V. 6-2020

#PBRC _2021-015

CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR AN ADULT
INFORMED CONSENT - PART I

Title of Study: USING THE FOODIMAGE™ APP TO ASSESS SMART INTERVENTIONS DESIGNED TO IMPROVE NUTRITION & REDUCE FOOD WASTE

Study Sponsor: USDA

Key Information

- **Why am I being asked to review this form?**
  - You are being asked to take part in a research study. This form is provided so that you may read and understand the reasons why you might or might not want to participate in the research. Your participation is voluntary.
- **What is the purpose, duration, and procedures of this study?**
  - The purpose of this study is to test the effects of interventions and free fruit and vegetable (FV) provisions on food waste and FV intake.
  - Your expected time in this study will be 28 days consisting of approximately 5 in person study visits and 3 follow up visits. There will also be multiple nudges sent to you in-between visits to provide facts or encouragement related to your intervention group. The final in person visit involves an exit survey that will be conducted at PBRC.
  - The procedures involved in this study include
    - Training on how to use the FoodImage smartphone app
    - Training on how to conduct household FV inventory
    - The completion of several surveys
    - The use of FoodImage to record all food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss)
    - Acquisition of FV provision (3x)
    - Receive intervention on healthy eating and importance of FV or stress management
    - The completion of a before and after Fruit and Vegetable Inventory via Microsoft Teams recorded call function
- **What are the possible risks and discomforts?**
  - This study involves no greater than minimal risk. The main risk is breach of confidentiality, and the PBRC team will work to minimize this risk by following existing best practices for data collection, handling, and analysis. Although unlikely, you may feel uncomfortable answering certain questionnaire questions. You do not have to answer any questions you do not want to answer.

- **What are the possible benefits?**
  - Participants may benefit by increased awareness of their food waste behaviors.
- **If you choose not to participate in the study, are there other choices?**
  - You have the choice at any time not to participate in this research study.
  - If you decide not to participate in this study, no other data will be collected

Detailed Information

1- Who is doing the study?

Investigator Information:

Principal Investigator:	Corby Martin, Ph.D. (225) 763-2585 John W. Apolzan, Ph.D. (Grant mPI)
Co-Investigators:	Brian Roe, Ph.D. (Grant mPI) Danyi Qi, Ph.D. Shengping Yang, Ph. D.

Dr. Martin and Dr. Apolzan direct this study. We expect about 46 adults will be enrolled in this study. The study will take place over a period of approximately 2-3 years. Your expected time in this study will be approximately 35 days, with approximately 5 of those days requiring an in-person visit at PBRC. Additionally, your demographics information from screening will be used in data analysis.

This project involves use of the FoodImage app. Ray Allan and Drs. Martin, Apolzan, and Roe are inventors of the FoodImage app, which will be tested during this project. Researchers may be required to call, text, videoconference, etc. if necessary for the intervention. They do not currently have any financial gain from the FoodImage app, however it could be available for licensing through LSU-Pennington in the future. If a license is acquired, Drs. Martin, Apolzan, and Roe may possibly receive a royalty payment.

2- Where is the study being conducted?

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

3- What is the purpose of this study?

The purpose of this study is to test the effects of interventions and free fruit and vegetable (FV) provisions on food waste and FV intake.

4- Who is eligible to participate in the study?

Inclusion and Exclusion Criteria

Inclusion criteria include:

- Male or female, age 18-62 years
- Body mass index (BMI) 18.5 – 50 kg/m2, based on self-reported height and weight
- Ownership of an iPhone, which the participant is willing to use for the study
- Access to Apple ID, password, and email address and willing to use them in the course of the study
- Performs a majority of household food shopping and preparation
- If children are present in household, all children are between 6-18 years
- Able to meet the schedule demands for the study

Exclusion criteria include:

- Not able to use an iPhone
- Refusal or unable to use the smartphone app to collect data in free-living conditions
- Households that purchase groceries less than 1 time per week
- More than 2 children living in the household
- Pennington Biomedical Research Center employee, as previous reviewers argued that they are not representative of the community
- Unwilling to sign consent to use web screener questions for data set and analysis.

You may not qualify for this study based on other exclusion criteria not listed. The study coordinator will go over this information with you in detail.

5- What will happen to you if you take part in the study?

- ***In-person visits to PBRC***
  - On day -8, you will be asked to come to PBRC to receive training and complete surveys (Baseline, USFSS SF, MacSSS, Household Needs, Food Preference). If deemed necessary by the study team, these surveys may be sent to you via email to complete at home.
  - On day 0, you will receive your first FV box and get randomized into one of two intervention groups. You will then receive an intervention session that lasts approximately 45-60 minutes. This and other intervention sessions may be recorded by your coach. These recordings may be reviewed by the study team, namely Drs. Martin, Apolzan, and Roe, to help them learn how to improve similar interventions. Also, the recordings will help the team deliver the intervention more consistently.
  - On days 8* and 16*, you will come into PBRC to receive your second and third FV boxes.
- **Free-living (at home)**
  - On day –8*, you will conduct a household FV inventory via a recorded Microsoft Teams call with a PBRC staff member and transmit data to PBRC

- On day -8 or-7, you may be asked to complete surveys at home (Baseline, USFSS SF, MacSSS, Household Needs, Food Preference) within 24 hours of visit. If not completed, a PBRC employee will call to obtain the needed information. Unfinished surveys will be completed at Visit 2.
- During days –7 to -1*, you will use FoodImage to record food acquisition & food waste from storage clean outs
  - You will also use FoodImage to record all food acquisition, intake and waste (prep, plate and clean outs) for approximately 3 days (ideally including 1 weekend date)
- On days 0-35*, you will use FoodImage to record food acquisition & food waste from storage clean outs
- Sometime between days 16-23*, you will use FoodImage to record all food acquisition, intake and waste (prep, plate and clean outs) for approximately 3 days (ideally including 1 weekend date)
- On day 25*, you will conduct an ending home FV inventory via recorded Microsoft Teams call with PBRC staff member and come into PBRC to complete an exit survey.
- During this free-living period, researchers may be required to call, text, videoconference, etc. if necessary for the intervention.

* All Study Days and Visit Timing are approximate. The exact day of a study procedure or appointment may vary slightly due to changes in subject or research facility schedule.

The following table shows what will happen on each day of your time in the study:

Study Day	Visit & Timing	Participant Activity
Prior to D -15*		Respond to recruitment, qualify for study and schedule study staff phone call.
-15*	**Study Call** (~0.5 hours)	Call with study staff to determine if study is a good fit.
-8*	**Visit 1** (~3 hours)	Attend training @ PBRC to: • Provide informed consent. • Measure height weight and BMI. • Complete Baseline Survey (demographics, including SNAP eligibility assessment, socioeconomic variables), FV Preferences Survey, and Household Needs Survey (self-reported demographics, allergies, intolerances, and restrictions for household members). If deemed necessary by the study team, surveys may be completed after the appointment via a link that is emailed to the participant. • Learn how to conduct household FV inventory. • Install and learn how to use the FoodImage app.
-8*	Day of* V1	Conduct a video home inventory of all Fruits & Vegetables (fresh, frozen, or otherwise preserved) via Microsoft Teams Call with study staff member.

-7 - -1*	Week* following V1	**Baseline Data Collection** Use FoodImage to record food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss). • For approximately 3 (24 hour) days (ideally including 1 weekend date) use FoodImage to record all food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss).
0	**Visit 2** *~ +7* days from V1* (~ 3 hours)	Complete unfinished surveys. Randomization within matched pairs to one of two groups: **Treatment Group** *Food Waste & Substitution* • Receive fruit and vegetable box. • Lifestyle Interview • Begin Intervention **Control Group** *Stress Management* • Receive fruit and vegetable box. • Lifestyle Interview • Begin Intervention
0-7*	Week* following V2	Interventionist will check in with ppt goals and will send group specific nudges via participant's preferred form of communication between V2 and V3.
0-35*	Ongoing until end of study	Use FoodImage to record food acquisition (Shop) & food waste from storage clean outs (Toss); continue interacting with PBRC staff on respective interventions.
8*	**Visit 3** *~ +7* days from V2* (~ 2 hours)	Visit PBRC to receive free box of FV and receive follow up intervention/reinforcement.
8-15*	Week* following V3	Interventionist will check in with ppt goals and will send group specific nudges via participant's preferred form of communication between V3 and V4.
16*	**Visit 4** *~ +7* days from V3* (~ 2 hours)	Visit PBRC to receive free box of FV and receive follow up intervention/reinforcement.
16-23*	Week* following V4	Interventionist will check in with ppt goals and will send group specific nudges via participant's preferred form of communication between V4 and V5.
16-23*	Week* following V4	**Follow Up Data Collection** Use FoodImage to record food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss). • For approximately 3 (24 hour) days (ideally including 1 weekend date) use FoodImage to record all food acquisition (Shop), food prep (Prep), intake (Eat) and waste (Toss).
24*	Day before* V5	Conduct a home inventory of all Fruits & Vegetables (fresh, frozen, or otherwise preserved) via a Microsoft Teams Call with a study staff member.

25*	**Visit 5** *~ +7* days from V4* (~ 1 hour)	Visit PBRC to: • Complete exit survey and review ending home Fruit & Vegetable inventory. • Measure Height, Weight &BMI.

6- What are the possible risks and discomforts?

This study involves no greater than minimal risk. The main risk is breach of confidentiality, and the PBRC team will work to minimize this risk by following existing best practices for data collection, handling, and analysis. Although unlikely, you may feel uncomfortable answering certain questionnaire questions. You do not have to answer any questions you do not want to answer.

7- What are the possible benefits?

Participants may benefit by increased awareness of their food waste behaviors.

8- If you do not want to take part in the study, are there other choices?

You have the choice at any time not to participate in this research study. If you choose not to participate, any health benefits to which you are entitled will not be affected in any way.

9- If you have any questions or problems, whom can you call?

If you have any questions about your rights as a research volunteer, you should call the Institutional Review Board Office at 225-763-2693 or the Executive Director of Pennington Biomedical at 225-763-2513. If you have any questions about the research study, contact Dr. Corby K. Martin at 225-763-2585 or John W. Apolzan at 225-763-2827.

10- What information will be kept private?

Every effort will be made to maintain the confidentiality of your study records. However, someone from the Pennington Biomedical Research Center and Ohio State University may inspect and/or copy the records related to the study. Results of the study may be published; however, we will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

11- Can your taking part in the study end early?

Dr. Martin or Dr. Apolzan can withdraw you from the study for any reason or for no reason. Possible reasons for withdrawal include missing clinic visits, failing to comply

with study instructions from the study staff, or failure to perform study related procedures. The sponsor of the study may also end the study early.

You may withdraw from the study at any time without penalty; however, not all data Pennington Biomedical has previously collected can be removed from the study.

If your participation in the research ends early because of the investigator or by your choice, termination procedures may need to be completed or follow-up data may need

12- What if information becomes available that might affect your decision to stay in the study?

During the course of this study there may be new findings from this or other research which may affect your willingness to continue participation. Information concerning any such new findings will be provided to you.

13- What charges will you have to pay?

There will be no study related costs to you other than the cost of traveling to the Pennington Biomedical Research Center. It is possible for you to incur cost from the use of the FoodImage app, which will use cellular data from your plan if you are not connected to WiFi.

14- What payment will you receive?

You will be compensated $100 for successful completion of week 1 and $165 for successful completion of the remaining 21 days (max compensation = $265). You will also receive a free fresh seasonal FV box once per week during the final 21 days.

Your check will be requested from the LSU payroll department when you complete the appropriate milestones. It usually takes about 3-4 weeks for it to arrive at Pennington Biomedical Research Center.

U.S. citizens, legal resident aliens, and those who have a work-eligible visa will need to provide their social security number to receive payment.
You are subject to a 1099 for receiving compensation. Payments in excess of $600 per calendar year are considered taxable income. If you will be paid more than $600, Pennington Biomedical/LSU will report this income to the IRS.

Non-US citizens are subject to having taxes withheld from payment and will need a passport, visa, and 1-94 for payment to be processed.

I authorize that all information provided on this Informed Consent form and HIPAA Authorization form, including any and all personal and financial data, may be shared with the Internal Revenue Service (IRS) for tax reporting. This data will be securely retained indefinitely

15- Will you be compensated for a study-related injury or medical illness?

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 procedures in which you participate, you will be referred to a treatment facility. Medical treatment may be provided at your expense or at the expense of your health care insurer (e.g., Medicare, Medicaid, Blue Cross-Blue Shield, Dental Insurer, etc.) which may or may not provide coverage. The Pennington Biomedical Research Center is a research facility and provides medical treatment only as part of research protocols. Should you require ongoing medical treatments, they must be provided by community physicians and hospitals.

16- Signatures

By signing this consent form, I agree to participate in the study as it is described. The study has been discussed with me and all my questions have been answered. I understand that additional questions regarding the study should be directed to the study investigators. I agree with the terms above and acknowledge that I will be given a copy of this signed consent form.

With my signature, I also acknowledge that I have been given either today or in the past a copy of the Notice of Privacy Practices for Protected Health Information.

_____
Printed Name of Volunteer

_____ _____
Signature of Volunteer Date

_____
Printed Name of Person Administering Informed Consent

_____ _____
Signature of Person Administering Informed Consent Date

Corby Martin
Principal Investigator

Data

If you give permission, your data will be collected and stored for future research. Your stored data may be used and reviewed at Pennington Biomedical Research Center or other locations used in future research. Do you give permission for your data to be used in future research?

Yes, I give permission _____ _____
Signature Date

No, I do not give permission _____ _____
Signature Date

Withdrawal of Consent

If you decide you would like to withdraw your consent to use your data, biospecimens or imaging, you must provide a written request to have your samples destroyed. In the event you withdraw your consent, it will not be possible to destroy the data, samples or imaging that have already been given to researchers.

For destruction of your data, biospecimens or imaging, you can send a request to the Principal Investigator at:

Corby Martin, Ph.D.
Pennington Biomedical Research Center
6400 Perkins Road
Baton Rouge, LA 70808