CONSENT TO PARTICIPATE IN A RESEARCH STUDY
-COVER SHEET-

Study title: *RIPP Study: Respiratory Illness, the COVID-19 pandemic, and Pregnant Women and their Offspring*
Study Sponsor: *NIH*

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 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 the study is to learn about the effects of lung infections (also called 'respiratory illnesses'), like COVID-19, the flu, and Respiratory Syncytial Virus- also called "RSV", in mothers and their babies, as well as other stressors of 2020 on maternal mental health.
- *Your time* in this study will be 1 study visit during your third trimester and 2 follow-up surveys after you deliver your baby.
- The *procedures* involved in this study include:
    - A blood draw
    - Collecting information about you and your medical history and mental health (study surveys)
    - Reviewing your and your baby's medical record
    - Optional: collection of samples of your cord blood and placenta at your delivery
- You will earn up to $225 for this study in gift cards: $75 at the study visit, then $75 for each of the two surveys completed after you deliver your baby.

What are the possible risks and discomforts?

This study involves no more than minimal risk to the participants. When blood is drawn, there is a small risk for lightheadedness, dizziness, and fainting. There is also a chance of infection and/or pain and bruising at the vein on your arm where the needle is put.
We will follow all standard procedures of research at Woman's Hospital to ensure your privacy.

What are the possible benefits?

We cannot promise any benefits from your being in the study. If you join, you may be helping future moms by contributing to what we know about maternal mental health and respiratory illnesses.

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 are no other choices.

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

Respiratory Illness, the Pandemic, and Pregnant Women and their Offspring: The RIPP Study

Principal Investigator: **Elizabeth Sutton, PhD**
Woman's Hospital, Research, Baton Rouge, LA
Co-Investigator: **Emily Harville, PhD**
Tulane University, Department of Epidemiology, New Orleans, LA

Who do you contact for questions about the study? Call Dr. Sutton at (225) 924-8446

1- What is the purpose of this study?

This is a research study to learn about respiratory illness like COVID-19, RSV and the flu in pregnant women and their babies, along with other stressors of the last few years on maternal mental health.

2- Who can join this study?

Women who are pregnant with one baby can join this study. Up to 500 women will be in this study at Woman's Hospital.

3- What will happen to you if you join the study?

The RIPP Study (*Respiratory Illness, the Pandemic, and Pregnant Women and their Offspring* study) and this form will be gone over with you before any study tests are done. If you decide to join, your total time in the study will be **1 study visit** and **2 surveys**. The surveys will be done 6 weeks and 6 months after you have your baby. You will answer questions either by yourself online, over the phone, or in person. It may also be offered to you to collect samples of your cord blood and placenta when you deliver your baby. What happens at each of these visits is listed below:

Study visit: About 30 minutes
When: During your 3rd trimester of pregnancy
Where: At Woman's Hospital

- **Review and sign the informed consent form** (this document)
- **Collect your health information**: The study team will ask you questions about your general medical history, mental health and thoughts about recent events.
- **Take a blood sample:** A blood draw of about 3 tablespoons will be collected.
- **Permission to use medical records for the study:** You will sign permission forms to allow the study team to request your and your baby's medical records.

Surveys: About 30 minutes
When: 6 weeks after delivery, 6 months after delivery
Where: Online, over the phone, or at Woman's Hospital (up to you)

- **Collect your health information:** Questions similar to those asked in the first visit will be asked again with the addition of information about your baby and parenting.

Woman's IRB RP Number: RP-22-012
Revised Approval Date: November 27, 2023
Expiration Date: N/A

****Collection of cord blood and placenta (called "delivery biospecimens") at delivery of your baby is optional****

Delivery biospecimens: Should you provide permission, the following will happen at your delivery:
When: When you deliver your baby
Where: At Woman's Hospital

- **Notification of study team:** If possible, the study asks you call or message the study team upon admission for delivery or scheduling of delivery.
- **Collection of cord blood:** The study team will collect a sample of the baby's cord blood, up to 50mL, after you baby has been delivered. This collection might happen while your placenta is still attached or after your placenta has been delivered.
- **Collection of placenta:** The study team will take small pieces of your placenta after it has been delivered.

Add your initials below to agree or not agree to have your delivery biospecimens collected:

Yes, I give permission: _____
Your initials

No, I do ***not*** give permission: _____
Your initials

For research staff only:
☐ *Check here if delivery biospecimen*

4- What are the possible risks and discomforts?

Risks from study procedures could include:

- **Blood sample**: There is the chance of infection and/or pain and bruising at the vein on your arm where the needle is put in. A small risk for lightheadedness, dizziness, and fainting is possible.
- **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.
- **If you have questions** about the study risks or do not understand any of the risks, you can ask Dr. Sutton. Although the chance of the listed risks are small, they do exist. If they occur, Dr. Sutton and her team will watch you closely and take appropriate medical action. Your primary care doctor is still responsible for your medical care.

5- What are the possible benefits?

We cannot promise any benefits from your being in the study. If you join, you may be helping future moms by contributing to what we know about maternal mental health and respiratory illnesses.

6- 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. You can also call ***Dr. Cathy Griffiths***. She is the Chief Quality Office over Research. Her phone number is 225-924-8739.
- 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.

7- If you do not want to join the study, are there other choices?

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 on.

8- Can you stop being in the study?

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 or email research@womans.org.

9- 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, study is canceled, or for other reasons.

You may withdraw from the study at any time without penalty; however, information Woman's and Tulane University has previously collected cannot be removed from the study. Early withdrawal from the study would result in not receiving total study compensation. ***If you decide you would like to withdraw your consent***, you must notify the study coordinator (call, text message, email, or letter) and/or mail a written request to the Principal Investigator at: Elizabeth Sutton, 100 Woman's Way, Baton Rouge, LA, 70817.

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

During this study, there may be new findings from this or other research which may affect your desire to continue. Information about any such new findings will be given to you.

11- What information will be kept private?

Every effort will be made to keep the confidentiality of your study records. Someone from Woman's Hospital Foundation Institutional Review Board, Woman's Hospital Research 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.

- 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 taking off your personal information from the data and samples. 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: Test results performed on your blood sample will not be shared with you or your baby, but results 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 or Identifiable Biospecimens: Any information that could identify you (called an "identifier") will be removed from your information. After this removal, the information or biospecimens could be used for future research studies or given to another investigator for future research without additional informed consent from you.

12- What charges will you have to pay?

None.

13- What payment will you get?

We will earn up to $225. A $75 gift card will be provided at the end of your in-person visit. When you finish the two surveys after you deliver, you will be given a $75 gift card (by mail, text message, or email) each time.

14- What if I have a study-related injury?

There is no money to pay your costs if you have an injury because of this study. Medical care can be gotten easily if an injury happens. The cost of this medical care will be the responsibility of you and/or your insurance company. You should call Dr. Sutton if you are hurt while taking part in this study: (225) 924-8446.

15- 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.

16 -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** **use military time*
_____	_____	____/____/____	__ __:__ __
Printed Name of **Person Obtaining Consent**	Signature of **Person Obtaining Consent**	**Date**	**Time** **use military time*

Woman's IRB RP Number: RP-22-012

Revised Approval Date: November 27, 2023
Expiration Date: N/A

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

17- What you need to know about future research with your biospecimens?

Research with your biospecimens (like blood and placenta) can help to find out more about understanding how the body works and causes of diseases, like pregnancy-related diseases as well as metabolic conditions like diabetes and heart disease. With your permission, your samples may be sent to researchers outside of the Woman's Hospital and Tulane. Any personal information that could identify you will be removed before the samples are shared.

What you should know about your biospecimens:

- The samples will be stored indefinitely (this means, without a set end time).
- If you agree to have your samples stored, you can change your mind later.
- For privacy and confidentiality, your samples will be labeled with a unique series of letters and numbers. Woman's and/or Tulane will store your samples with this unique identifier and the minimum number of personal identifiers to meet laboratory standards.
- The future research may or may not take place at Woman's or Tulane and may or may not involve Woman's or Tulane Researchers.
- You will not be compensated for any research studies that might be conducted in the future.
- You will not be told of the details of any specific research studies that might be conducted in the future.
- The collection of samples may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases.
- The research done with your specimens may also help to develop new products in the future, or may be used to establish a cell line or test that could be patented or licensed. You will not receive any financial compensation for any patents, inventions, or licenses developed from this research.
- Your samples that are collected for future research will not be have whole genomic, germline, somatic, or exome sequencing. This means that the researchers have no plans to look at or try to "read," the protein information that makes up your genes (DNA) from your sample.

Blood: If you give permission, your left over blood (up to 3 tablespoons) will be stored by this study. Your stored samples may be tested at Woman's or Tulane University or other locations used in future research. ***Do you give permission for your blood and data collected as part of this project to be used in future research?***

Yes, I give permission: _____ ***No***, I do ***not*** give permission _____
Your initials Your initials

Tissue: If you give permission, your left over tissue (tissue not be used for the purposes of the current study) will be collected and stored by this study. Your stored samples may be tested at Woman's or Tulane University or other locations used in future research. ***Do you give permission for your tissue and data collected as part of this project to be used in future research?***

Yes, I give permission: _____ ***No***, I do ***not*** give permission _____
Your initials Your initials