Endometriosis Group Care: Piloting an interdisciplinary group care model for endometriosis treatment

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INFORMED CONSENT DOCUMENT

Project Title: **Peer-Empowered Endometriosis Pain Support (PEEPS)**

Principal Investigator: Whitney Ross, M.D.

Research Team Contact: Catherine Mulligan, 314-273- 1898, mulliganc@wustl.edu

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

This is a research study conducted by Dr. Ross on interdisciplinary group care for people living with endometriosis-related chronic pelvic pain. In this study, we will evaluate if the Peer Empowered Endometriosis Pain Support (PEEPS) program helps improve pain and quality of life. PEEPS is an 8-week program that includes education from mental health, physical therapy, and gynecology experts, peer support, and yoga. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not. Before you decide whether to be in this study, you may wish to consider other options that are available to you.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, you will be asked to spend 2 hours per week for 8 weeks participating in PEEPS sessions. You will need to come to come to the Center for Outpatient Health on the Barnes Jewish Hospital campus for each session. During that time, you will be asked to participate in discussions on topics related to living with endometriosis and pelvic pain, and engage in yoga/mindfulness that is designed specifically for people with chronic pelvic pain. The main risks to you if you participate are loss of confidentiality in the case of a data breech, distress from discussing or answering surveys on chronic pain and mental health, and injury from participating in yoga.

You may benefit from volunteering because each of the components of this study have been shown to be beneficial to other people living with chronic pain. There is no cost to you and you will not be paid for being a volunteer participant. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you 1) are aged 18-48 years and were assigned female at birth, 2) have endometriosis diagnosed by surgery , 3) have no plan to have surgery in the next 12 weeks, and 4) are willing to attend eight 2-hour weekly sessions in St. Louis. The purpose of this research study is to test the new Peer Empowered Pain Support (PEEPS) program to see if it is effective in decreasing endometriosis-related pain, improving quality of life, and providing peer and clinician support to people living with endometriosis.

WHAT WILL HAPPEN DURING THIS STUDY?

By completing and signing this consent, you will give permission to the research team members to view your medical record to extract certain data and information pertinent to your medical and psychosocial history including prior and current treatments for endometriosis (medication, physical therapy, surgery, counseling, and alternative therapies). You will be contacted about scheduling your PEEPS sessions and be asked to complete surveys about your symptoms and quality of life.

If any information is missing or needs verification, you may be directly asked about it.

The surveys will ask about pain symptoms, and physical function, history of abuse/trauma, mood symptoms, quality of life measures, and experiences of discrimination in health care. You will set goals related to quality of life that you aim to meet by the end of your PEEPS participation. The surveys will be distributed via REDCap, which electronically securely stores the information. You will complete these surveys at enrollment/baseline, within 1 month of PEEPS Completion and 6-months.

PEEPS will include eight two-hour sessions led by an endometriosis specialist, a women's health physical therapist/certified yoga instructor and a clinical psychologist who specializes in chronic pain management. PEEPS activities include (but are not limited to) mindfulness exercises, yoga, group discussions, reflections, and education on various aspects of endometriosis.

During the study period, you will continue to receive appropriate care as determined by the gynecologist caring for your endometriosis and chronic pelvic pain and your primary care provider. If you are planning to have surgery, we will delay your study start date until at least eight weeks after surgery to allow for a full recovery. However, once you begin this study, you will be able to proceed with any treatments (e.g., medication changes, surgery, counseling, physical therapy, etc.) as recommended by your treating healthcare providers. If you desire to continue to participate in the study after surgery, written clearance from your surgeon with a description of your activity limitations will be required before you can return to the study.

People with endometriosis and chronic pelvic pain have intermittent pain exacerbations, sometimes due to common triggers like menses, ovulation, or intercourse, but many exacerbations are unpredictable and sporadic. At each session, you will be encouraged to reach out to your doctors to discuss any symptom changes or for urgent concerns regarding your health. We will screen for severe depression and suicidality at three questionnaire time points and have a plan to refer anyone in need of mental healthcare support should anyone experience severe depression or suicidality over the course of the study.

We will score your PROMIS Depression tool immediately and REDCap will flag patients who score in severe range (>70) at each of the three rounds of questionnaires. The PI and study coordinator will be notified immediately of this flag. A study member will call you and complete a thorough screen for suicidal ideation if you score in the severe range. If positive, you will be referred to the WUSTL Psychiatric Emergency Service. If no suicidal ideation is noted, we will offer you referral to WUSTL Outpatient Psychiatry, social work, and offer to contact your primary care provider to help facilitate further evaluation and treatment.

We may need to work with you on a plan that might include getting you to a medical facility for safety. We also want to provide you with contact information for available resources, should you decide you need assistance at any time. You can call the toll-free 24-hour National Suicide Prevention Lifeline at 1-800-273-TALK (1-800-273-8255) or St. Louis Behavioral Health Response at 1-800-811-4760 (https://bhrstl.org/crisis-hotline/).

<u>Will you save my research information to use in future research studies?</u>

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding endometriosis, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 40 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your active involvement will last for approximately one year.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Physical Discomfort

Yoga can cause discomfort if done incorrectly. The yoga will be led by a physical therapist with a focus on your safety and comfort. You are encouraged to modify any exercises to fit your current level of fitness and let us know if anything is uncomfortable so the exercises can be modified for you.

Psychological Disturbance

Some of the survey questions we ask may make you uncomfortable. You may skip answering any question you do not wish to answer. Some of the PEEPS discussion topics may make you uncomfortable; you may opt-out of sharing personal experiences.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WILL I BE PAID FOR PARTICIPATING?

You will receive $25 for completion of the baseline questionnaire and $50 for each of the two other time points (completion and six months). If you complete all portions of the study you will receive a total of $125 via gift card. If you do not complete all portions of the study you will be paid for those portions you do complete. You will receive compensation to apply towards parking and transportation.

You will be asked to provide your social security number (SSN). You may also need to provide your address if a check will be mailed to you.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from the NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at 314-273-2560 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information

request.

- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles may require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will keep any paper/hard copy records in locked office suites, in locked doors/cabinets. You will be given a unique participant ID. The link between you and your unique ID is maintained by the study team. Data collected from your medical record for purposes of this study will be maintained in your study file unless directly entered into the electronic database.

Data may be directly entered into the secure electronic database. Electronic data will be maintained in a password-protected database using secure network practices. Access to the electronic database is restricted to members of the study team who are given individual user IDs and passwords and their access is restricted on a role-specific basis. All web-based information transmission is encrypted. The data is all stored on a private, firewall protected network. Imaging that is copied or transmitted electronically is done so without any patient identifiers so that other investigators at other research centers receiving it will not know your name or that the data is yours.

The funding source for this research may require that we share the data from this study with others to make sure the results are correct and to use for future research. Your information will be shared in a way that cannot directly identify you.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, “How will you keep my information confidential?”

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University’s Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- Your treatment or the care given by your health provider.
- Your insurance payment or enrollment in any health plans.
- Any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant’s withdrawal from the research study or for safety reasons.
      - You will not be allowed to continue to participate in the study.

Can we contact you by email and/or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Reminders to complete surveys at their respective time points.
- Reminders about upcoming PEEPS sessions

Only the research team will have access to your email and text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish

us to stop sending these messages or need to contact us for an urgent situation, please contact the research team member identified at the top of this document.
You should be aware that there are risks associated with sending your health information via email and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes   _____ No
Initials   Initials

Do you agree to allow us to send your health information via text?

_____ Yes   _____ No
Initials   Initials

If you have an active My Chart account, we may use this as a way to communicate with you about the treatment and/or medical care you are receiving as part of this study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you will not be penalized or lose any benefits for which you otherwise qualify.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be safe for you to continue, because your condition has become worse, or because funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Catherine Mulligan, 314-273-1898. If you experience a research-related injury, please contact: Dr. Whitney Ross, 314-362-5470.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant, you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

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Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: N/A.

____________________________________ __________________________
(Signature of Participant) (Date)

____
(Participant's name – printed)

<u>Statement of Person Who Obtained Consent</u>

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

____________________________________ __________________________
(Signature of Person who Obtained Consent) (Date)

____
(Name of Person who Obtained Consent - printed)