, members of the POPS-PAT indicated that previous program participants who had been successful in supporting healthful eating, physical activity, and body weight change for their children would be ideal to provide this support (See POPS-PAT member letters of support). To address this, we collaboratively reviewed the body of literature related to the potential benefits of health advisors, and/or community health advisors. We found that there is strong research support that members of the POPS-PAT could address participant engagement, adherence, and longer-term maintenance.[63,64] For example, an RCT was conducted to empirically test the effectiveness of community health advisors in the retention and adherence of minority, low income women in a clinical trial.[65] The adherence rates for scheduled clinic visits for the community randomly assigned to a community health advisor model was significantly higher (80%) as compared to the control community who did not have health advisors care (65%). In another recent community-based study by Katula and colleagues (study consultant), community health advisors facilitated small group cognitive behavioral meetings targeting diabetes prevention and weight loss.[66] One- and two-year outcome findings demonstrate the promise of community health advisors in achieving outcomes (e.g. decreased glucose and adiposity), while containing the costs to implement the program.[67,68] A proposed mechanism of the effectiveness of community health advisors across studies and systematic reviewers is that they are trusted and trained socially supportive individuals that fill the roles of marketer, mentor, motivator, and monitor.[63-68] Based on the research literature of the benefits of providing social environmental changes that support adherence and maintenance, community health advisors show great promise for improving these outcomes in FBCO interventions. With the POPS-PAT we propose to adapt an existing community health advisor model to optimize program enrollment, participation, and retention across intervention conditions in our trial.[66-68] We plan to do so through the development of Parent Health

Advisors (PHA). Since the POPS-PAT members expressed commitment to providing a social-support safety-net for *i*Choose families, are from the target population, share common demographics and cultural traits, and have already experienced a FBCO—members of the POPS-PAT have agreed to expand their roles into a formal PHA model. In combination with the proposed PHA training, *we anticipate these characteristics will promote connectedness to, and trust with targeted families and improve adherence and outcomes.*

## Hypothesis to be Tested

The primary study hypotheses are:

- Effectiveness-- children in both conditions will reduce BMI-z scores significantly, when compared to baseline at 3, 6 and 12 months, but *i*Choose+ reductions will be significantly larger than Family Connections,
- reach—the sample will be representative of the eligible regional population on demographic and behavioral factors
- implementation—the intervention components will be delivered with high fidelity in both conditions, but costs will be lower for Family Connections
- maintenance—a sustainability action plan will be completed to include strategies for continued delivery of *i*Choose+ and/or Family Connections (outcome dependent)
- parent weight, parent/child behaviors, & tertiary outcomes that follow the same patterns as BMI z-scores
- community capacity for implementing and sustaining a locally relevant FBCO treatment and maintenance program will remain high over time

## Study Design: Biomedical

**1. Will controls be used?**
Parent/Child Dyads: yes
Community Advisory Board: no
Parent Advisory Team: no

**►IF YES, explain the kind of controls to be used.**
This is comparative effectiveness trial, below is a description of the two programs:

***i*Choose+.** *i*Choose+ is conceptualized to more accurately reflect the contact frequency and program duration of *Bright Bodies* which included weekly nutrition (parent/child together), behavioral (parent/child independently), and exercise (2/week; child only) session for 24 weeks. For an additional 24 weeks all *Bright Bodies* sessions continued to be delivered, but on a bi-weekly schedule. *i*Choose+ will contain the following components: (1) Clear communication *i*Choose workbooks for parents and children that provide the basis for all *i*Choose activities to assist families in changing physical activity, eating behaviors, and child weight status; (2) 12 family classes that reduce reading demands and incorporate numerous non-print education strategies, hands-on demonstrations, and pictorial instructions (each 2-hour class will be split evenly

between nutrition, exercise, and behavior change topics); (3) 12 IVR calls that provide reinforcement of class objectives, personalization of goals, and apply teach-back and teach-to-goal methods (two versions of each call will be used—one call for families that attended the class and one for those that did not); (4) 48 family exercise sessions to promote practice and mastery and encourage social support (six PA sessions are integrated within the family class for a total of 2 sessions/week); and (5) bi-weekly child newsletters to reinforce class messages and provide fun family activities. To increase the duration and contact after the initial 24 weeks, we will continue with a 6-month maintenance program, including bi-weekly IVR calls to parents and newsletters to children. The IVR structure will focus on relapse prevention through the reinforcement of program content and skill building opportunities while also allowing for goal setting and feedback relative to nutrition and physical activity outcomes.

***Family Connections.*** This intervention condition was developed using an integrated research-practice partnership with a goal to develop an evidence-based program that would be practical and attractive to families, and would match the resource availability for sustained delivery.[42] The intervention was based on the work of Golan and associates because the model:[25] (1) stressed a health-centered, rather than weight centric, approach; (2) demonstrated short and long-term effectiveness in reducing child BMI z-scores; (3) demonstrated effectiveness in improving parental health, and; (4) demonstrated that effectiveness in reducing child eating disorder symptoms.

*Family Connections* (the resultant program) highlights the need to address parental cognitive and behavior change, home environment change, and parental modeling of healthy behavior.[42] Strategies included 2, 2-hour sessions and targeted about 10-25 parents representing distinct children. As in our previous trial both parents of a given child will be welcome to attend, but only one parent will be identified as the point of intervention and parental data collection. Parents will also receive 10 follow-up sessions delivered via IVR. The calls will be completed with high frequency initially and then scaled back over time (i.e., 2-3 calls per month during months 1-3 and then 1 call per month during months 4-6).

For cohorts 1-2 these programs will be implemented at one Danville, Virginia site via space provided by Danville Parks and Recreation subcontracted partner. For cohort 3 the study will expand to include both this Danville site and a Chatham, Virginia site with space rented through the Pittsylvania County Parks and Recreation.

***Community Advisory Board and Parent Advisory Team.*** Both groups will meet monthly (e.g. using a mix of in-person and conference call meetings) and use a shared-decision making and participatory agenda meeting structure to guide all aspects of the study. The POPS and POPS-PAT groups will also meet together, as necessary, likely on a quarterly or bi-annual basis, to share ideas and report progress. As required by our PCORI funding

agency, our intent is to engage these influential partners in all aspects of planning the research, conducting the research, and disseminating findings.

**2. What is the study design?**

- Parent/Child Dyads: comparative effectiveness trial, with randomization at the individual dyad level
- Community Advisory Board and Parent Advisory Team: capacity evaluation includes a mixed-methods, longitudinal study design

**3. Does the study involve a placebo?**

No

## Human Participants

**1) Cohorts 1-2:**

**Children**

- **Ages:** 8-12 years
- **Sex:** male & females
- **Race:** all

**Parents/caregiver**

- **Ages:** ≥18 years
- **Sex:** male & females
- **Race:** all

**2) Cohort 3:**

**Children**

- **Ages:** 5-12 years
- **Sex:** male & females
- **Race:** all

**Parents/caregiver**

- **Ages:** ≥18 years
- **Sex:** male & females
- **Race:** all

**3) All Cohorts:**

**Community Advisory Board and Parent Advisory Team**

- **Ages:** ≥18 years
- **Sex:** male & females
- **Race:** all

**Subjects- see below**

1. **Provide target # of subjects (at all sites) needed to complete protocol.**
    - 174 parent/child dyads
    - 20 members of the Community Advisory Board
    - 15 member of the Parent Advisory Team

2. **Describe expected rate of screen failure/ dropouts/withdrawals from all sites.**

    Parent/child dyads:
    - 870= Estimated number of potentially eligible study participants (parent/child dyads) determined using pilot reach data from our planning grant in which participants were identified through medical record review at SOVAH Pediatrics (formerly Children's Healthcare Center)
    - 539= Total number of study participants (dyads) expected to be screened
    - 496= Total number of study participants (dyads) expected to be eligible of those screened
    - 174=Target sample size (dyads)
    - 130= Retained sample after 12 months

    We anticipate approximately 10% attrition from both the Community Advisory Board and Parent Advisory Team

3. **How many subjects will be enrolled at all sites?**
    - 174 parents/caregivers (and 174 children with assent)
    - 20 Community Advisory Board members
    - 15 Parent Advisory Team members

4. **How many subjects will sign a consent form under this UVa protocol?**
    - 174 parents/caregivers (and 174 children with assent)
    - 20 Community Advisory Board members
    - 15 Parent Advisory Team members
    - In addition, up to 496 subjects will be enrolled with waiver of documentation of consent. This group will include subjects who signed written consent for the main study, and subjects who completed the telephone survey but did not enroll in the main study.

5. **Provide an estimated time line for the study.**

    For parent/child dyads in the comparative effectiveness trial:
    - Cohort 1= intervention 6/2017-5/2018 (w/ 3-, 6-, & 12 months f/u)
    - Cohort 2= intervention 4/2018-3/2019 (w/ 3-, 6-, & 12 months f/u)
    - Cohort 3= intervention 2/2019-1/2020 (w/ 3-, 6-, & 12 months f/u)

    - Year 1: 66% enrolled, 33% completed
    - Year 2: 100% enrolled, 66% completed

- Year 3: 100% completed

For both the Community Advisory Board and Parent Advisory Team, 100% enrolled in Year 1; mixed-methods evaluation at end of each study year

## Inclusion/Exclusion Criteria

**1. List the criteria for inclusion**

Cohorts 1-2:

Parent/child dyads in the comparative effectiveness trial, families are eligible to participate if they

- have a child between -12 years old with a BMI percentile that is 85% or greater for their age and gender
- live in the Dan River Region
- are English speaking
- parents/caregivers ≥18 years of age

Community Advisory Board members were identified and named when the PCORI application was submitted:

- Representatives from organizations in the Dan River Region who have a child-focused organizational mission, invited as a stakeholder
- ≥18 years of age
- Willing and able to provide informed consent

Parent Advisory Team members:

- Parent who previously participated in a childhood obesity program and/or are the parent of a child ages 8-12 years of age
- ≥18 years of age
- live in the Dan River Region

Cohort 3:

Parent/child dyads in the comparative effectiveness trial, families are eligible to participate if they

- have a child between 5-12 years old with a BMI percentile that is 85% or greater for their age and gender
- live in the Dan River Region
- are English speaking
- parents/caregivers ≥18 years of age

Community Advisory Board members were identified and named when the PCORI application was submitted:

- Representatives from organizations in the Dan River Region who have a child-focused organizational mission, invited as a stakeholder
- ≥18 years of age
- Willing and able to provide informed consent

Parent Advisory Team members:

- Parent who previously participated in a childhood obesity program and/or are the parent of a child ages 5-12 years of age
- ≥18 years of age
- live in the Dan River Region

**2. List the criteria for exclusion**

Parent/child dyads:

- children with a major cognitive impairment based on medical record review or contraindications for physical activity
- families that are already participating in a childhood obesity treatment program

Community Advisory Board: none

Parent Advisory Team:

- Cannot simultaneously be enrolled in the comparative effectiveness trial and serve on the Parent Advisory Team

**3. List any restrictions on use of other drugs or treatments**.

Parent/child dyads

- families that are already participating in a childhood obesity treatment program will be excluded

Community Advisory Board and Parent Advisory Team: NA

## Statistical Considerations

**1. Is stratification/randomization involved?**

Yes

**►IF YES, describe the stratification/ randomization scheme.**

We will use simple randomization, at the parent-child dyad level. Randomization is not blinded. The researchers will have access to the randomization scheme.

**►IF YES, who will generate the randomization scheme?**

_____ Sponsor

_____ UVa Statistician. Insert name Answer/Response:

_____ UVa Investigational Drug Service (IDS)
___X__ Other: Wen You, statistician from Virginia Tech

**2. What are the statistical considerations for the protocol?**

- The primary end-point is 6-month reduction in BMI z-score.
- We calculated a standardized effect size relative to the differences in BMI z-scores and standard deviations *related to 6-month BMI z-score reduction* for *Family Connections (*0.07) and *Bright Bodies* as a target for the *i*Choose+ condition (BMI z-score reduction = 0.16).
- Follow-up assessments (3, 6, 12 months) will be scheduled by trained research staff. All assessments will be completed by a trained research staff member, following an established protocol from our manual of procedures (developed for our planning grant). All data will be collected and included in a single de-identified study data set and will not require linking of the electronic health record with study data (**IR-1; IR-2**). Questionnaires will be either orally administered by a trained researcher or completed via a computer-audio assisted assessment. Data completion checks will be completed for each participant at each assessment point and information that was missed inadvertently will be completed with the participant unless the participant explicitly decided to not complete a measure **(MD-1)**. The 3-month assessment will only include height and weight (to calculate BMI percentile rankings for children) for children. Adult participants will be assessed for weight/height and complete a brief interview to provide feedback on the program. Demographics will only be assessed at baseline. Descriptive, parametric, and non-parametric statistical methods will be used to compare continuous and categorical variables among the intervention groups at baseline. Data will be examined for the presence of outliers, violations of normality (for those continuous variables) and missing data. Major violations of normality will be corrected with an appropriate transformation procedure. Missing data will be handled multiple ways through not only last-observation-carried-forward simple imputation but also Bayesian multiple imputations, Heckman sample selection models and a newly validated multiple imputation approach that incorporates Heckman selection as an imputation model **(MD-2; MD-3)**. The maximum likelihood selection methods such as Heckman sample selection model are expected to be more efficient than multiple imputation methods while providing direct ways to test the underlying behavioral factors that drive missingness in the data. However, it is limited to missing outcomes relative to covariates are common in intervention trials. Therefore we will also do Bayesian multiple imputation and the multiple imputation combined with Heckman model as proposed by Galimard and colleagues.[98] In addition, based on the CONSORT guidelines for non-pharmacological trials, we will track participant dropout across each aspect of the trial and report on the number, proportion, and demographic characteristics

of those lost to attrition and the reasons for attrition, when at all possible **(MD-4)**.

NOTE: Due to COVID-19 social distancing regulations an amendment to this protocol expands questionnaire data collection for parents and children (8 years-12 years) to mailed paper and pencil modality. This modality will only apply to Cohort 3 12 month follow-up data. Assistance with reading the survey over the phone will be offered to those who request this service. Researchers will explore the data for response differences at this time point to help determine any undue impacts from this change.

- Interim analysis will occur after each of the three cohorts complete the 6-month assessment. Early stopping does not clearly apply to this trial, as there are no clear negative consequences. The extensive bibliography provided indicates the value of childhood obesity treatment programs and the minimal risk involved in such programs. Even if the primary outcome (child BMI z-score) does not show statistical improvements, other secondary end points may improve.

**3. Provide a justification for the sample size used in this protocol.**

Based on the relative BMI z-score differences and standard deviations related to 6-month BMI z-score reduction for *Family Connections (*0.07) and *Bright Bodies* we hypothesize an effect size of 0.73 (moderate to large effect) favoring *i*Choose+. To detect a significant difference between conditions, 58 or 64 children per group are needed to achieve 80% or 85% power with alpha of 0.05, respectively. When considering a typical attrition of 25% in this population, we project a sample size of ~87 participants is needed per condition (n=174 total) to achieve 85% power with approximately 64 dyads/condition completing 6-month assessment. Retention of families in our planning grant is currently 70% at 6-month follow-up.

**4. What is your plan for primary variable analysis?**

Primary Aim: Multi-level mixed effect models will be employed to control errors of non-independence, heteroskedasticity caused by individual and family heterogeneity, and potential covariates needed to be controlled for in order to detect the pure BMI z-score reduction differences between the two conditions. In its simplest form, the model generally can be shown as: $BMIzscore_{ijt} = a_j + X'_{ijt}\beta + \gamma d_j + W'_j\delta_j + \tau T_t + \theta d_j \cdot T_t + \mu_i + v_{it}$. All measures are obtained for 4 time periods: baseline, 3-, 6-, and 12-months. The family-level intercept, $a_j$, is allowed to vary by parent-child-dyads and to be a random variable. The *X*s are the individual child-level covariates and the *W*s are family-level covariates. The model also contains treatment group indicators, $d_j$, and time period indicators, $T_t$. Relative treatment effect between conditions will be captured by coefficient $\theta$. Individual child-level unobserved heterogeneity that is time invariant is represented by $\mu_i$ **(IR-5)**. Sensitivity analysis will be conducted to examine the robustness of the mixed effect model across different random-effect distribution specifications (e.g., normal, finite mixture of normal etc.). Our study is powered to detect the average treatment effect at 6 months since the main interest of the POPS-

CAB and POPS-PAT stakeholders is on reducing childhood obesity across the population in a region that experiences disparities across educational, economic, and racial sub-groups. However, we do plan on conducting exploratory subgroup analysis of the heterogeneity treatment effects (HTE) that will inform hypothesis generation that can be tested in future pragmatic trails for assessing the robustness of the interventions in achieving public health benefit across subgroups. The POPS-CAB and POPS-PAT identified three individual attributes that may modify program effect based on our NIH-R24 planning grant results: race, gender and parent health literacy status at baseline. Interactions (two-way and three-way) among those factors and time and group indicators will be added to the above multi-level mixed effect models to be tested. Even though we are not powered for the HTE analysis, all standard sub-group analysis estimation and reporting protocols will be followed. As part of the exploratory HTE analysis plan, we will also estimate the HTE method proposed by Imai and Ratkovic [99]which addresses HTE as a variable selection problem and the method is shown to be appropriate for exploring HTE.

**5. What is your plan for secondary variable analysis?**

Secondary Aim #1: Reach/representativeness will be analyzed following the recommendations of Glasgow et al.[90] Participation rate will be calculated as total n enrolled/ total n of eligible participants exposed to recruitment. To improve the comparison of representativeness we will, using a similar multi-level mixed effect logit models as presented above, create a summary effect size (ES) for differential characteristics by using the median ES across the comparisons of demographic, health, and behavioral information of participants versus those declining participation. (Using the median rather than the mean will minimize the influence of outliers). The median ES will then be subtracted from the participation rate to provide a summary measure of reach. Summary descriptive statistics reporting rates and cost of completion of in-person and IVR follow-ups will be computed for implementation indicators. Fidelity will be assessed as proportion of the intervention that is delivered as intended across intervention components based on IVR data and delivery agent fidelity checklists. These data will be reported descriptively and in concert with cost data. A concurrent mixed methods design will be used to collect quantitative and qualitative data collected on implementation and triangulated for interpretation.[100] Finally, summary RE-AIM metrics will be calculated as detail by Glasgow et al.

Secondary Aim #2: Using mixed methods,[100] quantitative capacity dimensions will be analyzed using repeated measures ANOVA, accounting for differences between community and academic members. Interviews will be transcribed. A minimum of two members will code meaning units from each transcript using NVIVO and a hybrid inductive-deductive analysis approach to identify emergent themes related to capacity dimension.[101-103]

Secondary Aim #3: Similar multi-level mixed effect models as in primary aim 1 will be used. The dependent variables will be family eating behaviors, child and parents' physical activity levels and parent weight at each time point. The coefficient $\theta$ will

capture the potential differences by treatment condition. For those discrete outcomes, appropriate link functions and distribution assumptions will be used in the modeling. Secondary Aim #4: At each time point, those who drop out of the study will be compared on key demographic variables with those retained in order to understand the mechanism of participation both by group mean tests and by selection bias testing in selection models. Different adherence/attendance to classes and phone calls will be summarized following similar usage metrics by Donkin including a composite measure of exposure (i.e., exposure=intensity x frequency x duration).[104] Both ANOVA and selection models that handle and test potent nonrandom dose exposure resulted from natural choices will be used to analyze dose responses.

**6. Have you been working with a statistician in designing this protocol?**
Yes

**IF YES, what is their name?**
Wen You, PhD, Associate Professor at Virginia Tech

**7. Will data from multiple sites be combined during analysis?**
No

## Information from Outside Institution

1. **List the names of outside institutions that will be supplying data and/or specimens for this study.**
   Contact and eligibility information of children are being provided by SOVAH Pediatrics and Piedmont Access to Health Services (PATHS) by review of medical records (see file: Tracking eligible children), but no other data is being provided by SOVAH Pediatrics or PATHS.

   The University of Nebraska Medical Center (UNMC) is responsible for developing and managing the web-based platform for the collection of self-reported behavioral and quality of life data from parents and children. However, UNMC is not screening or enrolling participants at their site, there only a single Danville site for this study.

2. **Describe the type of information you will receive from each site.**
   SOVAH Pediatrics and PATHS will provide the research team with contact information and basic demographics for eligible children who are between the ages of 5-12 years and >85$^{th}$ %ile BMI: name, address, phone, birthdate, gender, race/ethnicity, type of insurance. The web-based platform developed by UNMC will include: eating and physical activity habits, health status, quality of life, and perceptions of the home environment.

**3. Does the outside institution have an IRB?**
Yes, University of Nebraska Medical Center has an IRB. De-identified data will be sent to UNMC under contract.

A letter of support is provided from SOVAH Pediatrics and PATHS.

## Biomedical Research

**1. What will be done in this protocol?**

**Parent/Child Dyads.**
Families have an equal chance of being randomly assigned to any one of the two programs. They cannot choose to which program they are assigned.

**GROUP 1: iChoose**
The iChoose program will last for 12 months. During the first six months families will be asked to:

- Attend 12 small group educations sessions every other week. The health classes are for both the parent and child and will include information on nutrition and exercise.
- Attend one hour family exercise sessions two times a week (total of 48 sessions, 12 of which are part of the small group education sessions)
- Complete 12 automated telephone calls to provide support to help families reach your eating and physical activity goals.
- The child will also get 12 mailed newsletters to help them meet their program goals.

During the last six months of the program parents will continue to get support calls every other week (a total of 12 more calls) and your child will get 12 more newsletters.

See additional study procedures listed in #2 below.

**GROUP 2: Family Connections**
The Family Connections program will last for 6 months. During this time parents will be asked to:

- Attend 2 education sessions that are one week a part. The health classes are for parents/guardians only and will include information on parental role modeling regarding healthy nutrition and exercise behaviors.
- Complete 10 automated telephone calls to provide support families reach your eating and physical activity goals. There will be 2-3 calls per month during months 1-3 and then 1 call per month during months 4-6.

**Community Advisory Board and Parent Advisory Team.** Meeting procedures provided above in the study design section. (NOTE: the meetings are not part of the research procedures, only the mixed-methods evaluation, as described below. The participation in meetings is a contractual arrangement for advisory board members).

**2. List the procedures, in bullet form, that will be done for <u>RESEARCH PURPOSES</u> as stipulated in this protocol.**

**Interventions:** The iChoose and Family Connections interventions are described above and in the study design section.

**ALL** of the following procedures are being done for research purpose.

**SEE ATTACHMENTS:**

1. Parent Survey
2. Child Survey
3. Summative evaluation_iChoose parents
4. Summative evaluation_iChoose child
5. Summative evaluation_Family Connection parents
6. Summative evaluation_Family Connections child
7. CAB_PCORI_Capacity Eval QUANT survey
8. CAB_PCORI_Capacity Eval Qualitative survey
9. PAT_PCORI_Capacity Eval QUANT survey
10. PAT_PCORI_Capacity Eval Qualitative survey

**Parent/Child Dyads.**
The following health assessment will occur at baseline, 6-month and 12-month assessments among both the children ages 8-12 and parents.

- Height
- Weight
- Blood pressure
- Waist circumference
- Self-reported questionnaires (Parent Survey and Child Survey), pertaining to
    - Eating habits
    - Physical activity habits (via computer)
    - Quality of life/Health status (via computer)
    - Health literacy (via pencil/paper)
    - Home environment (parents only)(via computer)

At the 3-moth assessment: only height and weight are collected for parent and children. Parents will also complete a brief interview (PCORI 3 month assessment) examining program satisfaction, adherence, and retention.

At 6- and 12-month assessments: Post-program evaluation, quantitative ratings and qualitative interview.

For children ages 5-7, the Child Survey will be abbreviated to those measures validated for this age range. As such, only anthropometric data (height, weight, blood pressure, and waist circumference) and the Quality of Life questionnaire (as described on the 'Child Survey') will be collected. Assistance with computer administered surveys will be

provided for this age range by the research staff. Children 5-7 will also receive the same qualitative interviews at 6 and 12 months as the 8-12 year olds.

NOTE: Due to COVID-19 social distancing regulations an amendment to this protocol expands questionnaire data collection for parents and children (8 years-12 years) to mailed paper and pencil modality. This modality will only apply to Cohort 3 12 month follow-up data. Assistance with reading the survey over the phone will be offered to those who request this service. Researchers will explore the data for response differences at this time point to help determine any undue impacts from this change.

**Community Advisory Board**

- Mixed-methods evaluation, quantitative survey and qualitative interview questions, pertaining to: communication, trust, decision making procedures, conflict resolution, group roles, problem assessment, collective efficacy, leadership, accomplishments and impact, participation and influence, community power, resources, sustainability, and overall satisfaction.
- This evaluation will occur annually, or at three time points, during the study.

**Parent Advisory Team**

- Mixed-methods evaluation, quantitative survey and qualitative interview questions, pertaining to: communication, problem assessment, collective efficacy, leadership, participation and influence, community power, overall satisfaction, and influence. Qualitative will also include questions pertaining to PAT's role to assist in family recruitment activities and to assist in family adherence by providing a program 'safety net'.
- This evaluation will occur annually, or at three time points, during the study.

**3. Do you confirm that, except for blood draws through a peripheral site, that all invasive procedures will be performed by a licensed health care provider under the supervision of an MD?**

There are no invasive procedures in this protocol.

**4. Will you be using data/specimens in this study that were collected previously, with the use of a research consent form, from another research study?**

No

**5. Will any of the procedures listed in item # 2 have the potential to identify an incidental finding? This includes ALL procedures, assessments and evaluations that are being done for <u>RESEARCH PURPOSES</u> that may or may not be considered investigational.**

It is possible that a subject's blood pressure reading would be out of the range of normal

___X__The examination(s) utilize(s) the same techniques, equipment, etc., that would be used if the subject were to have the examination(s) performed for clinical care. **There exists the potential for the discovery of clinically significant incidental findings.**

- The PI takes full responsibility for the identification of incidental findings:
- The PI will inform the subjects verbally of all incidental findings that are of clinical significance or are of questionable significance**.**
- A follow-up letter describing the finding should be provided to the subject with instructions to either show the letter to their PC or if the subject has no PCP, the subject should be instructed to make an appointment at UVa or at the Free Clinic**.**

**6. Do any of the procedures listed above, under question # 2, utilize any imaging procedures for <u>RESEARCH PURPOSES</u>?**
No

**7. Will you be using viable embryos?**
No

**8. Will you be using embryonic stem cells?**
No

**9. If this protocol involves study treatment, explain how a subject will be transitioned from study treatment when they have completed their participation in the study.**

Once the family-based childhood obesity treatment interventions have ended, the parent/child dyad participants will resume their usual medical care, at their own cost.

**10. Will your study involve measures used to screen or assess for depression and/or suicidality <u>for research purposes?</u>** No

11. **Where will the study procedures be done?**
Check One:
____ UVA medical center facilities ( In patient or outpatient)
____ UVa , but not medical center facilities: LIST specific location
Answer/Response:
__X__ Other LIST specific location Answer/Response:
Danville site: These procedures will occur in community centers owned by our Parks and Recreation partners in Danville, VA.
Chatham site: These procedures will occur in the Pittsylvania Parks and Recreation Community Center in Chatham, VA.

At both sites efforts will be taken to make sure participants are comfortable during the health screenings and measurements will be taken in a private area.

**12. If the study involves medical risk and study procedures will be done outside of the UVa Medical Center what is your plan to protect the subjects in case of a medical emergency?**

Note: Exercise sessions are no greater in intensity than might be encountered in everyday life, during recreational activities offered by Danville Parks and Recreation.

*Check all applicable options:*

_____ MD, RN, onsite during procedures
__X___ Individual trained in CPR on site during procedures
_____ AED and Individual trained to use it onsite
__X___ Call 911
_____ Other : Describe Answer/Response:

**13. Are any aspects of the study kept secret from the participants?** No

**14. Is any deception used in the study?** No

## Taping/Photography

**1. Will participants be recorded on audiotape?**

Parent/Child Dyads: No
Community Advisory Board: yes, for research purposes
Parent Advisory Team: yes, for research purposes

**1a. What steps will be taken to protect the privacy of the subjects?**

All recordings will be assigned an anonymous id number, and names will be removed from transcriptions. All names will be removed from transcriptions. Audio files will be deleted once transcription is complete.

**1b. What data will be captured from the audiotapes?**

Qualitative interviews from the Community Advisory Board and Parent Advisory Team will be collected on audio tape.

**1c. When will data from the tapes be transcribed?**

Data from the audiotapes will be transcribed within 6 months of being collected.

**1d. When will the audiotapes be destroyed?**

The audiotapes will be destroyed after the transcriptions have occurred and been checked for accuracy.

**2. Will participants be photographed or recorded on videotape?**

Photographs may be used for promotion purposes for this protocol and only from all participants (parents, children, and Community Advisory Board and Parent Advisory Team members) who sign a photograph release form. Promotional activities will include various print and electronic media. Also, photographs may be used in the newsletters as a part of the iChoose+ program. Videotapes will not be used in this study.

**2a. Will their faces be shown?**

Yes

**2b. What steps will be taken to protect the privacy of the subjects?**

Photographs will only be used among participants who have signed a photo release form. This is not a requirement for participation in any aspect of this study. Names will not be attached to photographs unless otherwise approved by the participants.

**2c. What data will be captured from the photo or videotape that could not be obtained in other ways?**

The photographs are not for data or analysis purposes. Photographs will be used in IRB-approved ads, and/or conference presentations when subjects agree.

**2d. How is this data critical to this research?**

The photographs are not for data or analysis purposes.

**2e. When will data from the tapes be transcribed?**

N/A

**2f. When will the tapes be destroyed?**

There are no videotapes.

**2g. Will participants be photographed, recorded or videotaped without their knowledge?**

No

**3. If a subject withdraws from the study how will you withdraw them from the audiotape, videotape or photograph?**

If a subject withdraws they will not participate in any additional qualitative interviews involved with the Community Advisory Board and Parent Advisory Team capacity evaluation. Their previous recorded information, prior to when they withdraw, will still be used. If a participant withdraws who previously had a photo release form, we will not use their photographs for any additional promotional purposes effective the date of study withdrawal.

## Data and Safety Monitoring Plan

**Adverse events will only be collected or recorded if a causal relationship to the study intervention is suspected.** If any adverse event is considered serious and unexpected, the event must be reported to the IRB-HSR within 7 days from the time the study team receives knowledge of the event.

**1. Definitions**

**1.1 How will you define adverse events (AE)?**

An adverse event will be considered any undesirable sign, symptom or medical condition considered **related to the intervention**. Medical condition/diseases present before starting the intervention will be considered adverse events only if they worsen after starting the study and that worsening is considered to be related to the study intervention. An adverse event is also any undesirable and unintended effect of research occurring in human subjects as a result of the collection of identifiable private information under the research.

**1.2 How will you define an unanticipated problem?**

An unanticipated problem is any issue that involves increased risk(s) to participants or others. This means issues or problems that cause the subject or others to be placed at greater risk than previously identified, even if the subject or others do not incur actual harm. For example if a subject's confidentiality is compromised resulting in serious negative social, legal or economic ramifications, an unanticipated problem would need to be reported. (e.g., serious loss of social status, loss of job, interpersonal conflict.)

**1.3 What are the definitions of a protocol violation and/or noncompliance?**

**A protocol violation** is defined as any change, deviation, or departure from the study design or procedures of research project that is NOT approved by the IRB-HSR prior to its initiation or implementation**.** Protocol violations may be major or minor violations.

**Noncompliance** can be a protocol violation OR deviation from standard operating procedures, Good Clinical Practices (GCPs), federal, state or local regulation**s.** Noncompliance may be serious or continuing

Additional Information: see the IRB-HSR website at http://www.virginia.edu/vpr/irb/HSR_docs/Forms/Protocol_Violations_%20Enrollment_Exceptions_Instructions.doc

**1.4 What is the definition of a data breach?**

A data breach is defined in the HITECH Act (43 USC 17932) as an unauthorized acquisition, access, or use of protected health information (PHI) that compromises the security or privacy of such information.

**2. What risks are expected due to the intervention in this protocol?**

| **Expected Risks related to study participation** | **Pick One** |
|---|---|
| There is a small risk that breaches of privacy and/or confidentiality might occur. The risk of violation of subject privacy and confidentiality is minimal due to the requirements of the privacy plan in this protocol. | Occurs rarely |
| Serious side effects from being involved in an exercise program if participants have not been physically active are rare, but should be considered.<br>• Cardiovascular events (e.g, heart attack)<br>• Respiratory issues (e.g., asthma, shortness of breath)<br>• Muscle and/or bone injuries | Occurs rarely |
| Stress or anxiety in completing questionnaires | Occurs rarely |

**3. When will recording and reporting of unanticipated problems/adverse events begin?**

__X___After subject begins study intervention

**4. When will the recording/reporting of unanticipated problems/adverse events end?**

__ X __Subject completes participation in the protocol

## 5. Data and Safety Oversight Responsibility

### 5.1. Who is responsible for overseeing safety data for this study?

_____No additional oversight body other than PI at UVa Skip question 5.2

_____All site PI's (*for protocols in which there is no common protocol but data from multiple sites will be combined for analysis: Collaborative Site Analysis Studies)*

_____The UVa Cancer Center Data and Safety Monitoring Committee
_____Medical Monitor

_____DSMB/ DSMC

_____Research Monitor: Insert Name Answer/Response:
_____

__X___Other: Per our funded protocol: Study oversight will be provide by the MPI's (Dr. Zoellner and Dr. Estabrooks), Co-I's and Project Director and two qualified external (not on the study team or CAB and will likely be the same two SOVAH Pediatrics and Parks & Rec external members outlined above) members: 1) one with the role of evaluating the progress of the study, monitor adherence to research protocols in recruitment and intervention phases, and monitoring adverse events and, 2) an analyst who will monitor the integrity of analytic work.

### 5.2. What is the composition of the reviewing body and how is it affiliated with the sponsor?

Members of the study team may NOT also be members of the DMSB.

_____Information may be found in the UVa Cancer Center Institutional DSMP

_____ Collaborative Site Analysis Study- see CSAS section of this DSMP

__X___Other- See Above. There is no affiliation with the PCORI sponsor.

### 5.3. What items will be included in the aggregate review conducted by the PI?

_____NA- PI is not the overall person overseeing the safety data for this study.

__X___All adverse events

__X___Unanticipated Problems

___X__Protocol violations/Issues of noncompliance

_____Audit results

_____Application of dose finding escalation/de-escalation rules

These should be outlined under 2.4.

_____Application of study designed stopping/decision rules

_____Early withdrawals

_____Whether the study accrual pattern warrants continuation/action

__X___Endpoint data

_____Other: Specify Answer/Response:

5.4 **How often will aggregate review occur?**

For additional information on aggregate review see: www.virginia.edu/vpr/irb/hsr/continuations.html#aggreview

_____NA- PI is not the overall person overseeing the safety data for this study.

_____Per Enrollment/Events

__X___Annually

_____Semi-Annually

_____Quarterly

_____Monthly

_____Other: Specify Answer/Response:

**5.5. How often will a report, regarding the outcome of the review by the DSMB/DSMC, be sent to the UVa PI?**

A copy of these reports must be sent to the IRB if applicable as soon as they are received by the PI. Do not wait until the next continuation to submit them to the IRB.

_____NA- PI is not the overall person overseeing the safety data for this study.

_____Per Enrollment/Events

__X___Annually

_____Semi-Annually

_____Quarterly

_____Monthly

_____Other: Specify Answer/Response:

**5.6. How will a report of the information discussed in question 5.4 OR 5.5 be submitted to the IRB?**

__X___Part of IRB-HSR continuation status form

_____Separate report from DSMB/DSMC or UVa PI

_____Other: Specify Answer/Response:

**5. What is your plan for safety monitoring?**

Safety monitoring and aggregate review of adverse events, unanticipated problems, protocol violations and any data breach will be performed by the PI and IRB-HSR through continuation review at least annually.

**6. What is your plan for reporting a Unanticipated Problem, Protocol Violation or Data Breach?**

| Type of Event | To whom will it be reported: | Time Frame for Reporting | How reported? |
|---|---|---|---|
| **Unanticipated Problems** that are not adverse events or protocol violations<br>This would include a Data Breach. | IRB-HSR | Within 7 calendar days from the time the study team received knowledge of the event. | Unanticipated Problem report form.<br><br>*http://www.virginia.edu/vprgs/irb/HSR_docs/Forms/Reporting_Requirements-Unanticipated_Problems.doc )* |
| **Protocol Violations/Noncompliance** (*The IRB-HSR only requires that MAJOR violation be reported, unless otherwise required by your sponsor, if applicable.)*<br><br>**OR**<br><br>**Enrollment Exceptions** | IRB-HSR | Within 7 calendar days from the time the study team received knowledge of the event. | Protocol Violation, Noncompliance and Enrollment Exception Reporting Form<br><br>*http://www.virginia.edu/vprgs/irb/hsr_forms.html*<br><br>*Go to 3rd bullet from the bottom.* |
| **Data Breach** of Protected Health Information | The UVa Corporate Compliance and Privacy Office<br><br>ITC: if breach involves electronic data | As soon as possible and no later than 24 hours from the time the incident is identified.<br><br>As soon as possible and no later than 24 hours from the time the incident is identified. | UVa Corporate Compliance and Privacy Office- Phone 924-9741<br><br>**ITC:** Information Security Incident Reporting procedure, |

| | | | |
|---|---|---|---|
| | Police if breach includes items that are stolen:<br><br>Stolen on UVA Grounds<br><br>OR<br><br>Stolen off UVa Grounds- contact police department of jurisdiction of last known location of PHI | IMMEDIATELY. | http://www.itc.virginia.edu/security/reporting.html<br><br>Police: phone- (434) 924-7166 |

## Payment

1. **Are subjects being reimbursed for travel expenses?**

   No

2. **Are subjects compensated for being in this study?**

   Yes

**Parent and child dyad:**
Both the parent and the child will each receive a gift card for their time involved in each of the health screenings, including:

- beginning of the program (baseline): $25 gift card
- 3 month follow-up: $25 gift card
- 6 month follow-up: $50 gift card
- 12 month follow up: $50 gift card

**Community Advisory Board and Parent Advisory Team:** are not compensated completing the mixed-methods evaluations. Some are paid members of the study team, but additional individual payment is not provided for completion of the mixed-methods evaluation.

**2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?**
Child $150; Parent $150

**2b. Explain compensation to be given.**

Children and parent will receive a Wal-Mart gift card. We have worked in this region for 7 years and this is always the most favorable form of compensation. There is immense value in having immediate compensation for their time involved in the health screenings. Also, this study populations are transcient and are relatively difficult to track. Mailing, tracking and troubleshooting mailed payments will cause added burden to the research staff.

**2c. Is payment pro-rated?**

Yes. Parents and children can attend any of the health screenings/date collection and receive the compensation. They do not have to participate in any the program or in all of the health screening to qualify for compensation when they do attend the health screenings.

**2d. Is money paid from UVa or State funds (including grant funds) or will items such as gift cards be distributed through UVa?**

Yes, PCORI sends money to OSP and contracts to cover the cost of compensation to be given to subjects.

**2d(i). How will the researcher compensate the subjects?**

__X___ Gift card/Debit Card

**2d(ii). Which category/ categories best describes the process of compensation?**

__X___ Compensation will include an <u>alternative method</u> (petty cash, gift card, other) and <u>tax information will be collected</u>, securely stored, and submitted electronically to Procurement Services as required.

►If this box is checked and an alternate method will be used, justify why you are unable to issue checks through the UVa Oracle or state system.

We have worked in this region for 7 years and Wal-Mart gift cards are always the most favorable form of compensation. There is immense value in having immediate compensation for their time involved in the health screenings. Also, these study populations are transient and are relatively difficult to track. Mailing, tracking and troubleshooting mailed

payments will cause added burden to the research staff.

IMPORTANT: If you check this box you will be required to submit the subjects' name, Social Security number, full address and amount of payment to Procurement at the end of each calendar year. The Office of the VP for Research will send you instructions on this procedure at a later date.

---

## Risk/ Benefit Analysis

1. **What are the potential benefits for the participant as well as benefits which may accrue to society in general, as a result of this study?**

**Parent/child dyads:**
Participants will gain information about improving health behaviors and weight through the education sessions, physical activity sessions, telephone calls, and newsletters. The primary benefit participants may experience is education and personalized goal setting and monitoring that may results in improvements in diet and increase in physical activity. This information might lead to lifestyle changes which could result in decreased weight status and improved health status. At each of the health screenings, participants will receive a handout that explains the results of their Body Mass Index (BMI) results. During the group education sessions participants will receive a personal action plan, workbooks, educational handouts, and other small incentives such as water bottles and measuring cups. Below is an example list of incentives and price for each items:

- Water Bottles $1.50
- T-Shirts $2.00
- MyPlates $5.00
- Draw-String Bags $1.70
- UNO cards $4.00
- Jump Ropes $2.00
- Stress balls $2.00

**Community Advisory Board and Parent Advisory Team:**
For members of the Community Advisory Board and Parent Advisory Team, there is no guarantee of benefits for participating in this study. However, understanding perceptions of capacity will help promote equity among all members. In turn, this will improve the likelihood of developing a collaborative team, and one that can successfully implement and sustain a childhood obesity reduction initiative in the Dan River Region. The potential direct benefit of Phase 1 is the development of two childhood obesity

treatment programs that could be sustained in the region and fill a current gap in healthcare.

When local evidence is available to stakeholder and parents regarding differences in adherence, effectiveness, and maintenance of the two programs (*i*Choose+ vs Family Connections), along with data regarding the potential for system sustainability, informed decisions can be made to help reduce childhood obesity disparities in the medically underserved DRR. It is hoped that the information gained from this study may be helpful for the future treatment of childhood obesity and sustainability of evidence-based programs in the Dan River Region.

**2. Do the anticipated benefits justify asking subjects to undertake the risks?**
Yes, the anticipated benefits justify the risks.

**Parent/child dyads:**
There are minimal risks for participants involved in this study. The main risk of taking part in this program is a small risk associated with starting a physical activity program with iChoose+ if participants have not been physically active.

The other risks are the inconvenience of time and potential discomfort of participating in the health screening. It is possible that completing the assessments could cause stress or anxiety; however, the questionnaires contain minimally sensitive questions. Nonetheless, all community based project staff and university research assistants will be trained to deal with this anticipated anxiety and each individual will always have the right to refuse to participate or to answer any questions on the survey.

**Community Advisory Board and Parent Advisory Team:**
There is no foreseeable risk of adverse effects for participating in the mixed-methods capacity evaluations. The only foreseeable risk is the possible inconvenience associated with answering the questions.

## Bibliography

1. Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999-2004. *JAMA.* 2006;295(13):1549-1555.
2. Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA.* 2014;311(8):806-814.
3. Ogden CL, Flegal KM, Carroll MD, Johnson CL. Prevalence and trends in overweight among US children and adolescents, 1999-2000. *JAMA.* 2002;288(14):1728-1732.
4. Bloomgarden ZT. Prevention of obesity and diabetes. *Diabetes Care.* 2003;26(11):3172-3178.
5. Bethell C, Simpson L, Stumbo S, Carle AC, Gombojav N. National, State, And Local Disparities In Childhood Obesity. *Health Affairs.* 2010;29(3):347-356.

6. Rossen LM, Schoendorf KC. Measuring health disparities: trends in racial−ethnic and socioeconomic disparities in obesity among 2- to 18-year old youth in the United States, 2001–2010. *Annals of Epidemiology.*22(10):698-704.
7. Virginia Department of Health. *Unequal Health Across the Commonwealth: A Snapshot.* Richmond, VA: Virginia Department of Health: Office of Minority Health & Public Health Policy;2008.
8. Virginia Department of Health Division of Health Statistics. Virginia Health Statistics 2008 Annual Report 2008.
9. U.S. Census Bureau State & County. 2008. http://quickfacts.census.gov/qfd/states/51000.html. Accessed 04/2010.
10. Medically Underserved Areas/Populations. U.S. Department of Health and Human Services, Health Resources and Services Administration. http://muafind.hrsa.gov/.
11. Woolf SH, Jones RM, Johnson RE, et al. Avertable Deaths Associated With Household Income in Virginia. *American Journal of Public Health.* 2010;100(4):750-755.
12. State and Regional Obesity Data: Centers for Disease Control and Prevention (CDC). . U.S. Department of Health and Human Services 2008. http://apps.nccd.cdc.gov/BRFSS/. Accessed 04/2010.
13. Regional and State Unemployment. U.S. Department of labor; 2011. Accessed 2011.
14. BMI Data of School Children. Yanceyville: Caswell County Public School District; 2011.
15. Commonwealth's Health Approach and Mobilization Plan for Inactivity, Obesity, and Nutrition (CHAMPION). 2006:1-137. http://www.vahealth.org/NuPAFP/Champion/Files/PDFs/CHAMPION%20Obesity%20Prevention%20Plan.pdf. Accessed May 2, 2010.
16. Wolfenden L, Wiggers J, d'Espaignet ET, Bell AC. How useful are systematic reviews of child obesity interventions? *Obesity Reviews.* 2010;11(2):159-166.
17. Epstein LH, Wing, R., Penner, B.C., Kress, M.J., Koeske, R. Effects of Family-Based Behavioral Treatment on Obese 5-to-8 Year-Old Children. *Behavior Therapy.* 1985(16):205-212.
18. Epstein LH, Wing, R., Valoski, A., Gooding, W. . Long-Term Effects of Parent Weight on Child Weight Loss. *Behavior Therapy.* 1987(18):219-226.
19. Reinehr T. Effectiveness of lifestyle intervention in overweight children. *Proc Nutr Soc.* 2011;70(4):494-505.
20. Reinehr T, de Sousa G, Andler W. Longitudinal analyses among overweight, insulin resistance, and cardiovascular risk factors in children. *Obes Res.* 2005;13(10):1824-1833.
21. Golan M, Crow S. Targeting parents exclusively in the treatment of childhood obesity: long-term results. *Obes Res.* 2004;12(2):357-361.
22. Golan M, Weizman A, Apter A, Fainaru M. Parents as the exclusive agents of change in the treatment of childhood obesity. *Am J Clin Nutr.* 1998;67(6):1130-1135.
23. Altman M, Wilfley DE. Evidence update on the treatment of overweight and obesity in children and adolescents. *Journal of clinical child and adolescent psychology : the official journal for the Society of Clinical Child and Adolescent Psychology, American Psychological Association, Division 53.* 2015;44(4):521-537.
24. Epstein LH, Valoski A, Wing RR, McCurley J. Ten-year outcomes of behavioral family-based treatment for childhood obesity. *Health Psychology.* 1994;13(5):373-383.
25. Golan M, Kaufman V, Shahar DR. Childhood obesity treatment: targeting parents exclusively v. parents and children. *Br J Nutr.* 2006;95(5):1008-1015.

26. Savoye M, Berry D, Dziura J, et al. Anthropometric and psychosocial changes in obese adolescents enrolled in a Weight Management Program. *Journal of the American Dietetic Association.* 2005;105(3):364-370.
27. Savoye M, Nowicka P, Shaw M, et al. Long-term results of an obesity program in an ethnically diverse pediatric population. *Pediatrics.* 2011;127(3):402-410.
28. Savoye M, Shaw M, Dziura J, et al. Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial. *JAMA : the journal of the American Medical Association.* 2007;297(24):2697-2704.
29. Katzmarzyk PT, Barlow S, Bouchard C, et al. An evolving scientific basis for the prevention and treatment of pediatric obesity. *International journal of obesity (2005).* 2014;38(7):887-905.
30. Berrey M, Davy B, Dunsmore J, Berry D, Estabrooks P, Frisard M. Evaluation of pediatric weight management programs using the RE-AIM framework. Poster Presentation presented at Virginia Dietetics Association; 2012; Blacksburg VA.
31. Best A, al e. NCIC Working Group on Translational Research and Knowledge Integration. The language and logic of research transfer: Finding common ground. 2005.
32. Changing the conversation: Regional Assessments Healthcare Challenges and Opportunities. 2007:1-48. http://www.danvilleregionalfoundation.org/region/documents/2008-HealthAssessment.pdf. Accessed May 2, 2010.
33. Estabrooks PA, Glasgow RE. Translating effective clinic-based physical activity interventions into practice. *American Journal of Preventive Medicine.* 2006;31(4):S45-S56.
34. Slusser W, Staten K, Stephens K, et al. Payment for obesity services: examples and recommendations for stage 3 comprehensive multidisciplinary intervention programs for children and adolescents. *Pediatrics.* 2011;128 Suppl 2:S78-85.
35. Skelton JA, Beech BM. Attrition in paediatric weight management: a review of the literature and new directions. *Obesity reviews : an official journal of the International Association for the Study of Obesity.* 2011;12(5):e273-281.
36. Cote MP, Byczkowski T, Kotagal U, Kirk S, Zeller M, Daniels S. Service quality and attrition: an examination of a pediatric obesity program. *International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua.* 2004;16(2):165-173.
37. Denzer C, Reithofer E, Wabitsch M, Widhalm K. The outcome of childhood obesity management depends highly upon patient compliance. *European journal of pediatrics.* 2004;163(2):99-104.
38. Kirk S, Zeller M, Claytor R, Santangelo M, Khoury PR, Daniels SR. The relationship of health outcomes to improvement in BMI in children and adolescents. *Obesity research.* 2005;13(5):876-882.
39. Zeller M, Kirk S, Claytor R, et al. Predictors of attrition from a pediatric weight management program. *The Journal of pediatrics.* 2004;144(4):466-470.
40. Barlow SE, Ohlemeyer CL. Parent reasons for nonreturn to a pediatric weight management program. *Clinical pediatrics.* 2006;45(4):355-360.
41. Klesges LM, Williams NA, Davis KS, Buscemi J, Kitzmann KM. External validity reporting in behavioral treatment of childhood obesity: a systematic review. *Am J Prev Med.* 2012;42(2):185-192.

42. Estabrooks PA, Shoup JA, Gattshall M, Dandamudi P, Shetterly S, Xu S. Automated Telephone Counseling for Parents of Overweight Children A Randomized Controlled Trial. *Am J Prev Med.* 2009;36(1):35-42.
43. Kalarchian MA LM, Arslanian SA, Ewing LJ, Houck PR, Cheng Y, et al. . Family-based treatment of severe pediatric obesity: randomized, controlled trial. *Pediatrics.* 2009;124(4):1060-1068.
44. McLean N, Griffin S, Toney K, Hardeman W. Family involvement in weight control, weight maintenance and weight-loss interventions: a systematic review of randomised trials. *Int J Obes Relat Metab Disord.* 2003;27(9):987-1005.
45. Atlantis E, Barnes EH, Singh MA. Efficacy of exercise for treating overweight in children and adolescents: a systematic review. *International journal of obesity (2005).* 2006;30(7):1027-1040.
46. Collins CE, Warren J, Neve M, McCoy P, Stokes BJ. Measuring effectiveness of dietetic interventions in child obesity: a systematic review of randomized trials. *Archives of pediatrics & adolescent medicine.* 2006;160(9):906-922.
47. Oude L, Baur L, Jansen H. Interventions for treating obesity in children. *Cochrane Database Syst Rev.* 2009;1(CD001872).
48. Wilfley D, Stein R, Saelens B. Efficacy of Mainteance Treatment Approaches for Childhood Overwieght. *JAMA.* 2007;298(14):1661-1673.
49. Hystad HT, Steinsbekk S, Odegard R, Wichstrom L, Gudbrandsen OA. A randomised study on the effectiveness of therapist-led v. self-help parental intervention for treating childhood obesity. *The British journal of nutrition.* 2013;110(6):1143-1150.
50. Okely AD, Collins CE, Morgan PJ, et al. Multi-site randomized controlled trial of a child-centered physical activity program, a parent-centered dietary-modification program, or both in overweight children: the HIKCUPS study. *The Journal of pediatrics.* 2010;157(3):388-394, 394.e381.
51. Collins CE, Okely AD, Morgan PJ, et al. Parent diet modification, child activity, or both in obese children: an RCT. *Pediatrics.* 2011;127(4):619-627.
52. Arauz Boudreau AD, Kurowski DS, Gonzalez WI, Dimond MA, Oreskovic NM. Latino families, primary care, and childhood obesity: a randomized controlled trial. *Am J Prev Med.* 2013;44(3 Suppl 3):S247-257.
53. Croker H, Viner R, Nicholls D, et al. Family-based behavioural treatment of childhood obesity in a UK National Health Service setting: randomized controlled trial. . *International journal of obesity (2005).* 2012;36(1):16-26.
54. Kalarchian M, Levine M, Arslanian S, et al. Family-based treatment of severe pediatric obesity: randomized, controlled trial. *Pediatrics.* 2009;124(4):1060-1068.
55. Ogden CL, Kuczmarski RJ, Flegal KM, et al. Centers for Disease Control and Prevention 2000 growth charts for the United States: Improvements to the 1977 National Center for Health Statistics version. *Pediatrics.* 2002;109(1):45-60.
56. Beechler M. Obesity Prevention and Reduction Program Development Report. The Danville Regional Foundation; May 2009:1-19.
57. Motley M, Holmes A, Hill J, Plumb K, Zoellner J. Evaluating Community Capacity to Reduce Obesity in the Dan River Region. *American Journal Health Behavior.* 2013;37(2):208-217.
58. Zoellner J, Motley M, Hill J, Wilkinson M, Jackman B, Barlow M. Engaging the Dan River Region to reduce obesity: Application of the Comprehensive Participatory Planning and Evaluation Process. *Fam Community Health.* 2011;35(1):44-56.

59. Israel B, Eng E, Schulz A, Parker E, eds. *Methods in Community-Based Participatory Research for Health.* San Francisco: Jossey-Bass; 2005.
60. Minkler M, Wallerstein N, eds. *Community Based Participatory Research for Health: From process to outcomes.* 2nd edition ed. San Francisco: Jossey Bass; 2008.
61. Minkler M, Wallerstein N, Wilson N. Improving health through community organization and community building. In: Glantz K RB, Viswanath K editors, ed. *Health behavior and health education: Theory, research & practice*. San Francisco: Jossey-Bass; 2008.
62. Wallerstein N, Duran B. Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. *American Journal of Public Health.* 2010;Suppl 1:S40-46.
63. Swider SM. Outcome Effectiveness of Community Health Workers: An Integrative Literature Review. *Public Health Nursing.* 2002;19(1):11-20.
64. Jackson EJ, Parks CP. Recruitment and Training Issues from Selected Lay Health Advisor Programs among African Americans: A 20-Year Perspective. *Health Education & Behavior.* 1997;24(4):418-431.
65. Fouad M, Johnson R, Nagy M, Person S, Partridge E. Adherence and Retention in Clinical Trials: A Community-Based Approach. *Cancer.* 2014;120(07):1106-1112.
66. Katula JA, Vitolins MZ, Rosenberger EL, et al. Healthy Living Partnerships to Prevent Diabetes (HELP PD): Design and methods. *Contemporary Clinical Trials.*31(1):71-81.
67. Katula JA, Vitolins MZ, Rosenberger EL, et al. One-Year Results of a Community-Based Translation of the Diabetes Prevention Program: Healthy-Living Partnerships to Prevent Diabetes (HELP PD) Project. *Diabetes Care.* 2011;34(7):1451-1457.
68. Katula JA, Vitolins MZ, Morgan TM, et al. The Healthy Living Partnerships to Prevent Diabetes Study. *American Journal of Preventive Medicine.*44(4):S324-S332.
69. Berry D, Savoye M, Melkus G, Grey M. An intervention for multiethnic obese parents and overweight children. *Appl Nurs Res.* 2007;20(2):63-71.
70. Ho M, Garnett SP, Baur L, et al. Effectiveness of lifestyle interventions in child obesity: systematic review with meta-analysis. *Pediatrics.* 2012;130(6):e1647-1671.
71. Estabrooks P, Fisher E, Hayman L. What is Needed to Reverse the Trends in Childhood Obesity? A Call to Action. *Annals of Behavioral Medicine.* 2008;36(3):209-216.
72. Klesges L, Estabrooks P, Dzewaltowski D, Bull S, Glasgow R. Beginning with the application in mind: designing and planning health behavior change interventions to enhance dissemination. *Ann Behav Med.* 2005;29:66-75.
73. Estabrooks PA, Lee RE, Gyurcsik NC. Resources for physical activity participation: Does availability and accessibility differ by neighborhood socioeconomic status? *Annals of Behavioral Medicine.* 2003;25(2):100-104.
74. Zwarenstein M, Treweek S, Gagnier JJ, et al. Improving the reporting of pragmatic trials: An extension of the CONSORT statement. *BMJ (Clinical research ed.).* 2008;337:a2390.
75. US Department of Health and Human Services HRaSA. Effective Communication Tools for Healthcare Professionals
76. Fisher L, Hessler D, Naranjo D, Polonsky W. AASAP: A program to increase recruitment and retention in clinical trials. *Patient Education and Counseling.* 2012;86(3):372-377.
77. Jacobs JA, Jones E, Gabella BA, Spring B, Brownson RC. Tools for implementing an evidence-based approach in public health practice. *Preventing chronic disease.* 2012;9:E116.

78. Barlow S. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics.* 2007;120(Suppl 4):S164-192.
79. Screening for Obesity in Children and Adolescents: US Preventive Services Task Force Recommendation Statement. *Pediatrics* 2010;125(2):361–367.
80. Brito F, Zoellner J, Hill J, et al. Evaluating a parent workbook for childhood obesity management using clear communication strategies. Society of Behavioral Medicine Annual Meeting & Scientific Sessions.; Apr 2015; San Antonio, TX.
81. Shaw M, Savoye M, Cali A, Dziura J, Tamborlane WV, Caprio S. Effect of a successful intensive lifestyle program on insulin sensitivity and glucose tolerance in obese youth. *Diabetes Care.* 2009;32(1):45-47.
82. Edmunds JM, Beidas RS, Kendall PC. Dissemination and Implementation of Evidence-Based Practices: Training and Consultation as Implementation Strategies. *Clin Psychol (New York).* 2013;20(2):152-165.
83. Estabrooks P, Shoup JA, Gattshall M, Dandamudi P, Shetterly S, Xu S. The effectiveness of automated telephone counseling for parents of overweight children. *American Journal of Preventive Medicine.* 2009;36:35-42.
84. Pinard C, Hart M, Hodgkins Y, Serrano E, McFerren M, Estabrooks P. Smart choices for healthy families: A feasibility study for the treatment of childhood obesity in low-income families. *Health Educ Behav.* 2012;39:433-445.
85. Godin G, Shephard R. A simple method to assess exercise behavior in the community. *Can J Appl Sport Sci.* 1985 10:141-146.
86. Centers for Disease Control and Prevention. Public Health Surveillance of Fruit and Vegetable Intake Using the Behavioral Risk Factor Surveillance System. http://www.cdc.gov/brfss/data_documentation/PDF/fruits_vegetables.pdf
87. Hedrick V, Comber D, Estabrook P, Savla J, Davy B. The beverage intake questionnaire: Determining Initial validity and reliablity *J Am Diet Assoc.* 2010;110(8):1227-1232.
88. Hedrick VE, Savla J, Comber DL, et al. Development of a Brief Questionnaire to Assess Habitual Beverage Intake (BEVQ-15): Sugar-Sweetened Beverages and Total Beverage Energy Intake. *J Acad Nutr Diet.* 2012;112(6):840-849.
89. Centers for Disease Control and Prevention. *Health-Related Quality of Life (HRQOL). Healthy Days Core Module.* http://www.cdc.gov/hrqol/hrqol14_measure.htm.
90. Glasgow RE, Klesges LM, Dzewaltowski DA, Estabrooks PA, Vogt TM. Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. *Health Educ Res.* 2006;21(5):688-694.
91. Weiss B, Mays M, Martz W, et al. Quick assessment of literacy in primary care: The Newest Vital Sign. *Ann Fam Med.* 2005;3:514-522.
92. Warsh J, Chari R, Badaczewski A, Hossain J, Sharif I. Can the Newest Vital Sign Be Used to Assess Health Literacy in Children and Adolescents? *Clinical Pediatrics.* 2014;53(2):141-144.
93. Fagerlin A, Zikmund-Fisher BJ, Ubel PA, Jankovic A, Derry HA, Smith DM. Measuring numeracy without a Math test: Development of the subjective numeracy scale. *Med Decis Making.* 2007;27(5):672-680.
94. Zikmund-Fisher BJ, Smith DM, Ubel PA, Fagerlin A. Validation of the subjective numeracy scale: Effects of low numeracy on comprehension of risk communications and utility elicitations. *Med Decis Making.* 2007;27(5):663-671.

95. Linnan L SA. Process evaluation for public health interventions and research: An overview. In: Linnan L SA, ed. San Francisco: Jossey-Bass; 2002:1-23.
96. Zoellner J, Hill J, Barlow M, et al. Capacity Development and One-Year Progression of a Childhood Obesity Treatment Community Advisory Board. Poster presentation at the National Institutes for Minority Health and Health Disparities Conference, Dec 2014, Bethesda, MD; Under Review with Health Promotion Practice Jan 2016.
97. Newman SD, Andrews JO, Magwood GS, Jenkins C, Cox MJ, Williamson DC. Community Advisory Boards in Community-Based Participatory Research: A Synthesis of Best Processes. *Prev. Chronic Dis.* 2011;8(3).
98. Galimard JE, Chevret S, Protopopescu C, Resche-Rigon M. A multiple imputation approach for MNAR mechanisms compatible with Heckman's model. *Statistics in medicine.* 2016.
99. Imai K, Ratkovic M. Estimating treatment effect heterogeneity in randomized program evaluation. *The Annals of Applied Statistics.* 2013;7(1):443-470.
100. Creswell J, Plano Clark V. *Designing and Conducting Mixed Methods Research.* Thousands Oaks, CA: Sage Publication, Inc.; 2007.
101. Graneheim U, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Education Today.* 2004;24(2):105-112.
102. Elo S, Kyngäs H. The qualitative content analysis process. *Journal of Advanced Nursing.* 2008;62(1):107-115.
103. Patton M. *Qualitative Reserach & Evaluation Methods.* 3rd ed. Thousands Oak: Sage Pulblication, Inc.; 2002.
104. Donkin L, Hickie I, Christensen H, et al. Rethinking the Dose-Response Relationship Between Usage and Outcome in an Online Intervention for Depression: Randomized Controlled Trial. *J Med Internet Res.* 2013;15(10):e231.
105. Beyond Scientific Publication: Strategies for Disseminating Research Findings. *CARE: Community Alliance for Research and Engagement.*1-19. http://www.researchtoolkit.org/primer/docs/CARE%20Research%20Dissemination%20Guide.pdf.
106. Hatcher J, Schoenberg N. Human subjects protection training for communty workers: an example from "Faith Moves Mountatins". *Progress Community Health Partnersh.* 2007;1(3):257-265.

## APPENDIX: Non- UVa Personnel

1. **Explain the duties of non-UVA personnel on this protocol.**
   The following organization/individuals have sub-contracts to engage in the proposed work.
   - **University of Nebraska Medical Center**
     - ***Principal Investigator. Paul A. Estabrooks, PhD,*** Dr. Estabrooks is the Harold M. Maurer Distinguished Chair and Professor in the Department of Health Promotions, Social and Behavioral Health at the University of Nebraska Medical Center's College of Public Health. Working collaboratively with Dr. Zoellner, he will contribute to the

overall execution and management of the proposed research . His primary leadership role will be in the implementation and oversight of each of the active interventions, including process evaluation and intervention implementation quality control through monitoring electronic data and regular intervention team meetings. He will also provide support to Dr. Zoellner on the community capacity aims including the development and implementation of the community health worker protocol. In addition to overseeing the intervention implementation and process, Dr. Estabrooks will lead ongoing training for the intervention delivery staff on in-person meetings and responsiveness to IVR needs. Dr. Estabrooks will participate in the Community Advisory Board (CAB) throughout the project period. Dr. Estabrooks, along with Dr. Zoellner will be responsible for leading the dissemination of results through peer reviewed manuscripts and/or presentations at scientific meetings.

- ***Co-Investigator. Jennie L. Hill, PhD,*** Dr. Hill will provide oversight for adherence to data collection policies and procedures among community and research-based staff. She will continue in her role as a POPS-CAB member. She will work also work with the MPIs to execute the proposed project, including preparation of manuscripts, presentation at scientific meetings and dissemination back to the community.

- **SOVAH Pediatrics (formerly Children's Healthcare Center)**. The primary role of SOVAH Pediatrics is with study recruitment.
  - ***Deana Jones, Office Manager***, will collaborate with other staff nurses to develop a standard procedure for their institution to refer eligible families for potential study participation. Having this procedure in place will allow for continuous real time recruitment and a more streamlined process. Quarterly attendance at the CAB meetings to provide feedback and suggestions.

  - ***Stephanie Phelps, Recruitment Coordinator***, will provide continued expertise in participant recruitment processes. Will assist UVA research team with the initial screening and enrollment scheduling for referrals from SOVAH Pediatrics. Together with office manager will develop a standard procedure for referral for their institution. Will give feedback and suggestions at the CAB meetings held quarterly.

- **Piedmont Access to Health Services: PATHS.** The primary role of PATHS is with study recruitment. Two recruitment coordinators are identified form

the PATHS Danville office to refer patients to the Danville site and two TBD recruitment coordinators will be identified from the PATHS Chatham office to refer patients to the Chatham site.

- **Brandy Durham, Patient Service Representative Danville office,** will collaborate with the PATHS Director of Data Support (Robet Thurman) and the academic research team to identify, refer, and assist in reaching out to eligible families served by PATHS pediatricians.

- **Melinda Bennett, Registered Medical Assistant Danville office,** will collaborate with the PATHS Director of Data Support (Robet Thurman) and the academic research team to identify, refer, and assist in reaching out to eligible families served by PATHS pediatricians.

- **Carol Grant, RMA, Chatham Site Manager, Chatham Office,** will collaborate with the PATHS Director of Data Support (Robet Thurman) and the academic research team to identify, refer, and assist in reaching out to eligible families served by PATHS pediatricians.

- **Cynthia Hammel, RN, Chatham Office,** will collaborate with the PATHS Director of Data Support (Robet Thurman) and the academic research team to identify, refer, and assist in reaching out to eligible families served by PATHS pediatricians.

- **Hannah Lewis, RN, Chatham Office,** will collaborate with the PATHS Director of Data Support (Robet Thurman) and the academic research team to identify, refer, and assist in reaching out to eligible families served by PATHS pediatricians.

- **<u>The City of Danville Parks & Recreation.</u>** The primary role of The City of Danville Parks & Recreation is with program delivery of both iChoose and Family Connections, patient monitoring, and data collection.
  - ***Danielle Montague, Program Leader1*** –This position will be involved in the recruitment process via screening and enrollment of both physician and self-referred (through open enrollment) participants. The person will assist in developing relationships with schools, businesses, and healthcare providers to disseminate open enrollment recruitment information. The program leader will assist Virginia Tech research team in gathering outcome and process data. Most importantly, the individual will implement both the family education and exercise classes, lead fidelity and retention efforts, and coordinate/manage support calls. This position will attend the CAB quarterly meetings and PAT monthly meetings, and provide feedback to the Virginia Tech research team.

- ***Jonathon Wilson, Program Leader2*** – This position will be involved in the recruitment process via screening and enrollment of both physician and self-referred (through open enrollment) participants. The person will assist in developing relationships with schools, businesses, and healthcare providers to disseminate open enrollment recruitment information. The program leader will assist Virginia Tech research team in gathering outcome and process data. Most importantly, the individual will implement both the family education and exercise classes, lead fidelity and retention efforts, and coordinate/manage support calls. This position will attend the CAB quarterly meetings and PAT monthly meetings, and provide feedback to the Virginia Tech research team. A Personnel Change Form will be submitted when this person is added to the study team.

- ***Elizabeth Thomas, Program Leader3*** – This position will be involved in the recruitment process via screening and enrollment of both physician and self-referred (through open enrollment) participants. The person will assist in developing relationships with schools, businesses, and healthcare providers to disseminate open enrollment recruitment information. The program leader will assist Virginia Tech research team in gathering outcome and process data. Most importantly, the individual will implement both the family education and exercise classes, lead fidelity and retention efforts, and coordinate/manage support calls. This position will attend the CAB quarterly meetings and PAT monthly meetings, and provide feedback to the Virginia Tech research team. A Personnel Change Form will be submitted when this person is added to the study team.

- **Virginia Tech**

  - **Co-Investigator. Wen You, PhD,** is an Associate Professor in the Department of Agricultural and Applied Economics at Virginia Tech. Dr. You is a health economist and applied econometrician. She has a strong history of collaborating with behavioral scientists for health outcomes, including productive work with the MPIs during the past 5 years. Dr. You will be responsible for cost tracking related to intervention development and implementation across both *i*Choose and *Family Connections*. As an econometrician, Dr. You has extensive training in biostatistics and will oversee the analytic components of the project for the primary and secondary outcomes as well as cost data collection and analysis during the 3-year study. She will participate in the preparation of manuscripts and reports related to the study. As appropriate, Dr. You will be available to meet with

community partners related to analyses related to the study aims, costs, and methods for cost tracking.

- **Undergraduate/Graduate Research Assistants:** These include students studying in the Human Nutrition, Food, and Exercise Department at Virginia Tech University. Current students include: Jacob Nottingham (undergraduate), Kristina Caparrelli (undergraduate), Michaela Miller (undergraduate), and Renee Eaton (PhD student). All students have completed UVA CITI Human Subjects training.

- **<u>Parent Advisory Team</u>**
  - The Parent Advisory Team (PAT) members (estimated at approximately 10 parents) serve in a similar role as a community health worker or patient navigator. They will participate in three main areas. First, they will be asked to attend monthly meetings and trainings. Second, they will be asked to assist in distributing recruitment materials for our open referral/enrollment process. This will include helping potential families understand both programs and timing of the intervention sessions. Third, they will be asked to support family adherence and provide a program 'safety net'. This will include contacting enrolled families and supporting their needs to be successfully engaged it the program. These PAT members will NOT be collecting data, nor will they have access to outcome data. PAT members will NOT be responsible for any aspect of the signed informed consent or assent process. PAT members may NOT be simultaneously enrolled at participants in the childhood obesity treatment program.

  - We will be training 6 parents (Tia Yancey, Wanda Breedlove, Pamela Carter, Misty Roveta, Julie Matejko, and Sylvia Fitz) on research ethics. The principal investigator will keep training records for this group of study team members, which will be submitted with the annual continuation status form. If additional parents participate, the same procedures will be applied.

  - Mindy Greiner and Kaitlyn Cardoza are two additional graduating parents (from Cohort 2) who have joined the PAT as of April 2019. They have completed the same research ethics training as the previous PAT members and will be responsible for the same duties as

- **Morgan Barlow, Facilitator and Capacity Evaluator.** Morgan Barlow is a Research Analyst with Duke University's Center for Health Policy and

Inequalities Research at the Duke Global Health Institute. Ms. Barlow currently serves as the neutral facilitator for the POPS-CAB meetings and leads consensus decision making processes. She is well known, liked, and trusted among the POPS-CAB. She is also the external evaluator who leads data collection and evaluation for the POPS-CAB Community Capacity Evaluation Plan. We are requesting funds for Ms. Barlow to continue in this role. More specifically, in Years 1-3 she will facilitate the quarterly CAB meetings, and also participate in conference calls as needed. When neutral facilitation is needed for any of the planning or implementation aspects of this project, Ms. Barlow will play a key role in ensuring equal representation of the diverse community and academic stakeholders and promoting shared decision making power. Related to the community capacity assessment aim, she will also conduct annual structured interviews with members of the POPS-CAB. She will prepare interim reports after each phase of interviews and present these findings to the CAB, which will inform progression and sustainability.

**2. Explain your plans for training and oversight of these personnel**.

- The academic research team will have weekly conference calls to monitor the progress of the study and address any concerns, including IRB related protocol.
- The academic team will meet quarterly with the entire CAB to discuss the study's progress and oversight.
- For those CAB members who and also part of the childhood obesity treatment program recruitment and implementation team, there will be regular monthly meetings, which include training aspects. Intervention will be delivered by program coordinators at Danville Parks & Recreation with an undergraduate degree in wellness, physical education, nutrition, or a related degree. Training for intervention delivery will be completed using a consultation approach that achieved fidelity to intervention activities at a rate exceeding 90%. [66-68] Lesson plans, scripted PowerPoint assisted session materials, and fidelity checklists will be used to increase the likelihood of consistent delivery of each intervention as intended. In addition, intervention components facilitated by interactive voice response technology will be monitored by the program coordinator.
- The academic team will also meet monthly with the Parent Health Advisors to provide oversight for the parent members who are playing a supportive role to assist families to overcome barriers to attendance, call completion, and maintenance of changes). Prior to the interventions starting, the training program will consist of a ~36 hours program that will incorporate didactic education, experiential and role playing instruction, peer-mentoring, and observation. A UVA research member residing in the region (Bryan Price), is assigned to monitor the day-to-day activities of this group.

- Both groups will meet using a mix of in-person and conference call meetings and use a shared-decision making and participatory agenda meeting structure to guide all aspects of the study. As required by our PCORI funding agency, our intent is to engage these influential partners in all aspects of planning the research, conducting the research, and disseminating findings.

**3. How do you plan to access any study records the non-UVA personnel might maintain?**

All outcome data will be maintained by UVA personnel. The screening data that is primarily maintained by SOVAH Pediatrics and PATHS personnel will be retrieved in-person on a monthly basis, or earlier if needed, based on the status of recruiting process. If needed more frequently than monthly, screening data may also be faxed directly to the UVA researchers or mailed. The process, field notes maintained by the Parent Advisory Team, will also be retrieved on a monthly basis during regular team meetings.

**4. Will the non- UVA personnel be exposed to any additional risk while working on this protocol?**

No.

**5. List name of any other institution with which they have an affiliation**.

Non-UVa study team members have affiliations listed above.

**6. Will the non- UVa personnel have access to UVa patients or their health information along with any HIPAA identifiers prior to consent?**

These are not UVA patients. However, the only non-UVa personnel that will have access to HIPAA identifiers prior to consent are the nurses who are helping with screening at SOVAH Pediatrics and PATHS and the Parks & Rec program leader staff (all who have passed CITI certification) who may assist in telephone screenings after the initial contact by SOVAH Pediatrics or PATHS.

| YES | NO | |
|---|---|---|
| X | | 1. Name |
| X | | 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people and (2) The initial 3 digits of a zip code for all such geographic units containing 20,000 is changed to 000. |
| X | | 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of |

| | | |
|---|---|---|
| | | death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.<br>*[This means you may record the year but not record the month or day of any date related to the subject if the subject is under the age of 89. In addition if the subject is over the age of 89 you may not record their age and you may not record the month, day or year of any date related to the subject ]* |
| X | | 4. Telephone numbers |
| | X | 5. Fax numbers |
| | X | 6. Electronic mail addresses |
| | X | 7. Social Security number |
| | X | 8. Medical Record number |
| | X | 9. Health plan beneficiary numbers |
| | X | 10. Account numbers |
| | X | 11. Certificate/license numbers |
| | X | 12. Vehicle identifiers and serial numbers, including license plate numbers |
| | X | 13. Device identifiers and serial numbers |
| | X | 14. Web Universal Resource Locators (URLs) |
| | X | 15. Internet Protocol (IP) address numbers |
| | X | 16. Biometric identifiers, including finger and voice prints |
| | X | 17. Full face photographic images and any comparable images |
| | X | 18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.) |
| | X | 19. Any other information that could be used alone or in combination with other information to identify an individual. (*e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code* . ) |

**7. If any items above are checked YES, list names of non- UVa affiliated individuals who will have access.**

Deana Jones, Office Manager
Stephanie Phelps, Recruitment Coordinator
Danielle Montague, Program Leader1
TBD, Program Leader 2

## APPENDIX: Legal/Regulatory

**Recruitment**

The following procedures will be followed:

- Finder's fees will not be paid to an individual as they are not allowed by UVa Policy.
- All recruitment materials will be approved by the IRB-HSR prior to use. They will be submitted to the IRB after the IRB-HSR has assigned an IRB-HSR # to the protocol.
- Only those individuals listed as personnel on this protocol will recruit and or conduct the consenting process with potential subjects.

**Retention Incentives**

Any item used by the sponsor/ study team to provide incentive to a subject to remain in the study, other than compensation identified in the Payment section, will be submitted to the IRB for review prior to use. The IRB-HSR will provide the study team with a Receipt Acknowledgement for their records. Retention incentive items are such things as water bottles, small tote bags, birthday cards etc. Cash and gift cards are not allowed as retention incentives.

**Clinical Privileges**

The following procedures will be followed:

- Investigators who are members of the clinical staff at the University of Virginia Medical Center must have the appropriate credentials and been granted clinical privileges to perform specific clinical procedures whether those procedures are experimental or standard.
- The IRB cannot grant clinical privileges.
- Performing procedures which are outside the scope of the clinical privileges that have been granted may result in denial of insurance coverage should claims of negligence or malpractice arise.
- Personnel on this protocol will have the appropriate credentials and clinical privileges in place before performing any procedures required by this protocol.
- Contact the Clinical Staff Office- 924-9055 or 924-8778 for further information.

**Sharing of Data/Specimens**

Data and specimens collected under an IRB approved protocol are the property of the University of Virginia. You must have "permission" to share data/ specimens outside of UVa other than for a grant application and or publication. This "permission" may come in the form of a contract with the sponsor or a material transfer agreement (MTA) with others. A contract/ MTA is needed to share the data outside of UVa even if the data includes no HIPAA identifiers and no code that could link the data back to a HIPAA identifier.

- No data will be shared outside of UVa, beyond using data for a grant application and or publication, without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

- No specimens will be shared outside of UVa without a signed contract/MTA approved by the SOM Grants and Contracts office/ OSP or written confirmation that one is not needed.

**Prisoners**

If the original protocol/ IRB application stated that no prisoners would be enrolled in this study and subsequently a subject becomes a prisoner, the study team must notify the IRB immediately. The study team and IRB will need to determine if the subject will remain in the study. If the subject will remain in the study, the protocol will have to be re-reviewed with the input of a prisoner advocate. The prisoner advocate will also have to be involved in the review of future continuations, modifications or any other reporting such as protocol violations or adverse events.

Prisoner- Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.
For additional information see the OHRP website at
http://www.hhs.gov/ohrp/policy/populations/index.html

**Compensation in Case of Injury**

If a subject requests compensation for an injury, the study team should notify the IRB-HSR (924-9634/2439847) the UVa Health System Patient Relations Department (924-8315). As a proactive courtesy, the study team may also notify UVa Health System Patient Safety and Risk Management (924-5595).

On request, the study team should provide the Risk Management Office with the following information/documents:

- Subject Name and Medical Record Number
- Research medical records
- Research consent form
- Adverse event report to IRB
- Any letter from IRB to OHRP

**Subject Complaints**

During a research study, the study team may receive complaints from a subject. If the study team is uncertain how to respond to a complaint, or is unable to resolve it with the subject, the study team may contact the IRB-HSR (924-9634/243-9847), the UVa Health System Patient Relations Department (924-8315).

**Request for Research Records from Search Warrant or Subpoena**

If the study team receives a request for research records from a search warrant or subpoena, they should notify UVa Health Information Services at 924-5136. It is

important to notify them if information from the study is protected by a Certificate of Confidentiality.

## APPENDIX: Recruitment

**The following documents will be submitted for advertisement approval prior to subject recruitment:**

**For chart reviews:**

1. tracking eligible children
2. Physician letter
3. DualProgramBrochure
4. Opt Out post card
5. Telephone recruitment script_Physician Referral

**For open enrollment:**

6. Recruitment Flyer PCORI
7. Recruitment Newspaper Ad PCORI
8. Recruitment School Letter PCORI
9. Telephone recruitment script

**1. How do you plan to <u>identify</u> potential subjects?**

a.__X__ Chart Review/ Clinic Schedule Review/ Database Review from a database established for health care operations (departmental clinical database) or an Improvement Project .

<u>DHHS:</u> Study team requests Waiver of Consent to identify potential subjects.

<u>HIPAA:</u> Allowed under Preparatory to Research if PHI to be accessed.

<u>IMPORTANT</u>
Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

b____ Review of a database that was established to keep data to be used for future research such as the CDR, departmental research

database or use of data from a separate current active research protocol.

DHHS: Study team requests Waiver of Consent to identify potential subjects.

HIPAA: Allowed under Preparatory to Research if PHI to be accessed.

IMPORTANT
Keep in mind that PHI in the medical record may only be accessed by individuals who work under the UVa HIPAA covered entity; which means they who meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

The information from which you are obtaining potential subjects must also have an IRB protocol approval. If this item is checked, enter the IRB # below.

**IRB#** _____

If obtaining information from the Clinical Data Repository (CDR) insert IRB # 10797

c. ____ Patient's UVa health care provider supplies the UVa study team with the patients contact information without patients' knowledge.

d. __X__ Patient obtains information about the study from their health care provider. The patient contacts the study team if interested in participating. (Health care provider may or may not also be the a member of the study team)

DHHS: NA
HIPAA: Allowed under Health Care Operations

If this choice is checked, check 3d-INDIRECT CONTACT below.

e. __X__ Potential subjects will not be directly identified. They will respond to an advertisement such as a flyer, brochure etc.

If this choice is checked, check 3d- INDIRECT CONTACT below.
DHHS & HIPAA: NA

f. _____ Potential subjects have previously signed a consent to have their name in a registry/database to be contacted for future studies of this type.

**IRB# of registry/ database:** _____

DHHS & HIPAA: NA

g. __X__ Other*:* Specify Answer/Response:
Community Advisory Board members were identified and named when the PCORI application was submitted. These are representatives from organizations in the Dan River Region who have a child-focused organizational mission, invited as a stakeholder. Parent Advisory Team members are parents who previously participated in a childhood obesity program and/or are the parent of a child ages 5-12 years of age.

**If item # a, b or c is checked above and if this protocol involves the use of protected health information do you confirm the following to be true?**

- The use or disclosure is sought solely to review protected health information as necessary to prepare the research protocol or other similar preparatory purposes.
- No PHI will be removed from the UVa covered entity.
- The PHI that the researcher seeks to use or access is necessary for the research purposes.

Yes

**2. How will potential subjects be <u>contacted?</u>**

a.__X__Direct contact of potential subjects by the study team via letter, phone, direct e-mail. Members of study team ARE NOT health care providers of patients. Information will not be collected from psychotherapy notes.

<u>Note:</u> Letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

<u>DHHS/HIPAA:</u> Study team requests a Waiver of Consent and Waiver of HIPAA Authorization to contact potential subjects.

<u>IMPORTANT:</u>

Keep in mind that if PHI was collected during the identification phase that contact with potential subjects may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:

- a UVa student working in the UVa HIPAA Covered Entity*
- a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

b.____Potential subjects will be approached while at UVa Hospital or Health Clinic by a person who is NOT a member of their health care team. Information will not be collected from psychotherapy notes.

DHHS & HIPAA: Study team requests a Waiver of Consent and a Waiver of HIPAA Authorization to contact potential subjects.

IMPORTANT:
Keep in mind that contacting individuals in a clinical setting may only be performed by individuals who work under the UVa HIPAA covered entity; which means they meet one of the following criteria:
a UVa student working in the UVa HIPAA Covered Entity*
a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

You should share the following information with the potential subject:

- Your name
- Who you are: physician, nurse etc. at the University of Virginia.
- Why you want to speak with them
- Ask if you have their permission to explain the study to them
- If asked about how you obtained their information use one of the following as an option for response.
    - DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THEIR UVa PHYSICIAN: Your doctor, Dr. insert name wanted

you to be aware of this research study and gave us permission to contact you.
- We obtained your information from your medical records at UVa.
- Federal regulations allow the UVa Health System to release your information to researchers at UVa, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.

- IF THE PERSON SEEMS ANGRY, HESITANT OR UPSET, THANK THEM FOR THEIR TIME AND DO NOT ENROLL THEM IN THE STUDY. YOU MAY ALSO REFER THEM TO THE IRB-HSR AT 924-9634.

c.__X__Direct contact of potential subjects by the study team by approaching in person at UVa or via letter, phone, direct e-mail. Members of study team contacting potential subjects ARE health care providers of patients. [Note: letter sent to eligible patients from their physician at SOVAH Pediatrics and PATHS. The letter includes information about the projects and makes the parent aware that someone from the study team will call them with more information. They are able to opt out of this call by either calling the contact at SOVAH Pediatrics or PATHS or by sending back the opt out post-card. The opt out postcard is not prestamped. It includes no study identifiers other than the IRB #. First and last name of the parent is requested for opting out.]

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use.
See IRB-HSR Website for templates.

DHHS: Study team requests a Waiver of Consent to contact potential subjects
HIPAA: Allowed under Health Care Operations.

d.__X__ Indirect contact (flyer, brochure, TV, broadcast emails, patient provided info about the study from their health care provider and either the patient contacts study team or gives their healthcare provider permission for the study team to contact them.)

The indirect method used (flyer, brochure, TV, broadcast emails) must be approved by the IRB prior to use. The IRB does not need

to review any type of script to use when the potential subject responds to the indirect method.

DHHS & HIPAA: NA

e. __X__ Advisory Board Members:Potential subjects are not patients. The study does not include obtaining subjects' health information. Subjects will be contacted directly via email, phone, letter or presentation in group setting with consent then obtained individually in a private setting.

If you are not approaching them in person but using a letter, phone call or direct email please note that the letter, phone, direct email scripts must be approved by IRB prior to use. See IRB-HSR Website for templates.

DHHS: Study team requests a Waiver of Consent to contact potential subjects.
HIPPA: NA

3. **Will any additional information be obtained from a potential subject during "prescreening"?**

**Pre-screening** for IRB purposes is the term used to describe activities PRIOR to obtaining Informed Consent and may not include any research procedures.

The activities may involve pre-screening of potential subjects over the telephone or in person is generally performed to determine their initial eligibility for, and, interest in a study and is a common strategy in the recruitment process.
Questions appropriate for pre-screening address the specific inclusion/exclusion criteria for the study and other issues of suitability, for example, an individual's ability to come to the research site multiple times.
It is not appropriate at this point in the process (i.e. prior to obtaining informed consent/enrollment) to gather information that is not directly related to assessing eligibility and suitability (e.g. obtaining complete medical histories, obtaining blood specimens for lab tests).
An additional telephone script is not required, for this pre-screening process, in addition to any scripts required under Recruitment question # 2.

Yes

- The medical chart review at SOVAH Pediatrics and PATHS will include recording information regarding the child's name, last date seen in

the office, date of birth, sex, height, weight, BMI%, ethnicity, race, insurers type and primary care giver name, address, phone number.

- Additional data is illustrated in the attached telephone survey form . One of the key **secondary aims** is to determine reach/representativeness of the enrolled sample (also, a key IRB principle related to justice). Per our funded contract, we need to compare basic demographic and health literacy questions for families who are eligible and *did* enroll to those who were eligible and *did not* enroll. Subjects will be enrolled in this portion of the study via waiver of documentation of consent.

IF YES, submit any documents that will be used to collect pre-screening information so that the IRB may confirm what questions will be asked.
NOTE: To comply with HIPAA regulations only the minimum necessary information may be collected at this time. This means that only questions pertaining to the Inclusion and Exclusion Criteria may be asked.

IF YES,
DHHS: study team requests a Waiver of Documentation of Consent for Pre-screening questions.

HIPPA:
HIPAA does not apply if:
--no PHI is collected or
--if PHI is collected from a potential subject by an individual from a department that is not part of the HIPAA covered entity.

HIPAA does apply if the collection occurs by individuals* who work in a department that is part of the HIPAA covered entity.

In this case the collection will be covered under Health Care Operations/

These individuals are those that meet one of the following criteria:
--a UVa student working in the UVa HIPAA Covered Entity*
--a faculty or staff member in a PAID appointment in the UVA HIPAA Covered Entity*

**IF YES, Will any of the questions involve health information?**
Yes (weight status of child)

**IF YES, will you collect HIPAA identifiers with the health information?**
Yes

**IF YES, which HIPAA identifiers will be recorded?**
Name, address, telephone numbers

**Do you confirm that health information with HIPAA identifiers will not be shared outside of UVa until a consent form is signed or only shared in a de-identified manner?**
Yes

4. **Do you plan to ask the subjects to do anything, other than answering questions, for the study prior to signing a consent?**

For example: come to the first visit fasting, stop taking medications that may be an exclusion criteria, change diet. As this is still part of pre-screening one is not allowed to gather information that is not directly related to inclusion/exclusion criteria or other issues of suitability (e.g. is person able to come to UVa for multiple visits)

NOTE:
Only those members of the study team with a DEA# (license to prescribe drugs) are allowed to determine if a potential subject may be asked/informed to stop taking a drug which is an exclusion criteria.
It is recommended that the potential subject notify their health care provider if they plan to stop a prescription drug.

Yes

►**IF YES, explain in detail what you will ask them to do**.
For families who express interest in the study by responding through advertisements or flyers, their child will need to be screened for BMI inclusion criteria. Therefore, the child's height and weight will be taken prior to informed consent to check for study eligibility. In addition, they will answer the study questions similar to families who were identified via the medical record review at SOVAH Pediatrics and PATHS.

Tips to Study Team
You must document their verbal consent in the study records.
If a subject is asked to stop taking a drug, document the date and name of the person on the study team giving the verbal order to stop medications (again- must be a person with a DEA#).

DHHS: Study team requests the use of Verbal Consent (Waiver of Documentation of Consent) for minimal risk screening procedures.

HIPPA:
If the individual, obtaining consent, works under the HIPAA Covered Entity this is covered under Health Care Operations
If the individual obtaining consent does not work under the HIPAA covered entity, HIPAA does not apply.

5. **How will the consenting process take place with either the prospective subject, the subject's legally authorized representative or parent/legal guardian of a minor ( if applicable)?**

HIPPA:
If the individual, obtaining consent, works under the HIPAA Covered Entity consenting is covered under Health Care Operations.

If the individual obtaining consent does not work under the HIPAA covered entity, HIPAA does not apply.

Describe the setting for the consent process.
If the study is of a sensitive nature and/or includes a reference to a medical condition how will you protect the privacy of the potential subject when they are approached to participate?
Who will discuss the study with the potential subject?
Where will the consenting process take place?
How will you assess subject understanding?
How much time will pass between obtaining written consent and initiation of study procedures?
See Protocol Examples: Consenting Process for examples of how to answer this question.
If recruiting minors, specify how parental /guardian consent will be obtained prior to approaching the minor.

Answer/Response:

**SEE ATTACHMENTS:**
1. _consent_parent
2. _minor_assent
3. _consent_CAB
4. _consent_PAT

**Parents:** sign consent prior to enrolling in the main study and any study procedures.

**Child:** assent prior to enrolling in the main study (after parental signed consent is obtained)
The consent/assent process will take place in-person when the families arrive for their enrollment appointment. The consent and assent statements will be read aloud and all questions will be answered. The study procedures will occur the same day as consent. Note, the pre-screening process that occurs 1-3 weeks prior to enrollment also describes the study process and procedures, and a copy of the consent form is provided to the parents to review prior to their enrollment appointment.

**Community Advisory Board and Parent Advisory Team:** sign consent prior to participating in mixed methods evaluation which will occur at one of the regular meetings. Researchers are available to answer any questions.

**6. Will subjects sign a consent form for any part of the study?**

Yes

**7. Will the study procedures be started the same day the subject is recruited for the study?**

Yes

**►IF YES, explain in detail why the subject cannot be given more time to make a decision to consent.**
The informed consent documents will be provided about one week prior (e.g. mailed to families and emailed to CAB/PAT members) to the form being reviewed and signed at the in-person data collection day and/or meeting. Asking families and CAB/PAT members to sign the consent on one day and start the procedures on another day would cause additional time and travel burden, especially among those who may already struggle with rearranging work schedules and transportation.

**►IF YES, explain in detail what will be done to assure the potential subject has enough time to make an informed decision.**
See above – potential subjects will receive consent forms well in advance of enrollment. Subjects are enrolled and start procedures on the same day for their convenience.

**8. Is there the potential to recruit economically or educationally disadvantaged subjects, or other vulnerable subjects such as students or employees?**

Yes

**IF YES, what protections are in place to protect the rights and welfare of these subjects so that any possible coercion or undue influence is eliminated?**

The targeted Dan River Region is a medically underserved region. Due to excess burden of childhood obesity among low SES families, these families will be targeted for this study. All study staff will receive the necessary IRB training, including concepts related to coercion. The informed consent will be read aloud to participants and all questions will be answered to allow families to make an informed decision. Participants can withdraw from the study at any time, without penalty, and refuse to answer any study questions. The incentive structure is appropriate to compensate time involved in data collection component of this study and is identical to that of prior studies that our team has conducted in this region.

**9. Do you need to perform a "dry run" of any procedure outlined in this protocol?**

No. We have already performed all of these procedures with 101 families enrolled in our funded planning grant from 2013-2016. We need no further validation for any of our procedures.

**10. Is the study regulated by the Department of Defense (DoD)?**

No

## APPENDIX: Participation of Children

**1. Explain why this research topic is relevant to children**.

This is a childhood obesity treatment study. Childhood obesity in the study region is about 3 times higher than state averages. Childhood obesity contributes to a number of chronic diseases, including diabetes, heart disease and some cancers. Understanding effective treatment options, which are sustainable within the local systems of the medically underserved Dan River Region, is highly relevant to current and future children who struggle to achieve and maintain a healthy weight.

**2. Is the knowledge being sought in this study already available for children or is it currently being acquired through another ongoing study?**

There is a large body of literature and a number of systematic reviews documenting the efficacy of family-based childhood obesity (FBCO) interventions.[16-18,19,20,21-23] Unfortunately, there is little evidence that any FBCO treatment has been systematically translated into regular practice or reaches a large number of families in health disparate regions.[29] Further, there are substantial gaps in the literature related to the features within clinical and community settings that could improve the translation of FBCO interventions into typical practice.[30]

**3. Provide data that is available in adults in order that the IRB may judge the potential risk in children. If there is no adult data available, provide reasons why not. If this information is available in a sponsor's protocol, you may reference the section # here and not duplicate the information**.

See the background section of this protocol.

4. **Is the potential subject population likely to include wards of the state or children who are more at risk for becoming a ward of the state?**

   No

   **4a. Is the research in this protocol related to the child's status as a ward of the state?**

   No

   **4b. Is the research to be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards?**

   Yes

   **4c. Are you aware of the following requirement?**

   *If the consent form contains a signature line for both parents the study team will notify the IRB immediately, if at any time during the course of the research, it becomes known that a potential subject is a ward of the state or that a child already enrolled in this protocol becomes a ward of the state.*

   Yes

5. **Does this study involve a placebo arm?**

   No

6. **Will UVa researchers conduct the study outside the state of Virginia?**

   No

## Privacy Plan

**The following procedures must be followed.**

- The data will be secured per the Data Security Plan of this protocol.
- Only investigators for this study and clinicians caring for the patient will have access to data. They will each use a unique login ID and password that will keep confidential. The password should meet or exceed the standards described on the Information Technology Services (ITS) webpage about *The Importance of Choosing Strong Passwords.*
- Each investigator will sign the University's Electronic Access Agreement forward the signed agreement to the appropriate department as instructed on the form.

If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.

- UVa University Data Protection Standards will be followed http://www.virginia.edu/informationsecurity/dataprotection.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's "Electronic Storage of Highly Sensitive Data Policy". Additional requirements may be found in the University's Requirements for Securing Electronic Devices.
- If identifiable data is taken away from the UVa Health System, Medical Center Policy # 0218 will be followed.
- Data will be securely removed from the server/drive, additional computer(s), and electronic media according to the University's Electronic Data Removal Policy.
- Data will be encrypted or removed if the electronic device is sent outside of UVa for repair according to the University's Electronic Data Removal Policy.
- If PHI will be faxed, researchers will follow the Health System Policy # 0194.
- If PHI will be emailed, researchers will follow the Health System Policy # 0193 and University Data Protection Standards .
- Data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow Health System Policy # 0021.
- Both data on paper and stored electronically will follow the University's Record Management policy and the Commonwealth statute regarding the Destruction of Public Records.

***If you have a question or concerns about the required security standards contact ISPRO at it-security@virginia.edu***

**Summary of Requirements to Comply with UVa Health System, Medical Center and University Policies and Guidance as noted above:**

**Highly Sensitive Data** is:
-personal information that can lead to identity theft if exposed or
-data that reveals an individual's health condition and/or history of health services use.
**Protected Data (PHI)** a type of Highly Sensitive Data, is data combined with a HIPAA identifier
**Identifiable Data** under HIPAA regulations is considered to be *Highly Sensitive Data at UVa.*
A **Limited Data Set** (LDS) under HIPAA regulations is considered to be *Moderately Sensitive Data* at UVa. The only HIPAA identifiers associated with data: dates and or postal address information limited to town or city, state, and zip code.
Will not include subjects age if older than 89 or subjects DOB if older than 89.

| **Highly Sensitive Data (Identifiable Health Info per HIPAA )** | **Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)** |
|---|---|
| *General Issues* | *General Issues* |
| Discussions in private<br>Do not share with those not on the study team or those who do not have a need to know. | Do not share with those not on the study team or those who do not have a need to know |
| Password protect | Password protect |
| Physically secure (lock) hard copies at all times if not directly supervised.<br>If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance). | Physically secure (lock) hard copies at all times if not directly supervised. |
| For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely. | For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely. |
| Encrypt<br>See Encryption Solutions Guidance<br>*Files on Health System Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.* | |
| If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order. | If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVa Purchase order. |
| Store files on a network drive specifically designated for storing this type of data, e.g. high-level security server/drives managed by Information Technology Services or the “F” and “O” managed by Heath Systems Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device*. May access via VPN | |
| Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place | Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place |
| If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC | If collected without consent/ HIPAA authorization will NOT be allowed to leave UVa HIPAA covered entity unless disclosure is approved by the IRB and an MTA is in place prior to sharing of data |

| **Highly Sensitive Data (Identifiable Health Info per HIPAA )** | **Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)** |
|---|---|
| *Electronic Data Collection & Sharing* | *Electronic Data Collection & Sharing* |
| (e.g. smart phone app, electronic consent using tablet etc.)<br>MUST consult with ISPRO or Health System Web Development Office: 434-243-6702<br>▪ University Side: IT-Security@virginia.edu<br>▪ Health System: Web Development Center: | |
| *Individual-Use Device* | *Individual-Use Device* |
| Do not save to individual-use device* without written approval of your Department AND VP or Dean.<br>If approval obtained, data must be password protected and encrypted. | |
| Do not save an email attachment containing HSD to an individual use device<br>( e.g. smart phone) | |
| *E Mail* | *E Mail* |
| Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo | |
| Do not send via email on smart phone unless phone is set up by Health System | |
| Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address.<br>*NOTE: VPR & IRB staff do not meet this criteria!* | In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVa HIPAA covered entity.** |
| *FAX* | *FAX* |
| Verify FAX number before faxing | Verify FAX number before faxing |
| Use Fax Cover Sheet with Confidentiality Statement | Use Fax Cover Sheet with Confidentiality Statement |
| Verify receiving fax machine is in a restricted access area | Verify receiving fax machine is in a restricted access area |
| Verify intended recipient is clearly indicated | Verify intended recipient is clearly indicated |
| Recipient is alerted to the pending transmission and is available to pick it up immediately | Recipient is alerted to the pending transmission and is available to pick it up immediately |

| **Highly Sensitive Data (Identifiable Health Info Per HIPAA** | **Moderately Sensitive Data (Limited Data Set and Deidentified data per HIPAA** |
|---|---|
| *Electronic Data Collection & Sharing* | *Electronic Data Collection & Sharing* |
| (e.g. smart phone app, electronic consent using tablet etc…)<br>MUST consult with ISPRO or Health System Web Development Office: 434-243-6702<br>University Side: IT-Security@virginia.edu<br>Health System: Web Development Center:<br>Contract must include required security measures. | |
| May be Stored in Qualtrics<br>MAY NOT be stored in places like UVaBOX, UVa Collab or QuestionPro<br>May also NOT be stored I n non-UVA licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey etc.. | May be stored in places like UVaBox, UVaCollab, Qualtrics<br>May NOT be stored in non-UVa licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc. |
| *LOST OR STOLEN* | *LOST OR STOLEN* |
| Must report in accordance with protocol in accordance with the Information Security Incident Reporting Policy<br>Any data breach will also be reported to the IRB of record in the report meets the criteria of an Unanticipated Problem | Must report in accordance with protocol/ in accordance with the Information Security Incident Reporting Policy.<br><br>Any data breach will also be reported to the IRB of Record if the report meets the criteria of an Unanticipated Problem. |

** Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer,*
***The UVa HIPAA covered entity is composed of the UVa VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrison's), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.*

## APPENDIX: Sponsor

**Sponsor Information**

1. **Explain the sponsorship for this study.**
   This study is funded by a contract with Patient Centered Outcomes Research Institute (PCORI)

2. **Do you confirm that you will obtain a contract/ material transfer agreement with the sponsor via the School of Medicine Grants and Contracts Office or the Office of Sponsored Programs (OSP)** ospnoa@virginia.edu**?**

Yes

## APPENDIX: Transfer of Data Outside of UVa

**1. Who will data be sent to/shared with?**

- Dr. Wen You, Co-Investigator at Virginia Tech
- Dr. Paul Estabrooks, Co-Investigator at University of Nebraska
- Dr. Jennie Hill, Co-Investigator at University of Nebraska

**2. What identifiers will be sent with/shared with the data?**

**Table A: Identifiers per HIPAA under 164.514(b)(2)(i) and (ii)**

| YES | NO | |
|---|---|---|
| | X | 1. Name |
| | X | 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people and (2) The initial 3 digits of a zip code for all such geographic units containing 20,000 is changed to 000. |
| | X | 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older. *[This means you may record the year but not record the month or day of any date related to the subject if the subject is under the age of 89. In addition if the subject is over the age of 89 you may not record their age and you may not record the month, day or year of any date related to the subject ]* |
| | X | 4. Telephone numbers |
| | X | 5. Fax numbers |
| | X | 6. Electronic mail addresses |
| | X | 7. Social Security number |
| | X | 8. Medical Record number |
| | X | 9. Health plan beneficiary numbers |
| | X | 10. Account numbers |
| | X | 11. Certificate/license numbers |
| | X | 12. Vehicle identifiers and serial numbers, including license plate numbers |
| | X | 13. Device identifiers and serial numbers |
| | X | 14. Web Universal Resource Locators (URLs) |
| | X | 15. Internet Protocol (IP) address numbers |
| | X | 16. Biometric identifiers, including finger and voice prints |
| | X | 17. Full face photographic images and any comparable images |
| | X | 18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.) |
| | X | 19. Any other information that could be used alone or in combination with other information to identify an individual. (*e.g. you share the KEY to the CODE (not just the code), subject has a rare disease etc. )* |

**3. Do you confirm that you will obtain a contract/ material transfer agreement with whomever you are sharing data with outside of UVa via the School of Medicine Grants and Contracts Office or the Office of Sponsored Programs (OSP) ospnoa@virginia.edu?** Yes

## APPENDIX: Waiver of Documentation of Consent- telephone survey portion of study

**1. Does this study involve high risk genetic testing in which samples are not de-identified?**

No

**2. Does this study involve the use or disclosure of psychotherapy notes for research purposes?**

No

**3. Does this study meet the following criteria?**

**INSTRUCTIONS:** The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern;

No

**4. Does this study meet the following criteria?**

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Yes

**INSTRUCTIONS:** If you answered NO to both question#3 and 4, this study will not qualify for waiver of documentation of consent.
If you answered yes to either question # 3 or 4 answer question # 5

**5. An IRB approved script will be used in obtaining verbal/oral consent from the potential subject.**

**INSTRUCTIONS:**

Submit the verbal script to the IRB. A sample template may be found on the IRB-HSR website at http://www.virginia.edu/vprgs/irb/HSR_docs/advertising/Verbal_Consent_Script_Template_-_In_Person.docx

Confirmed.

**6. Do you confirm that no identifiable data collected under verbal consent/HIPAA authorization will be shared outside of UVa?**

Yes

## Waiver of Consent/Waiver of HIPAA Authorization

**Waiver of HIPAA Authorization**

For clarification on the HIPAA terminology used in this section view "HIPAA & WAIVER OF CONSENT PART 1: TERMINOLOGY" and "HIPAA&WAIVER OF CONSENT PART 2: PRIVACY PLAN"

**1. Is this section being completed regarding the sharing of a Screening Log?**

NO.

**2. Will you be using specimens and/or health information from living human beings?**

No, the initial telephone survey portion of this study contains demographic and health literacy questions.