Informed Consent Document-Providers

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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 (Provider)

Title of Study: mHealth to address uncontrolled hypertension among hypertensive homeless adults

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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 the study will last about 30 to 45 minutes for an interview.

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

This study likely helps you better address blood pressure control of some of your patients with hypertension. 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 to you. The topics discussed during this interview may be sensitive and may be uncomfortable for you to discuss. 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.

As an employee, if you decide not to take part in this study, your choice will have no effect on your employment status.

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.

Informed Consent for Participation in a Research Study (Provider)

- 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. 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 are involved in the care of patients who have hypertension. This research study is being done to collect your opinions on the challenges of achieving good hypertension control. We will do this through an interview.

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

The interview will last about 30-45 minutes and you will only complete one interview. About 20 medical providers and clinic staff will also be in the study, which will take place over the course of few months.

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 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 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.

You will also be asked if you agree to allow audio-recording of the interview. If you agree to audiorecording, you will be asked to sign a separate consent/authorization form stating this. We will audiorecord 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.

Informed Consent for Participation in a Research Study (Provider)

The interview will be one time and will last about 30-45 minutes.

Any identifiable information that you provide during the interview , for the purposes of this research, such as your name, address, and age, will not be used or distributed for future research studies.

During the individual interviews, 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. The topics discussed during this interview may be sensitive and may be uncomfortable for you to discuss. 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 relationship with your patients or your employment, salary, evaluation, or reputation at the clinics. Your responses and record of participation can't be linked to your employment record.

Other Risks

Potential loss of confidentiality is a risk of participation in this study. Precautions will be taken to minimize this risk. All identifiable data obtained from you, which only includes your name, 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.

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 and your patients. 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 some discussion of your patients' challenges with hypertension control may help you to better address them in future.

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

Informed Consent for Participation in a Research Study (Provider)

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.

Irrespectively, your participation or lack of in this research will not affect your employment at the clinics of Project Renewal.

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

You will not be compensated for participation in this study.

10. Will I have to pay for anything?

There is no cost for participation in this study. Your employment at 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 interviews and all information has been collected. This study may also be stopped or your participation ended at any time by the study team without your consent because:

- The principal investigator feels it is necessary for your well-being 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.
- 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 employment at the clinic.

13. How will you handle my study data and records and confidentiality?

Informed Consent for Participation in a Research Study (Provider)

Your medical information is not collected for this research study and will not be recorded. We use unique computer-generated ID codes for each enrolled subject and will capture all subject's data. Connecting your responses during the interview to your personal information is only possible through linking ID codes that are only available to and accessible by the PI and research study team members.

You will have the right to see and copy the information and responses you provided once the study is over in accordance with GWU policies and applicable law.

Your study data, in connection with this research, may be shared with and reviewed by Institutional Review Board at George Washington University and the National Institute of Health for purposes of overseeing this research.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You may choose not to participate in this study if you do not wish to give permission to use or share any of your information and responses.

Can I change my mind and withdraw permission to use or share my information?
Yes. You may change your mind and withdraw permission to use or share your study data and information for this study at any time by contacting the Principal Investigator as listed at the top of this form. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

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

14. 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:

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

15. 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.

Informed Consent for Participation in a Research Study (Provider)

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