PATIENT INTERVIEW CONSENT FORM
PARTUM TRIAL

TITLE: Patients' perspectives about conducting postpartum research – A substudy of the pilot PARTUM trial (Postpartum Aspirin to Reduce Thromboembolism Undue Morbidity)

SPONSOR: University of Calgary

PRINCIPAL INVESTIGATOR: Dr. Leslie Skeith, Telephone: 403-944-5246

RESEARCH COORDINATOR: Alexandra Garven, Telephone: 403-220-7631

This consent form is only part of the informed consent process. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand all information given to you. You will receive a copy of this form for your records.

BACKGROUND

You are being asked to take part in this research study because you are postpartum and have known risk factors for blood clots. Some women are at risk for developing blood clots in the legs or lungs (thrombosis) after they deliver a baby (postpartum). A blood clot can form in the lungs, which can be serious. The risk of blood clots is highest in the first 6 weeks following delivery.

While we know what the risk factors are for getting a blood clot after delivery, we still don't know what the best way is to prevent blood clots. Previous research trials tried to see if using daily injectable blood thinners after delivery could prevent blood clots. These trials were not successful because taking daily injectable blood thinners at home was not very popular. Many women who deliver babies and have modest risk factors for blood clots may be given injectable blood thinners while they are in hospital, but they usually do not go home on injectable blood thinners. A research trial called the pilot PARTUM trial is ongoing to see if taking low dose aspirin for 6 weeks after delivery can safely prevent blood clots compared to placebo pills.

We are interviewing postpartum women who have known risk factors for blood clots, to learn more about their experiences and barriers to take part in a research trial like the pilot PARTUM trial during a busy postpartum time.

We estimate that 15 participants from Calgary will be included in our interview study, to learn what is working and what is not working for our pilot PARTUM trial. Participants that take part in this interview study do not have to take part in the pilot PARTUM trial. The pilot PARTUM trial will include 384 participants from 8 centres around the world.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this interview study is to better understand different patient's perspectives and barriers in taking part in a postpartum research study like the pilot PARTUM trial. This will allow us to improve our larger research study, so we can better care for postpartum women who are at risk of blood clots.

WHAT WOULD I HAVE TO DO?

If you choose to take part, you will be contacted to take part in a single confidential 30-minute interview with one of the members of our research team. This can take place in person or over the phone at your convenience. The interview will be recorded, but they will be confidential with no identifying information collected.

WHAT ARE THE RISKS?

We will be talking about your experiences during a busy postpartum time, which can be a stressful or sensitive topic. You do not have to answer any questions that make you feel uncomfortable, and it is up to you how much information you choose to share.

There is a risk of a privacy or confidentiality breach, but we will take precautions to protect your personal information and we will only collect and use the minimal amount of information needed to answer our research question.

WILL I BENEFIT IF I TAKE PART?

If you agree to take part in this study, there may not be a direct benefit to you. Hearing your perspective will allow us to improve our larger research trial for patients like yourself, which looks at identifying better treatments to prevent blood clots for postpartum women.

DO I HAVE TO PARTICIPATE?

Your participation in this study is voluntary. The alternative to this study is not to take part. It will not affect your medical care if you decide not to be in this study, or to be in the study now, and then change your mind later. Not being in the study will not affect your medical care. If you withdraw your consent, the research team will no longer collect your personal health information for research purposes.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will not receive any money for participating in the study. If you choose to conduct the interview in person, then we will reimburse you for your parking.

WILL MY RECORDS BE KEPT PRIVATE?

We will protect your confidentiality.

- All information collected during your participation in this study will be given a unique study number, and will not contain information that identifies you, such as your name, address, etc.
- The link between your unique study number and your name and contact information will be stored securely and separate from your study records and will not leave an Alberta Health Services facility.
- Any documents leaving an Alberta Health Services facility will contain only your unique study number. This includes publications or presentations resulting from this study.
- Information that identifies you will be released only if it is required by law.
- Research records will be kept for 8 years, after this time they will be destroyed.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of taking part in this study, no compensation will be provided to you by the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form changes your right to seek damages.

SIGNATURES

Your signature on this form means that you have understood the information about your participation in the research project and agree to take part. In no way does this remove your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without affecting your health care. If you have further questions about this research, please contact:

Dr. Leslie Skeith: (403) 944-5246

Alexandra Garven (research coordinator): 403-220-7631

If you have any questions about your rights as a possible participant in this study, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

Participant's Name	Signature and Date
Investigator/Delegate's Name	Signature and Date
Witness' Name	Signature and Date

☐ **Witness Signature Required?**

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.

PARTUM

Participant Contact Sheet

Full Name: _____

MRN: _____

Phone Number: _____

Secondary Phone Number: _____

Email: _____

Preferred Method of Contact: Phone ☐ Email ☐

Address: _____

_____

_____

Baby's Name: _____

Baby's Sex: Male ☐ Female ☐

Emergency Contact

Full Name: _____

Relationship: _____

Phone Number: _____