

CONSENT FORM COVER SHEET

Study title: **The TOCO Study: Efficacy of Ibuprofen versus Indomethacin as Perioperative Prophylactic Treatment following Emergent Cerclage Placement for Pregnancy Prolongation, A randomized controlled trial**

Principal investigator: **Dr. Pamela Simmons**

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 to see if two medicines have the same chance to help stop preterm labor and prolong pregnancy at the time you have a cerclage placed. The two medicines are: ibuprofen and indomethacin. Both medicines are taken by mouth.
- Your time in this study will last up to 6 months.
- There is only 1 visit in this study. It will include:
 - Reviewing the informed consent form
 - Collecting information about you: your medicines, your health, your pregnancy
 - Assigning which medicine your doctor will give you after your cerclage placement
 - After you deliver your baby, information from your delivery record will be collected.
- The main risk for taking part in this study is loss of confidentiality.
- If you decide not to take part, there is not another option for this study.
- This study is being done with researchers at Woman's Hospital and the LSU-OB/GYN Clinic. Your study data 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.