# Pilot Trial of a Novel Cooking Skills Intervention (DPPCooks) to Prevent Diabetes

## NCT05166512

## 1/5/2022

**JHSPH IRB Research Plan for New Data Collection**

*IRB Version: 02Dec2021*

*For new data collection, new data collection plus secondary data analysis, biospecimen repositories, and data coordinating center protocols.*
***DO NOT DELETE ANY QUESTIONS FROM THIS TEMPLATE***

**PI Name: Julia Wolfson**
**Study Title:** Development and pilot evaluation of a novel cooking skills intervention to prevent diabetes
**IRB No.:** IRB00018839
**PI Version No. / Date:** V2/ 01/05/2022

**I. Aims of the Study:** *Describe the aims/objectives of the research and/or the project's research questions or hypotheses.*

The Aim of this study is to **test the feasibility, acceptability, and preliminary effectiveness of the DPP Cooks compared with the standard DPP.** We will conduct a randomized pilot trial to test the feasibility and acceptability of DPP Cooks compared with the standard DPP among low-income adults. Data collection will occur at baseline, 4 months, and 12 months. The primary outcome is weight loss. Secondary outcomes include: dietary intake and quality; cooking confidence, attitudes, behaviors, and class attendance. Post intervention, I will also conduct focus groups with two groups: 1) with participants to understand their intervention experiences, and 2) with providers to examine program implementation and satisfaction.

**II. Background and Rationale:** *Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.*

Incorporating targeted cooking skills interventions into behavioral weight loss programs to prevent type-2 diabetes, a growing public health problem that disproportionately impacts low-income populations, may be important to facilitate sustained dietary change, weight loss, and reduce risk of developing diabetes. The goal of this proposal is to create, and pilot test in a randomized pilot trial, a new cooking skills intervention to supplement the existing Diabetes Prevention Program while supporting the career development of a new investigator who aspires to a research career focused on preventing diet related diseases. Findings from this study will examine the importance of cooking skills for improving dietary intake, weight loss, and diabetes indicators, and will evaluate potentially important modifications to the DPP.

**III. Study Design:**

A. *Provide a BRIEF overview of your study design and methods. The study design must relate to your stated aims/objectives. DETAILS WILL BE REQUESTED LATER. If your study also involves analysis of existing data, please complete Section XI, "Secondary Data Analysis of Existing Data" in the last part of this research plan. If your study ONLY involves analysis of existing data, please use the research plan template for secondary data analysis (JHSPH IRB Research Plan for Secondary Data Analysis of Existing Data/Specimens).*

This study is a randomized control pilot trial testing the DPP Cooks against standard DPP. DPP is a 12 month diabetes prevention behavioral weight loss program developed by the CDC and implemented

nation wide. Participants meet weekly for the first 6 month in group sessions, then meet less frequently over the last 6 months to help them maintain the behavioral changes (re: diet and physical activity) they made in the first six months. For this trial, up to 48 participants will be randomized 1:1 to participate in the 12 month DPP or the 12 month DPP *plus* an additional 6 cooking skills sessions (DPP Cooks) during the first 4 months of the DPP. The primary outcome, weightloss, is collected at weekly DPP sessions. The secondary outcomes will be collected via online surveys at baseline, 4 months and 12 months, and via the Remote Food Photography Method (RFPM) at baseline and 4 months.

B. *Provide a sample size and a justification as to how you arrived at that number. If you use screening procedures to arrive at a final sample, distinguish the screening sample size from the enrolled sample size; a table may be helpful. For electronic survey studies involving online recruitment and survey completion: consider how you will set controls on how many people will join your study.*

The target sample size of 48 individuals, randomized 1:1 was based on the fact that this is a pilot feasibility trial so we are not necessarily concerned with detecting statistically significant results. Budget constraints preclude a higher sample size. This sample size will allow us to test the DPP Cooks with several cohorts to understand implementation and prepare for a larger, fully powered study in the future.

C. *Does your study meet the NIH definition of "clinical trial": "***A research study in which one or more human subjects are prospectively assigned to one or more interventions** (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes"? *If yes, the study must be listed on clinicaltrials.gov, study personnel must complete GCP training, and federally funded studies must post consent forms on approved sites, like clinicaltrials.gov.*

Yes, this study meets the definition of a clinical trial. The study has been entered in clinicaltrials.gov, but has not been published yet. It will be published when the IRB is approved prior to beginning any research activities.

## IV. Participants:

*Describe the study participants and the population from which they will be drawn. Specify the inclusion and exclusion criteria. If you plan to include children, note their ages and whether you will include children in foster care or who are wards of the State. Note if the participants are particularly vulnerable in terms of cognitive limitations, education, legal migration status, incarceration, poverty, or some combination of factors.*

A. **Inclusion Criteria:**

Participants will be adults (18 years or older) in the Baltimore area who are eligible for participation in the DPP and who are able to participate in the DPP Cooks sessions located at the Under Armour House on 1100 E Fayette Street. We will not impose a geographic restriction on where potential participants live/work, but they must be able get to weekly DPP sessions held at that time and location.

In addition to the above, inclusion criteria include the following:

**1.** Eligible for DPP based on CDC guidelines

2. Possession of a smart phone with camera
3. Can commit to 12 month study participation

For reference, the CDC guidelines for DPP participation are:

- 18 years of older and not pregnant at the time of enrollment
- BMI of 25 or higher **AND**
- HbA1C: 5.7-6.4% **OR** fasting plasma glucose: 100-125mg/dL **OR** 2-hour plasma glucose (after a 75g glucose load): 140-199 mg/dL **OR** previously diagnosed with gestational diabetes, **OR** high-risk result (score of 5 or higher) on the prediabetes risk test

B. **Exclusion Criteria:**

Exclusion criteria include:

1. Current or prior diagnosis of type 1 or type 2 diabetes
2. Non-English speaker
3. Participating in another study that may affect diabetes, diet or weight loss
4. Currently pregnant

***NOTE**: If you are recruiting participants or receiving, accessing, or using data from a U.S. health care provider, HIPAA review is likely to be required. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. Check "yes" to the HIPAA question in the PHIRST application.*

## V. Study Procedures:

*In this section, provide details of your procedures, particularly as they relate to human subjects. If this is a multi-center study, make the role of JHSPH clear. If you will collaborate with other institutions or organizations, or plan to subcontract JHSPH responsibilities to others, make clear their responsibilities in the Study Oversight section of this document. Be aware that all recipients of federal funding for non-exempt human subjects research must have a Federal Wide Assurance (FWA) , which is a promise to comply with human subjects research regulations.*

*If the JHSPH will serve as **data coordinating center**, indicate in the sections below which procedures JHSPH will not be performing. Additional information regarding data coordinating centers is requested in a later section.*

*If your study will develop in phases, address each item below by phase.*

A. **Recruitment Process:**

1. *Describe how you will identify, approach, and inform potential participants about your study. Include details about who will perform these activities and their qualifications.*

Participants will be recruited through several approaches which we developed in collaboration with the JH Medicine Recruitment Innovation Unit (RIU):

1. Social Media: We will advertise the study on social media (advertisements and social media strategy are attached) using paid ads. Paid ads will be run on social media platforms for varying

lengths of time that target the participant population inviting them to learn more about the study opportunity.

2. Community Outreach: We will also recruit through community outreach. Study fliers (attached) will be left at local community centers, businesses, residences, and religion institutions. Study coordinators will also accompany Barbara Bates-Hopkins during the ICTR's Day at the Market and offer study fliers to interested individuals. Those interested will be pre-screened. Study flyers will be left at local Housing Authority of Baltimore City community centers. Study coordinators will work with the Office of Resident Services at Housing Authority of Baltimore city to distribute fliers to residents in target areas and hold information sessions allowing residents the opportunity to learn about the project and be screened for enrollment. We will focus on Housing in the immediate areas around the Under Armour House including the Douglass Homes, Pleasant View Gardens, and Sommerset Homes.
3. Website Postings: A study advertisement will be posted to the JHU Announcements website to reach the student and faculty populations. Interest adults may email or call to be screened for eligibility.
4. Study Registry: When available (anticipated early 2022), we will post the study on the JHU Research Study registry with appropriate key words so that individuals who are interested in participating in research studies can find it and be pre-screened for eligibility.
5. Word of Mouth: Study fliers will be available at University of Maryland and some Johns Hopkins health care clinics and waiting rooms for self-referral by visitors. Staff and providers will be informed about the study and will mention the study to patients as well. Interested patients can then contact the study staff for more information and to be screened for eligibility.
6. DPP Screening: When individuals are being screened for DPP eligibility (for example after being referred by their healthcare provider or learning about the DPP through other means) by the DPP staff at the study partner organizations offering the DPP (e.g. The Brancati Center, the University of Maryland), the DPP staff will inform them about the opportunity to participate in this study. If the person is eligible for DPP and is interested in participating in the study, they will be referred to the study staff who will give them more information, and if interested and if the time and location of the weekly classes works for them,, will screen for eligibility for the DPP Cooks.

Study staff who conduct recruitment, screening, enrollment and consent will be public health masters level or PhD level students or staff study coordinators who have been trained in the responsible and ethical conduct of research. All student study staff will be supervised by Dr. Julia Wolfson, the PI of the study, an Assistant Professor in the Department of International Health at JHSPH. All staff will be trained by Dr. Wolfson and will be provided scripts and background information about the study.

2. *Address any privacy issues associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks*.

The privacy risks associated with recruitment are minimal. Participants will be proactively contacting the study staff if they are interested in learning more about the study and whether they are eligible to participate. The DPP (and the DPP Cooks) do not put participants at risk of stigma or repercussions if it would become known that they were interested in participating in the study.

Interested potential participants will need to provide their name and contact information, but we will ensure that PII will be stored only on password protected computers and documents saved on OneDrive.

We will need to share information about the identity of potential participants with DPP staff so they can be screened for eligibility based on CDC criteria. However we will be careful to do so only via documents shared via OneDrive, and not over email.

B. **Consent Process**:

1. *Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening*.

   a. *Who will obtain informed consent, and their qualifications*:

   Study staff (student research assistants or a staff study coordinator) or the PI, Dr. Wolfson, will obtain informed consent. Dr. Wolfson has a PhD in public health policy and 7 years experience conducting research in community settings. Dr. Wolfson will supervise and train all other study staff who will be obtaining informed consent. All staff will have the appropriate PEERRS certifications.

   b. *How, where, and when the consent discussion(s) will occur*:

   Informed consent will be discussed during the initial recruitment/ enrollment conversation(s) over the phone. Study staff will describe the study and participants will have the opportunity ask any questions about the study and will provide oral consent at the time they enroll in the study. Written consent will not be sought because DPP meetings will continue to be virtual, and there will not be an opportunity to obtain informed consent without imposing an additional burden on the study participants.

   c. *The process for determining whether a potential participant meets eligibility criteria. If you will collect personally identifiable information for screening purposes, collect only data needed for this purpose and explain what will happen to the data for individuals who are not eligible*:

   Eligibility for DPP will be assessed by DPP partner organization staff.

   Eligibility for the DPP Cooks study will be assessed by study staff.

   Study participants will be recruited and screened for eligibility via 2 ways. 1: they can contact the study staff after learning about the study during community recruitment, or 2: they will

learn about the study when they are screened for DPP eligibility (after being referred by their provider or other means). See the attached figure 'Recruitment and screening diagram' for more information on these 2 streams of recruitment and eligibility screening.

Eligibility criteria for DPP participation are well established and screening procedures have been in place for years by DPP program staff. These procedures will be followed per usual for this study. DPP staff will determine whether the participant is eligible for the DPP based on medical chart review or based on telephone screening (self-report) per usual protocols and in compliance with CMS standards. DPP eligibility criteria are the following:

- 18 years of older and not pregnant at the time of enrollment
- BMI of 25 or higher **AND**
- HbA1C: 5.7-6.4% **OR** fasting plasma glucose: 100-125mg/dL **OR** 2-hour plasma glucose (after a 75g glucose load): 140-199 mg/dL **OR** previously diagnosed with gestational diabetes, **OR** high-risk result (score of 5 or higher) on the prediabetes risk test

We will create a spreadsheet in which potential participants are all assigned a participant number and where the PII information will be stored. In all other study documents, the participant will be identified by their ID number, not the PII. The spreadsheet linking PII to the participant number will be stored in a separate folder in OneDrive. When a participant is not eligible, or chooses not to enroll in the study, their PII will be deleted immediately.

Community recruitment procedure:

When a potential participant expresses interest in the study, they will contact us (contact information will be provided on recruitment materials). If via study website or social media ad, they will also have the ability to fill out a brief online form that will collect their name, email, and phone number so that we can contact them. Participants who express interest in the study will be screened for eligibility over the phone by study staff. First, we will confirm that they are over 18, are able to attend DPP meetings at the Under Armour house, have a mobile phone (iPhone or Android) that can take photographs, and that they are able to commit to the 12 month study period. We will ensure that they do not meet the other exclusion criteria. We will ensure they fully understand the data collection obligations for the study participation and answer any questions they have. We will refer them to the DPP partner staff (e.g. Brancati Center or University of Maryland) for them to confirm eligibility using their usual procedures (see above). The DPP partner staff will then confirm with us via the OneDrive spreadsheet whether the potential participant is eligible (yes/no) per CDC guidelines to participate in the DPP. They will not share specifics about which eligibility criteria were met. We will then contact the participant to confirm with them that they are eligible for the study and work with them to find an

upcoming study cohort that works for their schedule. We will again go over the study protocol with them and obtain oral informed consent.

DPP referral recruitment procedure:

Potential participants who have already been determined to be DPP eligible by DPP program staff will give permission for DPP program staff to share their name and contact information with us so we can contact them. DPP program staff can also share our contact information with the participant so they can contact us. We will then reach out to them over phone, text, or email. When we get in touch with the potential participant study staff will screen them for eligibility over the phone. First, we will confirm that they are over 18, are able to attend DPP meetings at the Under Armour house, have a mobile phone (iPhone or Android) that can take photographs, and that they are able to commit to the 12 month study period. We will ensure that they do not meet the other exclusion criteria. We will ensure they fully understand the data collection obligations for the study participation and answer any questions they have. If the participant is eligible we will confirm with them that they are eligible for the study and work with them to find an upcoming study cohort that works for their schedule. We will again go over the study protocol with them and obtain oral informed consent. Study staff will notify the DPP program staff that this person has been enrolled in the study via updating the spreadsheet stored in OneDrive.

Study staff and DPP staff will also use phone calls and Zoom meetings to coordinate during the recruitment, screening, and enrollment process. We will not share any PII over email or other non-secure communication.

We will inform any potential participants who are not eligible for the study, but who do meet eligibility criteria for the DPP, that they are still able to enroll in the DPP and will provide them contact information for who to contact to enroll.

We will inform any potential participants who are not eligible for DPP but who were interested in the study that they can still sign up for cooking classes offered by our community partner and will share with them contact information for how to sign up.

d. *Whether you will obtain a signature from the participant or will use an oral consent process*:

We will obtain oral consent as we are enrolling participants over the phone, and may not have any in person interaction with the participants until DPP Cooks cooking sessions (or at all if DPP Cooks sessions are virtual due to COVID-19).

e. *Whether you will obtain a legally authorized representative's signature for adults lacking capacity*:

n/a

f. *If children are included in the study, if and how you will obtain assent from them*:

n/a

g. *If children are included in the study, how you will obtain permission for them to participate from their parent, legal guardian, or other legal authority (if child is in foster care or under government supervision). If any of the children are "wards of the state", additional regulatory requirements will apply:*

n/a

h. *If you are seeking a waiver of informed consent or assent, the justification for this request*:

n/a

i. *Whether you will include a witness to the consent process and why*:

n/a

j. *If the language is unwritten, explain how you will communicate accurate information to potential participants and whether you will use props or audio materials*:

n/a

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

| **Country** | **Consent Document(s) (Adult Consent, Parental Permission, Youth Assent, etc.)** | **Languages** |
|---|---|---|
| USA | Adult Oral Consent | English |
| | | |
| | | |

C. **<u>Study Implementation</u>**:

1. *Describe the procedures that participants will undergo. If complex, insert a table below to help the reviewer navigate*.

All participants will receive the DPP intervention, a 12 month behavioral weight loss intervention developed by the CDC. The DPP is an evidence-based, standardized curriculum. It requires 1 year of program enrollment divided into two phases. In phase one, participants attend at least 16 1-hour weekly group sessions, and phase 2 includes at least 6 one-hour sessions during the last 6 months.

In the DPP, participants will have weekly group meetings with a trained coach and other participants (usually between 8-12 people in a cohort). Participants receive coaching and social support around topics such as nutrition and physical activity. Participants receive written materials to support their behavior change. They report current weight and minutes of physical activity at every DPP session which is recorded by the coach.

DPP sessions will take place virtually over Zoom.

In the DPP Cooks group, participants will also receive 6 additional 2-hour cooking skills classes throughout the first 4 months of the study period. The cooking classes will be taught by a professional chef-instructor at the *American Heart Association Simple Cooking with Heart Teaching Kitchen* located in the Under Armour House at 1100 E Fayette Street in Baltimore City. DPP Coaches will also attend the cooking classes. Research Assistants from the study team will also be on hand to assist and to help with clean up.

If the teaching kitchen is not open due to COVID-19 restrictions, cooking classes will also take place virtually over Zoom. The professional chef-instructor has experience leading virtual classes since classes pivoted to virtual in March 2020. If cooking sessions are virtual, we will deliver food and equipment needed for each session to the participant's home or arrange a pick up time for participants to pick up food at the teaching kitchen location (study staff will prepare bags of food for pick up and will be available at pre-arranged time for participants to come pick up). Study staff will not enter the home, but will deliver it to the participant's doorstep and will remain outside (and masked) to ensure it is received.

**We begin this study with virtual DPP Cooks classes. We will not begin in person classes at the teaching kitchen until we have been approved by the IRB to do so.**

The standard DPP group (control) will be offered a cooking skills session at the completion of the study as well as a participant workbook from the DPP Cooks.

All participants will have the following data collected:

| **Measure** | **Method** | **Baseline** | **4 months** | **12 months** |
|---|---|---|---|---|
| Weight loss (kg and % of body weight) | In DPP meetings | X | X | X |
| Diet quality (3 days at each timepoint) | RFPM | X | X | |
| Cooking skills/ attitudes/ behaviors | Online Survey | X | X | X |
| Food Agency | Online Survey | X | X | X |
| Cooking confidence | Online Survey | X | X | X |
| Food security status | Online Survey | X | X | X |
| Demographics | Online Survey | X | | |
| Acceptability of the DPP cooks | Interview | | | X |
| DPP session attendance | DPP Coaches | | | X |

2. *Describe the number and type of study visits and/or contacts between the study team and the participant, how long they will last, and where/how they will take place*.

As described above, participants will participate in the DPP, which meets weekly for approximately 1 hour for six month, then approximately monthly for the last 6 months. Participants in the intervention arm (DPP Cooks) will have an additional 6 sessions in a teaching kitchen (2 hours each, 12 hours extra total). If the teaching kitchen is not open due to COVID-19 transmission rates, cooking classes will be held virtually over Zoom. If cooking sessions are virtual, study team staff will deliver the food and equipment needed to participant's homes. Study staff will maintain a safe distance when they deliver and will not enter participant's homes. Staff will drop off food and make sure it is received.

**We begin this study with virtual DPP Cooks classes. We will not begin in person classes at the teaching kitchen until we have been approved by the IRB to do so.**

The DPP Cooks arm will also be sent text messages during the latter 8 months of the intervention (after the 6 cooking sessions are complete) to act as cues to action to keep cooking and using the skills and recipes they developed.

Weight loss data will be collected per usual during DPP sessions by the coach. During virtual DPP, weight has been self-reported by the participant using DPP provided scales. Weight data is reviewed by the DPP team for quality and any issues are resolved with the participant. Weight data is collected in compliance with CMS standards. Weight data will be inputted by DPP staff into a spreadsheet saved on OneDrive. Participants will be identified by their study ID number only.
Diet quality will be collected by the participant by taking photographs of all the food they eat over a 3-day period and uploading those photographs to the SmartIntake app. Participants will be reminded to do this based on text messages from the study team, and the study team will be on hand to assist participants if they run into any problems or need help. Participants will be given a reference card to include in food photographs (e.g. a blank white care with some lines on it to help gage potion size as well as a paper food tracker and guidebook). Other measures of interest will be collected using online surveys (Qualtrics) at baseline, 4 months and 12 months. Finally, we will invite participants to share their thoughts and experiences with the DPP Cooks intervention in in-depth interviews (over Zoom or phone) at the end of the study (12 months).

3. *Describe the expected duration of the study from the perspective of the individual participant and duration overall*.

The duration of the study is 12 months from start to finish. From the participant's perspective they will attend DPP sessions and some participants will have 6 extra cooking classes. Data collection will not require in person study visits. The participant will have a training session with study team staff to help them install and learn how to use the RFPM app and record their data. This session will take place over zoom before baseline data collection begins.

4. *Provide a brief data analysis plan and a description of variables to be derived.*

The key independent variable for all analyses is an indicator of whether or not the participant is in the control (standard DPP) group or the intervention (DPP Cooks) group. The other key variable is an indicator of time (baseline, 4 months, or 12 months). The primary outcome variables are weight loss (in kg lost, and in % of body weight lost). The secondary outcome variable is dietary intake/quality. We will use the data from the RFPM to calculate Healthy Eating Index-2015 scores. We will also be able to measure fruit and vegetable, as well as carbohydrate intake. Additional secondary outcomes from survey measures will include cooking confidence, cooking attitudes, cooking behaviors, cooking skills, food agency, and food security status. For most analyses we will compare changes in scores from baseline to 4 months and baseline to 12 months between intervention and control groups.

5. *Answer the following **if they are relevant to your study design**:*

A. *If the study has different arms, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the assignment.*

DPP cohorts will be the unit of randomization to avoid cross over due to the group meeting format of the DPP. Randomization will occur the same way for everyone regardless of how they are recruited. We will run 2 DPP cohorts concurrently and one will be the intervention arm, and one will be the control arm. Participants will be assigned to the two study arms randomly. Once participants enroll in the study, they will be assigned to the 2 study arms using a random number function in Excel. Because the intervention requires a weekly DPP meeting, and this needs to fit in to the participant's life, we will create cohorts for randomization for whom 2 DPP meetings would be convenient. For example, if there is a DPP group on Thursday at 5:00 and another on Wednesday at 6:00 or 2 Thursday at 5:00 groups, we will create a spreadsheet of individuals for whom DPP meetings on Thursday at 5:00 or Wednesday at 6:00 will work. Then, we will use the random number function in Excel to assign those participants to 2 groups. We will also randomly determine which DPP cohort will be the intervention and which will be the control.

B. *If human biospecimens (blood, urine, saliva, etc.) will be collected, provide details about who will collect the specimen, the volume (ml) and frequency of collection, how the specimen will be used, stored, identified, and disposed of when the study is over. If specimens will be collected for use in future research (beyond this study), complete the "Biospecimen Repository" section below.*

n/a

C. *If genetic/genomic analyses are planned, address whether the data will be contributed to a GWAS or other large dataset. Address returning unanticipated incidental genetic findings to study participants.*

n/a

*D. If clinical or laboratory work will be performed at JHU/JHH, provide the JH Biosafety Registration Number.*

n/a

E. *If you will perform investigational or standard diagnostic laboratory tests using human samples or data, clarify whether the tests are validated and/or the lab is certified (for example is CLIA certified in the U.S.).* ***For clinical tests of human biospecimens, no results may be returned unless completed in a certified lab.*** *Explain the failure rate and under what circumstances you will repeat a test. For all human testing (biomedical, psychological, educational, etc.), clarify your plans for reporting test results to participants and/or to their families or clinicians. Address returning unanticipated incidental findings to study participants.*

n/a

*F. If your study involves medical, pharmaceutical or other therapeutic intervention, provide the following information:*

a. *Will the study staff be blind to participant intervention status*?

n/a

b. *Will participants receive standard care or have current therapy stopped*?

n/a

c. *Will you use a placebo or non-treatment group, and is that justifiable*?

n/a

d. *Explain when you may remove a participant from the study*.

n/a

*e. What happens to participants on a study in which there is a medical intervention when the study ends*? *Will participants continue to have access to the study intervention? What happens if they leave the study early?*

n/a

f. *Describe the process for referring participants to care outside the study, if needed*.

n/a

## VI. Data Custody, Management, Security, and Confidentiality Protections:

*Data security and management plans must meet institutional standards. If you need assistance, contact jhsph_cybersecurity@jhu.edu.*

*Investigators are responsible for ensuring the security of data from the time of collection, through any transfers from one system to another, analysis, sharing, storage, and ultimate archiving and disposal. The questions below seek to elicit your plans for these protections. Feel free to add information.*

| |
|---|
| **1. Data Sources**: Identify the source(s) of data. |
| |

☒ Participant/Parent-Guardian/Legally Authorized Representative
☐ JHM medical records (from Epic)

*Note: Please complete the **Data Trust Risk Tiers Calculator** available on the Applications and Forms page on the JHSPH IRB website: https://www.jhsph.edu/offices-and-services/institutional-review-board/applications-and-forms/, and upload a copy of the those documents to the "Miscellaneous- Other" section of your PHIRST application. In addition, review the Data Protection Attestation for Research and/or Healthcare Operations at the link below and certify your attestation of compliance to those requirements:* (https://intranet.insidehopkinsmedicine.org/privacy_office/_docs/additional_information/Data%20Protection%20Attestation.pdf.

☒ **I certify my attestation of compliance to JHM Data Protection Requirements**

☐ Non-JHM medical records
☐ Outside data provider (CMS, National Death Index, Insurance Co., etc.)
☐ Other existing records (*please specify*):

**2. Data Content**: Will you collect, use, and/or record personal identifiers about study participants for any purpose? Please look at the list of identifiers in Question 3 to help answer this question. **Note: Limited Data Sets (including dates, ages, and zip codes) are considered to be "identifiable".**

☒ Yes: Continue with Question 3
☐ No: Skip to Question 6

**3. Data Identification:** Identify the Personally Identifiable Information (PII)/Protected Health Information (PHI) you will access/collect by checking the box(es) below for "Recruitment" and "Study Data" needs.

| Recruitment | Study Data | PII/PHI to be Accessed/Collected |
|---|---|---|
| ☒ | ☒ | Name, signature, initials or other identifiable code |
| ☐ | ☒ | Geographic identifier (address, GPS location, etc.) |
| ☐ | ☐ | Dates (birth, death, clinical service, discharge, etc.) |
| ☒ | ☒ | Contact information (phone number, email address, etc.) |
| ☐ | ☐ | Identification numbers (SSN, driver's license, passport, etc.) |
| ☐ | ☐ | Health records identifiers (medical record #, insurance plan, etc.) |
| ☐ | ☐ | Text of clinical record notes |
| ☐ | ☐ | Device identifiers (implants, etc.) |
| ☐ | ☐ | Internet identifiers (IP address, social media accounts, etc.) |
| ☐ | ☐ | Biometric identifiers (fingerprints, retinal scan, voice print, etc.) |
| ☐ | ☒ | Audio Recordings |
| ☐ | ☐ | Video or full-face photographic images |
| ☐ | ☐ | Genomic / Genetic data |
| ☐ | ☐ | Other identifiers (*list here*): |

**4. Identifiers:** If you have checked any of the boxes above, how will you protect personal identifiers?

☒ Will delete all identifiers (explain **when** you will delete identifiers): We will delete all identifiers when a participant either a) decides they do not want to enroll in the study or b) when their

participation in the study concludes and all data has been completed and compensation has been distributed.

☒ Will separate identifiers from analytic data and will store the link/code. Please explain where you will store the link/code: All participants will be assigned an ID that will link them to their PII. The PII l be stored on a separate spreadsheet stored in a different OneDrive folder than all other study cuments.

☐ Will use a method to make it harder to connect the data with the study participant (jiggering date, use other methods to obfuscate, etc.). *Please explain:*

**5. Data Transit Plans and Protections:** Identifiable data may transfer, sometimes with multiple steps, from mechanisms for collection to storage. For example, participants may complete a web-based survey, which is then downloaded to a storage platform. Briefly identify these steps and the protections for each step (including encryption used at each step).

☐ Will delete all identifiers prior to transfer

☐ Will separate identifiers from analytic data and will store the link/code prior to transfer. *Please explain where you will store link/code:*

☒ Other (*please specify*): Online surveys, interview transcripts and other study data will be stored with only the Participant ID included. Participant names will be deleted at the first possible opportunity (e.g. when a Qualtrics survey is downloaded, or when a transcript is received). For the RFPM data, photogrphaic data is sent to the Pennington team automatically through the SmartIntake app and are stored on the Automated Data Management Utility (ADMU). Food images are then used to estimate energy intake by trained Pennington staff. Participant data sent is deidentified and does not contain PII. As stated above, the only spreadsheet that links Participant IDs to identifying information will be stored separately on the OneDrive.

**6. Device(s) used for <u>data collection</u>:** Identify the computing device(s) being used for identifiable data receipt/collection. Check all that apply.

☒ Provided or managed by JHSPH IT

☒ Study-provided, and not managed by JHSPH IT. These must include the following protective controls:

- Data encrypted while "at rest" (on a storage device)
- Security patches and updates are routinely or automatically applied
- Devices have access controls so that:
  - Each person accessing the device is uniquely identified (username)
  - Passwords are sufficiently strong to prevent compromise
  - All access is logged and recorded
  - Unauthorized access is prevented
- Approved access list is reviewed periodically for correctness

☐ Other (*please specify*):

**7. Data Collection:** Describe the format of data received/collected. Check all that apply.

☐ Paper/Hard Copy (must be secured in transit and placed in a secure cabinet/room)
☒ Audio recording
☐ Video recording
☐ Received directly by research team member and entered into file/database
☒ Mobile or Web App (custom developed). *Review guidance and provide attestation of compliance*
☐ Mobile or Web App (purchased). *Specify product and version*:
☒ Online survey. *Specify mechanism/platform*:
☐ 3rd party collector (*please specify*):
☐ Existing data shared with JHSPH by data provider via electronic access/transfer
☐ Duplicate and backup copies will be secured with same rigor as original data
☒ Other (*please specify*): Weight loss data reported by participant and shared/recorded during DPP meetings. DPP coach will share that data with the research team by inputting the data in a spreadsheet saved on OneDrive in which participants are identified only by their participant number.

Dietary intake data collected by the participant via photographs uploaded to the SmartIntake app.

The study team and our partners at Pennington who developed the SmartIntake App attest that the SmartIntake app complies with the JHU guidance for web-based applications.

- All data is stored in PBRC's datacenter. Data is never stored in the cloud.
- PBRC's datacenter is secured with only authorized personnel allowed access
- PBRC web servers are regularly patched with latest security updates
- All data transferred from the SmartIntake app to PBRC is encrypted and requires an API key for authentication
- The DCAP website requires authentication for all users
- DCAP users are limited to only viewing data for studies they are authorized to access.
- Personal identifiable Information collected by SmartIntake and DCAP may consist of an email address of the participant (email addresses my be generated by institution to avoid using participant's personal email address.)
- Application development aligns with JH security checklist.
- Application developers are familiar with OWASP and have incorporated recommendations as appropriate.
- Data collection review confirms that only the minimum necessary sensitive data isbeing collected.
- Requirements for JH Mobile App Solution have been reviewed.
- Application has been tested for security vulnerabilities using appropriate tools consistent with OWASP standards.
- Plan for the removal of the app has been created: participants will be instructed to delete the app from their phones after their 4 month data collection is complete.
- Plan for ongoing support (including development and deployment of patches) has been created, and includes allocation of necessary funding.

**8. Devices/Platforms used for Analysis, Storage, Processing:** Identify where the identifiable or de-identified data will be analyzed/stored. Check all that apply.

☒ Pre-approved storage and analysis platforms managed by JH/JHSPH for which security and risk mitigation measures are known.

*Identify pre-approved storage platform(s) being used:*

***JHM Preferred:***

☐ JH SAFE Desktop ☐ JH PMAP

***Other Approved Platforms:***

☒ JH One Drive/JHSPH OneDrive ☐ JH IT-Managed Network Storage ☒ JHM/JHSPH Qualtrics

☐ JHSPH HPCC ☒ JHSPH SharePoint ☐ JHSPH Shares ☒ JHU REDCap

☐ MARCC-Secure Environment

☒ Platform(s) not managed by JH/JHSPH, not pre-approved, and require a risk assessment review from JHSPH Data Security (*please describe*): Pennington team (subcontract) will be responsible for analyzing the dietary data collected by the participant using the SmartIntake app. Data is transferred automatically and is stored and managed on the ADMU.

- Describe risk mitigation measures that are in place: Data transferred and stored is deidentified. Any communication with the JHU team and Pennington will reference participants by their ID number not by name or other identifying information.

Note: The following are examples of platforms/storage solutions that are **not pre-approved to store identifiable information** and require a risk assessment from JHSPH Data Security:

- Other solutions not managed by IT@JH, e.g., commercial cloud storage (Box, Dropbox, iCloud, personal OneDrive, Google Drive, Amazon storage, etc.)
- JHU Independent Departmental Servers
- Local Computer owned by JH
- Other computers or devices owned/managed by study team members and used for other than secure web access
- USB/Portable data storage device

**10. Access to Data and Access Controls:** How will you ensure that only authorized individuals can access the data? What access controls will you put into place to ensure that only authorized individuals may access and use the data. (For example, OneDrive *guidance* illustrates how to share files with "people you specify". *JHSPH-Shares* addresses providing permissions to individual people.) Check all that apply. Note: If you need assistance implementing secure access controls, contact *jhsph_cybersecurity@jhu.edu.*

☒ Will provide access to data in accordance with OneDrive/JHSPH-Shares guidance posted on JHU IT websites

☒ Will use secure access controls to limit access to individual-level data

☐ Will use secure access controls to provide other researchers controlled access only to aggregated study data

**11. Data Sharing:** Clarify if data are to be shared externally with third parties, including sponsors and other investigators, and whether only aggregated data will be shared, or if you will share individual-level data. Describe sharing and protection plans for that sharing, including the proposed use of data agreements.

*Consider the following:*

- *Information about your data sharing in the consent forms*
- *Information about data sharing laws in the country where data will be collected, and if they limit sharing, how you will comply with those limitations?*
- *Whether data will be shared in aggregate only, or individual level data*
- *Whether you plan to make the data publicly available, and in what form.*

☒ Will not share data with outside investigators

☐ Will share aggregated data only

☐ Will share individual-level data without identifiers

☐ Will deposit data into an existing data repository for future research (e*xplain*):

☐ Other sharing information:

**12. Duration and Destruction**: Explain how long data will be retained and the plan for eventual return, deidentification or destruction of data, including moving data to an archive.

We will retain all deidentified study data for at least 4 years to use to publish manuscripts and to have on hand for additional analyses we may need to conduct to support applications for future funding. Any identifiers will be deleted as described above.

**A. Certificate of Confidentiality:**

*All NIH studies include Certificate of Confidentiality (C of C) protections with the grant; the consent form must include the C of C language provided in our template. Other funders may obtain C of C protections through NIH. (https://grants.nih.gov/policy/humansubjects/coc.htm )*

Does the study have Certificate of Confidentiality protections? Yes ☒ No ☐

## VII. Risks of the Study:

A. *Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including physical, psychological, emotional, social, legal, or economic risks, and the risk of a breach of confidentiality. Include risks beyond individuals to include the study population as a group and community risks. Ensure that the risks described in the consent documents are consistent with the risks outlined in the research plan.*

The risks of harm or discomfort that may happen as a result of taking part in this study are not expected to be more than in daily life. It is possible that there is some risk of injury (minor cuts or burns) during the hands-on cooking classes. However, these risks are no greater than during regular

daily food preparation. There may also be risk of food allergy events during the cooking classes, but again, this risk is no higher than in daily life. As with all data collection, there is the possibility of breach of confidentiality.

B. *Describe steps you will take to mitigate or minimize each of the risks described above. Include a description of your efforts to arrange for care or referral for participants who may need it.*

The DPP is a proven intervention that has been widely implemented nationally. In this study, the DPP is not being modified in any way and will be conducted by DPP Coaches without any involvement from the study team. To protect against potential breach of confidentiality, all data will be immediately de-identified and only participant ID codes will be used on all quantitative and qualitative data. The spreadsheet linking participant ID codes to participant's identifying information will be stored separately in the JHU OneDrive. No names or other identifying information will ever be used in any publication or dissemination materials. All study data will be stored on locked, password protected computers equipped with two- factor identification systems for the OneDrive. Risks of injury during the cooking classes is minimal, but study staff and the chef instructor will have first aid kits on hand to handle any minor cuts, burns or other injuries. In addition, kitchen safety and safe knife handling will be emphasized during the classes. To avoid food allergy events, prior to any food tasting or cooking activities we will ask participants about any known food allergies, and will clearly identify all ingredients in the recipes we prepare and taste.

C. *Describe the anticipated frequency and severity of the harms associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an "anticipated" adverse reaction to occur in a study participant, and how severe do you expect that reaction to be?*

We do not anticipate any of the risks involved would be greater than those expected during daily life.

D. *Describe the research burden for participants, including time, inconvenience, invasion of privacy in the home, out of pocket costs, etc*.

Participants will participate in the DPP (at least 16 weekly sessions of the first 6 months and at least 6 sessions in the last 6 months) and in the DPP Cooks arm will also participate in 6 2-hour cooking classes over the first 4 months. Participants will answer surveys at 3 time point, will complete 3 days of dietary recall (by taking pictures on their smart phone) at 2 time points, and will have the option to wear a CGM for 14 days at 2 time points. They will also have the option to participate in an in-depth interview after the completion of the program. In total, data collection activities should be a minor inconvenience and time commitment. Invasion of privacy is a very low risk and we do not anticipate any out of pocket costs.

E. *Describe how participant privacy, and if relevant – family privacy - will be protected during data collection if sensitive questions are included in interviews, or if study visits occur in the home setting.*

Sensitive questions are not included in any data collection documents and there are no in person or in home data collection activities.

## VIII. Direct Personal and Social Benefits:

A. *Describe any potential direct benefits the study offers to participants ("payment" for participation is not a direct personal benefit).*

All participants will complete the DPP and will gain knowledge and social support to lose weight and improve their risk of developing type-2 diabetes. Participants in the cooking classes will also gain knowledge and skills related to healthy cooking and food agency. Participants in the DPP only arm will be offered the opportunity to alsk take one of the cooking classes as well at the conclusion of the study.

B. *Describe potential societal benefits likely to derive from the research, including value of knowledge learned.*

More than 30 million Americans have diabetes and another 84 million have pre-diabetes. Diabetes is a leading cause of mortality and morbidity and disproportionately affects low-income and racial/ethnic minority populations. Findings from this study may identify potentially important modifications to the DPP that could improve our ability to prevent type-2 diabetes. Procuring and preparing food is a daily occurrence and this study will provide new, detailed, and directly observed information that will inform not only the DPP Cooks intervention but that may be useful to create new or improve existing cooking interventions aims at building cooking skills necessary for consumption of a healthy diet. Overall, this study may produce new knowledge that will be important for improving diet quality and preventing diabetes and other diet related diseases.

## IX. Payment or Token of Appreciation:

A. *Do you plan to provide a non-monetary token of appreciation (food, soap, tea, chlorine tablets, etc.) to study participants? If no payment is provided, the JHSPH IRB strongly encourages providing such tokens. If yes, please describe below.*

DPP Cooks participants will receive a Participant Workbook (attached) that will accompany and serve as a resource for the cooking classes. They will also receive food for the recipes that will be cooked at each class and will be able to take any left over food home with them. In the standard DPP arm, participants will also be offered the Participant Workbook and a cooking class (with accompanying food) at the conclusion of the 12 months. Participants who opt in will also be provided a CGM for 14 days at baseline and 12 months.

B. *If you plan to provide a monetary payment, describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain*.

All participants will be compensated $100 ($20 after baseline data is completed, $20 after 4 month data collection is completed, and $60 after 12 month data collection is completed).

C. *Include the possible total remuneration and any consequences for not completing all phases of the research.*

If participants do not complete all phases of the study they will only be compensated for the phases they did complete.

## X. Study Management:

### A. Oversight Plan:

1. *Describe how the study will be implemented. List all parties, including collaborators and subcontractors, who will be "engaged" in the human subjects research project and their roles .*

   The PI of the study is Dr. Julia Wolfson, an assistant professor in the department of international health. Dr. Wolfson will supervise all study staff including student research assistants and staff study coordinators. All study staff will complete the necessary human subjects research training modules. As this research is part of a K01 grant, Dr. Wolfson's research mentor, Dr. Nisa Maruthur will also supervise and provide oversight for the study.

2. *What are the qualifications of study personnel implementing the project*?

   Dr. Wolfson has a PhD in public health policy and has 7 years of experience conducting research. Dr. Nisa Maruthur is an Associate Professor in the division of General Internal Medicine at JHU with more than 10 years of experience conducting community interventions and implementing DPP in Baltimore.

3. *How will non-professional personnel (data collectors) involved with the data collection and analysis be trained in human subjects research ethical protections? (Use the JHSPH Ethics Field Training Guide available on the JHSPH IRB website. If* the study is a clinical trial, consider using the JHSPH Good Clinical Practice (GCP) For Social and Behavioral Research Field Guide).

   All study staff who interact with participants will do the Good Clinical Practice for Social and Behavioral Research training.

4. *If the JHSPH PI is responsible for data collection and will not personally be on-site throughout the data collection process, provide details about PI site visits, the supervision over consent and data collection, and the communication plan between the PI and study team*.

   n/a

### B. Protocol Compliance and Recordkeeping:

*Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. (For assistance, contact*: housecalls@jhu.edu *Please provide information about study oversight to ensure compliance with IRB approval and regulatory and institutional requirements. If the study team does not follow study procedure, what is your plan for reporting protocol non-compliance?*

The study team will have a shared OneDrive folder in which all study documents and protocols will be saved. The study team will have weekly meetings, and every person brought on to the study team will have an orientation meeting with Dr. Wolfson. Dr. Wolfson will be responsible for all correspondence with the IRB and all other study documentation.

### C. Safety Monitoring:

1. *Describe how participant safety will be monitored as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role and what is that person's specific charge?*

   The participation in DPP does not pose any safety risks to participants and DPP do not exceed those of daily life. DPP is a proven preventive intervention and has not been associated with safety concerns in prior extensive research. However, Dr. Maruthur is a board certified general internist who will supervise all aspects of safety during this study.

2. *If a Data Safety Monitoring Board (DSMB), or equivalent will be established, describe the following*:

   a. *The DSMB membership, affiliation and expertise*.

   n/a

   b. *The charge or charter to the DSMB*.

   n/a

   c. *Plans for providing DSMB reports to the IRB*.

   n/a

3. *Describe plans for interim analysis and stopping rules, if any*.

   none

D. **Reporting Unanticipated Problems/Adverse Events (AEs) to the IRB (*all studies must complete this section*)**:

*NOTE: The IRB does not require PROMPT reporting of all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.*
***Anticipated** AEs may be reported with the Continuing Review/Progress Report.*

*Describe your plan for reporting to the JHSPH IRB, local IRBs, and (if applicable) to the sponsor. Include your plan for government-mandated reporting of child abuse or illegal activity*.

While we do not anticipate any adverse events, should any arise (e.g. a person cutting themselves during class) we will report all adverse events to the IRB immediately.

E. **Other IRBs/Ethics Review Boards:**

*If other IRBs will review the research, provide the name of each IRB/ethics review board and its Federal Wide Assurance number, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances). **For federally funded studies, subrecipients MUST have a Federal Wide Assurance (FWA) number from the OHRP. The IRB overseeing the subrecipient should be registered with the OHRP. The JHSPH IRB will not have oversight responsibility for international subrecipients, and generally will not oversee data collection at external U.S. institutions Please contact jhsph.irboffice@jhu.edu with questions.***

| Non-JHSPH IRB/REC | FWA Number |
|---|---|

| | | | |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

F. **"Engaged" in Human Subjects Research:**

*For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.*

**Insert collaborator names and FWA numbers, if available. Note who will be "engaged" in human subjects research by filling in the following table:**

| | JHSPH | Pennington Biomedical Research Center (Not "engaged") | |
|---|---|---|---|
| For federally funded studies, collaborators' FWA | 00000287 | 00006218 | |
| Primary Grant/Contract Recipient | | X | |
| Grant/Contract Subrecipient | | | |
| Hiring Data Collectors | | | |
| Training Data Collectors | | X | |
| Obtaining Informed Consent and/or Identifiable Data | | | |
| Accessing/Analyzing Identifiable Data | | | |
| Overseeing storage, access and use of biospecimens | | | |

**COMPLETE THE FOLLOWING SECTIONS WHEN RELEVANT TO YOUR STUDY:**

## XI. Secondary Data Analysis of Existing Data:

A. **Study Design:**

1. *Describe your study design and methods. The study design must relate to your stated aims/objectives.*

   n/a

2. *Provide an estimated sample size and an explanation for that number.*

   n/a

3. *Provide a brief data analysis plan and a description of variables to be derived.*

n/a

B. **Participants:**

1. *Describe the subjects who provided the original data and the population from which they were drawn.*

n/a

*Note: If you are receiving, accessing, or using data from a U.S. health care provider, the need for HIPAA review is likely. If you plan to bring identifiable health information from a foreign country to a U.S. covered entity (e.g., lab at the Hopkins SOM), HIPAA may be triggered. If either of these conditions is met, check "yes" to the HIPAA question in the PHIRST application.*

2. *If you plan to analyze human specimens or genetic/genomic data, provide details about the source of those specimens and whether they were collected using an informed consent document. If yes, explain whether your proposed use is "consistent with" the scope of the original consent, if it potentially introduces new analyses beyond the scope of the original consent, and/or if it introduces new sensitive topics (HIV/STDs, mental health, addiction) or cultural/community issues that may be controversial.*

n/a

3. *Explain whether (and how) you plan to return results to the participants either individually or as a group*.

n/a

## XII. Oversight Plan for Student-Initiated Studies:

A. *For student-initiated studies, explain how the PI will monitor the student's adherence to the IRB-approved research plan, such as communication frequency and form, training, reporting requirements, and anticipated time frame for the research. Describe who will have direct oversight of the student for international studies if the PI will not personally be located at the study site, and their qualifications.*

n/a

B. *What is the data custody plan for student-initiated research? (Note: Students may not take identifiable information with them when they leave the institution.)*

C. n/a

## XIII. Creation of a Biospecimen Repository:

*Explain the source of the biospecimens, if not described above, and what kinds of specimens will be retained over time. Clarify whether the specimens will be obtained specifically for repository purposes, or will be obtained as part of the core study and then retained in a repository.*

*A. Describe where the biospecimens will be stored and who will be responsible for them.*

n/a

B. *Describe how long the biospecimens will be stored, and what will happen at the end of that period.*

n/a

C. *Explain whether the biospecimens will be shared with other investigators, inside and outside of JHU, how the decision to share will be made, and by whom. Include your plans, if any, for commercial use. Also explain how downstream use of the specimen will be managed, and what will happen to left-over specimens*.

n/a

D. *Describe whether future research using the biospecimens will include specimen derivation and processing (cell lines, DNA/RNA, etc.), genomic analyses, or any other work which could increase risk to participants. Explain what additional protections will be provided to participants.*

n/a

E. *If future research could yield unanticipated incidental findings (e.g., an unexpected finding with potential health importance that is not one of the aims of the study) for a participant, do you intend to disclose those findings to the study participant? Please explain your position.*

n/a

F. *Explain whether the specimens will be identifiable, and if so, how they will be coded, who will have access to the code, and whether the biospecimens will be shared in linked (identifiable) form*.

n/a

G. *Explain whether the repository will have Certificate of Confidentiality protections.*

n/a

H. *Explain whether a participant will be able to withdraw consent to use a biospecimen, and how the repository will handle a consent withdrawal request.*

n/a

I. *Describe data and/or specimen use agreements that will be required of users. Provide a copy of any usage agreement that you plan to execute with investigators who obtain biospecimens from you.*

## XIV. Data Coordinating Center:

*Complete if JHSPH serves as the Data Coordinating Center.*

A. *How will the study procedures be developed?*

n/a

B. *How will the study documents that require IRB approval at each local site be developed? Will there be some sort of steering or equivalent committee that will provide central review and approval of study documents, or will template consent forms, recruitment materials, data collection forms, etc. be developed by and provided to the local sites by the coordinating center without external review?*

n/a

C. *Will each local clinical site be overseen by its own IRB with an FWA, or will a Single IRB review the study? State whether the coordinating center will collect IRB approvals and renewals from the clinical centers; if not, explain why.*

n/a

D. *How will the coordinating center provide each local site with the most recent version of the protocol and other study documents? What will be the process for requesting that these updates be approved by local clinical center IRBs?*

n/a

E. *What is the plan for collecting data, managing the data, and protecting the data at the coordinating center?*

n/a

F. *What is the process for reporting and evaluating protocol events and deviations from the local sites? Who has overall responsibility for overseeing subject safety: the investigators at the recruitment site, the Coordinating Center, the Steering Committee, or a Data and Safety Monitoring Board (DSMB)? Is there a DSMB that will evaluate these reports and provide summaries of safety information to all the reviewing IRBs, including the coordinating center IRB? Please note that if there is a DSMB for the overall study, then the coordinating center PI does not have to report to the coordinating center IRB each individual adverse event/problem event that is submitted by the local site PIs.*

n/a

G. *Some FDA regulated studies have different AE reporting criteria than that required by the IRB (IRB Policy No. 103.06). How will you reconcile the different requirements, and who is responsible for this reconciliation?*

n/a

H. *Who is responsible for compliance with the study protocol and procedures and how will the compliance of the local sites be monitored and reviewed? How will issues with compliance be remedied?*

n/a

## XV. Drug Products, Vitamins, Food and Dietary Supplements:

*Complete this section if your study involves a drug, botanical, food, dietary supplement or other product that will be applied, inhaled, ingested or otherwise absorbed by the study participants. If you will be administering drugs, please upload the product information.*

A. *List the name(s) of the study product(s), and the manufacturer/source of each product.*

| Name of Study Product | Manufacturer/Source |
|---|---|
| | |

| | |
|---|---|
| | |

B. *List each study product by name and indicate its approved/not approved status.*

| Approved by the FDA and Commercially Available | Approved by Another Gov't Entity (provide name) | Cleared for Use at Local Study Site |
|---|---|---|
| | | |
| | | |
| | | |

C. *If your study product has an Investigational New Drug (IND) application through the U.S. Food and Drug Administration, provide the IND number, and the Investigators Brochure.*
n/a

*Who will hold the IND?*

n/a

D. *If your study product is a marketed drug, provide the package inserts or other product information. If the study product WILL NOT be used for its approved indication, dose, population, and route of administration, provide a detailed rationale justifying the off-label use of the study product.*

n/a

E. *If the study product does not require FDA approval (e.g., dietary supplements, botanicals, products not subject to the U.S. FDA, etc.), provide safety information (as applicable) and a certificate of analysis.*

n/a

F. *Explain who will be responsible for drug management and supply, labeling, dispensing, documentation and recordkeeping. Complete and upload into PHIRST the Drug Data Sheet available on the JHSPH IRB website at www.jhsph.edu/irb.*

n/a

G. *What drug monitoring and/or regulatory oversight will be provided as part of the study? Please describe.*

n/a

## XVI. Medical Devices:

*Complete this section if your study will involve an approved or investigational medical device (**diagnostic**, non-significant risk, significant risk).*

A. *List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it*

*is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval or its equivalent from a local authority, to ensure that the device is in good working order.*

| Name of Study Product | Manufacturer/Source | Powered? |
|---|---|---|
| | | |
| | | |
| | | |

B. *List each study product by name and indicate its status as approved by a government authority or not approved.*

| Approved by the FDA and Commercially Available | Approved by Another Gov't Entity (provide name and approval information) | Not Approved |
|---|---|---|
| | | |
| | | |
| | | |

C. *If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a* ***diagnostic device****, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so, and explain how those results will validated (or not) against the current "gold standard".*

n/a

D. *If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.*

n/a

E. *If you are using an investigational device that is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study. Provide a description of the device, and upload a picture or manufacturing schematics into PHIRST. Provide any other information relevant to a determination of its safety to be used for the purposes outlined in this research plan.*

n/a