# Information Sheet Template (Waiver of Documentation of Informed Consent)

VA Central IRB
VA Institutional Review Board for Multisite Studies

**INFORMATION SHEET FOR:** ***Continuing the Conversation: A Multi-site RCT Using Narrative Communication to Support Hypertension Self-Management among African-American Veterans*****.**

You are being asked to participate in a research study conducted by <Site Name and location>. We are conducting a study to to learn about ways we can help African American Veterans who have high blood pressure. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

**WHY IS THIS STUDY BEING DONE?**

We are conducting a research study to learn whether we can help Veterans keep their blood pressure under good control with the support of text messaging. For this part of the study, we will be recruiting up to 600 Veterans at two VA Medical Centers: Corporal Michael J. Crescenz and Jesse Brown. In total for the whole study, we will recruit 620 Veterans. The lead site for this project is Edith Nourse Rogers VAMC. This study is funded by the VA through the VA Health Services Research & Development Program (HSR&D).

**WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?**

**For this study, you do NOT have to come into the VA – you can participate entirely by phone.** You can participate from your home if you have access to the Internet. If you do not have Internet in your home, you can participate from another location where you can access Internet – please be aware that you will be asked to answer questions about how you manage your blood pressure, so you may want to choose a place with some privacy.

Your participation in the project will take about **6 months**. Overall, this research study will take about 3 years. This study includes randomization. If you decide to take part in this study, this is what will happen:

- The research team will look at your health records to gather information about your blood pressure, medications and other health conditions.
- Baseline Call: You will be scheduled to have a phone call with the study coordinator. This call should take between 60-90 minutes to complete.
    - Once you are on the phone with the coordinator, you will be asked to give some information in order to sign you up to receive texts from the VA Annie texting system.
    - You will be asked to check your blood pressure at home using a home blood pressure machine (taking a total of 3 readings), and to tell the coordinator your blood pressure readings. The coordinator can help guide you on how to take your blood pressure.
    - You will then be asked to answer survey questions about your health.
    - You will be placed into one of two study groups. This will be decided by a flip of a coin. The text messages you receive will based on your group assignment.
    - At some point you may be asked to make a selection about which text messages to receive. If you do not make a selection, this selection may be made for you.

- You may be asked to view some videos on managing your blood pressure, including videos of other Veterans sharing their stories about how they manage their blood pressure.

- Text messages for 6 months: Everyone in this study will have text messages sent to their mobile phone for 6 months, beginning after the Baseline call.
    - You will receive text messages each week. These texts will include information for you about managing your blood pressure and making healthy choices.
    - Sometimes you will be invited to respond to a question sent through the text message.
    - Text messages fees may apply if you do not have unlimited texting plan.
    - We ask that you report to the study coordinator any phone number changes during the time of participation of this study.

- Follow up Call after 6 months: You will be asked to participate in a follow-up call in 6 months.
    - This 6-month follow-up call will take approximately 60 minutes. On this call, you will again be asked questions from a survey and you will check your blood pressure three times and tell the coordinator your blood pressure readings

- This study is being overseen by a Principal Investigator (the study leader) in Bedford, Massachusetts but you will receive all instructions and contact by a research coordinator from your site.

**ARE THERE ANY RISKS OR DISCOMFORTS?**

Any research study has possible risks and discomforts. The procedures in this study may cause all, some or none of the risks listed. Unforeseeable (unanticipated) risks also may occur:

- Risks that may be associated with participation in this study are:
    - Feeling uncomfortable about answering the survey questions
    - Inconvenience to your time for completion of the study activities
    - Loss of confidentiality
    - Risk of accident or injury if you read texts while driving or walking or doing other activities that require your attention. Please make sure you are always choosing a safe time to read and respond to your texts. Please do not read or respond while driving.

- Every effort will be made to make you comfortable when answering surveys or watching videos. Every effort will be made to schedule calls when it is a convenient time for you. This study does record your full social security number in order to make sure all information gathered about you is correct and yours. All efforts will be made to keep the information you provide safe and confidential, and only approved, necessary study persons will have access to your information.

- If at any time the researcher feels your participation increases your risk for any health condition, you will be withdrawn from study participation.

- Risks of the usual care you receive are not risks of the research and are not included in this consent form. You should talk with your health care providers about risks of usual care.

**ARE THERE ANY BENEFITS?**

We can't promise that you will get any benefits from taking part in this research study. However, possible benefits may include:

- Increase in what you know about blood pressure control
- Feeling more confident that you can manage your blood pressure
- Better control of your blood pressure
- Your health may improve

Additionally, the information we get from this study might help us treat Veterans in the future.

**WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?**

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

Any information you share is kept strictly confidential. Information obtained from you will not be given to anyone not working on this study without your written consent, except as required by law or regulation. Data files will be stored on a secure VA computer and will be password protected. The study data will not identify you by name, nor will anyone except the study staff for this study see records containing your personal information. This study involves patients from more than one VA. Any information shared with other VA's will not be linked directly to you or identify you.

Only authorized persons will have access to the information gathered in this study. Members of the Bedford VA study team will have access to information which may identify you. Your audio recordings may be listened to by a VA- approved transcription service. Once the transcription is completed, audio-recordings will be fully erased from the VA server at that time. There are times when we may have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

**WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?**

- You will receive $30.00 as a Thank You for your participation in the baseline over-the-phone visit.
- After receiving text messages for 6 months, you will recieve $30.00 as a Thank You for your participation in the 6-month follow-up over-the-phone visit.

**WHO CAN I TALK TO ABOUT THE STUDY?**

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury was due to your not following the study procedures. If you should have a medical concern or get hurt or sick as a result of taking part in this study, call: Dr. Sarah Cutrona, or study coordinator Kathryn DeLaughter

*(List local site contacts)*

DURING THE DAY:

Dr./Mr./Ms. FILL IN APPROPRIATE INFO HERE>>> at FILL IN APPROPRIATE INFO HERE>>> and

AFTER HOURS:

Dr. /Mr./Ms. FILL IN APPROPRIATE INFO HERE>>> at FILL IN APPROPRIATE INFO HERE>>>.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.