Study Title: Evaluating household food behavior with a smartphone app (FoodImage)

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IRB Review Plan
This is a subcontract project with Ohio State University as the lead institution and Pennington Biomedical Research Center (PBRC), part of the Louisiana State University system, as the subcontractor who will conduct the human subjects research. PBRC will pursue the research outlined herein and share the resulting data with Dr. Roe at OSU.

Objectives
Long-term Goals and Specific Objectives

Our *long-term goal* is to improve global sustainability and enhance food security while improving the competitiveness of the U.S. food system by reducing U.S. household food waste. To reduce household food waste, we must first improve the accuracy, convenience and standardization of its measurement so that evaluations of waste reduction initiatives have more statistical power, less statistical bias, less measurement error, and greater representativeness of targeted populations. Such improved evaluative capacity can stimulate research and program assessment, which then guides prioritization of emerging private and public programs and policies aimed at reducing household food waste.

Specific objectives include:

(1) Development of FoodImage, a smartphone app that measures household food waste and food-waste-related behaviors,
(2) Assess differences in the accuracy, time burden and perceived convenience of measurements taken with the FoodImage app versus the current state-of-the-art household food waste measurement approach (a pen-and-paper diary), and
(3) Use the FoodImage app in a pilot randomized controlled trial designed to evaluate the effectiveness of reducing household food waste through behavioral nudges in the form of personalized feedback about food waste levels and household-specific reduction goals.

Background
About one-third of U.S. food is wasted with two-thirds of this waste attributed to consumers. The United States proposes to cut food waste in half by 2030 and, while many policies are available, those that change consumer waste behavior will be integral to achieving U.S. goals. However, we lack quality data about household food waste because popular data collection methods (diaries and waste stream analyses) suffer major shortcomings. Hence, rigorous evaluation of consumer interventions prove elusive.

We propose to improve the accuracy and convenience of household food waste measurement so that consumer food waste program evaluations yield more power, less bias, less measurement error, and greater representation of targeted populations. We will improve measurement via the development of the **FoodImage smartphone app**, a technology leveraging the investigators' expertise in creating and deploying apps to measure food intake and deliver nutritional interventions in free-living household conditions. We will validate the app against weighed waste in a controlled laboratory setting and then deploy the app in free-living conditions as part of a pilot randomized controlled trial to evaluate if behavioral nudges in the form of personalized feedback and goals can reduce household food waste. The FoodImage app will extract GPS coordinates (latitude and longitude) from the smartphone when food images are taken. This information will be used to determine participants' location when food waste data are captured with the FoodImage app.

The study will yield an app ready for future study deployment while analyses of the data will inform rapidly evolving policy discussions concerning optimal approaches to reduce food waste. These outcomes align with program priorities to understand the economics of food waste and to use behavioral economics to address consumption behavior.

Rationale and Significance

Countries around the world have resolved to reduce food waste in order to help achieve global food security and sustainability goals [1-6]. About one-third of global edible food is lost or wasted annually [7] while the global production of uneaten food generates greenhouse gas emissions estimated to exceed those created by the third largest greenhouse gas emitting nation [8]. The Organization for Economic Cooperation and Development identified reducing food waste as an avenue to increase the availability of food [9], while the Obama administration announced in September of 2015 a first ever food waste reduction goal for the United States of 50% by 2030. While present in the entire post-harvest supply chain, food waste at the retail and consumer levels is particularly prevalent in the United States. In 2010, 133 billion pounds of edible food at the retail and consumer levels went uneaten (1,249 calories per person per day) with about two-thirds of this waste attributed to consumers [10]. This represents not only a significant waste of resources, but also substantial negative environmental externalities as about 95% of food waste enters U.S. landfills. Food waste is the largest source (35.2 million tons) and the most deleterious component (in terms of greenhouse gas emission) of U.S. municipal solid waste [11-14].

Because so much food waste is attributable to consumer residential behavior (about 47% according to BSR's 2013 analysis), it is critical to articulate, evaluate and prioritize the numerous possible household food waste intervention strategies. ReFED [15] articulates several categories of possible household interventions ranging from labeling interventions to packaging alterations to general education campaigns, where each category is likely to give rise to several variants requiring evaluation. While it is encouraging that the World Resources Institute (2016) has issued global standards for food waste accounting and reporting, a recent review of consumer food waste studies [16] reveals few published studies measuring individual level food waste created by U.S. consumers [17] [18], and these studies focus on consumer behavior in all-you-can-eat buffet settings that may yield limited insight for other dine-out or eat-in settings. Quality data is lacking for the United States.

Inclusion and Exclusion Criteria

Inclusion Criteria

In order to enroll in this study, subjects must meet the following criteria for inclusion:

- Age 18-65 years
- Body Mass Index 18.5 – 50 kg/m^2, based on self-reported height and weight
- Shops for groceries
- Conducts some of the food shopping and food preparation for their household
- Be willing to do food shopping for the study (if necessary)
- Have an iPhone and an operable Apple ID, password, and email address and is willing to use these to collect data during the study, acknowledging that data usage, and associated charges, are a result of study participation
- Be willing to complete all study procedures corresponding to their randomization group

Exclusion Criteria

In addition to those who do not meet inclusion criteria, subjects who meet any of the following criteria will be excluded from enrollment:

- Persons who are severely immune compromised
- Persons who are pregnant, as assessed by self-report.

Number of Subjects

Approximately 24 participants are expected to complete Phase 1. The 24 participants from Phase I, plus an additional 20 participants, will complete Phase II for a total of 44 participants. Pennington Biomedical Research Center employees are not eligible to participate.

Recruitment Methods

After IRB approval is received, a sample of 44 adults will be recruited from the Baton Rouge, Louisiana area to participate in the study. Phase I will enroll a total of 24 participants. Phase II will enroll an additional 20 participants, totaling 44 enrollees. Recruitment will be completed by PBRC's Recruitment Core. The Recruitment Core manages all community outreach and recruitment services for human research studies at PBRC, such as screening all incoming calls to determine initial study eligibility; assisting in partnership development, specifically with local community groups, physicians, and healthcare facilities; and serving as the first line of contact for all human research study participation. Incoming calls are directed to a call center that is operated by 3 full time recruiters and is equipped with a Uniform Call Distributor (UCD) system. A UCD system expands the capability of a traditional phone system and allows multiple individuals to call simultaneously and be directed to the next available recruiter. The core utilizes an electronic message tracking application that tracks the outgoing phone call activity and a "smart" electronic phone screen system that screens potential participants upon initial phone contact and seamlessly matches them to alternative studies when deemed ineligible for the original study for which they called. In 2012, the core launched a new web-screener for participants to be able to go on-line, choose a study that are interested in and complete a preliminary screening. The system is able to tell the participant upon completion whether they are eligible at that point in the screening process and if they are ineligible the screener will alert them to other studies that they are eligible for and at that point could continue to screen for those studies. If the participant is eligible they are then contacted by a live recruiter to complete the

screening process and schedule their first screening appointment. We anticipate approximately 132 phone screens to enroll 44 participants (3:1 ratio).

Study Timeline
It is estimated to take up to 1 year to recruit participants for this study. It will take approximately 3 years to complete the study and all data analyses. Participation in this study will take approximately 3-4 weeks. The length of participation is virtually identical for participants who complete Phase I and II vs. Phase II only. This is due to Phase I including about one to two hours of laboratory-based procedures prior to participants being trained and asked to use the FoodImage app to track food waste for 4 to 7 days over the subsequent week. Participants who only complete Phase II will not conduct the laboratory-based procedures but all other procedures will be identical.

Study Endpoints
The primary endpoint of this study is food waste and food waste behavior. We will explore these endpoints via the following aims and objectives:

- Development of FoodImage, a smartphone app that measures household food waste and food-waste-related behaviors; and assess differences in the accuracy, time burden of, and perceived convenience of measurements taken with the FoodImage app versus the current state-of-the-art household food waste measurement approach (a pen-and-paper diary) with and without a food scale
- Use the FoodImage app in a pilot randomized controlled trial designed to evaluate the effectiveness of reducing household food waste through behavioral nudges in the form of personalized feedback about food waste levels and household-specific reduction goals.

All data from the FoodImage app (including home address and GPS coordinates from food images) will be used as a study endpoint.

Procedures and Visit Description

The study will accomplish three activities:

1) Development of the FoodImage Smartphone app
2) Testing the FoodImage app with consumers in a lab setting (Phase I)
3) Randomized Controlled Trial of behavioral nudges to reduce household food waste (Phase II)

FoodImage App Development

The programming and development team that created a previous app called SmartIntake® agreed to build the FoodImage app. Originally, we expected the FoodImage app to rely on some features of the SmartIntake app, though FoodImage was ultimately built from scratch. The FoodImage app sends participants' images and accompanying data (e.g., receipts, food descriptions, Participant ID number, and timestamp) to a secure PBRC server where a team will analyze the images to estimate food waste.
The coverage and capabilities that will distinguish the FoodImage app from the SmartIntake® app will include:

A. **Comprehensive measurement of food waste**. The FoodImage app will quantify food waste at all stages where food waste occurs at the consumer level (e.g., left-overs after a meal, cabinet or refrigerator/freezer purges, food preparation, etc.). The existing SmartIntake® app quantifies *plate* waste that is present at the end of meals and this is used to calculate food intake (food intake = food selection minus plate waste). SmartIntake® does not, however, determine if the plate waste was discarded, saved to eat later, etc., thus, it cannot determine if *plate* waste is *food* waste.
B. **Receipt scanning capability**. An exploratory module will be developed in which receipts from food purchases are scanned. This will provide the potential to calculate the dollar value loss of waste using prices actually paid by the participant. While this module is exploratory and not primary, it holds promise for assessing the exact purchase value of food waste and for exploring hypotheses that link food acquisition price to eventual food consumption and food waste.

Phase I (Overview)

Phase I of this study will consist of testing the FoodImage App with participants in a lab setting. The primary purpose of Phase I will be to test the measurement features of the FoodImage app under controlled conditions and to obtain user satisfaction data about the app. Participants will use three methods in the lab setting:

1) the FoodImage app,
2) a pen-and-paper record, where the participant will visually estimate portion sizes, and
3) a pen-and-paper record, where the participant will use a kitchen scale to weigh the foods.

Participants will be randomly assigned to the order in which these methods will be used, as described below. It is noted that, by necessity, the last method that will be used is a pen-and-paper record with a kitchen scale since this procedure will cue participants to the actual weight of the foods and corrupt their visual estimates, should the visual estimation procedure occur after the method that relies on a kitchen scale. Thus, the order in which participants first use FoodImage vs. a pen-and-paper record with visual estimates of portion size will be counterbalanced. The two orders that will be balanced among participants are:

1) FoodImage, pen-and-paper records with visually estimated portion size, then pen-and-paper records with the ability to use a kitchen scale.
2) Pen-and-paper records with visually estimated portion size, FoodImage, then pen-and-paper records with the ability to use a kitchen scale.

Accuracy will be evaluated for both the FoodImage app and the two methods that rely on pen-and-paper records by comparing estimated food waste from these three methods to directly weighed food waste. Participants will use these three methods to estimate the amount of:

1) food waste that is generated when they prepare provided foods,
2) the resulting food portions that represents the amount of served food during a simulated meal, and
3) the amount of food that remains (plate waste) after the study staff discards a randomly selected amount of the served foods (participants will not eat any food).

Participants will also use all three methods to document foods from a simulated shopping trip, where participants will be provided with a grocery bag(s) of foods products and one or more receipts. It is recognized that some food products may not require use of the kitchen scale since

the packaging contains the weight or portion size of many foods. Finally, participants will also use all three methods to document foods that are to be discarded from a simulated kitchen clean out. To simulate the kitchen clean out, study staff will present to the participant a series of food products on a counter and participants will be asked to document what and how much food would be thrown away (the foods will not actually be discarded). The training materials that will be used to teach participants how to use the pen-and-paper records and FoodImage app are included in Appendix A.

Following the laboratory-procedures described above, participants in Phase I will complete questionnaires assessing their satisfaction with the FoodImage app, if they prefer to use the FoodImage app vs. a pen-and-paper record, etc. (these questionnaires are detailed below).

Phase II (Overview)

Phase II of this study is a randomized controlled trial of behavioral nudges via the FoodImage app to reduce household food waste. Phase II will occur in participants' natural environment (free-living conditions) and will include the 24 participants enrolled in Phase I and an additional 20 participants. Phase II, participants will be trained to use the FoodImage app to capture data on food purchases, food waste that occurs during food preparation, food waste that is present after eating, and food waste from food purges in free-living conditions. During data collection, subjects will record the source, reason, and destination of all food waste in the app.

Participants will use the app to collect food waste data for approximately 4 to 7 days over the first week of Phase II and these data serve as baseline data. Participants will then be provided with approximately a one-week break where they will not use the app to track food waste (or do any other study procedures). After the one-week break, participants will return to the center and will be randomly assigned (1:1 ratio) to one of the following groups:

1. Stress Management (Control Group). These participants will use the app to record food waste for approximately 4 to 7 days over the subsequent week. They will also receive information on stress management (Appendix C.1).
2. Food Saver (Intervention Group). These participants also will use the app to record food waste for approximately 4 to 7 days over the subsequent week. They will also be provided with the following:
    a. Feedback on the amount of food waste their household created during the first week,
    b. A goal to reduce the next week's food waste by 20% or more, and
    c. Tips on how to reduce household food waste adapted from current consumer campaigns (e.g., Food: Too Good to Waste Implementation Guide and Toolkit, EPA 2016). This includes advice to limit purchases of unnecessary foods, donate or freeze unwanted and unspoiled foods, prioritize keeping and then eating left-overs, minimize waste during food preparation by preparing and serving smaller portions, purchase only needed foods, and purchase foods that are not near the expiration date (see Appendix C.2). A PBRC staff member will deliver tips to each respondent in this group via in-person and remote sessions (call, text, email, videoconference etc.).

After approximately one week, the Stress Management and Food Saver groups will return to the Center to complete questionnaires about the usability of the app and, for participants who also completed Phase I, focus groups or cognitive interviews (Appendix B.3.b).

Visits

All participants in this study will complete 3 visits at Pennington Biomedical Research Center. Visit 1 will differ for participants in Phase I and Phase II. Visits 2 and 3 will be the same for participants in both Phases. Procedures are listed below.

Visit 1 (V1) – Phase I participants (Day 0)
Visit 1 will last approximately 4 hours for Phase I participants. Procedures at V1 include the following (Procedures in italic text are only completed by Phase I participants. As noted below, participants who only enroll in Phase II conduct all other non-italicized procedures.):

- Provide informed consent
- Eligibility will be verified
- *Receive training on use of the FoodImage app and pen-and-paper records, with and without use of a kitchen scale, to capture food waste data in the laboratory setting*
- *Capture data from food shopping, preparation, eating, and kitchen clean out events*
- *Complete the following questionnaires:*
    - Lifestyle and Demographics Questionnaire
    - *User Preference Survey*
    - *PSSUQ*
    - *User Satisfaction Survey*
- Body weight will be measured and recorded by study staff
- Height will be measured and recorded by study staff and used to calculate BMI
- Receive training on use of the FoodImage app to capture data in a free-living environment during food shopping, preparation, eating, and tossing events for approximately 4 to 7 days over the next week.

Study staff will keep in contact with participants over their free-living data collection to ensure data quality and participant compliance.

Visit 1 (V1) - Phase II participants (i.e., participants who did not enroll in Phase I) (Day 0)
Visit 1 will last approximately 2.5 hours for Phase II participants. Procedures at V1 include:

- Provide informed consent
- Eligibility will be verified
- Body weight will be measured and recorded by study staff
- Height will be measured and recorded by study staff and used to calculate BMI
- Complete the Lifestyle and Demographics Questionnaire
- Receive training on use of the FoodImage app to capture data in a free-living environment during food shopping, preparation, eating, and tossing events for approximately 4 to 7 days over the next week.

Study staff will keep in contact with participants over their free-living data collection to ensure data quality and participant compliance.

All participants will have an approximate one-week break after they finish collecting data for ~4 to 7 days during the week following Visit 1. This results in approximately 2 weeks between Visits 1 and 2.

Visit 2 (V2) – Phase I and Phase II enrollees (~Day 14)

Visit 2 will last approximately 3 hours for both Phase I and Phase II participants. Participants will be contacted by study staff before the date of V2 to remind them of their appointment. Procedures at V2 include:

- Body weight will be measured and recorded by study staff
- Randomization to either:
    - Stress Management group (these participants will receive information from a study interventionist about stress management via an in-person meeting during Visit 2 and via the multimedia capabilities of a smartphone, e.g., text messages, emails, phone calls)
    - Food Saver group (these participants will receive information from a study interventionist about reducing food waste via an in-person meeting during Visit 2 and via the multimedia capabilities of a smartphone, e.g., text messages, emails, phone calls)
- Receive refresher training on use of the FoodImage app to collect data in their home setting for approximately 4-7 days over the subsequent week. Participants' follow-up visit, or Visit 3 (V3) scheduled.

Visit 3 (V3) – Phase I and Phase II enrollees (~Day 21)

Visit 3 will last approximately 1.5 to 2 hours for both Phase I and Phase II participants. Prior to V3, participants will receive a phone call to remind them of their appointment. Procedures at V3 include:

- Review the data collected over the free-living period and discuss the implementation of the stress management or food waste reduction suggestions.
- Complete the following questionnaires:
    - Food Environment Questionnaire
    - Waste Toss Methods Questionnaire
    - User Satisfaction Survey
    - Post-Study System Usability Questionnaire (PSSUQ)
    - Food Waste Tip Questionnaire (Intervention/Food Saver Group only)
- Complete a focus group or cognitive interview to assess thoughts and attitudes towards the app, pen-and-paper records, food environment, and food waste behaviors (Phase I participants only).
- Body weight will be measured and recorded by study staff

Additional visits are possible if more assistance is needed with the app or to resolve data collection problems, such as technical challenges with the app. These may be in-person, via email, via text or any other mode of communication.

Table 1. Schedule of Visits and Procedures		
	Phase 1 Enrollees	Phase 2 Enrollees
N	24	20
Phase 1		
Visit 1 (V1): Day 0	~4 Hours	~2.5 Hours
Consent, eligibility verification, Lifestyle and Demographics Questionnaire, body weight, height, BMI	X	X
Training on and use of the app and pen-and-paper records to capture food waste data in laboratory setting	X	
User Preference Survey, PSSUQ, User Satisfaction Survey	X	
Phase 2 (the following procedures occur at the end of Visit 1)		
Training on use of app to collect data in free-living setting. Instructed to collect food waste data with the app for approximately 4 to 7 days over the following week. Instructed to then take approximately a one-week break, with Visit 2 occurring at the end of the break.	X	
Visit 2 (V2): ~Day 14	~3 Hours	
Randomization to the Stress Management or Food Saver group and delivery of each groups' instructions and materials	X	
Refresher training for use of app to collect data in the home setting for approximately 4 to 7 days over the next week. Additional training, information, and behavioral nudges will be deployed via phone, email, and text until Visit 3, which will occur approximately one-week later.	X	
Body Weight	X	
Visit 3 (V3): ~Day 21	~<2 hours	
Meeting with staff to discuss collected data and implementation of behavioral nudges	X	
Food Waste Tip Questionnaire	X (Food Saver group only)	
Focus groups or cognitive interviews	X (Phase I participants only)	
Food Environment Questionnaire, Waste Disposal Methods Questionnaire, PSSUQ, User Satisfaction Survey	X	
Body Weight	X	

Description of Questionnaires

- *Eat, Prep, and Toss food waste records*- These pen and paper records will be used during Phase I and are consistent with previous food waste studies (Appendix A.1.e & A.1.f).
- *User Preference Survey*- This survey asks questions to help staff understand participants' acceptability and preference for using the FoodImage app and pen-and-paper records to record food waste (Appendix B.1.a).
- *Post-Study System Usability Questionnaire (PSSUQ)*- This is a validated questionnaire to assesses satisfaction with electronic platforms [19], such as the FoodImage app (Appendix B.2.b).
- *User Satisfaction Survey*- This survey asks questions to help staff understand participants' satisfaction with using an iPhone app (FoodImage) to take and send photos of food waste (Appendix B.2.c).

- *Food Environment Questionnaire*- This questionnaire asks questions about purchasing food for the household (Appendix B.2.d).
- *Waste Toss Methods Questionnaire*- This questionnaire asks questions about how participants typically dispose of food in their household (Appendix B.2.e).
- *Food Waste Tip Questionnaire* – This questionnaire asks questions to help staff understand participants' satisfaction with receiving training tips to help reduce food waste (Appendix B.3.a).

Data Analysis and Specimen Management
Phase I analysis objectives include:

1) Determining if food waste measured with the FoodImage app is equivalent to the criterion value (directly weighed food waste) for each source (plate waste, food purges, etc.). Error (the difference between food waste measured with the FoodImage app and the criterion value) will also be quantified for each source.
2) Determining if food waste measured with each of the pen-and-paper diary methods (with and without a kitchen scale) is equivalent to the criterion value for each source. Error will also be quantified for each source.
3) Determining if the error from the FoodImage app is smaller than error from the pen-and-paper records.
4) Determining if satisfaction ratings differ significantly between the app and the pen-and-paper record approaches.
5) Determining if the amount of time respondents took to complete measurements differed between the app and diary approaches.
6) Qualitative assessments by respondents of the desirable and undesirable features of the app and pen-and-paper records.
7) Determining if the variance of waste measures differed between the app and pen-and-paper record approaches.
8) Assessing the accuracy of receipt data as captured by participants using the app.

Power Analysis. We base our power analysis on plate waste data gathered from previous research conducted at PBRC [20]. With an N of 24, we are powered to detect equivalence within 20 grams with power of 0.80 and alpha of 0.05. Also, *t*-tests to determine if the error from the app (weighed food waste minus estimated waste) differs significantly from the error from the diary method is powered to detect differences as small as 12.8 grams.

It is hypothesized that food waste will be equivalent (within 20 grams) when measured with the app vs. direct weights of food waste, while food waste measured with the diary method will not be equivalent to directly weighed food waste. It is also hypothesized that the error from the app will be significantly smaller than error from the diary method.

Phase II analysis objectives include:

1) Quantifying baseline distributions for total weight of household food waste

2) Determining the effectiveness of the behavioral nudge in altering
    a) Total daily weight of household food waste,
    b) Total daily weight of each source of household food waste by occasion, including
        i) plate waste,
        ii) food prep waste,
        iii) purge waste,
    c) Total daily weight of each source of food waste by food type (e.g., dairy, meat, fruits, etc.) and by macronutrient,
    d) Daily percent of served food that is wasted, and
    e) Total amount of food purchased by weight and value.
3) Quantifying satisfaction levels with the FoodImage app as measured in Appendix B.1.a. (User Preference Survey) and Appendix B.2.c (User Satisfaction Survey),
4) The demographic, household and attitudinal factors measured in Appendix B.2.d (Food Environment Questionnaire) related to
    a) Effectiveness of the behavioral nudge intervention in reducing food waste generated and all subcomponents listed above, and
    b) Satisfaction levels with the app as measured in Appendix B.2.c (User Satisfaction Survey).

Withdrawal of Subjects
Subjects may be withdrawn from the study if they are non-compliant with study procedures and they will be notified of their withdrawal via telephone or mail. Subjects may voluntarily withdraw from the study at any time. No additional data will be collected and they will be considered drop outs in the study.

Risks to Subjects
This study involves no greater than minimal risk. The main risk is breach of confidentiality, and the PBRC team will work to minimize this during data collection, handling, and analysis.

Potential Benefits to Subjects
Participants may benefit by increased awareness of their food waste behaviors.

Setting
All research procedures will be conducted at PBRC and in participants' natural environment.

Resources Available
PBRC has all the necessary equipment needed to undertake and execute the proposed research project successfully. All investigators and staff have offices or cubicles. Investigator offices are each equipped with a desk, chair, filing cabinets and shelves, telephone with voice mail, printer, and access to a photocopier and fax. Computers are equipped with software for statistics, data management, and word processing, and computers are connected to the PBRC mainframe with internet access and email access through Outlook Express. Information Technology (IT) provides full technical support to all members of the faculty and staff. PBRC has all the technological equipment and staff needed to conduct the present study. These information technologies assure efficient data handling and optimal communication among the investigators and the team.

Compensation
Participants will be compensated $30 for successful completion of Phase I and $175 for successful completion of Phase II (maximum compensation = $205 for participants who complete both Phase I and Phase II).

Confidentiality and Provisions to Protect the Privacy Interests of Subjects
Participants' records will be kept confidential to the extent allowed by law. Only Drs. Corby Martin, John Apolzan, and Brian Roe, the Ohio State University research team, and the PBRC research team will have access to the information participants provide. Information may also be shared with necessary Institutional Review Boards and Offices for Human Research Protection (OSU Institutional Review Board, Pennington Biomedical Research Center IRB, and the Office for Human Research Protection (OHRP)). We will use an identification number rather than participants' names on study records. The information participants provide will be stored on secured network drives and will not be identified using any personal information.

Participants' names and other facts that might identify them will not appear when we present this study or publish its results. The findings will be summarized and reported in group form. Participants will not be identified personally. All participants will have ample opportunity during consent and throughout the study to ask questions concerning study procedures. These questions will be answered promptly and fully by study staff to ensure participant ease. A participant may choose not to answer questions or participate in study procedures at any time.

Data Safety Monitoring Plan
Study recruitment, study progress, participant complaints, data collection, data management, data integrity, data security, and eventually data analysis will be staffed at weekly meetings at PBRC, in which the PI will be in attendance. Also, Dr. Roe and his team will be briefed on the progress of data collection at regularly scheduled teleconference, which will occur approximately once every month or every other month.

Compensation for Research-Related Injury
No form of compensation for medical treatment or for other damages (i.e., lost wages, time lost from work, etc.) is available from the Pennington Biomedical Research Center. In the event of injury or medical illness resulting from the research the participant will be referred to a treatment facility. Medical treatment may be provided at their expense or at the expense of their health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. PBRC is a research facility and provides medical treatment only as part of research protocols. Should the participant require ongoing medical treatments, they must be provided by community physicians and hospitals.

Economic Burden to Subjects
There will be no study related costs to the participant with the exception of traveling to the PBRC for the study visits. However, use of the FoodImage app will use data from the participant's cellular data plan. Hence, it is possible that the participant would incur cost for this data and this is clearly disclosed in the consent form.

Consent Process

All subjects participating in the study will provide written informed consent. The consenting process will take place in private rooms at Pennington Biomedical Research Center and will be conducted according to Pennington Biomedical consenting guidelines and practices. Participants can take the consent form home to review prior to deciding if they wish to enroll. All participants are free to withdraw from the study at any time.

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