UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Location Initiated Individualized Texts for Adolescent Health (LIITAH)

Company or agency sponsoring the study: NIH

Principal Investigator: Susan J. Woolford, MD, MPH, Department of Pediatrics, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: Some adolescents have difficulty making healthy eating choices throughout the day. The purpose of this study is to explore whether sending text messages and using geo-location to send text messages when adolescents or their parents are likely to make eating choices will help them make healthier eating choices.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You / your child need not participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? Adolescents between the ages of 13 and 17 years old along with their parent.

3.2 How many people are expected to take part in this study? Approximately 400 to 500 people are expected to take part in different aspects of the study. Approximately 150 to 180 people are expected to take participate in this part of the study in which the mobile application is tested.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study? The trial of the mobile application will last for 6 weeks.

Participants will be scheduled for an enrollment session during which teens and parents will complete an online enrollment survey addressing demographics, baseline characteristics, preferences, level of interest in making dietary changes and any specific changes they wish to make. In addition, their height and weight will be measured. They will download the LIITAH mobile app and receive instructions in its

use and ways to tailor features to their preferences (e.g., graphics, language). They will then be randomized to be in either the intervention or the control group.

Baseline Data: For the first 2 weeks the app will record when they are present in a restaurant and ask users to submit photos of their food. In week 3 the program features described below will be activated for the intervention group.

Intervention Group: *Point of Purchase (POP) messages will encourage healthy choices when participants are noted to be in a restaurant.* Participants will be asked to keep the app running on their phone. They will receive a ping when the app identifies that they are in a fast food restaurant followed by a POP prompt, tailored to their preferences and the options available at that location. If the app does not ping when they enter a restaurant, they will be asked to register that location by tapping the 'register location' button on the app and entering the restaurant name. Users will also be asked to take a picture of any items they buy and to provide information that would help to determine the nutrients in the food. This information may be added via audio, text, or made from a selection of descriptive buttons (e.g., to indicate small, medium or large sizes).

Tailored healthy lifestyle messages will be delivered at times selected by participants. In addition to messages prompting healthy choices at the point of sale, participants will receive tailored messages promoting healthy lifestyle choices. Participants will select the timeframe during which they would like to receive these daily messages. The messages will be tailored to their values, characteristics and preferences, and will address topics such as increased physical activity, obtaining sufficient sleep, and healthy nutrition.
Participants in the intervention group will also be encouraged to use the other features of the app (e.g., goal setting, point system, and communication between parent and child – or friends and child if preferred and consents have been obtained).

Control Group: Participants will receive instructions for identification of restaurant locations and submitting annotated photos of their purchases, but they will not receive the other features.

Participants are expected to not text or access the phone apps while driving.

4.2 How much of my time will be needed to take part in this study?
Over the 6-week study, participants will receive text messages when in fast food restaurants and at other times that they indicate are convenient. Participants will also be encouraged to submit a photo of their food choice and rate the food choice which will take about 2-5 minutes. Other interaction with the app (e.g., due to the point system or goal setting) is anticipated to take no more than 10 minutes per day. Participants will be contacted as often as once a week by a member of the research team to ensure that the app is working and to answer any questions.

4.3 When will my participation in the study be over?
Participation in the study will be over after the 6-week trial and the post-trial semi-structured interview has been completed. We will ask participants if they would like to be recontacted in the future for any additional studies or study-related matters, and if they would like to keep the app on their phones.

Participants who had the control version of the app would be able to experience the intervention version of the app.

Would you like to be recontacted in the future for any additional studies or study-related matters?

☐ Yes, I would like to be recontacted.
☐ No, I would not like to be recontacted.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with the National Institutes of Health.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are: Participants may receive messages during inconvenient times. There is a small chance that participants may not like the messages they receive, or experience increased stress as a result of receiving them. Lastly, there is a small chance of breach of confidentiality.

The researchers will try to minimize these risks by: programming the system to send messages only when participants are in eating venues, or during time frames indicated by users, and pretesting all messages with adolescents before they are sent during the study. All information collected about participants is stored on a secure password-protected computer that is only accessible to members of the study team and our development partners (MEI Research Ltd. and Plot Projects).

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.
As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You /your child should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You and your child may not receive any personal benefits from being in this study. However, there is the possibility that your child or children in the future may decrease their intake of fast food due to this research.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your or your child's willingness for either of you to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have? Participation in the study is completely voluntary.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You and your child are free to leave the study at any time. If you and your child leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information". As parents and children must participate together, a withdrawal of either parent or child will mean that both are withdrawing from the study.

7.2 Could there be any harm to me if I decide to leave the study before it is finished? No, there is no harm associated with leaving the study before it is finished. You or your child may choose to leave the study at any time**.** You will be asked to complete an exit interview prior to leaving the study.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your/your child's best interest to stay in the study.
- You/your child become ineligible to participate.
- Your/your child's condition changes and you or your child need treatment that is not allowed while you are taking part in the study.
- You or your child do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study? You and your child will each receive a $50 Visa gift card for your participation in the enrollment session. You will receive the gift card approximately 6 weeks after joining the study in the mail. Also, you and your child will each receive a $50 Visa gift card for your participation in the post study interview. You will receive the gift card approximately 6 weeks after completing the interview in the mail.

8.3 Who could profit or financially benefit from the study results? The principal investigator initiated this study and will use the findings to inform future grant applications.

The company whose product is being studied: MEI Ltd is the company that led the development of the technology used in the study.

The researchers conducting the study: The principal investigator collaborates with MEI Ltd but does not have a financial relationship with them.
No copyrights or patents currently exist for the interventions used in this study.

The University of Michigan and/or the creators of this intervention may in the future be paid licensing fees for the technology used in this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information? Your research information will be stored in a password protected file and only members of the research team and our development partners (MEI Research Ltd. and Plot Projects) will have access to this information.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you / your child can take part in the study.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your child's condition or its treatment.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. These data include:

- Demographic information
- Personal identifiers
- Other information

MEI Research Ltd., is a company the University of Michigan research team has partnered with to develop the study's mobile app. The data collected by the app will be de-identified, meaning your name will not be attached to any of the information collected. MEI Research Ltd. and the company that they collaborate with, Plot Projects, will have access to this data for tailoring purposes. This data includes:

- Your food preferences
- Your cultural preferences

- Geolocation data tracked by the app
- Pictures and text submitted by the user

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Susan J. Woolford, MD, MPH
Mailing Address: 3oo N. Ingalls, Ann Arbor, MI 48109
Telephone: 734 615 8214
Study Coordinator: Theresa Kowalski-Dobson
Mailing Address: 3oo N. Ingalls, Ann Arbor, MI 48109
Telephone: 734-262-2455

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*
- Other (specify):_____

12. SIGNATURES

Sig-A

Assent to Participate in the Research Study - Adolescent

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Sig-E

Legally Authorized Representative or Parent Permission

Subject Name: _____

Parent/Legally Authorized Representative:

Printed Legal Name: _____

Signature: _____

Address: _____

Date of Signature (mm/dd/yy): _____

Relationship to subject: Parent Spouse Child Sibling Legal guardian Other

If "Other," explain: _____

Reason subject is unable to consent: _____

If this consent is for a child who is a ward of the state (for example, a foster child), please tell the study team immediately. The researchers may need to contact IRBMED.

Consent to Participate in the Research Study - Parent

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Consent to allow adolescent's friend to communicate with them via the LIITAH mobile app - Parent

I agree to let (friend's name) _____ communicate with (adolescent's name) _____ via the LIITAH app (to provide encouragement and support.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____