INFORMED CONSENT FORM

Protocol Title: Text BP: Comparing standard office based follow up versus text-based remote monitoring in the management of postpartum hypertension.

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UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPPA AUTHORIZATION FORM

Protocol Title:	TextBP: Comparing standard office based follow up versus text-based remote monitoring in the management of postpartum hypertension
Principal Investigator:	Sindhu Srinivas, MD, MSCE 5 Dulles, 3400 Spruce Street Philadelphia, PA 19104 215-662-4789
Emergency Contact:	24-hour Labor and Delivery Phone 215-662-3815

Why am I being asked to volunteer?

You are being invited to participate in a research study because your pregnancy or delivery was complicated by a hypertensive disorder of pregnancy (high blood pressure). Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. 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. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form. This process is known as informed consent. The study will evaluate whether monitoring your blood pressure using text messaging after you go home can help improve the care postpartum women with hypertension. If you decide to participate, you may or may not be in the group who checks their blood pressures at home and sends and receives text messages.

What is the purpose of this research study?
Women who have elevated blood pressure during pregnancy and after delivery are at risk of complications of hypertension even after they go home. These risks can be decreased with good blood pressure monitoring and control.

This study will test if sending blood pressure values from home using text messaging helps doctors monitor blood pressure, treat elevated blood pressures, and improves the health of the mother. There will be two groups, and you will have an equal chance of being assigned to either group. Before you go home you will be assigned to one of the two groups by chance, like flipping a coin; neither you nor the researchers will have any control over which group you are assigned to. The text message group will receive a blood pressure cuff to take home. This group will receive text message reminders to check blood pressures at home, text back a value for two weeks, and receive feedback about their blood pressure after every text. This group will also be asked to complete a post-study survey. The Routine (Usual Care) group will receive routine postpartum care as if they were not participating in a study, which is an office visit a few days after you go home to check your blood pressure. Your participation in this study will provide us with the opportunity to study the usefulness of this type of intervention for the care of postpartum women with high blood pressure.

How long will I be in the study? How many other people will be in the study?
You will participate in the study from the time you go home until you postpartum visit (approximately 6 weeks after you deliver your baby). Study staff will collect data from your medical records during the pregnancy through your postpartum visit. We expect a total of about 206 women to participate in this study over approximately one year.

What am I being asked to do?
You are being asked to participate in a study that studies the effect of text messaging on the care of hypertension after delivery.

Before any research activities take place, a member of the research team will review this informed consent form with you. If you decide to participate, you will sign this form.

If you decide to participate, you will be randomized (like flipping a coin) to one of two groups.

If you are in the Usual Care group, you will take part in the following:

1. You will be scheduled for a visit in the office the week after you go home so that your blood pressure can be checked.

2. Study staff will collect information from your medical records regarding your blood pressures, your delivery process, your health facts, and your pregnancy.

If you are in the Intervention (text message) group, you will take part in the following:

1. You will receive a blood pressure cuff and be instructed on its use
2. You will receive two text messages a day for two weeks reminding you to check your blood pressure and text back your value.
3. You will receive a text message back giving you feedback on your blood pressures.
4. You will receive a brief survey around 2-3 weeks postpartum. It should take no longer than five minutes.
5. Study staff will collect information from your medical records regarding your blood pressures, your delivery process, your health facts, and your pregnancy.

What are the possible risks or discomforts?
Participation in this study is expected to present very few physical or psychological risks.

Time We estimate that it will take less than five minutes to complete the survey. Taking blood pressures and texting the values should take less than five minutes every time.

Expense It is possible that you will incur an expense for sending and receiving text messages if in fact you do not have unlimited message service. This depends on your cellular telephone plan. You will receive on average four texts per day for two weeks if in the text messaging group and send two texts per day for two weeks.

Confidentiality cannot be guaranteed, but all measures will be taken to ensure that information will be password protected and accessible to the primary investigator and research personnel. We will use our best efforts to keep the information about your secure, and we think the risk of accidental disclosure is small.

Text messages will be sent from an online text messaging service (WaytoHealth). Only your cellular telephone number will be provided to this service and the service's privacy policy ensures that they will not sell or distribute this information.

What if new information becomes available about the study?
During the course of this study, we may find more information that could be important to you. This includes information that, once learned, 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.

What are the possible benefits of the study?
Your participation in the program could benefit you in several ways. If you are in the text message group and this improves the care of your blood pressure after delivery, you may have better control which can improve your health. The results of this study could also benefit future patients. However, participation in this study is for research purposes and no health benefit is guaranteed for you.

What other choices do I have if I do not participate?
Your alternative to providing your consent is to not participate in this study, in which case you would continue to receive your usual postpartum hypertension care, which is the same care that women enrolled in the Routine (Usual Care) group of the study receive.

You may choose not to participate in this study without adversely affecting your present or future care at the University of Pennsylvania Health System.

Will I be paid for being in this study?
You will not be paid for being in this study.

Will I have to pay for anything?
There are no costs for participating in the study; however whether you are charged for text messages received as part of the study depends on the rates set by your cellular phone service provider. At this time you believe you have unlimited text capabilities. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study.

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

This study is expected to end after all participants have completed all visits, and all information has been collected. The study is expected to take one year. This study may also be stopped at any time by your physician or the Department of Obstetrics and Gynecology without your consent because:

- The Primary 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.
- You have not followed study instructions.
- The study Principal Investigator or the Department of Obstetrics and Gynecology has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your information will be held in a research database on a password protected computer in a locked office in the Department of Maternal Fetal Medicine. Only the principal investigator or study staff will have access to this computer.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What information about me may be collected, used or shared with others?
The following information may be used or disclosed for the research project.

- Name, address, telephone number, date of birth
- Medical record number
- Personal medical and obstetrical history, including information from this pregnancy, delivery, and postpartum period.
- Results from a physical examinations, tests or procedures

Why is my information being used?
Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right.

Who may use and share information about me?
The following individuals may use or share your information for this research study:

- The Principal Investigator and study staff.
- Authorities from this institution, including The University of Pennsylvania Institutional Review Board (IRB) which is a group of people who are responsible for making sure the rights of participants in research are respected. Members or staff of the IRB at this medical center may also contact you about your experience with this research. You do not have to answer any questions asked by the representative of the board.
- The University of Pennsylvania Office of Human Research Protection (the office that audits research studies)
- Authorized members of the University of Pennsylvania and the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.).

Who, outside of the School of Medicine, might receive my information?

<u>Oversight organizations</u>

- The Office of Human Research Protections

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?
Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?
Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. (Dr. Sindhu Srinivas, Hospital of the University of Pennsylvania, Maternal Fetal Medicine, 2 Silverstein, Philadelphia, PA 19014). If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

Who can I call with questions, complaints 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 page one of this 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 Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent and HIPAA authorization form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date

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