VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Lara Harvey, MD MPH **Revision Date: 2/13/2026**
Study Title: Impact of an Educational Podcast for Patients with Chronic Pelvic Pain
Institution/Hospital: Vanderbilt University Medical Center

Name of participant: _____ Age: _____

Greetings, thank you for your interest. This form tells you about our research study. Please read carefully. We are happy to answer any questions. You will be given a copy of this consent form.

Key Information:

The purpose of this research study is to study the impact of an educational podcast on pelvic pain. Your participation is voluntary and you may stop participating at any time. If you decide to take part in this research, you may receive the standard treatment for pelvic pain, or you may receive the standard treatment plus access to an educational podcast series. You will be randomly assigned to receive access to the podcast or to receive standard care. If you are assigned to receive access to the podcast, participating in this research will involve listening to a podcast series. All participants will complete three ten-minute online surveys over the course of 6 months. Reasons you may choose to participate in this research are if you want to learn more about pelvic pain and possible benefits of listening to the podcast, such as improved quality of life, reduced stigma, or increased satisfaction with your medical care. Reasons you may choose not to participate in this research include not wanting to listen to a podcast or if you do not want more information about medical conditions. You may benefit directly from your participation in the study.

If you have questions about the research study, please contact Dr. Annie Apple at ***annie.apple@vumc.org*** or Dr. Lara Harvey at ***lara.harvey@vumc.org***.

Detailed Information:

Why are we doing this research and why are you asked to participate?
You are being asked to take part in this research study because we want to study if a podcast on chronic pelvic pain can help patients.

Do you have to be in this research and can you stop if you want to?
You do not have to be in this research study, and you can stop being in this study at any time.
You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights.
If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.
Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

What will you do and how long will it take?

Participants will be randomly assigned to a condition group, which is like flipping a coin. You will know which condition group you are assigned to in this research.
If you are assigned to listen to the podcast, you will be asked to listen to a podcast series on your personal device (phone or computer). Each podcast will last approximately 20 minutes. There will be at least 6 podcasts to listen to. Topics discussed in the podcast include definition and diagnosis of chronic pelvic pain, medical treatments of endometriosis, surgical treatments of endometriosis, mental health and other related topics. All participants will be asked to complete online surveys about your symptoms and experiences on three separate occasions over 6 months. The surveys will take about 10 minutes to complete. You will be asked about your symptoms of pelvic pain, prior treatments, and how your pain impacts different components of your life. You will also be asked about your social support and feelings of loneliness. You will also be asked about your satisfaction with receiving medical care.

What good things might come from this study?

a) The benefits to science and humankind that might result from this study: developing more educational resources for patients with chronic pelvic pain, increasing access to specialists in pelvic pain
b) The benefits you might get from being in this study: learning more information about your health, improvement in symptoms, greater satisfaction with your medical care

Are there any risks or discomforts for this study? Can anything bad happen to you?
You may feel sad or uncomfortable when completing the surveys.
You may feel sad or uncomfortable when listening to the podcast.

What are the unforeseeable risks?
Because this treatment is investigational, meaning non-FDA approved, there may be unknown or unforeseeable risks associated with participation.

Is there compensation in case of study-related injury?
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.
There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

How can you find out the results of the study?
The results will most likely be published in a medical journal which is publicly available. The publication will be sent to you if requested.

What are the alternatives to participating?
If you choose not to participate, your medical care will not be impacted in any way.

What compensation will you receive for participating in the study?
You will not receive compensation for participating in this study.

Are there any reasons the researchers may remove you from the study?
Researchers may remove you from the study if you are no longer eligible.

What happens if you choose to stop being in the study?
You can leave the research at any time; it will not be held against you.

If you decide to leave the research, contact the investigator so that the investigator can remove you from the research study. Data collected at the point of withdrawal will still be analyzed unless you request it is removed. You may be asked to explain why you want to withdraw.

Who can you talk to about this study?
If you should have any questions about this research study or possibly injury, please feel free to contact **Annie Apple, MD** at **484-320-0710** or my Faculty Advisor**, Lara Harvey, MD MPH** at **615-343-5700**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

How will your confidentiality and privacy be maintained?
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We may share some information about you for others to use for research, but to protect your privacy we will not share information that could identify you, like your name.

Data will be stored in a secure platform and only approved study personnel will have access to the data. Data will be coded to prevent breeches of confidentiality.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in the study consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt University Medical Center, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies (for example, HHS, FDA, etc.), other sites in the study, data managers, insurance providers

and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in the study consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.
You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds this data. To ensure the scientific quality of the research study, you will not be able to review some of your research data until after the research study is finished.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title