UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: BETTER Living

Company or agency sponsoring the study: National Institutes of Health

Principal Investigator: Lara Coughlin, PhD, Department of Psychiatry, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. 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 family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to give your consent before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about certain conditions and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of direct benefit. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study, such as the amount of time required. In your decision to participate in this study, consider all of these matters carefully.

The purpose of the study is to get feedback from people, like you, to help us develop programs to improve wellness and health behaviors. Most study activities can be completed remotely, by phone, text message or online survey, with the complete study taking 2 months.

This study involves a process called randomization. This means that the group you are assigned to is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feeling uncomfortable with answering some personal questions. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by improving health programs for people by using new ways to communicate health information. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be up to 60 minutes for the baseline survey, which can be completed today or at a later date, a 30-minute phone call a week later, a few minutes a day to view and reply to text messages over a two-week period, followed by two 60-minute surveys (in 1 and 2 months, respectively) which can be completed online or by phone.

You can decide not to be in this study. Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
The purpose of the study is to get feedback from people, like you, to help us develop programs delivered by phone and text messages to improve wellness and health behaviors.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to 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?
To take part in this study you must be 18 years or older and have completed the screening survey.

3.2 How many people are expected to take part in this study?
We expect to enroll about 85 people in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
If you decide to join the study, this is what will happen:

First, you will complete a baseline survey that asks questions about your background and health behaviors, including alcohol and drug use, eating behaviors, and preferences. This survey can be completed online or by phone.

From here, you will be randomly assigned (like rolling a dice) to one of four study groups so we can get your feedback on different ways to communicate health information by phone and text message. Regardless of what group you are assigned, you will complete a phone or video call, called the mid-way call, where you will talk about your health behaviors and, depending on the group you are assigned, may develop personally-relevant reminders that we will send to you via text message over the following two weeks. The information discussed during the mid-way call will differ by group. One group will focus on identifying future activities that that they are looking forward to, another will focus on creating plans for what to do in different situations, a third group will include both topics, and the fourth group will talk about resources for different health behaviors and the study components. The mid-way call will be audio recorded, but no identifying information will be discussed in this session. If you do not agree to be audio recorded, you can still participate in this study.

During the two weeks following this phone call, you will receive daily text messages asking about daily behaviors, such as drinking alcohol, and asking about your preferences.

Then, we will ask you to complete two additional surveys in 1- and 2-months, respectively, with questions similar to those ones we ask at the start of the study as well as new questions that ask about your thoughts about this study. These surveys may be completed by phone/video chat or online.

4.2 How much of my time will be needed to take part in this study?
The baseline survey, post-test and 2-month follow-up surveys will each take up to 60 minutes to complete. The mid-way call will take about a half hour. The daily text message questions that you will receive for two weeks will take about 5 minutes a day to respond to.

4.3 When will my participation in the study be over?
Your participation in the study will be over after you complete the 2-month follow-up survey.

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 or identifiable biospecimens 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?

Some of the questions we ask are about sensitive or personal information such as your mental health or alcohol and other drug use. Sometimes these questions can make you feel uncomfortable or upset. You don't have to answer any questions you don't want to. However, some questions require a response to continue in the study and receive payment for your survey. You are free to leave the study at any time.

There is a small risk of loss of privacy/confidentiality. To protect your privacy during telephone meetings we will make sure that no one can overhear the conversation. We encourage you to use a password or passcode on your phone to help with the privacy of the text messages on your personal phone. We will do everything we can to protect your identity and keep your answers confidential, except as noted in section 9.1. When your survey answers and audio files are collected, they are labeled with a number. Survey answers and audio files are stored separately from your name, phone number or other information that might let someone other than the researchers connect the information to you. You will be asked during audio recorded sessions to try not to say your name or any information that would allow someone to determine who you are from the audio recording. Study paper forms are stored in locked file cabinets. Computer files are saved with passwords. You will not be identified in any reports on this study.

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, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any problems that you have during this study.

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 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 may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

Some people find completing the surveys to be helpful. We will share information about community and national resources with you, which you may find to be beneficial. We hope to learn more about ways to deliver health information as a result of this study.

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 willingness 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 verbally consent to 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?
Participating in this study is voluntary. Choosing not to participate will not affect your medical care in any way.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you 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".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
We do not expect that you would experience any harm if you decide to leave the study before it is finished.

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 best interest to stay in the study.
- You become ineligible to participate.
- You 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?
Taking part in this study will not cost you anything. As with any cell phone, depending on your text/data plan, you may be charged for text/data use on your personal phone bill.

By verbally consenting, 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 will receive $30 for completing the baseline survey, $30 for completing the mid-way phone call, $35 for completing the post-test, $40 for completing the 2-month follow-up survey, and $3 daily for responding to text message surveys, for a total of $42 if you respond to all text messages. If you complete at least 90% of all surveys, including phone and text message surveys, you will receive an additional $25 upon completion of the study. You can earn up to a total of $202 for your participation in the study which will be paid in gift cards (e.g., e-gift cards sent via Amazon).

8.3 Who could profit or financially benefit from the study results?
No person or organization has financial interest in the outcome of 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

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?
You may be worried about the privacy of your answers. We won't share your answers with anyone except the researchers of this study. We will ask for your contact information so that we can contact you about the study. This personal information will not be linked to any of your survey answers. Research records will be kept in a separate research file that does not include names or other information that is likely to allow someone other than the researchers to link the information to you.

The surveys you complete online, by phone or by text will be administered using Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/). Qualtrics meets the rigorous privacy standards imposed on health care records by the Health Insurance portability and Accountability Act (HIPAA). There are security precautions in place to protect against unauthorized access, but there is still a small risk of unauthorized access. No identifying information is directly linked to your answers. For more information, Qualtrics security and privacy statements can be found at http://www.qualtrics.com/security-statement and http://www.qualtrics.com/privacy-statement.

All study cell phones will be password protected and only be accessed by study staff. We encourage you to use a strong password/code on your phone (mix of lower case and upper-case letters, numbers, and symbols) and to view study messages in private spaces. Your confidentiality will be kept to the degree permitted by the technology being used. If you choose to complete an assessment using a video chat platform that is not affiliated with the University of Michigan (e.g., Facetime), it is possible that you could be automatically recorded by the platform – similar to when you use these platforms in everyday life. Although every reasonable effort will be taken, confidentiality during actual text message or phone/video communication cannot be guaranteed.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the

research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Your consent 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.

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 can take part in the study.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB 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
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your 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.

The information that we collect from you will be stripped of identifiers (meaning any of your personal information, such as name or email) and used for future research studies or distributed to another researcher for future research studies without additional informed consent. The study sponsor, the National Institute of Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health, requires that we share your de-identified data with other researchers to help learn how to promote wellness. Study staff will remove all personal information before any data files are transferred to the repository. Your de-identified data will be protected, following laws that protect the use of health information, and studied only for health research purposes.

9.3 What happens to information about me after the study is over or if I leave the study before it is finished?

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

9.4 When does my permission to use my information expire?
Your permission will not expire unless you cancel it.

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
- Report a problem
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Lara Coughlin, Ph.D.
Mailing Address: 2800 Plymouth Road, Ann Arbor, MI 48109-2800
Telephone: 734-936-3101

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 consent to participate in the next section means that you have received copies of the following document:

- 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.*

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. 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.

Do you agree to participate in BETTER Living?

☐**YES** – I have read and understand the information above and I CONSENT to participate in this study.

Legal Name: _____

Consent to audio recording solely for purposes of this research

This study involves audio recording which will only be used by the study team for internal quality assurance purposes. Please enter your name below if you agree to be recorded. If you do not agree to be recorded, you CAN still take part in the study.

Legal Name: _____

Consent for Future Contact: We may contact you again in the future to offer you a chance to take part in new research studies. If you're contacted and are willing to participate in a new study, you'll be asked to sign a separate consent form for that study. Your contact information will be kept by the BETTER Living research investigators and stored in a password-protected computer data file. It will only be available to the Investigators and research staff of the BETTER Living study and their future studies. If you have questions, feel free to ask them.

Do you agree to be contacted about future studies?

☐**YES** – I CONSENT to be contacted about future studies.

☐**NO** – I do not wish to be contacted about future studies. I understand that I may still participate in this study, even though I do not want to be contacted about future studies.