Informed Consent Document-Patients

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Title: mHealth to Address Uncontrolled Hypertension Among Hypertensive Homeless Adults

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Informed Consent for Participation in a Research Study (Patients)

Title of Study:	mHealth to address uncontrolled hypertension among hypertensive homeless adults
Principal Investigator:	Ramin Asgary, MD, MPH George Washington University Milken School of Public Health Department of Global Health 950 New Hampshire Avenue NW Washington, D.C., 20052 raminasgary1@gwu.edu (202) 994-6803

Key Information:

You are being asked to take part in a research study about the effect of mobile health strategies on hypertension control among patients who experience homelessness. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

By doing this study, we hope to learn the impact of mHealth strategies and SMS texting on better management of hypertension and to collect information regarding the experience of SMS texting on the challenges of achieving good hypertension control. Your participation in this research will last about 6 months.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

This study helps persons with hypertension such as yourself better control their high blood pressure. Detailed description of benefits is provided below in Detailed Consent Form section.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There is no physical risk in participating in this study but you may experience some emotional discomfort discussing your challenges. There is also a risk of loss of confidentiality discussed below. For a complete Description of risks please see below the Detailed Consent Form section.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled and your medical care or services and the clinic will not be affected.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

The person in charge of this study is Dr. Ramin Asgary. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: (202) 994-6803
This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.

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- You have questions about your rights as a research subject.

Detailed Consent Form:

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to evaluate the impact of mobile health strategies on hypertension control among patients who experience homelessness. We are asking you to take part in this research study because you have hypertension, the medical condition being studied. This research study is being done to evaluate the impact of mHealth strategies and SMS texting on better management of hypertension and to collect your experience of SMS texting and opinions on the challenges of achieving good hypertension control. We will do this through accessing your medical records and collecting information about your hypertension and through an interview.

3. How long will I be in the study? How many other people will be in the study?

Each patient will be in this study for a period of 6 months during which all information about their hypertension management will be collected and they will be receiving related SMS texting to improve their hypertension management. Some patients (about 30) will also be selected to go through an interview. The interview itself will last about 30-45 minutes and you will only complete one interview.

4. What will I be asked to do in the study?

If you agree to participate in this study, you will be asked to sign this consent/authorization form. Then you will be randomly enrolled into an intervention or a control group. Nevertheless, all participants will be enrolled into a SMS text messaging program and receive a mobile phone. The

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mobile phone is provided to you at no cost and if it is lost or broken, it will be replaced at no cost to you. It will also include 6 months of free phone plans. You will be asked to return the phone at the end of your participation in the study. You continue to see your physicians in the clinic and receive usual care for all your medical problems irrespective of your group assignment. If you are in the control group, you will receive periodic SMS texts during a 6 month period about your overall health, your upcoming clinic visits, your medications, diet and healthy life style. If you are in the intervention group, you will also receive specific information and SMS texts about your hypertension control. You have opportunity to ask questions and receive related feedback via SMS texting. Whenever you are in the clinic for your clinic visit, a research assistant may ask you questions about adherence to your medications. Additionally, if you are selected, you will also be asked to participate in a one-on-one interview in which you will be asked questions about your opinions on and experience with the challenges of achieving good hypertension control, your experience of SMS texting, and the ways providers could further help patients better control their hypertension. During the interview we only ask some questions that you can provide verbal answers to if you wish. We will not collect any laboratory tests or perform any other procedure on you for the purpose of this study. However, your doctor may perform exams and tests as usual part of your care. We will access your medical record to collect information about your hypertension that your providers has collected but we will not be involved in any way in your medical care for your hypertension or any other conditions you may have. You will continue to get all your usual care prescribed by your provider in the clinic today and afterward.

If you are selected for an interview, you will also be asked if you agree to allow audio-recording of the interview. If you agree to audio-recording, you will be asked to sign a separate consent/authorization form stating this. We will audio-record this interview so we can analyze it better after the interview is completed. Audio-recording is required for participation in this study. You may decide not to consent to audio-recording, in which case you may not participate in the study. Any identifiable information that you provide during the interview, such as your name, address, age, and medical record number, for the purposes of this research will not be used or distributed for future research studies.

During the individual interviews, if you are selected to participate in one, some of your direct responses such as quotes from you could be presented in any resultant reports or publications. These quotes or any other data from you are all de-identified and there is no way to relate or connect these specific quotes to you personally.

5. What are the possible risks or discomforts?

Risk of Study

We do not anticipate any physical risk for participating in the study. This study does not change your clinic visits or care your hypertension. The content of SMS texts are all health related and design to improve health and or remind you of your upcoming clinic appointments or encouraging you to take your medications. The topics discussed during the interview may be sensitive and may be uncomfortable for you to discuss. You may

experience some emotional discomfort discussing your challenges. During the interview, you do not have to answer any questions that you do not want to answer. If you are not comfortable with the interview, you can choose to stop the interview and withdraw from the study at any time. You can retract any answer or statements you made at any time during the interview. Your participation in the study will not affect your care at the clinic. Additionally, your provider in the clinic is responsible for your continuity care and available to discuss and address any related care.

Other Risks

Potential loss of confidentiality is a risk of participation in this study. Precautions will be taken to minimize this risk. All your hypertension and medical data are recorded in your medical records and by your providers. All identifiable data obtained from you, including your name, address, and birthdate, will be stored electronically in password-encrypted files which will be only accessible to Dr. Ramin Asgary and Research Assistant and will not be shared with anyone outside of the study team. There will be no connection between data from your medical records and your name, date of birth or other identifiable data except through a computer generated ID that will be unique to you and only accessible by the PI and Research Assistant.

However, participation in this research may involve some risks that are not currently foreseeable.

6. What if new information becomes available?

During the course of this study we may find more information that could be important and applicable to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

You are not expected to benefit personally from being in this study, but it is likely that SMS texts that provide healthy life style tips and reminders for clinic visits and some discussion of your challenges with hypertension control may help you and your provider better address them in future. You can discuss these challenges further with your provider.

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We hope that, in the future, other people with uncontrolled hypertension might benefit from this study because we will better understand the difficulties in achieving hypertension control which will help to improve their hypertension care.

8. What other choices do I have if I do not participate?

Your participation in the study is completely voluntary. The alternative is not to participate in the study.

You can discuss this further with your provider if you wish. Whether or not you participate in this research will not affect your care at the clinic.

9. Will I be paid for being in this study?

You will not be compensated for participation in this study. However, you will receive a one-time $20 MetroCard for transportation cost that could be related to this study.

10. Will I have to pay for anything?

There is no cost for participation in this study. Your services and care in the clinic will not be affected in any way by participating in this study.

11. What happens if I am injured from being in the study?

For any medical emergencies please contact 911.
If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the George Washington University (GWU) to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed the SMS texting intervention and interviews and all information has been collected. This study may also be stopped or your participation ended at any time by your physician or study team without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.

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- You have not followed study instructions.
- The principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at Project Renewal. In compliance with GWU and Project Renewal shelter clinics' policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the Project Renewal Clinics, where you get your care, who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with GWU policies and applicable law.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study. This will include Institutional Review Board and the National Institute of Health.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

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What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study

- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information? Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The GWU IRB Office number is (202) 994-2715. The GWU's IRB is made up of:

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 Researchers, doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the GWU Institutional Review Board (IRB) at (202) 994-2715.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent Process for Non-English Speaking Subjects (using a translated consent form OR "Short Form" in Subject's Spoken Language)

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

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Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date