

CONSENT FORM COVER SHEET
Version 2 | November 3, 2020

Study title: **The COMB Study: The Effect of COVID-19 on the Microbiome during Pregnancy**
Principal investigator: **Elizabeth Sutton, PhD**

You may be eligible to take part in a research study. 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 today, you are free to leave at any time if you change your mind.

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

- This is research. Doctors and scientists do research to learn about diseases and how to treat them. Research can be different than regular medical care. The purpose of this study is look at how the microbiome changes in pregnant or newly postpartum women with or without COVID-19 infection. Your “microbiome” is made up of the bacteria and viruses that naturally live in and on our bodies.
- Your time in this study will last for about 1 hour.
- There is only 1 visit in this study. It will include:
 - Review the informed consent form
 - Collecting information about you: your medicines, your health, and coronavirus testing and symptoms
 - 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 study
- The main risks for taking part in this study are: loss of confidentiality and possible discomfort during the mouth or rectal swab.
- If you decide not to take part, there is not another option for this study.
- This study is being done with researchers at Tulane University. Your study data and specimens will be shared with them.

Please take the time to read this entire consent 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 make a decision about taking part.

If you decide to take part in the study, you will be asked to sign this form.