# CONSENT TO TAKE PART IN RESEARCH

*XXXX*

Mobile Health Hypertension Prototype

*Principal Investigators: XXXX*

**You are being asked to take part in a research study. Taking part in research is voluntary.**

Your decision whether or not to take part will have no effect on the quality of your medical care. Please ask questions if there is anything about this study you do not understand.

## What is the purpose of this study?

The purpose of the study is to evaluate the functionality and usability of an at-home blood-pressure monitoring system in development by XXXX.

## Will you benefit from taking part in this study?

You might not personally benefit from being in this research study.

By creating and refining an at-home blood pressure monitoring system we hope to gather information that may help people in the future.

## What does this study involve?

Your participation in this study may last up to 2 weeks.

If you decide to participate, you will be given a blood-pressure monitor and a tablet computer to take home with you. You will be asked to use the blood-pressure monitor to take your blood pressure frequently, as directed by your doctor, but normally once per day. The tablet will then read the blood pressure from the monitor and transmit your readings to a secure computer system. Your doctor (and his or her medical team) will have access to your blood-pressure readings stored in the system. However, during the course of the study you will contact your doctor as you do today – you will not interact with your doctor via this system.

You will receive training from a medical professional on how to use the blood-pressure monitor and training from a researcher or medical professional on how to use the software on the tablet.

## If you take part in this study, what activities will be done only for research purposes?

If you take part in this study, the following activities will be done only for research purposes:

At the end of the study you will be asked to participate in an interview with researchers on the reliability and ease of use of the system.

**What are the risks involved with being enrolled in this study?**
No risks are expected. It is important you understand this blood pressure device is not part of your standard care. If you notice your blood pressure is not normal do not depend on the device to notify your doctor. You should call your doctor as usual instructions.

We do everything reasonably possible to protect your confidentiality, but there is always a slight risk that someone might gain access to your records.

**Other important items you should know:**

• **Leaving the study:** You may choose to stop taking part in this study at any time. If you decide to stop taking part, it will have no effect on the quality of your medical care. However, you will be asked to return the blood-pressure monitor and tablet computer.

• **Number of people in this study:** We expect about XX people to enroll in this study.

• **Funding:** XXXX provides funding to XXXX for this research.

• **Product Development:** If the results of this research are used to develop a product sold for a profit, you will not share in the profit. You will not receive money from the profits.

**How will your privacy be protected?**
The information collected as data for this study includes: systolic and diastolic blood pressure, pulse rate, and date and time blood-pressure readings where taken. We may also utilize software that tracks the order of button taps and clicks on the tablet computer to help us evaluate the ease of use of the system.

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential.

Blood-pressure readings will be stored on the tablet and also in a secure computer system. When you return the tablet, all information on the tablet will be erased. Your blood-pressure data will be kept throughout the duration of this project; we expect that will be less than one year. Afterward, your blood-pressure data will be erased.

The computer system is secure and accessible only by your doctor's medical team and by the research team. You will be assigned a unique random identification number and all of your information in the system will refer to this identification number. Other identifiers (such as

your Social Security Number or Patient ID number) will *not* be stored in the tablet or computer system.

The information collected for this study will be used only for purposes of research as stated earlier in this form.

**Who may use or see your health information?**

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at XXXX.

The information collected for this study may be used by researchers or officials of the following institutions.

- XXXX
- XXXX
- XXXX

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over.

It is possible for a court or government official to order the release of study data including information about you.

**What if you decide not to give permission to use and share your personal health information?**

If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

**Will you be paid to take part in this study?**

No payments are associated with this study.

**Whom should you call with questions about this study?**

If you have questions about this study or concerns about a research related injury, you can call the research director for this study: XXXX at XXX-XXX-XXXX during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research at XXXX, you may call the Office of the Committee for the Protection of Human Subjects at XXX-XXX-XXXX during normal business hours.

**CONSENT**

I have read the above information about Mobile Health Hypertension Prototype and have been given time to ask questions. I agree to take part in this study and I have been given a copy of this signed consent form.

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|---|---|
| Participant's Signature and Date | PRINTED NAME |
| Researcher or Designee Signature and Date | PRINTED NAME |