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

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

What you should know about a research study

- We give you this consent form so that you may read about the purpose, risks and benefits of this research study.
- The main goal of research studies is to gain knowledge that may help people in the future.
- You have the right to refuse to take part, or agree to take part now and change your mind later on.
- Please review this consent form carefully and ask any questions before you make a decision.
- Your participation is voluntary.
- By signing this consent form, you agree to participate in the study as it is described.

1- Who is doing the study?

Investigator Information:

Principal Investigator: Corby K. Martin, Ph.D.
Phone: 225-763-2585
Fax: 225-763-3022
Email Address: Corby.Martin@pbrc.edu

Co-Investigators: John W. Apolzan, Ph.D.,
Phone: 225-763-2827
Email Address: John.Apolzan@pbrc.edu
Robbie Beyl, Ph.D.,
Brian E. Roe, Ph.D., Ohio State University

Dr. Martin directs this study. The study will take place over a period of 2 years. We expect about 44 people from the Baton Rouge area will be enrolled in this study and your time in the study will be approximately 3-4 total weeks. The study will be conducted in two phases:

- Phase I will enroll 24 participants and your expected time in this study will be 1 day.

- In Phase II of the study, all 24 participants from Phase I will continue and 20 additional participants will enroll. Your time in Phase II will be about approximately 21 days.

This project will result in the development of the FoodImage app, which will be pursued as intellectual property for Pennington Biomedical. Drs. Martin & Apolzan are inventors of the FoodImage app, which is being developed and tested during this project.

2- Where is the study being conducted?

This study takes place at the Pennington Biomedical Research Center in Baton Rouge, LA.

3- What is the purpose of this study?

The purpose of this study is to test the use of an iPhone app, FoodImage, as a way to measure food waste.

4- Who is eligible to participate in the study?

In order to participate in this study, you must:

- Be able to provide consent
- Be 18 to 65 years of age
- Have a body mass index of 18.5 – 50 kg/m^2
- Conduct some of the shopping and food preparation for the household
- Have an iPhone and a working Apple ID, password, and email address
- Be willing to use an iPhone app during the study in the lab and at home
- If you participate in Phase I, be willing to use pen-and-paper food records during the study in the lab
- Not be pregnant

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?

Phase I (lab-based). You will be trained to use the FoodImage smartphone app to capture images of foods in the lab. You will also be trained how to use two versions of pen-and-paper food records. With the first version, you will estimate the portion sizes of foods visually. With the second version, you will have access to a kitchen scale to weigh the portions of foods. You will then use these methods to report on food waste that the study staff show you in the lab. You will be asked to document foods from a simulated shopping trip and kitchen clean out in the lab. You will also be asked to complete questionnaires.

Phase II (free-living). You will be asked to use the FoodImage app for approximately 4 to 7 days over one week to track food purchases and food waste. You will not use pen-and-paper food records during Phase II. You will then have a one week break before

returning to the center. When you return to the center, you will be randomly assigned to one of two groups.

- If assigned to the **Food Saver group**, you will receive additional information and training in a meeting (held either in person at Pennington Biomedical Research Center or by phone or a similar method) with one of our staff. After receiving the information and training you will continue to use the app to record food waste for approximately 4-7 additional days. You will also receive feedback, goals, and tips.
- If assigned to the **Stress Management group**, you will receive additional information and training in a meeting (held either in person at Pennington Biomedical Research Center or by phone or a similar method) with one of our staff. After receiving the information and training you will continue to use the app to record food waste for approximately 4-7 additional days. You will also receive feedback, goals, and tips.

At the end of Phase II, you will answer questions in either a focus group or one-on-one meeting with staff pending your phase of enrollment and complete some questionnaires ask about your experience with the app.

The following table shows what will happen at each study visit:

	Phase I enrollees	***Phase II enrollees**
	n=24	n=20
Visit 1 (V1)		
Consent	X	X
Questionnaires, training on use of app to collect data in free-living setting	X	X
Training on app and paper-and-pen food records in lab setting	X	
Height, weight, BMI	X	X
Visit 2 (V2)		
Randomization	X	X
Intervention group material distribution	X	X
Weight	X	X
Visit 3 (V3)		
Meeting with staff to review data collected and implement of behavioral nudges	X	X
Questionnaires	X	X
Weight	X	X
Interview regarding app	X	X
*24 participants will complete Phase I, then continue on to Phase II		

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?

We cannot promise any benefits from your being in the study. If you take part in this study, you may help others in the future.

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. You may withdraw from the study at any time without penalty; however, all data Pennington Biomedical has previously collected cannot be removed from the study. Possible reasons for withdrawal include non-compliance with study procedures and not taking pictures of your meals and food waste. Also, the sponsor of the study may end the study early.

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?

If you agree to take part in this study, we will pay you up to $205.00. You will receive $30 for the successful completion of Phase I. You will receive $175 for the successful completion of Phase II.

Your checks will be requested from the LSU payroll department. One check will be requested for $30 after completion of Phase I. A check for $175 will be requested after you complete Phase II. It usually takes about 3-4 weeks for checks to arrive at Pennington Biomedical Research Center. When checks arrive, they will be distributed to you by the study coordinator.

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

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 K. Martin, Ph.D.
Principal Investigator