INFORMED CONSENT and HIPAA AUTHORIZATION

Study title- short: Oli Study

Study title- full: A prospective, multi-center, single-arm clinical study to assess the performance of a predictive, non-invasive device in predicting cumulative blood loss ≥500mL or any blood loss with signs and/or symptoms of hypovolemia within 24 hours after the birth process

Study Sponsor: Baymatob Operations Pty Ltd

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 health and 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 this study is to test a device and see if it can predict who may have heavy bleeding after giving birth.
- *Your time* in this study is about 2 days. If you chose to join the study, the ***Oli*** would be put on when you are in labor and removed after you give birth. Later that day or the next day, a study team member will visit to ask about your feelings about the device.
- The *procedures* involved in this study include:
    - Answering questions about yourself, your health, and your pregnancy
    - Wear the ***Oli*** when you are in labor (or as long as possible/comfortable)
    - Answering a short survey after your baby is born

What are the possible risks and discomforts?

There is a possibility of skin irritation or discomfort where the ***Oli*** touches your body. Staff can take it off or assist with this discomfort if it happens. The possible risks and discomforts are believed to be minimal.

What are the possible benefits?

It is possible that you may not receive any benefit from this study, but this research may help doctors take better care of pregnant patients in the future.

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 is no other option, but you will still get your usual care.

Will I get paid?

You will get a $50 gift card after you complete the survey about your feelings on wearing Oli.

Please take the time to read this entire 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 decide about taking part in the study.

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

Woman's IRB RP Number: RP-25-024-WH
Revised Approval Date: November 19, 2025
Expiration Date: October 05, 2026

The Oli Study: *A prospective, multi-center, single-arm clinical study to assess the performance of a predictive, non-invasive device in predicting cumulative blood loss ≥500mL or any blood loss with signs and/or symptoms of hypovolemia within 24 hours after the birth process.*

Principal Investigator: ***Elizabeth Sutton, PhD***
Woman's Hospital
100 Woman's Way, Baton Rouge, LA 70817

Medical Monitor: ***Alison Rodriguez, MD***
Woman's Hospital
100 Woman's Way, Baton Rouge, LA 70817

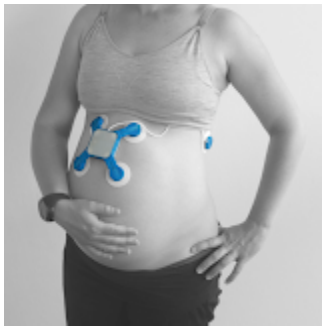
Study-related phone number (24 hours): 225-512-5546

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from Woman's even if you are not in the study.**
- **Take as much time as you need to read this form and decide what is right for you.**

What is the purpose of this study?

- Bleeding after childbirth is normal and expected. Postpartum hemorrhage is heavy bleeding (more than expected) after childbirth. It is the leading cause of maternal deaths around the world.
- In the last 40 years, the number of deaths from postpartum hemorrhage have not gotten better.
- Right now, doctors have a hard time guessing if postpartum hemorrhage will happen and only see this bleeding after bleeding has begun.
- The purpose of this study is to test if the ***Oli*** can predict postpartum hemorrhage before childbirth.

The Oli Wearable



Who can join this study?

Women who are at least 18 years old, at least 36 weeks pregnant, and in labor can join this study.

What will happen to you if you join the study?

The study and this form will be reviewed with you before any study activities are done.
If you decide to join, your total time in the study will be about 2 days.
If you join the study, your doctor and nurses will know you are in the study.

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Description of Study Procedures

- **How many people will be in the study?** About 1,000 laboring women across the United States and Australia will be participating in this study. We expect about 150 women from Woman's will complete the study.
- **Length of time in the study:** You will be in the study for about 2 days. If you chose to join the study, the ***Oli*** would be put on when you are in labor and removed after you give birth. Later that day or the next day, a study team member will visit to ask about your feelings about the device.
- **Informed Consent:** If you choose to be in the study, the study and this document will be discussed with you. You will have all your questions answered and verbally agree to be in the study and sign this form before any study procedures begin.
- **Study procedures:**
    - **Health history**: We will ask you questions about yourself, your health, and your pregnancy.
    - **Device**: You will wear the ***Oli*** on your belly during labor. It will be removed after delivery.
    - **Survey**: You will answer a survey about your thoughts on the device, like how comfortable it was to wear.
    - **Medical record review**: The study team will collect information from your and your baby's medical records for the study after you deliver your baby. We will collect data about your pregnancy, delivery, and your baby's health.

If you join the study, you can choose to have the study team let your doctor know.
Add your Initials below to agree or not agree:

_____ **Yes**, I AGREE to the study team letting my doctor know I joined the Oli study.

OR

_____ **No**, I do NOT agree to the study team letting my doctor know I joined the Oli study.

What is expected of you if you join the study?

If you join the study, the study team asks that you:

- Wear the ***Oli*** for the duration of your labor at Woman's Hospital
- Call the study coordinator if you have any questions or concerns or if you would like to stop being a part of the study.

What are the possible risks and discomforts?

There is a possibility you can get a skin rash or irritation where the device touches you. If this happens we will remove the device and check if further treatment is needed. If you know you have sensitive skin or allergy/hypersensitivity to the medical gel or adhesive used to attach the electrodes to your body, it is recommended that you do not join the study. Persons responsible for the removal of the ***Oli*** are thoroughly trained in proper removal techniques.

What are the possible benefits?

The study does not offer direct benefit for either the participant or their unborn baby. The purpose of research is the development of important knowledge, which may help other moms or babies in the future.

If you have any questions or problems, whom can you call?

- Call the Research Coordinator at 225-512-5546 with any questions.
- Call ***Ericka Seidemann***, Woman's Human Protections Administrator, at 225-231-5296 with questions about your rights as a research volunteer, concerns, or suggestions about the study.
- Call ***Dr. Rodriguez*** at 225-924-8980 with questions about the research study or if you think you have a research-related injury or medical illness.

What if you say you don't want to be in this study?

- Nothing bad will happen because of what you decide.
- You can still get medical care at Woman's.
- 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 and quit.
- If you don't want to join, there is no other option.

Can you stop being in the study? What happens if you change your mind?

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 (call or text) at 225-512-5546 (24 hours) or email research@womans.org. There are no consequences for withdrawal.

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, the study is canceled, or for other reasons.

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

We will tell you if we learn anything that may change your mind about being in the study.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. If you sign this form, you agree for the researchers at Woman's Hospital to use or give (disclose) your health information/record that identifies you for this study. The information that will be given to the researchers is for this study only. Your information will be used by the study team connected with this project. Woman's Hospital is required by law to protect your health information. By signing this form, you let Woman's Hospital use and/or release your health information for this research. Those persons who get your health information may not be required by laws to protect it and may share your information with others without your permission, if allowed by laws governing them.

What health information may be used or released for this study? This will include information from your medical records, procedures, interviews, and tests. Information related to your medical care at Woman's Hospital will go in your research record. This could include anything in your medical record, including physical exams, imaging studies or tests done in the lab. Medical records are available to Woman's Research staff. Staff will view your records only when needed as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone unless you provide your written consent, or it is required or allowed by the law.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples.

The health information listed above may be used by and/or released to:

- Members of the research team and other authorized staff at Woman's Hospital
- Baymatob Operations Pty Ltd and their contracted research organization Avania
- Federal agencies as required by law
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else

We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be shared if required by law. The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals about the study and its findings. We will keep your identity private in any publication or presentation. The information from this study could be used for future research studies or given to another investigator for future research without additional informed consent from you. Before the information is shared, any information that could identify you will be removed from your identifiable information.

When I sign this form, how long does my permission last? There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely done.

By signing this form, you are saying you understand that:

- This form is to allow the release of my health information for use in the research study listed on the first page.
- Plans for how my health information will be used is written in this form.
- Researchers may use my information to see if I can be in this study.
- My data can be transported outside of the geographic region for the study.
- Researchers may use my information to check results for the study.
- Researchers may use my information to check on side effects from the study.
- Woman's Hospital staff may use this information to see that the study is being done how it should be.
- Study monitors may use this information to see that the study is being done how it should be.
- This health information may be given to insurance companies for medical bills.
- I can cancel this permission to release information at any time before the information has already been released. To cancel, I should contact anyone on the study team or send a written letter to the person on the consent form.
- If my health information has been added to a research database or registry already and there is no identifying information, my information cannot to be taken out.

- If I do not sign this form, I will not be able to take part in this study. But I understand that Woman's Hospital will not change my medical care based on if I sign this form or not.

- I understand there is a chance that information released by this agreement may be re-disclosed by whomever gets my information, that it may no longer be protected by HIPAA.
- I understand a photocopy of this form may be relied upon as if it were the original.

What charges will you have to pay?

None. The study will not cost you anything. You or your insurance company will be responsible for the costs of your regular medical care, as usual.

Will you receive payment?

If you join the study, you will get a $50 gift card after you complete the survey about your feelings on wearing Oli.

Will we tell you the results of the study?

No. We will not tell people in the study about what we find with the device. The results of the device are hidden from us, and only standard Woman's monitoring will be used to inform your clinical care. At the close of the study, there is a chance that results on how the device works will be published, and that information will be available to you. What is published will not include anything that can identify you.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. The ClinicalTrials.gov ID number is NCT06655207.

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.

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 understand that there will be no penalty or loss of benefits by refusing to participate in this study or deciding later that I do not want to participate in this study or revoking my consent. 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**

_____	_____	____/____/____	____:____
Printed Name of **Person Obtaining Consent**	Signature of **Person Obtaining Consent**	**Date**	**Time**

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