INFORMED CONSENT and HIPAA AUTHORIZATION

Study title: "Her Health" Study: A randomized controlled trial to test the effectiveness of the ***Her Health Program*** to add healthcare value in the postpartum period

Study Sponsor: The Donaghue Foundation

KEY INFORMATION

This form has information to help you decide about taking part in this research study.
All of this information is important, but here are some key points to help you make a decision:

Why am I being asked to review this form?

- You are being asked to join a research study. Doctors and scientists do research to learn about health and to learn about diseases and how to treat them. Research can be different than medical care.
- This form is for you to read and understand why you might or might not want to join.
- Joining is completely up to you. Even if you sign up, you are free to quit if you change your mind.

What is the purpose, length of time, and procedures of this study?

- The *purpose* of this study is to learn if a program Woman's Hospital has made, called the ***Her Health Program***, can help women get healthcare in the first year after having a baby.
- *Your time* in this study will be about 12 months. The study starts between your third trimester and your first week after you have a baby and ends about one year later.
- The *procedures* involved in this study include:
    - Answering questions about yourself, your health, your neighborhood, and your well-being
    - Surveys about your feelings about your healthcare and knowledge of your healthcare
    - Linking of your medical records and doctors' visits during pregnancy and in the year after having your baby
- After you agree to join the study, you will be put into 1 of 2 groups at random: either the ***"Her Health Program"*** group (where you join the program during the first year after having your baby) or the "***Usual Care***" group (where you will see your doctors as normal during your first year after having your baby).
- If you are put into the ***Her Health Program*** group: You will be connected with a ***Her Health*** navigator who will help you and work with your doctors to get you the healthcare (appointments, tests, medicines, counseling, etc.) that is recommended for you in the first year after having your baby.
- You will earn up to $135 for being in the study. You will receive a $60 gift card after your group assignment (called "randomization") and a $75 gift card when you finish your end-of-study surveys.

What are the possible risks and discomforts?

There is a low chance of a security breach – this means that it is unlikely for someone not a part of the research staff to see your data. Although we have very tight security measures, we will let you know if we discover this happens.

What are the possible benefits?

If you are placed in the ***Her Health Program*** group, you will get support from our team during the first year after having your baby. It is possible that you may not receive any benefit from this study.

If you do not join the study, are there other choices?

You can choose at any time to not be in this study. If you don't want to join, there is no other option.

Please take the time to read this entire form. Please ask any questions you have about the study. You may also wish to discuss this study with your family, friends, and doctor to help you decide about taking part in the study.
If you decide to take part in the study, you will be asked to sign this form.

The "Her Health" Study

A randomized controlled trial to test the effectiveness of the ***Her Health Program***

Principal Investigator: ***Elizabeth Sutton, PhD***
Co-Investigator: ***Renada Deschamp, MPA***
Medical Monitor: ***Robert Clifton Moore, MD***
Woman's Hospital
100 Woman's Way, Baton Rouge, LA 70817

Study-related phone number (24 hours): 225-428-7464

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from Woman's even if you are not in the study.**
- **Take as much time as you need to read this form and decide what is right for you.**

What is the purpose of this study?

- The "fourth trimester" is the period of time after you have a baby. Pregnancy changes your body a lot, and recovering from pregnancy can be hard. It can be important to focus on your health and healthcare during the fourth trimester to make sure you have good health later in your life.
- The *purpose* of the study is to learn if a program Woman's Hospital has created, called the ***Her Health Program***, can help women be healthy and get healthcare in the first year after having a baby.

Who can join this study?

Women who are at least 16 years old, who are pregnant or have had a baby in the last 7 days, use Medicaid insurance, and live in certain areas of Baton Rouge, Louisiana, can join this study. Up to 500 women will be in this study at Woman's Hospital.

What will happen to you if you join the study?

The study and this form will be reviewed with you before any study activities are done. If you decide to join, your total time in the study will be about **12 months**. There are **2 parts** to this study: research visits (the enrollment visit and end-of-study surveys) and the program ("Her Health"). If you join the study, you can choose to have the study team let your doctor know.

Part 1: Research visits

1. Starting Visit: *1 or 2 visits at Woman's Hospital, about 40 minutes total*
   We will first see if you qualify to be in the study. Then, if you choose to enroll, we will collect your study data and assign you to your group. Some of these activities can be done while you are pregnant but others have to be completed after you have your baby. This visit may be split into 2 shorter visits if it is easier for you- one during your third trimester and the other after you have your baby; or all the activities can be done after you have your baby. It is up to you. The activities for this visit (or these 2 visits) include:

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- **Reviewing and signing of the Informed Consent and HIPAA Authorization form** (this document)
- **Collecting your information***:* The study team will ask you questions about you and your health (like your age, race, education), where you live, and your well-being. We will also collect information so we can contact you.
- **Surveys:** You will fill out surveys about your feelings and knowledge of your healthcare.
- **Group assignment:** You will be put into a *study group*- either the ***"Her Health Program"*** group (where you join the program during the first year after having your baby) or the "***Usual Care***" group (where you will see your doctors as normal during your first year after having your baby). You will be put into one of the study groups at random (like flipping a coin). A computer will decide what group you are in, so neither you nor the study team can pick your group. You have a 33% (1 out of 3) of being put in the Usual Care group and a 66% chance (2 out of 3) of being put in the Her Health Program group. Note- this will always happen after you have had your baby.
- **Study compensation ($60 gift card)** will be given to you after delivery and your group assignment.

2. End-of-study Surveys: *Online surveys (on your own)*, *about 30 minutes*
   You will be given a second set of surveys at the end of the study (about 12 months after having your baby) that asks again about your feelings and knowledge of your healthcare.
   Study compensation ($75 gift card) will be given to you after you complete your second surveys. The research team will review your electronic health records at Woman's Hospital, your doctor's office, and the Louisiana Department of Health and link your health records to your study data. (Information collected from your health record could include: medical history, appointments, procedures, screening tests and results, vaccine records, billing information, birth control, kept/missed appointments, etc.)

Part 2: Study Program

- If you are put in the ***Usual Care*** group: You will go to your doctor's visits as usual during your first year after having your baby.
- If you are put in the ***Her Health Program*** group: You will still have your usual care as well as receive the ***Her Health*** program. The ***Her Health*** program uses an extra healthcare team member (called a community health worker navigator) to work with patients and their care team. You will have a visit with your navigator after having your baby before you leave the hospital if there is enough time (if not, you will check in within your first week after having your baby). You will have check-ins about every week for your first 3 months postpartum and then about once a month until you are 1 year postpartum. These visits can be in-person or virtual (telehealth, phone, or text). At these check-ins, you and your navigator can talk about how you are feeling, and what healthcare and/or support you need. You will also receive 4 short "lessons" about healthcare history and how to speak up for yourself in your healthcare.

What is expected of you if you join the study?

If you join the study, the study team asks that you:

- Answer the survey questions the best that you can.
- Call the study coordinator if you are thinking of quitting the study.

What are the possible risks and discomforts?

There is a low chance of a security breach – this means that it is unlikely for someone not a part of the research staff to see your data. Although we have very tight security measures, we will let you know if we discover this

happens. If you have questions or do not understand the study risks, you may discuss them with Dr. Sutton. Your doctor is still responsible for your medical care.

What are the possible benefits?

If you are placed in the ***Her Health Program*** group, you will get support from our team during the first year after having your baby. It is possible that you may not receive any benefit from this study. Taking part in this study may not help you, but it might help other women in the future.

If you have any questions or problems, whom can you call?

- Call ***Ericka Seidemann****, Woman's Human Protections Administrator, at 225-231-5296* with questions about your rights as a research volunteer, concerns, or suggestions about the study.
- Call ***Dr. Sutton*** *at 225-924-8446* with questions about the research study or if you think you have a research-related injury or medical illness.

What if you say you don't want to be in this study?

- Nothing bad will happen because of what you decide.
- You can still get medical care at Woman's.
- You have the choice at any time not to join this research study.
- The care you get from your doctors will not change if you decide not to be in the study.
- You can join now and change your mind later and quit.
- If you don't want to join, there is no other option.

Can you stop being in the study? What happens if you say yes but change your mind later?

Joining this study is your choice. You may decide not to join the study or quit the study at any time. The care you get from your doctors will not change if you decide to quit the study. *To stop being in the study or discuss stopping*, you should contact the study coordinator by phone at 225-428-7464 (24 hours) or email research@womans.org.

Can your taking part in the study end early?

The study team can take you out of the study at any time without your permission. They may take you out of the study in the unlikely event the study may be harmful to you, you don't follow study directions, we find out you don't qualify, the study is canceled, or for other reasons.

What if information becomes available that might affect your choice to stay in the study?

We will tell you if we learn anything that may change your mind about being in the study.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. If you sign this form, you agree for the researchers at Woman's Hospital to use or give (disclose) your health information/record that identifies you for this study. The information that will be given to the researchers is for this study only. Your information will be used by the study team connected with this project. Woman's Hospital is required by law to protect your health information. By signing this form, you let Woman's Hospital use and/or release your health information for this research. Those persons who get your health information may not be required by laws to protect it and may share your information with others without your permission, if allowed by laws governing them.

What health information may be used or released for this study? This will include information from your medical records, procedures, interviews, and tests. Information related to your medical care at Woman's Hospital will go in your research record. This could include anything in your medical record, including physical exams, imaging studies or tests done in the lab. Medical records are available to Woman's Research staff. Staff will view your records only when needed as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone unless you provide your written consent, or it is required or allowed by the law.

Several people and organizations may review or received your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples.

The health information listed above may be used by and/or released to:

- Members of the research team and other authorized staff at Woman's Hospital
- The Donaghue Foundation
- Federal agencies as required by law
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be shared if required by law. The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals about the study and its findings. We will keep your identity private in any publication or presentation. The information from this study could be used for future research studies or given to another investigator for future research without additional informed consent from you. Before the information is shared, any information that could identify you will be removed from your identifiable information.

When I sign this form, how long does my permission last? There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely done.

By signing this form, you are saying you understand that:

- This form is to allow the release of my health information for use in the research study listed on the first page. Plans for how my health information will be used is written in this form.
- Researchers may use my information to see if I can be in this study.
- Researchers may use my information to check results for the study.

- Researchers may use my information to check on side effects from the study.
- Woman's Hospital staff may use this information to see that the study is being done how it should be.
- Study monitors may use this information to see that the study is being done how it should be.
- This health information may be given to insurance companies for medical bills.
- I can cancel this permission to release information at any time before the information has already been released. To cancel, I should contact anyone on the study team or send a written letter to the person on the consent form.
- If my health information has been added to a research database or registry already and there is no identifying information, my information cannot to be taken out.
- If I do not sign this form, I will not be able to take part in this study. But I understand that Woman's Hospital will not change my medical care based on if I sign this form or not.
- I understand there is a chance that information released by this agreement may be re-disclosed by whomever gets my information, that it may no longer be protected by HIPAA.
- I understand a photocopy of this form may be relied upon as if it were the original.

What charges will you have to pay?

None. The study will not cost you anything. You or your insurance company will be responsible for the costs of your regular medical care, as usual.

What payment will you get?

We will give you up to $135 for your time if you join the study. You will get a $60 gift card after the starting visit activities, and a $75 gift card after completing your end-of-study surveys.

Will we tell you the results of the study?

No. We will not tell people in the study about what we find. However, we plan to publish the results in an academic journal. (What we publish will not include anything that can identify you.)

How will the study team reach me?

The study team may contact you by email or phone about this research. By giving Woman's Hospital Research your email and/or phone number, you agree to receive communications by unencrypted email and/or text message.

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Signatures

By signing this consent form, I agree to take part in this study as it is described. This study has been explained to me and all of my questions have been answered. I can call the study investigators, listed on page 2, with any further questions I may have. This study has been reviewed and approved by an Institutional Review Board. I understand that there is a level of risk that any information transmitted in an unencrypted email or text message could be read by a third party. I agree to the terms above and acknowledge that I will be given a copy of this consent form. I have not waived any of my legal rights by signing this form.

_____	_____	____/____/____	____:____
Printed Name of **Subject**	Signature of **Subject**	**Date**	**Time**

_____	_____	____/____/____	____:____
Printed Name of **Person Obtaining Consent**	Signature of **Person Obtaining Consent**	**Date**	**Time**

The study subject has indicated to me that the subject is unable to read. I certify that I have read this consent form to the subject and explained that by completing the signature line above the subject has agreed to take part.

_____	_____
Signature of Reader	Signature of Witness

ASSENT (MINORS)

Your signature documents your permission for the named child to take part in this research.

_____	_____	____/____/____	__ __:__ __
Printed Name of Child	Signature of Child	**Date**	**Time**

_____	_____	____/____/____	__ __:__ __
Printed Name of **Parent or Legally Authorized** To consent for the child to participate	Signature of Parent **Parent or Legally Authorized** To consent for the child to participate	**Date**	**Time**

I attest that the identity of the individual giving consent has been verified.

_____	_____	____/____/____	__ __:__ __
Printed Name of **Witness to Consent/Assent Process**	Signature of **Witness to Consent/Assent Process**	**Date**	**Time**

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