HFI Core Validation Consent Form

Title of Research Study: Innovation in Measurement for Diet-Related Disease Research: Optimizing Utility and Reach to Reduce Health Disparities – The Food at Home Study

Investigator Team Contact Information: Dr. Jayne Fulkerson
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Researcher Name: Dr. Jayne Fulkerson Researcher Affiliation: University of Minnesota School of Nursing Phone Number: 612-624-4823 Email Address: fulke001@umn.edu	Study Staff Phone Number: 612-625-7347 Email Address: food-at-home@umn.edu

Supported By: This research is supported by the National Cancer Institute at the National Institutes of Health.

Key Information About This Research Study
The following is a short summary to help you decide whether to be a part of this research study. More detailed information is listed later in this form.

What is research?
- The goal of research is to learn new information in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?
We are asking you to take part in this research study because you are 18 years or older, you do most of the grocery shopping and or meal preparation for your household and you speak English or Spanish at home.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
We are creating a survey that is like a checklist called a home food inventory. The inventory is about foods people keep in their home for snacks and meals. It can be completed on paper or on an electronic tablet computer. The checklist will be in either English or Spanish. Having participants complete this checklist in our study will help us learn about the types of foods people have in their homes. We will also measure your height and weight and ask about the food you eat to better understand how these things relate to the types of food you have in your home.

How long will the research last?
We expect that you will be in this research study for one month.

What will I need to do to participate?
To participate in the study, you will need to allow researchers to come to your home for a data collection visit. During this home visit, you will have your height and weight measured, answer survey questions, and complete a checklist of the foods you have at home (i.e., the Home Food Inventory). You will also need to allow the researchers to go through your home (e.g., freezer, refrigerator, cupboards) to complete the same checklist about the food you have at home. You will also participate in two telephone calls about a week apart where you will tell researchers about the food you ate the day before.

Is there any way that being in this study could be bad for me?
There are no serious risks to being in the study. However, you could feel uncomfortable having researchers come to your home or you could feel uncomfortable answering questions about the type or amount of food you have in your home or having your height or weight measured.

Will being in this study help me in any way?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

What happens if I do not want to be in this research?
There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study
The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 350 people from the Twin Cities metropolitan area will be in the main trial of this research study.

What happens if I say "*Yes, I want to be in this research*"?
If you say YES to being in the research study, two study staff members will come to your home. The team will describe the study in more detail, answer any of your questions and work with you to complete the consent form. You will complete a checklist about the foods in your home. The researchers will fill out the same checklist at the same time so we can compare our answers to yours. One member of the research team will measure your height and weight. To protect your privacy, height and weight measures will not be said out loud but can be shared in writing if requested. You will also be asked to fill out a second brief survey using an iPad. This survey will ask questions about you, the people who live in your household, and the food you buy. The iPads will be provided by the study for use during data collection and you will return them to study staff before they leave your home. You will not be accountable for any accidental loss or damage of the iPads. The home visit will take about two hours. After the researchers come to your home, they will call you two times in the next two weeks and ask about the food you ate the day before. Each call will last about 30 minutes. The information about the food you ate will help us understand how the food in your home is similar or different from the food you ate over the course of the day. Two weeks after the research visit, you will complete the checklist of the food you have at home again; this time you will complete it on your own and mail it to us. This research will help us to understand how foods in the home vary over time.

What are my responsibilities if I take part in this research?
If you take part in this research, you will need to allow study staff members to come into your home and give them access to where you store your food (refrigerator, cupboards, closets or any other place you keep food).

What happens if I say "Yes", but I change my mind later?
You can leave the research study at any time and no one will be upset by your decision.

If you decide to leave the research study, contact the investigator so that the investigator can let the study team know not to contact you for any additional measurement.

If you choose not to be in this study or decide to stop being in this study, there is no penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care, your academic standing as a student, or your present or future employment.

If you decide not to be in the study anymore, we will keep and analyze any of the data we have already collected. We will not collect any more data from you.

Will it cost me anything to participate in this research study?
There will be no cost to you for any of the study activities or procedures.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

We may publish the results of this research or share the resulting data. However, we will keep your name and other identifying information confidential.

Additional sharing of your information for mandatory reporting
If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

Certificate of Confidentiality
To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries. The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children or vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research. You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Data Collected
Any identifying information of research participants (e.g., name, address, phone number) will be stored on University of Minnesota's Box secure storage and will be accessible only to research staff who have received permission from the Principal Investigator. De-identified data will be stored in a file separate from identifying information and accessed only with a secure password and permission. All paper documents will be stored in the School of Nursing in a locked data storage room. All paper documents will be shredded 5 years after completion of the study, electronic data files will be deleted 7 years after completion of the study and your phone number, name, and address will be kept for 10 years after completion of the study and then deleted.

De-identified data that are collected during this research could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Will I receive research test results?
YES
If you are interested in your height or weight measurements, we can let you know this information privately at the data collection visit.

What will be done with my data and specimens when this study is over?
We will use and may share data for future research. Data collected in this study may be made available for others to use, including for future research studies on similar or different topics, teaching, or other purposes. This could include for profit companies. Our goal is to make more research possible. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your data.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP).

To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. You could be removed from the study if the study team feels unsafe during a home data collection visit.

Will I be compensated for my participation?
If you agree to take part in this research study, you will receive up to $125 for your time and effort. At the first home visit, you will receive a gift card for $50 after you allow staff to complete the food checklist, you complete the food checklist, you complete a survey and have your height and weight measured. You will still receive the $50 if you skip questions on the survey or chose not to have your height and weight measured. You will receive an additional $25 for completing each of the two food interviews (telling us about the food you ate the day before over the phone) and another $25 for mailing back the checklist about the food you have at home.

Payment will be made using a pre-paid debit card called Greensphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after you complete each part of data collection.
You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees. The debit card system is administered by an outside company. The company, Greensphire, will be given your name, address, and birthdate. They will use this information as part of the payment process. Greensphire will not receive any information about your health status or the study in which you are participating.

Do you have any questions about what we have talked about so far?

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may contact me in the future to see whether I am interested in participating in other studies in the future by Dr. Fulkerson or investigators known to her.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information
☐ The participant is visually impaired
☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____ _____
Signature of Witness Date

_____
Printed Name of Witness

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