CONSENT TO PARTICIPATE IN A RESEARCH STUDY
-COVER SHEET-

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 the 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 $135 for being in the study. A $60 gift card after your first visit 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 made, 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, had a baby in the last 7 days, use Medicaid insurance, and live in certain areas in 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").

Part 1: Research visits

1. Starting Visit: *1 visit at Woman's Hospital, about 40 minutes*
   We will have a visit to see if you qualify to be in the study, then collect your study data if you choose to enroll, and assign you to your group. This visit includes:
   - **Review and signing of the informed consent 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 about your healthcare and knowledge of your healthcare.

- **Group assignment:** You will be put into a *program* 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) at the beginning of the study. A computer will decide what group you are in. Neither you nor the study team can pick your group. You have a 33% (1 out of 3) of being in the Usual Care group and a 66% chance (2 out of 3) of being in the Her Health Program group.
- **Study compensation ($60 gift card)** will be given to you at this visit.

2. End-of-study Survey: *Online surveys (on your own)*, *about 30 minutes*
   You will have a survey at the end of the study (about 12 months after having your baby) to ask again about your feelings about your healthcare and knowledge of your healthcare. **Study compensation ($75 gift card)** will be given to you after you complete your surveys. The research team will review your electronic health record at Woman's, your doctor's office, and the Louisiana Department of Health and link 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 they are scheduled 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 before you leave the hospital after having your baby 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.

If you join the study, you can choose to have the study team let your doctor know: Add your Initials below to agree or not agree.

_____ (initials) Yes, I **AGREE** to the study team letting my doctor know I joined the Her Health study.

OR

_____ (initials) NO, I do **NOT** agree to the study team letting my doctor know I joined the Her Health study.

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

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happens. If you have questions about the study risks or do not understand any of the 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*** with questions about your rights as a research volunteer. Her phone number is at 225-231-5296. She is the Human Protections Administrator at Woman's.
- Call ***Ericka Seidemann*** with concerns or suggestions about the study. Her phone number is at 225-231-5296.
- Call ***Dr. Sutton*** with questions about the research study or think you have a research-related injury or medical illness. Her phone number is 225-924-8446.

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 information will be kept private?

Every effort will be made to keep the confidentiality of your study records. Someone from the Woman's Hospital Foundation Institutional Review Board, Woman's Hospital Research Center and researchers working with us, Woman's Hospital Research and Development Committee, and federal agencies as required by law may inspect and/or copy the medical records related to the study.

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- Privacy and Confidentiality: We will give you a special study number (or "ID") to store your study information. This study ID lets us not need to use your identity in study records. All study information collected at Woman's will use this study ID. Only the study team will be able to access your study information. We work hard to limit risks of breach of confidentiality and privacy by removing your personal information from the data. We also limit these risks by storing data on encrypted and secure web-based databases. We will keep your study records forever. The records will be stored in a password-protected database. Again, although steps will be taken to keep privacy, total confidentiality cannot be certain.
- Results of the study: Results of the study may be published. We will keep your name and other identifying information private. Other than as set forth above, your identity will remain confidential unless disclosure is required by law.
- Identifiable Private Information: 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 (called an "identifier") will be removed from your identifiable information.
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.

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 Enrollment visit, and a $75 gift card after doing 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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