Biometrics in Longitudinal Uptake for Early Monitoring and Assessing Perinatal Patterns of Emotions in Depression (BLUESMAPPED)

NCT number: TBD
Version: May 12th 2026

Informed Consent Form for Participation in the BLUESMAPPED Study

Study Title: Biometrics in Longitudinal Uptake for Early Monitoring and Assessing Perinatal Patterns of Emotions in Depression (BLUESMAPPED)

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INTRODUCTION

Perinatal depression is a type of depression that affects individuals during pregnancy or within the first year postpartum. This study investigates the use of using wearables - electronic devices worn to measure different health information - to obtain data to help predict the individual risk of developing this type of depression in women who had already had depression at least once in her life. In this initial study (also known as a pilot study) we will assess participant comfort and satisfaction with using wearables during the perinatal period as well as the quality and completeness of the data gathered with the wearable.

This consent form describes this research study and provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your family, friends, your personal physician, other health care professionals and elders, or any trusted members of your community.

Taking part in this study is voluntary. You do not have to participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

The goal of this study is to see if wearable devices (like smartwatches or fitness trackers) can collect information that helps us figure out the chance of someone getting depression during pregnancy or after giving birth. We also want to know how people feel about wearing these devices during this time—if they are comfortable and happy using them. In the future, we hope to build a tool that can help predict who might get depression, using the information from the wearables. This could help doctors and nurses give support earlier.

HOW MANY PARTICIPANTS WILL TAKE PART IN THIS STUDY?

It is anticipated that 10 people will be recruited to take part in this study.

This study should take 2 years to complete and the results should be known in about 6 months after conclusion. You will be expected to participate for 6 months but you may choose to

continue using the wearable for another 3 months after that.

WHAT WILL HAPPEN DURING THIS STUDY?

Research Tests and Procedures

During this study, you will be asked to complete a variety of tests and assessments . Some of these will overlap with clinical care (i.e. EPDS once every 3 months). Other tests will be conducted solely for research and will not be part of your regular clinical care. These tests include:

1. Continuous Monitoring: You will be randomized to either receive a wearable device, either the Oura Ring or the EmbracePlus watch. Data from either device will be collected continuously starting from enrollment. Both devices track heart rate (HR), temperature and sleep patterns.
2. Mood, Anxiety, and Energy Self-Assessment: Daily self-ratings of mood, anxiety, and energy levels will be recorded using a form sent electronically.
3. Questionnaires and Surveys: Every two weeks, you will complete 2 forms. These will measure your symptoms of depression and anxiety, which are important for predicting future mental health outcomes. You will also complete questionnaires every two weeks regarding life events and health complications, and use of health services.
4. Final Assessment: At 3 months postpartum, you will undergo a final assessment. A subset of participants will be invited to participate in semi-structured qualitative interviews about your experiences in the study.
5. After the 3 months, you may choose to continue tracking and using the wearable for another 3 months. In this case an additional exit questionnaire will be done at 6 months.

Information Collected	Prior to enrollment	At baseline	Daily	Continuously	Every 2 weeks	3 months post-partum
Eligibility	x					
Baseline Information		x				
Qualitative interview on Participant Study Experience with wearable and study duration(Optional interview)						x
Sleep, Activity, Heart Rate				x		
Mood, Anxiety, Energy			x			x
Clinical Symptoms Questionnaires and Surveys					x	
Life Events Questionnaires and Surveys		x			x	x

Birth Outcomes						x
Depression Relapse		x	**As indicated			x

**Depression relapse information is collected if symptoms suggest potential relapse.

Research Interviews

You may voluntarily participate in one semi-structured qualitative interview. The interview will take about one hour, either in person or via a secure video conference, and will explore your experience in the study.

Participant Data and Duration

You will participate in this study from enrollment through 12 weeks postpartum. The total participation duration includes the time of continuous data collection via the Oura ring/EmbracePlus watch, time completing assessments throughout the study, as well as the time participating in the exit interview if selected. The daily questionnaires take approximately 5 minutes to complete, and the biweekly questionnaires take approximately 15 minutes to complete. Interviews last 45 minutes to 1 hour (baseline and exit) . After the exit interview you may choose to continue using the wearable and tracking symptoms for another 3 months. Your participation will end at 6 months post-partum.

Important Notes

- Results from the research-specific tests will not be shared with you, your healthcare provider, or included in your medical records unless you become depressed or there is an incidental finding of clinical relevance, and that you have indicated at the end of the consent form you would like to be notified of the findings. In any of these situations, we will contact you and with your permission we will communicate the finding to your primary health care provider.
- The wearable device is randomly assigned, you will not be able to switch from one device to another.
- You are encouraged to wear the wearable device continuously, only taking it off for charging.
- You will be sent the wearable device via mail if you are not able to pick up the device in-person at WCH. You will also need to mail back the device at the end of your participation in the study. An envelope will be provided to you for mailing the device back.
- If you wish to know the results from any research tests, please contact the study team.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Wear the OURA ring/EmbracePlus watch continuously throughout the duration of the study
- Complete 1 questionnaire daily about your mood and energy levels
- Complete 3 questionnaires every 2 weeks about your mental health and major life events
- Complete a baseline assessment and postpartum final assessment at the end of the study
- Tell the study staff if you change your mind about being in the study
- Return the wearable to the research staff at the end of the study
- If the device is lost or broken, you are required to report the incident to the research

team as soon as possible. Steps for replacement or withdrawal from the study will be discussed. and get a replacement

You have the option to participate in one semi-structured interview about your experiences with the study (this is optional) and to continue tracking for up to six months postpartum. If you wish to take part in the semi-structured interview, you can provide consent to be contacted for scheduling. At the end of this consent form, you will have the opportunity to indicate whether you agree to be contacted for interview scheduling once the appropriate measures have been completed. Please note that we will include the first five individuals who sign up and are available for an interview during our outreach in this portion of the study.

If needed, you will be provided with an iPhone 13 for the duration of the study. A consent iPhone borrowing agreement will shared with you and upon agreeing to these terms you will be given the device. Use of the device is restricted to study related activities only. The device will remain the property of the research team, and you are responsible for its safekeeping. If the device is damaged, lost or stolen, you will need to report the incident to the research team as soon as possible. At the conclusion of the study, you must return the device within two weeks. If a device is not returned, the research team will send up to two reminder notifications via email or phone.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. You are encouraged to contact the research team, if you choose to withdraw from the study. Wearable must be returned to the researchers in case of withdrawal.

You may withdraw your permission to use information that was collected about you for this study at any time before anonymization by letting the research team know. This will be considered a withdrawal from the study.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation in the study may be stopped early, and without your consent, for reasons such as:

- New information shows that the research is no longer in your best interest
- The research team decides to stop the study
- You are unable to complete all required study activities
- You are experiencing negative mental health effects
- The Research Ethics Board withdraws permission for this study to continue

If you are removed from this study, the research team will discuss the reasons with you and where appropriate, plans will be made for your continued care outside of the study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

The main risk of this study is the possibility of a breach of your privacy. Your data will be assigned a unique study ID, and identifying information will be stored separately from research data.Only authorized members of the research team will have access to the data.

All data will be stored on secure WCH servers in accordance with privacy regulations and institutional policies. Some participants may experience discomfort or emotional distress during the process. If at any point you feel upset or uncomfortable, please notify the research team. You will be provided with appropriate support and resources. You will be informed of any new information regarding potential risks as it becomes available throughout the study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you agree to take part in this study, there may or may not be direct benefits to you. The aim of

this study is to test the feasibility of using data collected from a wearable device and surveys to predict the risk of postpartum depression. Knowing more about perinatal depression may aid in the decision-making process of persons developing perinatal depression in the future.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

Your identifying information (e.g., your name, address) and study data will be kept confidential in accordance with all relevant privacy laws, including the Personal Health Information Protection Act (PHIPA) of Ontario. Only the necessary information required for the purposes of this study will be collected, and this may include accessing your medical records, with your permission.

An auto-generated transcript of your interview will be stored, as well as your consent form, on secure password-protected servers at WCH. The transcript will not be shared with any persons outside of the research team. The transcripts will be kept until they are analyzed, and study results published, and then they will be destroyed. The interview will be stored in the research database and titled by your study ID and the fact that you are a research participant.

All individuals involved in the study, as well as authorized personnel from Women's College Hospital, are committed to respecting your privacy. No one outside the organizations or individuals listed below will have access to your personal information unless required by law, or you provide consent.

Organizations with Access

The following authorized representatives may access your medical records to ensure that the information collected is accurate and that the study is conducted according to ethical standards:

- The Women's College Hospital Research Ethics Board, which oversees the ethical conduct of this study
- Women's College Hospital representatives who oversee the research process
- Study monitors, auditors, and regulatory authorities

Although these organizations may have access to records that identify you, they are required to maintain the confidentiality and security of your information.

Study Data

Information collected as part of the study (called "study data") may be shared with these authorized organizations. However, your name, address, and other directly identifying information will not be included. Instead, records may use participant codes, initials, sex, and date of birth to ensure your privacy.

Adding Information to Your Health Record

Your participation in this study will be documented in your Women's College Hospital health record. This means that healthcare providers who are not part of this study may know about your participation. Any study-related information, such as documentation of your consent, study treatments, or test results, will be stored in the hospital research drive which is not part of your medical record.

Collection of Gender, Race, and Ethnicity

This study is collecting information about participants' gender, race, and ethnicity because these characteristics may influence how people respond to the study intervention. Providing this information is voluntary, and you may choose whether to share it or not.

Use of Email for Study Communication

If you agree to communicate via email as part of this study, please be aware that these methods are not fully secure. Risks include the possibility of emails or messages being seen by others, intercepted, or misdirected. Additionally, your service provider may be able to access and store copies of these communications. Sensitive information or emergencies should not be communicated via email, as these messages are not monitored outside of regular work hours. If you require urgent assistance, please contact emergency services.

Online Surveys, Third Party Websites and Web Based Apps

The study uses the OURA ring and EmbracePlus, wearable device that records biological data related to your wellbeing. As a participant, you will either be using the Oura ring or the EmbracePlus watch. You will be assigned randomly to either device.

If you are assigned to wear the Oura ring, you will be given a study ID and email address for deidentification purposes. The email account will allow you to create an account in the Oura mobile app. The data collected from the ring will be transferred to Oura Teams, where they are downloaded to the WCH computers. You have the right to revoke access to the data collection anytime during the study if you no longer wish to be a part of the study, but any data collected before this will still be included in the study. Your information may be processed in and transferred or disclosed to countries in which OURA ring affiliates are located and in which their service providers are located or have servers.

The Oura ring is not owned or operated by WCH, but we would like you to use the device and its associated app so that we can collect data from it for this study. You will not be prompted to provide personally identifying information when creating an account for the app, instead, a study-specific fake ID will be given to you for account registration and login. Only the research team and you ,the participant will know these credentials. The Oura ring privacy policy states that personal data collected will be processed with privacy-protection techniques such as aggregation, de-identification, or anonymization. Oura is a global company with servers around the world, and your personal data may at times be processed on servers located outside of Canada. The Oura Ring Cloud Drive is based in the US and Finland. Although data protection laws vary among countries, regardless of where your personal data is processed, Oura complies with data privacy frameworks around the world. (More information available at: https://support.ouraring.com/hc/en-us/articles/360025586673-How-Oura-Protects-Your-Data).

If you are assigned to wear the EmbracePlus watch, you will be given a study ID to access a mobile app used by EmbracePlus, where you will see some of your data. The study ID will allow you access the EmbracePlus mobile app. The data collected from the watch will be stored in the mobile app, then uploaded in real-time to the Empatica Cloud, where it can be accessed by the research team through our portal. You have the right to revoke access to the data anytime during the study if you no longer wish to be a part of the study, but any data collected before this will still be included in the study. Your anonymized data as well as your IP address will be collected and processed in the Empatica Cloud that is based in the United States. The Empatica privacy policy states that personal data are processed in a way to guarantee security, protection, and confidentiality. Empatica has the appropriate safeguarding measures to protect personal data in compliance with applicable data protection laws. (More information available at: https://www.empatica.com/privacy/). Please note that whenever data is transferred to foreign jurisdictions, it may not have the same level of protection as Canada, and it might be accessible to foreign law enforcement and national security authorities.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not result in any additional costs to you or your private health care insurance. All procedures and tests related to the research will be covered by the study, and

there will be no charges for taking part. If any unforeseen costs arise, they will be communicated to you in advance.

You will be provided with parking/transit tokens ($12 total) via cheque wire transfer or cash if you need to commute to the hospital for onsite study-related activities.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will be compensated $75 for participating in the study. You will be compensated an additional $30 if you decide to participate in the optional interview at the end of the study. Compensation will be given through either a wire transfer ,cash or cheque.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to receive the study's findings, please contact the research team, and they will provide the information.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this consent form, you do not waive any of your legal rights, nor does it relieve the researcher or associated institutions of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

Additionally, the findings of this study may be presented at scientific conferences or published in peer-reviewed journals. If you wish to obtain these results, please let the study team know.

What if researchers discover new information about your health?

The tests or procedures that we do during this study might reveal medical information about you that is not part of the objectives of this study but may be relevant to your health. This type of medical information is called an incidental finding. Some incidental findings could be related to treatable conditions or they could be related to factors that may affect your current or future health care. If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information and we will ask your permission to contact your health care provider and inform them of the finding.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution. That person is:

Dr. Blanca Bolea	416-323-6400 ext. 4221
Name	Telephone

Research Ethics Board Contact

If you have questions about your rights as a participant or concerns about ethical issues related

to this study, you can talk to someone who is not involved in the study at all. That person is the Chair of the Research Ethics Board, who can be contacted at ethics@wchospital.ca, or you can leave a message at 416-351-3732 ext. 2325.

Signature Page(s): Documentation of Informed Consent

Study Title: Biometrics in Longitudinal Uptake for Early Monitoring and Assessing Perinatal Patterns of Emotions in Depression (BLUESMAPPED)

Participant Statement of Consent

By signing this consent form, I acknowledge that:

- This research study has been fully explained to me and all of my questions have been answered to my satisfaction.
- I have been informed of alternatives to participation in this study.
- I know that I have the right not to participate and the right to withdraw from this study without affecting the care I receive at, employment at, or other relationship with WCH now or in the future for me or my family.
- The potential risks and benefits (if any) of participating in this study have been explained to me.
- I know that I may ask, now or in the future, any questions I have about this study.
- I have been told that information about me and my participation in this study will be kept confidential and that no personally identifying information will be disclosed without my permission unless required by law.
- I have been given sufficient time to read the information in this consent form.
- I do not give up any of my legal rights by signing this consent form
- I understand that my family doctor/health care provider will/may be informed of study participation
- I understand that the devices lent to me are for research purposes and if lost/stole/or damaged I must immediately inform the research team.
- I understand that I have to return the device(s) to the research team once requested or at the end of the study.
- I consent to communicate via email and understand I am not to share any personal or sensitive information via email
- This informed consent document may be placed in my medical records
- I understand that I can print a signed and dated copy of this consent form upon its submission.

Please initial one of the boxes below to indicate whether or not you want to be informed of all medically actionable incidental research findings.

	YES, I consent to be in the study.(*if yes, they will be asked to provide their first name, last name, email address and phone number below)*
	NO, I do not want to be in the study.

	YES, I agree to be told about any medically actionable incidental findings and have my primary practitioner notified of the findings.
	NO, I do not want to be told about medically actionable incidental findings.

Please initial one of the boxes below to indicate whether or not you want to participate in the optional semi-structured qualitative interview about your experiences in the study.

	YES, I agree to participate in the optional semi-structured qualitative interview.Please contact me to schedule this.
	NO, I do not want to participate in the optional semi-structured qualitative interview.

Signature Page(s): Documentation of Informed Consent

Study Title: Early detection of perinatal depression using passive sensing and machine learning: A research protocol for a feasibility study