Key Information

Study title: *Perinatal-Related Cardiovascular Disorders (PERCVD) Registry*
Principal investigators: **Michelle Matter PhD,** Tulane University
Elizabeth Sutton PhD, Woman's Hospital
Co-Investigators: **Robert Clifton Moore MD,** Woman's Hospital
24-hour number: (225) 428-7464

- This first part gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.
- Taking part in this study is *completely voluntary.* It is up to you to take part in this research study. Even if you decide to join the study, you are free to leave at any time if you change your mind.
- We are asking if you want to volunteer for a research study about people who have had severe cardiovascular diseases that are related to pregnancy. By doing this study, we hope to learn more about the genes that may be related to these conditions.

What will happen if you join the study?

If you join, your part in this research will last about *1 day* with extra online surveys for years after if you chose to answer them. During the study, we will ask that you:

- Give us consent for your study participation
- Answer questions about your general medical and pregnancy history
- Swab the inside of your cheeks and mail the swab back to us
- Check in with us about your health

Do you have to join this study?

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join.

What are the risks and benefits if you join this study?

- This study involves no more than minimal risk to the participants.
- When the buccal (cheek) swab is performed, minor irritation may occur, although rare.
- We will follow all standard procedures of research at Woman's Hospital and Tulane University to protect your privacy.
- We cannot promise any benefits from your being in the study.

What do you need to know to decide if you should join this study?

People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to join this study:

Main reasons you may want to join the study:

- ✓ You want to contribute to the knowledge we have about cardiovascular diseases in and after pregnancy.

Main reasons you may <u>not</u> want to join the study:

- ✓ You do not feel comfortable providing a sample for genetic testing.
- ✓ You do not feel comfortable sharing your personal information and/or medical history.

Will you be compensated for being in this study?

You will receive a $50 gift card after your sample is received.

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study.
Remember, it is okay to say no.
You can still get your medical care if you are not in the study.

Woman's IRB

Initial Approval Date: May 06, 2024
Study Expiration Date: May 06, 2025
RP Number: RP-24-007-WH

Informed Consent Form

- **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 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.**

Why are you being asked to be in this research study?

- The study team wants to learn more about pregnancy-related cardiovascular diseases and what causes them.
- By doing this study, we hope to find out more about the genes that play a role in cardiovascular diseases.
- We are asking people like you, who have or had a history of a pregnancy related cardiovascular disease (or have a relative that has), to help answer this question.
- 200 people at least 18 years old will be part of this study.

What if you don't understand something?

- This form may have words you don't understand. If you want, research staff can read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.

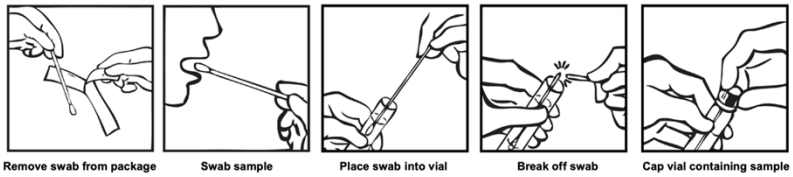
What will happen if you decide that you want to be in this study?

First, we will see if you qualify to be in the study. We will confirm that you have or have had a pregnancy related cardiovascular disease. If you qualify for the study, we will do these things:

- Virtual Study Visit:
  - ✓ We will obtain your consent to participate in the study, which includes to review your medical record data if available to us at Woman's Hospital.
  - ✓ We will ask questions to obtain your medical and pregnancy history such as your health, what you eat, and if you exercise, smoke, or drink alcohol, what medicines you take and questions about your pregnancies.
  - ✓ We will review the instructions for collecting and sending off the cheek swab for genetic testing.
- On your own:
  - ✓ Cheek swab for genetic testing collection: Instructions are included below and a copy will also be sent with the test kit. First you will rinse your mouth for 30 seconds with water. Then you will follow these steps to collect your sample:

Instructions For Use (see diagram below)

1. Open package containing swab and collection vial.
2. Peel open the swab package and remove swab.
3. Swab the sample. Common samples can include surfaces, feces, cheeks (buccal), etc.
4. Open the collection tube and insert swab tip into the reagent.
5. Break the swab tip leaving the swab tip in the collection vial.
6. Cap and invert vial several times. The sample is stabilized and ready for transport/storage prior to purification of DNA and/or RNA.



- ✓ Health check-in's: Study staff may periodically contact you to collect information about your current health status (about every 1 or 2 years).

What is expected of you if you join the study?

As a participant in the study, the study team asks that you:

1. Complete your virtual study visit with research staff.
2. Complete your cheek swab according to the instructions and mail the kit back to us.
3. Complete your health check-ins.
4. Call your study contact if there are any problems or if you are thinking about withdrawing from the study.

How long will you be in this study?

You will be in the study for about 1 week (for health history information and cheek swab collection). Follow up health check-ins could happen for several more years. It will include one virtual visit that will happen whenever is convenient for you.

What are the risks of being in this study?

The risks of joining this study are:

- Irritation after buccal (cheek) swab. This irritation is rare and resolves on its own if it does occur.
- Collection of your personal information: 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. We will do our best to protect your privacy, as explained in more detail later in this form.
- If you have questions about the study risks or do not understand any of the risks, you can contact one of the investigators of the study or the coordinator who enrolled you.

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.

What happens if you say yes but change your mind later?

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at Woman's.
- If you decide to stop being in the study, you may send an email to research@womans.org or mail a letter to Dr. Elizabeth Sutton at 100 Woman's Way, Baton Rouge, LA 70817.

Will it cost you anything to be in the study?

The study will not cost you anything.

Will you be paid for being in the study?

Yes. We will give you a $50 gift card. This is to pay for your time in the study. You will be paid in the form of a gift card either by mail, text message, or email after your cheek swab is received at our lab. If you change your mind and decide not to send in your sample, you will not receive compensation.

Will being in this study help you in any way?

We do not think that being in this study will help you personally. But it may help people with pregnancy-related cardiovascular diseases in the future. **Reminder**: You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

What information will be collected about you in the study?

During the study, we will need to learn private things about you, including:

- General contact and background information about you, such as your name, age, marital status, insurance type, education level, language spoken, employment status, zip code at time of delivery.
- Medical information about you, such as: general health and pregnancy history.
- You will perform a cheek swab at home and mail it in for testing. You must agree to this collection to be in the study. We will use your samples for genetic testing. This testing will look at the genes that may be responsible pregnancy-related and general cardiovascular diseases. Other genes may be studied as new research is available.
- We will do a genetic test called whole genome sequencing using your samples. This process allows us to see your entire genetic code. This code is what determines things specific to each person, such as hair and eye color and risks for diseases.
- We will not use the samples we collect from you for commercial profit. They will only be used to help us learn more about pregnancy related cardiovascular diseases.

Who will see this information? How will it be kept private?

- The local study team will know your name and have access to your information.
- We will do our best to keep your information confidential, but absolute confidentiality cannot be guaranteed.
- We will take your name off information and study samples collected from you during the study. We will give your information and study samples a code, so that no one can identify you.
- All of your genetic test results will be labeled with a code. We also want you to know that even though we will give your test results a code, those results are unique to you. As technology changes, it may become possible for people to identify you from these results.

- When we share the results of the study in medical journals and at scientific meetings we will not include your name or anything else that could identify you.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are:
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ Woman's Institutional Review Board
  - ✓ Woman's Hospital Research Center
  - ✓ Woman's Research and Development Committee
  - ✓ Tulane University
  - ✓ 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.

Are there extra privacy risks because of the genetic testing?

Yes. Genetic testing involves certain risks. Genetic testing can sometimes reveal information about you or, in some cases, your family members, since genetic conditions may be shared among relatives. If someone else learns about this information, there is a risk of being discriminated against, feeling stigmatized, or having trouble getting a job or insurance. Your genetic information is unique to you. So even if it does not include your name or other identifying information, there is also a risk someone could trace your information back to you. While the researchers think the chance of someone being able to identify you through your genetic information alone is small, this risk may change in the future as people find new ways of tracing information. The genetic testing will be done for research purposes only, and we do not plan to return any results to you or your doctor.

Where and for how long will your information and samples be kept?

- Your samples will be labeled with a de-identified code and sent to BGI Genomics (San Jose, CA) for analysis.
- Once we give your information and study samples a code, we will keep the key to this code in a locked file.
- Only Woman's Hospital research will be able to link it to you.
- Study data will be stored indefinitely at Tulane University and Woman's Hospital. The key to the code will not be destroyed so the investigators can still reach you for follow-up surveys and future research opportunities.
- We will not put information about you from the study in your medical record.

If you stop being in the study, what will happen to your information and samples collected in the study?

- We will be able to take your information and samples out of the study after it has started, if it has not yet been used in the study analysis or publications.
- If you wish to have your information and samples taken out of the study, call the study coordinator at (225) 428-7464 or email research@womans.org.

Will your information or samples from the study be used for anything else, including future research?

No. Your information will be used only for this study. It will not be used for future research, either with or without identifiers.

Will we tell you the results of the study?

This is up to you. If you opt-in and your genetic results show well-known mutations (differences in your DNA) we will send them to you. You can follow up with your doctor or a genetic counselor once you receive these results.

Also, we plan to publish the results in an academic journal, but what we publish will not include anything that can identify you.

What if new information comes up about the study?

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

How will the study team reach you?

The study team may contact you by phone, email, or text message about this research. There is a risk that any information sent in an unencrypted email or text message could be read by someone else. By giving the study team your email and/or phone number, you agree to receive unencrypted email and/or text messages.

What if you have questions?

- Please call the head researcher of the study – (Elizabeth Sutton at 225-924-8446, or the coordinator who contacted you at 225-428-7464)– if you:
  - ✓ have any questions about this study
  - ✓ feel you have been injured in any way by being in this study
- You can also call the research office at Woman's if you cannot reach the study team, have questions about your rights as a research participant, or want to speak to someone not directly involved with this study. To do so, call Ericka Seidemann, Human Protections Administrator, at 225-231-5296 or email research@womans.org.

SIGNATURES

By signing the document, I am saying:

- ✓ I agree to be in the study.
- ✓ I know that joining this study is voluntary.
- ✓ Someone has talked with me about the information in this form and answered all of my questions.

I know that:

- ✓ I can stop being in the study at any time without any penalty.
- ✓ I can still get medical care at Woman's no matter what I decide.
- ✓ This study has been reviewed and approved by an Institutional Review Board.
- ✓ I can call the research office at Woman's at 225-231-5296 if I have any questions about the study or about my rights or I can call the study investigator at the number at the top of this form.
- ✓ I do not give up any of my legal rights by signing this form.
- ✓ I have been given a copy of this form.

I agree to be part of this study:

_____	_____	_____
Your name *(please print)*	**Your signature**	**Date**

_____	_____	_____	____:____
Printed name *(person obtaining consent)*	Signature *(person obtaining consent)*	Date	Time

I want my genetic results shared with me if possible: *check one*

___ YES ___ NO

I agree to be contacted for future cardiovascular research related to this study: *check one*

___ YES ___ NO

_____	_____	_____
Your name (please print)	**Your signature**	**Date**

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

Woman's IRB

Initial Approval Date: May 06, 2024
Study Expiration Date: May 06, 2025
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