Title: A Pilot Randomized Controlled Trial of Vaginal Estrogen on Postpartum Atrophy, Perineal Pain, and Sexual Function

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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**A Pilot Randomized Controlled Trial on Vaginal Estrogen on Postpartum Atrophy, Perineal Pain, and Sexual Function**
Principal Investigator:	**Catherine Hudson, MD**
Sponsor:	**The Ohio State University Wexner Medical Center**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

You are being asked to take part in this study because you have experienced a perineal tear after your vaginal delivery at The Ohio State University. The perineum is the area by the urinary, vaginal, and rectal openings. The vulva includes the female external reproductive organs.

The goal of this study is to test the safety, feasibility, and effectiveness of using vaginal estrogen cream Estrace®, to treat vulvar symptoms, including dryness, itchiness, perineal pain and pain with intercourse, in postpartum patients. You will receive either a vaginal estrogen cream or a placebo cream. A placebo cream contains inactive ingredients. The vaginal estrogen cream has been proven to improve dryness, lubrication, and elasticity in

postmenopausal patients. The study will try to evaluate if similar results are seen in postpartum patients with a perineal tear.

2. How many people will take part in this study?

Approximately 112 subjects will take part in this study at The Ohio State University.

3. What will happen if I take part in this study?

Prior to taking part in this study you will be asked to review and sign this consent form.

Screening/Registration

After you have signed this consent form, you will:

- be asked for some demographic information
- be randomly selected by chance to receive either Estrace® vaginal estrogen cream or placebo cream during a 6-month long study. You will be given instructions to place 1gram of the cream, "a pea-sized amount," on the perineum nightly for two times a week. We will schedule your next visit prior to discharge from the hospital
- 30 minute follow up at a clinic at 6 weeks, 3 months, and 6 months postpartum
- be asked to fill out a diary describing rates of sexual activity and cream use prior to clinic visits

Clinic Encounters

You will be asked to return to the clinic for three clinic visits: 6 weeks, 3 months, and 6 months postpartum. At each of these three visits, you will:

- Complete 5 questionnaires asking about genital symptoms, pain, and sexual function as well as your satisfaction with the treatment. You will be given as much time as you need to complete these questionnaires. The health care provider will also ask you about any problems that you may be having with the cream.
- Receive a pelvic exam to monitor tissue quality and wound healing. You will be asked about any pain or discomfort you experience during the process, and your answers noted in a questionnaire.

You will receive a refill of your medication at your 3 month visit

End of Study

After your 6 month clinic visit, you will not be scheduled for any further visits. You will be notified if you received Estrace® vaginal estrogen cream or placebo cream during your treatment protocol. You will receive a 15 minute follow up telephone call from one of our study coordinators up to 1 year after you have completed participation in the study. They may ask you questions regarding genital symptoms, pain, and sexual function

4. How long will I be in the study?

You will be in the study for approximately 1 year.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You may have side effects while on this study. Everyone taking part in the study will be watched carefully for any side effects. However, the study team does not know all the side effects that may happen. Expected adverse events are light vaginal bleeding, vaginal pain, mild allergic reaction or breast tenderness. There is minimal risk associated with vaginal estrogen and placebo cream but you may potentially experience vaginal discomfort or an allergic reaction with use of the product. Symptoms of light vaginal bleeding, vaginal pain or breast tenderness are expected during the normal postpartum time. Unexpected or serious adverse events include serious allergic reaction, venous thromboembolism (blood clots), neoplasia (cancer), acute kidney injury, stoke, death or other. As prior literature indicates, however, these events are extremely low.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risk of Discomfort During Questionnaires

You will be asked to answer questions about your body (including your vagina) and your sexual activity. It is possible that answering these questions may make you feel uncomfortable. You will be given as much time as you need to complete these questionnaires. You do not have to answer any question on the questionnaires that make you feel uncomfortable.

Risk of Breach of Confidentiality

As part of this study you are at risk for a breach in confidentiality of your protected health information (PHI). We will protect your PHI by storing your data in a secure database and coding your PHI however you are still at risk for a breach in confidentiality.

7. What benefits can I expect from being in the study?

There may or may not be any direct benefit to you for participating in this study. If the intervention improves your symptoms, it might help with management of vaginal atrophy and sexual function. It is hoped that the information gathered during this study will help research to improve the sexual function and quality of life for future postpartum patients.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Your provider will discuss appropriate options available to you regarding your condition. Available options will be dependent on your health and severity of your condition and can vary from patient to patient.

9. What are the costs of taking part in this study?

There will be no direct cost for you to participate in the study. There is no standard treatment for vulvar or perineal symptoms after a vaginal delivery. You will not be billed for the treatment that you receive. You will not be billed for any study-related visits.

10. Will I be paid for taking part in this study?

You will receive $10 compensation after your 6 week visit. You will be enrolled in a raffle to win a $100 gift card if you complete the 6 month visit. You have 1 in 112 chance of winning the $100 gift card at the end of the study period.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
- Records about the study device.

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:

  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Catherine Hudson, MD** or **Pamela Escobar Smith, MD** at **614-293-4643**.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the HIPAA Privacy Officer in the College of Medicine at **614-292-2856** or by mail at:

HIPAA Privacy Officer
Suite E2140
600 Ackerman Road
Columbus, OH, 43202

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Catherine Hudson, MD** or **Pamela Escobar Smith, MD** at **614-293-4643**.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time