UNIVERSITY OF MICHIGAN AND HURLEY MEDICAL CENTER
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: REACH OUT PARTNERS

Company or agency sponsoring the study: National Institute of Health/ National Institute on Minority Health and Health Disparities (NIH/NIMDH)

Names, degrees, and affiliations of the researchers conducting the study:
William Meurer, MD, MS, Department of Emergency Medicine, The University of Michigan
Lesli Skolarus, MD, MS, Department of Neurology, The University of Michigan
Rockefeller Oteng, MD, Department of Emergency Medicine, Hurley Medical Center

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 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 diseases 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 treating your disease or condition. 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. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether changing af a text-messaging program could help lower your BP. You will receive some text messages encouraging healthy behaviors and reminders to take your blood pressure. You will also get messages to encourage you to reach out to your partner. REACH OUT is a 3-month text messaging intervention. If you pay per text message with your cell phone company, regular text messaging costs apply.

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 asking you about your current recorded BP. The messages are meant to be motivational, but there is a small chance you may be distressed by them. More detailed information will be provided later in this document.

This study may not offer any benefit to you not, but may benefit others in the future by helping us gain important information about how to help people manage their high BP.

We expect the amount of time you will participate in the study will be about 3 months.

You can decide not to be in this study. Alternatives to joining this study include discussing BP with your primary care physician. The study team can also provide you with informational pamphlets regarding your high BP and how to manage it.

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 this study is to see whether mobile health interventions can help lower blood pressure.

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?
You can join this study if you are

- Inclusion Criteria
  - Age of 18 or greater
  - Must have cell phones with text-messaging ability and willingness to receive texts
- Exclusion Criteria
  - Able to read english
  - Prisoner
  - Pregnant
  - Other serious medical conditions that prevent self-monitoring of BP

3.2 How many people (subjects) are expected to take part in this study?
We expect up to 400 participants to be enrolled.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You will start by completing a survey telling the research team about yourself**.** You will also be given educational materials about BP. A BP monitor will be given to you to use to take your BP at home. You will be taught how to take your own BP, and how to text back to the study team.

If during the first 3-weeks your partner still has high BP, the REACH OUT Program will continue. If your partner does not have elevated blood pressure during these 3-weeks, your messages will also not continue.

There are different types of text messages you could receive while participating in the REACH OUT program, including messages to encourage healthy behaviors and reminder texts to take your BP at home. You will receive

these messages daily, but may potentially be able to modify the frequency of messages depending on technical capabilities.

A follow-up visit will occur at 3 months. At this visit, your BP will be measured by the REACH OUT team. You will also be asked to complete additional surveys. The REACH OUT team may meet you at your doctor's office (if you happen to already have a scheduled doctor's appointment around the time of the follow-up visits), in the ED research space, a mutually convenient location (e.g. home, library, or restaurant). If necessary, follow-up visits may also be conducted remotely, the research team would ask for a picture of the BP cuff on your arm, blood pressures, and to complete the surveys. If you want to continue receiving these messages after the study you may have the option to do that, however, you will no longer be in the research study and can stop the messages at any time.

At the end of the study period, some participants may be asked to participate in a focus group or interview so we can learn about your opinions on REACH OUT. We may ask you by phone, text, or in person to participate. We may record and will write down notes about what is said during these interviews so that we have a record and can accurately remember your opinions.

This program does not replace your usual health care. If you have a problem or question about your blood pressure or medical problems, you will still need to contact your healthcare team.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as report any adverse reactions you may have during the study.

4.2 How much of my time will be needed to take part in this study?

You will be asked to participate in the study for about 4 months from when you enroll. You will be asked to complete a survey at the time you enroll in the study and 3 months. These will take about 30-60 minutes. You will also receive text messages to text in your BP, which require you to take your BP and text back (about 5 minutes each time). You may also be asked to participate in a focus group or interview about your experience with the program (about 2 hours).

4.3 When will my participation in the study be over?

If your partner does not text, or does not have elevated blood pressure in the first 3-weeks, your participation will be over at that point.

Following the 3-week screening, your main participation will be over after about 3 months from the day you enroll. It may be slightly longer for those who participate in focus groups.Depending on when you joined the study, you may be able to continue your text messages for up to 12 months, but will not be considered a research participant.

4.4 What will happen with my information and/or biospecimens used in this study?
Your collected information may be shared with the NIH/ NIMHD.

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 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:

BP monitoring: During the surveys we will ask about your general health, and during the self-monitoring BP text messages we will be asking you about your current recorded BP. The messages are meant to be motivational, but there is a small chance you may be distressed by them. You do not need to answer any question you do not want to, and you can stop the text messages at any time.

Confidentiality: We will collect information about you during the course of the study. There is the possibility that this information could be obtained by non-study staff. We will do everything we can to protect your confidentiality. We will keep any information that might identify you, such as your name and phone number, in a locked filing cabinet or a restricted computer file that is secure and password-protected. We take this risk very seriously and will do our very best to protect your confidentiality, if you decide to participate. Also, there is an extremely small risk that information from the telephone lines used in the automated text messaging system could be intercepted by an outside party. Your phone number will not be given to outside vendors including telemarketers.

The company sending out the text messages will also keep your information confidential and will not share your information with anyone. Your information will not be used for any reason besides study purposes.

Please note- this program does not take the place of your doctor. Doctors will **not** be evaluating all of the information participants report during their automated text messaging system. If you have any urgent questions, health problems, or dangerous BP levels they should be addressed with your doctor, or call 911.

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 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, we hope that your participation in this study will result in important health benefits to you.

If you agree to participate in the study you may see improvement in your BP. You may learn something new about how to live a healthier lifestyle. Even if you don't benefit personally, the study will help us gain important information about how to help people manage their high BP.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Since this is a small, beginning study, we do not anticipate results that will change your care. If you wish to receive a copy of any publication resulting from this study, we are happy to share that with you. You may receive information about the study (newsletters, results, and other updates) after your participation is over through text, email, or postal mail.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

You do not have to participate in the study, it is completely voluntary. You can discuss managing your BP with your primary care physician. The study team can also provide you with informational pamphlets regarding your high BP and how to manage it.

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. You can follow the instruction on the REACH OUT text message instruction page provided to you at enrollment.

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" (below) or follow the instructions on the REACH OUT text message instruction page provided to you at enrollment.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

We do not know of any harm that may happen if you decided 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 reasons why the researchers may need to end your participation in the study. Some examples are:

1. Your partner withdraws or stops their messages.
2. The researcher believes that it is not in your best interest to stay in the study.
3. You become ineligible to participate.
4. Your condition changes and you need treatment that is not allowed while you are taking part in the study.
5. You do not follow instructions from the researchers.
6. 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?

There are no costs or billing for this study. However, if you pay per text message with your cell phone company, regular text messaging costs apply.

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

By giving consent, 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 be given an automated BP cuff and $20 at your enrollment. You will be given $20 after completion of your 3-month follow-up visit

Participants asked to participate in the focus groups/interviews may receive food and up to $30 following completion of the session.

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

9. CONFIDENTIALITY OF SUBJECT RECORDS

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?
The known or expected risks are: The risks to participating are minimal. You may experience inconvenience. You may experience some discomfort when taking your blood pressure. This study contains risk associated with transmitting data, including loss of confidentiality.

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways. If there are physical copies of your information, it will be stored in a locked area, accessible only to research staff, and will not be made part of your medical record. Your research information will be entered into a password protected computer and your name will be separated from the data. Mosio, a U of M-selected vendor specializing in text message based research and protections will be sending out the text messages throughout the research study. Access to this data is limited to authorized personnel via login to a secure site. The original data on the Mosio server will be deleted to industry standards after study completion. The personal data accessible to Mosio will include your phone number, and the information you text message, including your blood pressure, and potentially information regarding your physician appointments. All study personnel have been trained in how to protect your personal health information and we take this very seriously. The study uses a SSL encrypted web-based application with secure log-ins to access. There is a very small risk that someone could obtain your contact information from the study website.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally 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. The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You 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.

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

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. We may post a de-identified data set after the study is complete to be shared with other researchers for future research.

9.3 What happens to information about me after the study is over or if I cancel my permission?

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 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).

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: William Meurer
Mailing Address: 1500 E Medical Dr, Ann Arbor, MI
Telephone: 734-615-2766

Study Coordinator: Mackenzie Dinh MS
Mailing Address: 1500 E Medical Dr, Ann Arbor, MI
Telephone: 734-647-0865

You may also express a 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: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

Hurley Medical Center Institutional Review Board
Research Center
One Hurley Plaza, 6 West, A Wing
Flint, MI 48503
Telephone: 810-845-0838 and 517-648-4968

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, or Hurley Medical Center Patient Relations office at 1-810-262-9220. *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 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 Hurley medical record.)*

12. SIGNATURES

- o Yes, I would like to receive follow-up newsletters and information regarding Reach Out after completion of the study.
- o No, I would not like to receive follow-up newsletters and information regarding Reach Out after completion of the study

- o Yes, I agree to be audio recorded if asked to participate in the post-study focus group.
- o No, I do not agree to be audio recorded if asked to participate in the post-study focus group.