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 Cognition

Sponsor: National Institute of Health/National Institute on Minority Health and Health Disparities (NIH/NIMDH)

Researchers:

William Meurer, MD, MS, Dept. of Emergency Medicine, The University of Michigan
Lesli Skolarus, MD, MS, Dept. of Neurology, The University of Michigan
Deborah Levine, MD, MPH, Dept. of Internal Medicine, The University of Michigan
Dominic Borgialli, 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.

Participants who agree to continue in Reach Out Cognition will receive the Reach Out daily healthy behavior text messages and weekly prompted blood pressure (BP) self-monitoring for about 6 months. Reach Out Cognition will include self-administered BP measurement and surveys. Some of the features of the study depends if you have a phone with photo capability (at minimum). Specific instructions and materials for your phone will be provided to you.

1.2 Risks:

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: (1) discomfort with monitoring your BP; (2) the messages are meant to be motivational, but there is a small chance you may be distressed by them; (3) if using the app, downloading a company's app; (4) extremely small risk that information from the telephone lines used in the automated text messaging system could be intercepted by an outside party. We take all of these risks very seriously; to help prevent this from happening, we will keep any information that may identify you (like name and phone number) in a locked filing cabinet and/or a password-protected computer. Also, your phone number will not be given to outside vendors including telemarketers.

1.3 Benefits:

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

1.4 Time commitment:
About 6 months.

1.5 Voluntary Participation:
You can decide not to be in Reach Out Cognition. 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: Hypertension (HTN) is one of the most important cardiovascular risk factors. It affects about 78 million Americans. Home BP (BP) monitoring may be an important and effective strategy for BP management. The purpose of this study is to test whether we can use mHealth (mobile health) interventions to assess your BP and monitor your thinking.

3. WHO MAY PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?
You can join this study if you are:

- 18 years of age or older
- Completed 12 month outcome assessment for Reach Out
- Must have a cell phone with the capability to send picture text-messages

3.2 How many people (subjects) are expected to take part in this study?
We expect up to 240 participants to be enrolled in this study.

4. INFORMATION AOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

You will be consented by a study staff member, complete a baseline survey. In the survey you will tell the research team about yourself, your knowledge of technology, and how you process through thoughts and decisions (cognition). You may continue to receive some of the text messages you received during Reach Out.

1) healthy behavior texts
2) weekly reminder texts to take your BP at home

Once in the study, You will be given specific instructions based on whether you have a phone with smartphone capability (Bluetooth, apps, etc) or not. A new BP monitor will be given to you to use to take your BP at home. You will be asked to take your BP weekly using the BP cuff. You will be given the group-specific materials including instructions and training.

If you have a smartphone, you will be asked to download the BP cuff app to your cell phone and trained on how to use the app. You may need to know your Google or Apple ID to install the app, as well as email address. If you do not have an email address, we can help you create one. We will pair your device with the BP app. You will be sent a reminder text message to complete a Bluetooth enabled BP measurement. The app will seamlessly transmit your BP reading to the app server. In order to get the data, we will train you on how to download data via the Bluetooth app, and send the data to the study team either via email to a secure study team email. If technical difficulties arise, the study team will conduct an in-person or virtual outcome visit to download final BPs from the Bluetooth app. If these technical issues occur, the study team may ask to download data prior to the outcome visit.

Participants without apps or Bluetooth capable phones will be sent a reminder text message prompting a photograph BP procedure. We will ask the participant to include a photograph of their arm taking their BP when they text in their BP. We will instruct participants to send the picture, and text message 3 BP measurements. Participants will be instructed to take 3 consecutive measures and adhere to the American Heart Association best practices for measuring blood pressure. This will be done via secure texting via Mosio.

At around 3 and 6 months, you will receive reminder text message(s) to complete a survey link. You may also be mailed and called as reminder(s) for these outcomes, and to assist with technology troubleshooting.

Resources and instructions are available on ReachOutED.com.

Participants who do not respond to outcome requests or indicate technical difficulties, may be contacted by the study team via phone or text to troubleshoot with participant.

You may be contacted to be invited to participate in other mHealth or stroke prevention trainings, if interested. You may also be asked to participate in a focus group.

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 6 months from when you enroll.

You will be asked to complete a survey at the time you enroll in the study, 3 months, and 6 months. These will take about 20-30 minutes. 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?
About 6 months from the day you enroll. It may be slightly longer for those who participate in focus groups.

4.4 What will happen with my information and 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: The risks to participating are minimal. You may experience inconvenience. You may experience some discomfort when taking your BP.

(1) BP monitoring: We may ask you to submit a picture of you measuring your BP. The picture does not have to include any identifying information (i.e. face, etc.).

(2) You will receive survey links to complete questionnaires, directly connected to secured database(s). Reach Out will use a secure, password-protected web-based application for data collection and surveys.

(3) Depending on your phone capability you may transmit your BP over Bluetooth app. The risks associated with these apps are stated in their terms and conditions, as with any app you download. You should read these terms and conditions. The app may collect data and information including account information, user data, usage information, cookie information, third party services for basic services, third party services for data sharing, third party data, and additional information provided to app. Some of these features can be changed in account settings. This is not Reach Out, but company data and privacy policies.

(4) This study contains risks associated with transmitting data online, including loss of confidentiality. We have protections in place to minimize these technical risks, including the use of secure logins limited to authorized study staff and vendors, as well as data storage standards. Protections related to data storage standards include collecting the minimum amount of PHI necessary, encryption of all stored data, and other protections.

You will be encouraged to set pass codes for cell phone and application access control. If not connected to wifi, the app will use some of the data you have purchased from your cell phone company over the course of 6 months.

In using a BP company's app, we are subject to their terms and conditions. The study team will provide you with the terms and conditions at consent, and will attempt to update the terms and conditions on our study website (reachouted.com) or via newsletter, if there are significant changes. As is typical with all apps you may download to your phone, the BP app may collect data and information in a variety of ways when you use their services. As Reach Out is setting up your app, we will show you in the settings how to stop use of a feature, un-pair device, or delete account.

Inconvenience will be minimized by allowing you to choose the times of the day that you take your BP. Answering the survey/interview questions is voluntary. You can skip any questions that you don't want to answer, whatever the reason, and you don't have to tell us why. It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question. Additionally, in sharing BP data, (via Bluetooth cuff or pictures) this will not be sent to researchers unless initiated by you.

To keep your information confidential, your survey responses and study data will be entered into a database and stored on a secured server. Any physical copies will be stored in a locked area, accessible only to clinic staff, and will not be made part of your medical record.

Mosio is the company sending out the text messages, and will keep your information confidential and will not share your information with anyone. Mosio may retain a portion of your BPs and your phone

number throughout the study for quality control purposes and to notify study staff if a problem is later detected with the analysis performed. They 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, and no one will be reviewing BP or survey data in real-time. 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 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 have the option of choosing to possibly 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 decide not to continue with Reach Out Cognition after you complete Reach Out. 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.

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 Cognition 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 many reasons why the researchers may need to end your participation in the study. Some examples are:

1. The researcher believes that it is not in your best interest to stay in the study.
2. You become ineligible to participate.
3. Your condition changes and you need treatment that is not allowed while you are taking part in the study.
4. You do not follow instructions from the researchers.
5. 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, cellular data and 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
- 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 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 a BP cuff, $20 at 3-month outcome, and $30 after completing the 6-month. If you are asked to participate in a focus group, you may receive food and up to $20 following completion of the session. Payments will be in the form of cash or a gift card.

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 and authorization to release your protected health information

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 BP. 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. We will not share data that identifies you with anyone outside of the study. 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. This data will be stored in REDCap and/or qualtrics. 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 BP, 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.

The research team will have printed terms and conditions available for the app that is asked to be downloaded to your phone, so that you may understand the policies of those specific apps, which are not created or supported by Reach Out.

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 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

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: 810-257-9974
Fax: 810-262-4768

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

Consent to Participate in the Research Study

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 consent 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): _____

Time (HH:MM): _____

- ❑ **I have had the opportunity to ask questions and have those questions answered to my satisfaction.**
- ❑ I would like to receive follow-up newsletters and information regarding Reach Out after completion of the study.
- ❑ If asked to participate in the post-study focus group, I agree to being recorded during discussion.

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.

Legal Name: _____

Title: _____

Signature: _____

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