359 Blackwell Street
Suite 200
Durham, NC 27701
fhi360.org

INFORMED CONSENT FORM – FOCUS GROUP DISCUSSIONS

Blue text indicates variable text differing between Wits MRU and Two Oceans in Health. Purple text indicates text for Oregon Health & Sciences University [at bottom, using OHSU format].

Study title: Formative study for developing patient-reported outcomes (PROs) for measuring contraceptive-induced menstrual changes (CIMCs)

Study protocol number: 2118333

Study sponsor: FHI 360

Study funder: The Gates Foundation

Study sites: Durban, South Africa and Santo Domingo, Dominican Republic

[*Wits MRU*: Good day, my name is_____ (insert name), and I work for Wits MRU (Wits MatCH Research Unit) of the University of the Witwatersrand based in Durban. We are working in collaboration with researchers at FHI 360 in the United States. I would like to invite you to consider participating in a research study.]

[*Two Oceans in Health*: Hello, my name is_____ (insert name) and I work for Two Oceans in Health here in Santo Domingo. We are working in collaboration with researchers here at Profamilia and at FHI 360 in the United States. I would like to invite you to consider participating in a research study.]

Introduction

This form, called an Informed Consent Form, will explain what this study is about. Please read this form or have it read to you. Before you decide if you want to join this study or not, we want to explain the study, its risks, its potential benefits, and what you will be asked to do. You may ask questions as we discuss the study, so that you understand what the study is about. It is important you know the following:

- Your participation in this study is entirely voluntary.
- You can ask questions now or at any time during the study.
- If you join the study, you can change your mind later and quit the study at any time.

Before you decide whether to join this study, a member of the study staff will explain:

- The purpose of this study
- How the study may help you or others

- Any risks you may face while participating in this study
- What is expected of you during the study.

Once you understand the study, and if you decide to take part, you will be asked to sign this consent form, and you will be given a signed copy of it to keep. This process is called informed consent.

Purpose of the Research Study
We are doing this research to understand how people experience any changes to their periods or menstrual cycles while using [contraception/family planning]. You are being invited to volunteer because you are using contraception and are between 18 and 49 years old.

If you join the study, you will be in a group discussion with about 4 to 7 other people. The discussion will last about 70 to 85 minutes. The study will have about 8 to 12 similar discussions with other people.

What the Group Discussion Will Include
The group discussion will be in a private area. We will ask you and the other group members to talk about changes you have had in your period while using [contraception/family planning], the impact of these changes on your life, and what information about these changes are important for people to know before starting [contraception/family planning].

[Wits MRU: Digital Recording
In order to ensure that we can have a true and accurate record of the group discussion, you will be asked to allow the interviewer to digitally record the discussion. This is so that the study staff can make sure that it is being carried out correctly and that they understand what is being said by participants. Digital recording is a requirement for participation. Each digital recording/disk will be transcribed, and all recordings/disks will be erased within two years of publication of study findings, or if there is no publication, no later than six years after the study has ended. Information from the recordings/disks may be presented at professional meetings or in written articles, in which case no names or other personal identifiers will be used.

The group discussion will be confidential to the extent possible; you will be identified only by a unique number assigned to you, and no individual names will appear on the audio file or the transcript of the group discussion. No one, except the study team at Wits MRU and FHI 360, will have access to the audio file or the transcript of the group discussion. You can decide to withdraw from the group discussion at any time. If you do not want the group discussion to be digitally recorded, you are not eligible to participate, since it is important that we get to listen to the digital recordings so as to understand exactly what is being said.]

[*Two Oceans in Health*: We will record the audio of the group discussion. Your name will not be part of the recording. The recording will be transcribed (i.e., written out) for the research team to fully study all the information shared during the discussion. If you do not want to be audio recorded, you will not be able to join the study.

Audio Recording
I agree to be audio recorded. YES ☐ NO ☐]

Possible Risks of Being in the Study
There are few risks to you because you are joining this study. You may feel uncomfortable talking about [contraception/family planning] or your period during the discussion. [Our study staff members are trained to create a supportive and safe environment for talking about sensitive issues and will refer participants who display signs of distress to local clinics for further health care management]. We will ask you and everyone in the group discussion not to share information from the discussion with other people. But there is a chance others in the group may tell someone you were taking part in the study or share what you said.

Possible Benefits of Being in the Study
There are no direct benefits to you for being in this study. The research may help other people who have changes to their periods while using [contraception/family planning] in the future.

You Decide if You Want to Join the Study
Taking part in this research study is voluntary. This means you are free to decide if you want to be a part of the study or not. You do not have to answer any questions you do not want to answer in the group discussion. If you agree to be in the study and then you change your mind, you are free stop being a part of the study any time without any penalty or loss of benefits that you already have.

How We Will Keep Your Information Private
We will protect information about you in this study to the best of our ability. We are asking you and others in the group discussion not to share information from the discussion with other people outside of the group, but there is a chance others may tell someone you were taking part in the study or share what you said.

Any information we collect about you that could identify who you are—for example, your name or contact information—will be kept private to the best of our ability. This information will only be shared with the research team to complete the study or if the ethics committees that reviewed this research ask for it.

We will not use your name or information that could identify you in any reports we make about the study. What you say in the group discussion will not be linked to your name or other information that could identify you. Information from the group discussion that does

not identify you may be shared with others, like other researchers who are doing other studies, the Gates Foundation that funded the study, or regulatory agencies like the United States Food and Drug Administration, also called "the FDA". If we do this, we will not ask for your permission or signature again. If we do this, we will not ask for your permission or signature again because we have told you about it here.

[*Wits MRU*: **South African Protection of Personal Information (POPI)**
Your data will be collected, processed, and stored according to the South African Protection of Personal Information (POPI) Act of 2013. All study documents will be stored for a duration of 10 years as required by Good Clinical Practice (GCP).

Wits MRU uses a separate contact about future research consent.]

[Two Oceans in Health: Contact about Future Research
I give the researchers permission to keep my contact information and to contact me for future research projects. YES ☐ NO ☐

Certificate of Confidentiality
This research is covered by something called a Certificate of Confidentiality from the United States Food and Drug Administration. It helps protect the privacy of research participants like you. The certificate protects against the release of information that could identify you from this research study for any legal proceedings or to anyone not connected to the research, unless exceptions apply. This certificate does not prevent you from sharing information about you or about your participation in this research study. The certificate does not stop us from releasing information that is required by United States federal, state, or local law. For example, researchers must report if they think there is child abuse and neglect, harm to self or others, or communicable diseases.]

Payment
You will be paid [Wits MRU: R400.00/Two Oceans: a USD 10 coupon and USD 5-15 depending on travel distance] for your time during and transportation to and from the group discussion if you complete the discussion.

If You Have Questions About the Study
Please feel free to contact us about the project -now or in the future, or to ask for any updates. We appreciate the time you may take to participate in this study.

If you have any questions, concerns, or complaints about this study or study procedures, you can [Wits MRU: call the Study coordinator, Nzwakie Mosery, from Wits MRU at 031-0011915/083 962 7003 or Professor Jenni Smit, who is the Wits MRU Principal Investigator of the study at 082 926 5762/Two Oceans in Health: See principal investigator information below].

[*Wits MRU*: The Human Research Ethics Committee of the University of the Witwatersrand and the Institutional Review Board at FHI 360 have approved the recruitment of participants for this study. The Institutional Review Boards/ethics committees oversee the protection of people participating in research studies.

The study has been structured in accordance with the Declaration of Helsinki (last updated October 2013), which deals with recommendations guiding doctors in biomedical research involving human participants.

If you want any information regarding your rights as a research participant, or complaints regarding this research study, you may contact the following person from The University of the Witwatersrand's Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants:

- Professor Paul Ruff
- Chairperson of the Human Research Ethics Committee (Medical) at the University of Witwatersrand
- Telephone no. 011 717 2301, or by e-mail at paul.ruff@wits.ac.za.]

[*Two Oceans in Health*: This research has been reviewed by the Institutional Review Boards at FHI 360, the University of the Witwatersrand, Two Oceans in Health and Consejo Nacional de Bioética en Saludwill (CONABIOS). If you have any questions or concerns about how you are being treated by the study or your rights as someone in the study, you may contact:

Dr. José Plácido Montero, Executive Director of CONABIOS
Ave. Bolívar # 902, La Julia
Santo Domingo, Dominican Republic
Phone: (809) 262-2216
Email: conabios_rd@yahoo.com].

Study principal investigators and addresses
Amelia Mackenzie at FHI 360, 359 Blackwell St. Suite 200, Durham, North Carolina, 27701, United States, +1-919-544-7040

Jennifer Smit at the Maternal, Adolescent and Child Health Research Unit at University of the Witwatersrand (WITS MRU), 40 Dr AB Xuma Street 11th floor, Suite 1108-9 Commercial City Durban, South Africa, 4001, +27 31 001 1941

Marija Miric at Two Oceans in Health, Calle Caonabo #22, Gascue, Santo Domingo, República Dominicana, +1 809-508-1824

YOUR AGREEMENT

[*Wits MRU*

Declaration of the volunteer

I understand the purpose of this study. I have read the above information. I have had the opportunity to ask questions, and any questions that I asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to stop my participation at any time.

_____	_____	_____
Participant Print Name and Surname (or thumbprint if applicable)	Participant Signature	Date Time: _____:____ H H : M M
_____	_____	_____
Print Name and Surname Person obtaining consent	Signature	Date Time: _____:____ H H : M M

Consent to digital recording

I have been informed that the *interview* will be digitally recorded. I know that I can refuse to participate if I do not want to be digital recorded. I voluntarily give permission for the *interview* to be digitally recorded.

_____	_____	_____
Participant Print Name and Surname (or thumbprint if applicable)	Participant Signature	Date Time: _____:____ H H : M M
_____	_____	_____
Print Name and Surname Person obtaining consent	Signature	Date Time: _____:____ H H : M M

]

[*Two Oceans in Health*:

YOUR AGREEMENT

I confirm the nature and purpose of the study have been explained to me. The potential benefits and possible risks of joining this study have also been explained to me. I know the group discussion will be audio recorded, and I have agreed to be recorded. I have asked any questions about the study, and the answers have been explained to me. I agree to join the study as a volunteer and understand that I can stop being in this study at any time.

_____ _____

Your signature or mark Date

RESEARCHER AGREEMENT

I confirm the nature and purpose, the potential benefits, and possible risks associated with being a part of this research study have been explained to the person who signed above.

_____ _____

Signature of person who reviewed this form with you Date

Medical Record Number_____

Name_____

Date of Birth_____

CO1450

OHSU Clinical Consent and Authorization Form

SUMMARY OF KEY INFORMATION ABOUT THIS STUDY

STUDY TITLE: Formative study for developing patient-reported outcomes (PROs) for measuring contraceptive-induced menstrual changes (CIMCs)

OHSU eIRB STUDY NUMBER: [*eIRB Study Number*]

PRINCIPAL INVESTIGATOR (Study Doctor): Alison Edelman, MD 503-494-3666

INTRODUCTION:

You are being asked to join a research study. This consent form contains important information to help you decide if you want to join the study or not. This is a voluntary research study. You do not have to join the study. Even if you decide to join now, you can change your mind later. Please ask the study staff if you have any questions about the study or about this consent form.

PURPOSE:

The purpose of the study is to learn more about how periods or menstrual cycles change while using contraception or family planning. We are conducting group discussions at several different study sites around the world. The goal of these group discussions is to understand how people describe and experience changes to their periods or menstrual cycles.

Please take your time and read this document carefully before deciding. You should not join this research study until all of your questions have been answered to your satisfaction.

DURATION:

Medical Record Number_____

Name_____

Date of Birth_____

CO1450

Your participation in the study will consist of one visit to review this consent and a second for the group discussion with about 3 to 6 other people, some of whom may be from your community. The discussion will last between 70 and 85 minutes. These will take place either in person or virtually.

Your participation in this research is completely voluntary. You can choose not to participate. If you decide to participate, you can change your mind and stop participation at any time, for any reason.

Please ask the study staff, at any time, if you have any questions about the study or about this consent form.

PROCEDURES:
If you decide to take part in this study, you will be asked to review and sign this consent form, and we will give you a copy to keep. You will then meet with a group of 3 to 6 other people to discuss how contraception or family planning has changed your period or menstrual cycle.

This study does not include any genetic testing.

RISKS: You may feel uncomfortable talking about contraception and your period during the group discussion, or if other people in the discussion bring up a topic that makes you feel uncomfortable. We will ask everyone in the group discussion not to share information from the discussion with other people outside of the group afterwards. But there is a chance that others in the group may tell someone you were taking part in the study or share what you said.

BENEFITS: You will not directly benefit from taking part in this research. This study may help other people who have changes to their periods while using contraception in the future.

ALTERNATIVES: You may choose not to participate in this study. This is a voluntary research study. You do not have to join the study.

END OF CONSENT SUMMARY

Medical Record Number_____

Name_____

Date of Birth_____

INTRODUCTION & PURPOSE

STUDY TITLE: Formative study for developing patient-reported outcomes (PROs) for measuring contraceptive-induced menstrual changes (CIMCs)

PRINCIPAL INVESTIGATOR (STUDY DOCTOR):
Alison Edelman, MD 503-494-3666

WHO IS PAYING FOR THE STUDY? The Gates Foundation

WHO IS PROVIDING OTHER SUPPORT FOR THE STUDY? FHI 360

STUDY CONTACT INFORMATION

Purpose	Role	Name	Phone Number	Email
For medical study questions (study doctors and nurses)	Study Doctor	Alison Edelman, MD	503-494-3666	whru@ohsu.edu
	Research Nurse Practitioner	Marci Messerle Forbes, FNP	503-494-3666	whru@ohsu.edu
	Group Discussion Facilitator	Laura Jacobson, PhD	503-494-3666	whru@ohsu.edu
For non-medical study questions	Study Coordinator	Maddie Delacerda	503-494-3666	whru@ohsu.edu
For 24-hour medical emergencies	911	Emergency Dispatch	911	
	Health Care Provider On-Call	OHSU Operator	503-494-9000	

INTRODUCTION

This form, called an Informed Consent Form, will explain what this study is about. Please read this form or have it read to you. Before you decide if you want to join this study or not, we want to explain the study, its risks, its potential benefits, and what you will be asked to do. You may ask questions as we discuss the study, so that you understand what the study is about. It is important you know the following:

- Your participation in this study is entirely voluntary.
- You can ask questions now or at any time during the study.

- If you join the study, you can change your mind later and quit the study at any time.

Before you decide whether to join this study, a member of the study staff will explain:

- The purpose of this study
- How the study may help you or others
- Any risks you may face while participating in this study
- What is expected of you during the study.

WHAT IS THE PURPOSE OF THIS STUDY? WHY AM I BEING ASKED TO JOIN THIS RESEARCH STUDY?

You have been invited to be in this research study because you are between 18 and 49 years old and you are using contraception or family planning. The purpose of this study is to understand how people experience any changes to their periods or menstrual cycles while using contraception or family planning.

WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?

If you decide not to take part in this study, you may choose to be a part of a different study if one is available.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

As many as 126 people will take part in this study which will be conducted at Oregon Health & Science University and other hospitals and universities internationally. Of these participants, we expect up to 60 people will be screened and up to 42 will participate in the study at OHSU.

PROCEDURES

WHAT ARE THE STUDY GROUPS?

There are no study groups for this research. We will ask all participants in the group discussion about the same things.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to be in this study, it will include 2 visits and last up to 60 days.

WHAT TESTS AND PROCEDURES WILL I HAVE IF I AM PART OF THIS STUDY?

The two visits will take place either in person or virtually.

Visit 1:
At this visit you will review this consent form and have a chance to ask any questions about the study or the informed consent process. Once you understand the study, and if you decide to take part, you will be asked to sign this consent form, and you will be given a signed copy of it to keep.

Visit 2:
This visit is the group discussion. You will meet with a group of 3 to 6 other people to discuss changes to your period with contraception. We will ask you few questions about yourself before the discussion begins.

The group discussion will be in a private area. We will ask you and the other group members to talk about changes you have had in your period or menstrual cycles while using contraception or family planning, the impact of these changes on your life, and what information about these changes are important for people to know before starting contraception.

To ensure that we can have a true and accurate record of the group discussion, we will record the audio of the discussion. If the group discussion you are a part of is taking place virtually, we will record both the audio and video. This is so that the study staff can make sure that it is being carried out correctly and that they understand what is being said by participants. No individual names will appear on the audio file or the transcript of the group discussion. No one, except the study team at OHSU and FHI 360, will have access to the audio file, video recording, or the transcript of the group discussion. Digital recording is a requirement for participation. If you do not want to be audio/video recorded, you will not be able to join the study.

RISKS

There are risks with participating in this study. This section tells you about the most common risks researchers know about.

WHAT RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
Although we will make every effort to protect your identity, there is a small risk of loss of confidentiality. We will ask you and everyone in the group discussion not to share information from the discussion with other people afterwards. But there is a chance others in the group may tell someone you were taking part in the study or share what you said.

Some of the questions in the group discussion may seem very personal or embarrassing. You may feel uncomfortable talking about contraception or your period during the discussion. You may refuse to answer any of the questions that you do not wish to answer. Our study staff members are trained to create a supportive and safe environment for talking about sensitive issues and if needed, we will help you to find a counselor.

FUTURE RESEARCH

HOW WILL MY INFORMATION BE USED?

We may share your information for future research in the following ways:

Sharing with the study team: We will label your information with a code, so what you say in the group discussion is not linked to your name or any other identifiable information.

Sharing as required by funders or scientific journals: When we publish the results of the study, we may be required to submit the data to the funder or publisher. This would allow the study data to be used in the future by other researchers. Before we share data with the funder or publisher, we will remove any information that could identify you.

If we do this, we will not ask for your permission or signature again because we have told you about it here.

CONFIDENTIALITY, PRIVACY, & HIPAA AUTHORIZATION

WHAT INFORMATION IS BEING COLLECTED, USED, AND SHARED AND WHY?

We will collect information about you as described throughout this form in order to conduct and oversee this research study. The information collected will be focused on menstrual cycles and contraception.

HOW WILL MY INFORMATION BE PROTECTED?

We will protect information about you in this study to the best of our ability, but we cannot guarantee total privacy. We are asking you and others in the group discussion not to share

information from the discussion with other people outside of the group, but there is a chance others may tell someone you were taking part in the study or share what you said.

We will take the following steps to keep your personal information confidential. A code number will be assigned to you for all data collected. Only the study team will be able to link the code number back to you. Your research information will be labeled in a way that directly identifies you only if needed for a specific research reason. We will not use your name or your identity for any reports, publications, or publicity purposes unless we have your special permission. Information from the group discussion that does not identify you may be shared with others.

Information privacy and security:
You must use your own discretion during the group discussions when choosing what to disclose or share with the group. There is a risk that other group members may not choose to keep the information discussed in group sessions confidential, and they may disclose information you share in the group with others, including individuals outside the group setting.

We will record the group session(s) described above for later processing, including reference and transcription. By joining the group session(s), you agree to give OHSU permission to record and process your participation in those group sessions.

The information you provide to, and/or receive from, other study group participants, is NOT medical advice, care or treatment or a medical recommendation. Should you have a medical question, you agree to consult with your provider.

Virtual Group Sessions: We may use virtual meeting tools to conduct group sessions. Your video image will be displayed to other group participants. By joining the meeting, you are agreeing and directing OHSU to display and disclose this information.

WHO WILL MY INFORMATION BE SHARED WITH?
We may share this information with others outside of OHSU who are involved in conducting or overseeing this research, including:

- Funder of this study, The Gates Foundation, and people or organizations who help them do the research.
- The Sponsor of this study, FHI 360.
- Regulatory agencies, like the United States Food and Drug Administration (FDA).
- Office of Human Research Protections (OHRP), a federal agency that oversees research.
- Other researchers who may use your information for future research studies.

If we do this, we will not ask for your permission or signature again because we have told you about it here.

We may share this information with others outside of OHSU for reasons other than the research, including:

- Public health and safety authorities: Under Oregon law, if the information you provide in the group discussion shows that there might be child or elder abuse, we must report it to appropriate authorities.

When we send information to someone outside of OHSU, it may no longer be protected under confidentiality laws, so we cannot promise that they will keep it private.

DO I HAVE TO SIGN THIS AUTHORIZATION?
You do not have to sign this authorization. If you do not sign this informed consent form, you cannot be in the study because we need to use your information to do this study. If you decide not to take part in this study, it will not affect your ability to get health care services, enroll in any health plans, or get payment or insurance coverage for services.

HOW LONG WILL MY INFORMATION BE USED OR SHARED?
We may continue to use and share your information as described above indefinitely.

WHAT IF I CHANGE MY MIND?
Taking part in this research study is voluntary. You may change your mind at any time about participating in the study or any part of the study without any penalty.

If you no longer want your health information to be used and shared:
Send a written request or email to the address below stating that you are taking back your permission (authorization):

OHSU Women's Health Research Unit
3181 SW Sam Jackson Park Road
Mailcode: UHN70
Portland, OR 97239
Email: whru@ohsu.edu

Your request will be effective on the date we receive it. However, we will not be able to remove information that has already been used or shared with others.

Medical Record Number_____

Name_____

Date of Birth_____

BENEFITS

WHAT BENEFITS CAN I EXPECT FROM TAKING PART IN THIS STUDY?
You will not directly benefit from being in this study. However, the research may help other people who have changes to their periods while using contraception in the future.

PARTICIPANT'S RIGHTS

DO I HAVE TO TAKE PART IN THIS STUDY AND CAN I CHANGE MY MIND LATER?
Your participation in this study is voluntary:

- You do not have to join this or any research study.
- If you join the study and later change your mind, you have the right to quit at any time without any penalty.
- If you join the study, you do not have to answer any questions you do not want to answer in the group discussion. We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.
- You do not have to be in research studies offered by your doctor.

  Your health care provider may be one of the study doctors of this research study and, as a researcher, is interested in both your clinical care and the conduct of this study. Before entering this study, or at any time during the study, you may ask for a second opinion about your care from another doctor who is not involved in this study.
- Deciding to not take part in this study will not affect your ability to get health care services, enroll in any health plans, or get payment or insurance coverage for services.

WHAT HAPPENS IF I DECIDE I DON'T WANT TO CONTINUE, OR IF THE STUDY DOCTOR HAS TO TAKE ME OUT OF THE STUDY? Talk to the study staff if you change your mind and want to withdraw from the study.

The study staff may remove you from all or part of the study for any of these reasons:

- You are no longer eligible to participate
- You do not follow the study team's instructions.
- The study is stopped by the sponsor, IRB, or FDA.

The study staff will talk to you about any follow-up you might need to make sure you stop the study safely.

WHAT WILL HAPPEN TO MY INFORMATION IF I WITHDRAW FROM THE STUDY?
The information we collect from you will be provided to the sponsor. They will be stored with a coded identifier to protect your privacy. Once provided to the sponsor, we will not be able to destroy your data if you decide in the future, you do not wish to participate in the research.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT MY RIGHTS IN THIS STUDY?
This research has been approved and is overseen by an Institutional Review Board (IRB), a committee that protects the rights and welfare of research participants.

You may talk to the OHSU Research Integrity Office/IRB at (503) 494-7887 or irb@ohsu.edu for any of the following reasons:

- Your questions, concerns, or complaints are not being answered by the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at: https://secure.ethicspoint.com/domain/media/en/gui/18915/index.html or by calling toll-free (877) 733-8313. Messages can be anonymous, and voicemail is available 24 hours a day, seven days a week.

COSTS & LIABILITY

WHAT WILL I (OR MY INSURANCE COMPANY) BE BILLED FOR IF I PARTICIPATE IN THIS STUDY?
There will be no cost to you or your insurance company to participate in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?
You will be paid $100 if you participate in the group discussion.

Payment for participation is considered taxable income, even if the payment is by gift card or ClinCard debit card. We may ask for your social security number or tax ID so that we can process

payments for your participation in this study. If you do not have or do not want to give us a social security number or tax ID, we will deduct taxes from the payment. If you are an individual who is undocumented, we must report all payments to the IRS. If OHSU pays you (for example, from job wages, payments for study participation) more than $600 within one calendar year, we are required to report this information to the IRS and issue you a 1099/1042.

We may pay you with a debit card. There may be fees (for example, if the card is inactive for an extended period of time), which will be deducted from the balance on your card. We will give you a separate card member agreement and FAQ sheet with details on how to use the card.

WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?
If you believe you have been injured or harmed as a result of participating in this data collection, contact the Women's Health Research Unit at 503-494-3666 or whru@ohsu.edu.

OHSU and the funder do not offer any financial compensation or payment for the cost of any injury or harm. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim.

If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887 or email irb@ohsu.edu.

WILL ANY OF MY INFORMATION FROM THIS STUDY BE USED FOR COMMERCIAL PROFIT?
We may use your information to develop products that may have potential commercial value to a company, OHSU, or its researchers. We will not give you property rights or ownership, or any other financial benefits for these discoveries. You will also not be legally responsible for anything that occurs because we used your information.

WHERE TO FIND MORE INFORMATION ABOUT THE STUDY

WHERE CAN I GET MORE INFORMATION?

Medical Record Number_____

Name_____

Date of Birth_____

You can talk to the study staff about any questions or concerns you have about this study or to report side effects or injuries. Outside of regular clinic hours, you can speak with a health care provider on-call. Contact names and phone numbers can be found at the beginning of this form. If you have any questions, concerns, or complaints about this study now or in the future, please contact Alison Edelman, MD, at 503-494-3666 or the Women's Health Research Unit at 503-494-3666.

Please feel free to contact us about the project - now or in the future, or to ask for any updates. We appreciate the time you may take to participate in this study.

SIGNATURE

I have read (or someone has read to me) this form and have been able to ask questions and have them answered. By signing below, I agree to be in this study and authorize the use and sharing of my health information for research as described in this form. I will be given a copy of this signed form.

Participant Printed Name	**Participant Signature**	**Date**
Person Obtaining Consent Printed Name	**Person Obtaining Consent Signature**	**Date**