The Effect of COVID-19 on the Microbiome during Pregnancy
The "COMB" Study

Principal Investigator:

Elizabeth Sutton, PhD
Research | Woman's Hospital
100 Woman's Way, Baton Rouge, LA 70817

Medical Monitor:

Beverly Ogden, MD
Woman's Hospital
100 Woman's Way, Baton Rouge, LA 70817

Co-Investigators:

Emily Harville, PhD
Sam Sherchan, PhD
Tulane University
1440 Canal Street, Suite 2000
New Orleans, LA 70112

Karli Boggs, MD
Felicia LeMoine, MD
Kaitlyn Taylor, MD
Louisiana State University Health Sciences Center
500 Rue de la Vie, Suite 400
Baton Rouge, LA 70817

Who Do You Contact for Questions About the Study?

- **Call Dr. Sutton at (225) 924-8446**
- **Email research@womans.org or Dr. Sutton at Elizabeth.Sutton@womans.org**

Purpose

- Your "microbiome" is made up of the bacteria and viruses that naturally live in and on our bodies.
- This is a research study to look at how the microbiome changes in pregnant women with or without COVID-19 infection.
- You are being asked to be in this study because you are pregnant or recently had a baby
- Pregnant women who had COVID-19 or have not had COVID-19 are being asked to take part in this study

About the Study

- About 160 pregnant or newly postpartum women will be in this study at Woman's Hospital.
- Your total time in this study will be about 1 hour.

If you choose to be in the study, the study and this document will be discussed over the phone or in person with you (or with your legally authorized representative). The study will be discussed with you before you have any tests performed.

Study Visit

There is only 1 visit in this study. The study visit will include:

- **Review of the informed consent form (this document)**
- **Collecting information about you:**
  - Review of what medicines you have taken or take now
  - Review your health
  - Review of any coronavirus symptoms and testing
- **Mouth swab:** a swab will be rubbed on the inside of your mouth for less than 1 minute

- **Rectal swab:** a swab will be rubbed on the inside of your rectum for less than 1 minute by your healthcare provider (nurse or doctor)
- **Collection of your left-over blood samples:** if any of your blood that was drawn for labs your healthcare provider ordered is left-over once all your tests are run, this blood will be stored for future studies about COVID-19 and the microbiome in pregnancy

Once collected, your samples will be stored at Woman's Hospital and then shipped to Tulane University for analysis of your mouth and gut microbiome. Your left-over blood samples for future study will also be stored at Tulane University indefinitely and will not be shared with researchers outside of this study.

Your Medical Record

The study team will collect data from your medical records for the study after you deliver your baby. We will collect data about your pregnancy, delivery, and your baby's health.

Benefits

There is no direct benefit for being in this study. What we learn during this study may help us understand the impact of COVID-19 in pregnant women in the future.

Risks

- **Mouth swab**: There are no known risks in swabbing your mouth. However, in some cases, swabbing of your mouth could be uncomfortable during the collection.
- **Rectal swab**: There are no known risks for a rectal swab. However, in some cases, swabbing of your rectum could be uncomfortable during the collection. If you had an epidural during your labor, it is possible you may not be able to feel the swab.
- **Blood sample**: Because the study will use "left-over" blood, there is no needle stick needed to collect a blood sample for this study.
- **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 extremely tight security measures, we will let you know if we discover this happens.

Alternatives to Taking Part

The other option is not to be in the study.

Can you Stop Being in the Study?

- Joining this study is your choice.
- Not wanting to be in the study will involve no penalty or loss of benefits which you would normally have.
- You may quit the study at any time without penalty or loss of benefits to which you are otherwise entitled.
- You may refuse to participate or withdraw from the study at any time without affecting your medical treatment. Any data information or samples not yet used at that time for study results will be deleted and destroyed.
- If you withdraw from the study, any remaining leftover serum/plasma being stored for future use related to this project will also be destroyed.
- To stop being in the study or discuss stopping, you should contact the study coordinator by phone at 225-231-5275 or email (research@womans.org).

Confidentiality and Privacy

- You will not be identified in any way if the results of this study are published. Your personal information may be disclosed if required by law.
- 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.
- Some agencies may view or copy your study information or your medical record data to make sure the study data is correct.
- By signing this form, you are allowing these agencies to see that information. They may include: Woman's Hospital Foundation Institutional Review Board, Woman's Hospital Research Center and collaborators, Woman's Hospital Research and Development Committee, and federal agencies as required by law.

Collection of identifiable private information

Personal identifiers (like your name and date of birth) might be removed from the study data in the future. The data that does not identify you may be used for future research studies or given to another investigator for future research.

Financial Information

Being in this study will not cause extra charges. The mouth and rectal swab will be paid for by Woman's Hospital. You will not be paid for being in the study.

Who Do You Contact for Questions About the Study?

Contact the Dr. Elizabeth Sutton at (225) 924-8446 with questions about the study procedures or any concerns. Contact Ericka Seidemann, Human Protections Administrator, at (225) 231-5296 if you have any concerns or complaints about the study, or for questions about your rights as a research subject.

IF THE PATIENT IS COVID-19 POSITIVE OR SUSPECTED COVID-19 POSITIVE: The study staff obtaining informed consent should document that an informed consent discussion occurred, the method by which it occurred (in person, via phone, etc.), and the subject's understanding of the information presented.

If consenting is done via phone:

- Have a three-way phone call with the participant, investigator, and a witness
- Identify who is on the call
- Have the witness confirm that all questions are answered
- Have the investigator confirm that the participant consented to take part and has signed the consent document

To document informed consent:

- Have the participant (or LAR) sign the consent form and keep the original
- Place a copy of the consent form in the participant's chart, signed by the investigator and a witness
- Include a statement in the chart about how consent was obtained (in person, via phone, etc.)
- Include a witness confirmation that the participant consented
- Include a statement that the original consent form cannot be retained due to contamination concerns

Signatures

BLOOD SAMPLES FOR FUTURE USE: Add your Initials below to agree or not agree to have your blood stored for future research related to this project:

_____ (initials) Yes, I **AGREE** to the storage of my blood for future use related to this research project (microbiome and COVID-19 research)

OR

_____ (initials) NO, I do **NOT** agree to the storage of my blood for future use related to this research project (microbiome and COVID-19 research)

SURVEY: If you are in or plan to be in the *Pregnant during COVID-19 Research Study*, researchers would like to link your survey responses and your medical record data to your microbiome samples. Add your Initials below to agree or not agree to have your information linked:

_____ I **AGREE** to having my past and future survey responses and medical data from the study, *Implications of and Experiences Surrounding Being Pregnant During the COVID-19 Pandemic*, included with my participation in this study.

OR

_____ I **DO NOT** agree to having my survey responses and medical data from the study, *Implications of and Experiences Surrounding Being Pregnant During the COVID-19 Pandemic*, included with my participation in this study.

This study has been explained to me and my questions have been answered. I can call the study investigator(s), listed on page 1, with any further questions I may have. This study has been reviewed and approved by an Institutional Review Board. I have been given a copy of this consent form. I agree to take part in this study. I have not waived any of my legal rights by signing this form.

_____	_____	__ __ : __ __
Signature of Subject	Date	Time
_____	_____	__ __ : __ __
Signature of Investigator	Date	Time
_____	_____	__ __ : __ __
Signature of Person Obtaining Consent	Date	Time
_____	_____	__ __ : __ __
Signature of Witness to Verbal Consent*	Date	Time

**Required for patients with COVID-19 infection or suspected infection*

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