INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

The Carevix Device: Assessing pain and effectiveness of a suction-based cervical stabilizer for IUD insertions in the clinic setting: a randomized, controlled (CARE) trial

IRB #25731 – Patient Consent

You are being asked to participate in a research study. This consent and authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

WHY IS THIS STUDY BEING DONE?

An IUD insertion is a medical procedure that takes place inside the uterus. When IUD insertions are performed, often the cervix needs to be stabilized to achieve intrauterine entry. The standard approach for cervical stabilization uses an instrument called a tenaculum. This leaves two punctures on the cervix, which can cause pain and bleeding. There is a new device called Carevix™, which is a suction-based atraumatic cervical stabilizer that can be used for intrauterine procedures that require stabilizing the cervix to achieve entry into the uterus.

Left: Single tooth tenaculum, Right: Carevix™

The purpose of this study is to evaluate patient-reported pain and provider-reported bleeding, ease of use and efficiency comparing the standard tenaculum to the Carevix™ device. This Carevix™ device received FDA clearance as of January 2023.

We are asking you if you want to be in this study because you will undergo an IUD insertion.

The study is being conducted by Alissa Conklin, MD through Indiana University School of Medicine.

HOW MANY PEOPLE WILL BE IN THE STUDY?

You will be one of 100 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

You will undergo your planned standard of care procedure. Before the procedure, you will be randomized to have either the tenaculum (standard) or the Carevix™ device used during the procedure.

You will be asked 5 times what your pain score is throughout your IUD insertion procedure: at baseline (before the procedure begins), at placement of either the Carevix device or tenaculum before any traction is placed on your cervix, with traction on the cervix before the IUD is inserted, and then immediately after the IUD is inserted.

After the completion of your procedure, you will then be asked to complete a questionnaire on paper about your demographics, your past experiences with birth control, medical history, current medications, and your procedure experience. This takes, on average, about 1-2 minutes to complete.

This procedure is performed as a one-time only event and your participation in this study is a one-time only event.

You will not receive the results of any of the survey questions because it is being done only for research purposes.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

Either of these devices may cause bleeding on the cervix. With the Carevix suction-based cervical stabilizer device it is possible that the suction from the device could not release and would require an additional few seconds to release the suction. This device is currently in use by trained healthcare providers across the world. We do not have all of the data on how many times this device has been used globally. However, of the data collected internationally so far, there was one adverse event where the suction did not immediately disengage which caused mild bruising and bleeding, neither of which required any interventions above the standard silver nitrate application. If this were to occur, the device would be disassembled within 2-3 seconds. It is possible that both the tenaculum and the Carevix™ device could cause pain during the procedure.

You may be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer.

There is a risk someone outside the study team could get access to your research or medical information from this study. More information about how we will protect your information to reduce this risk is below.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured as a result of participating in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, signing this form won't take away any of your legal rights if you are injured.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

We do not know if you will have any personal benefits from taking part in this study, but there may be a possibility of decreased pain and bleeding. We hope to learn things to help others in the future.

WILL I BE PAID FOR PARTICIPATION?
You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?
The study team will collect information about you from your medical records. This may include information that can identify you, such as your name, contact information, and medical record number. Information from your medical records will be used to make sure you meet the inclusion criteria for the study and the date and type of your intrauterine procedure or to inspect and/or copy your research records for quality assurance and data analysis. Other medical records within your electronic health record may be accessed.

The information released and used for this research will include all of your medical records. Those records may contain information related to mental health, alcohol or substance abuse, HIV/AIDS, sexually transmitted diseases, and/or results of genetic testing.

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians OB/GYN

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US governments or agencies as required by law
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - The United States Food and Drug Administration (FDA)

After your medical record information is released for purposes of this research study, your information may no longer be protected under federal privacy laws, such as HIPAA. However, your identifiable information will still be stored securely and only used as described in the consent.

Information collected for this study may be used for other research studies or shared with other researchers who are conducting their own research studies. This may include sharing with researchers outside Indiana University and sharing with private companies. It may also include making the information available in public

and private databases of research data so that other researchers can use the information to answer research questions.

If we share your information in this way, we will remove information that could identify you, such as your name and contact information before any information is shared. Since identifying information will be removed, we will not ask for your additional consent for this sharing.

A description of this clinical trial will be available on 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 this website at any time.

HOW WILL MY INFORMATION BE PROTECTED?

We will do our best to keep your personal information private, but we cannot promise complete confidentiality. We won't share any information that we think could be used to identify you in publications about this study. However, your personal information may be shared outside the research study as described above and/or if required by law.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

If you have questions about this study or encounter a problem with the research, contact the primary researcher, Dr. Alissa Conklin at alconkli@iu.edu.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about any research study, or to obtain information or to offer input, please contact the IU Human Research Protection Program office at 800-696-2949 or at irb@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with your IU Health OB/GYN provider.

If you change your mind and decide to leave, the study team will help you withdraw from the study safely. If you decide to withdraw, please email Dr. Alissa Conklin at alconkli@iu.edu. You would need to provide your name and date of birth and that information would be utilized to find the survey recorded from the date of your procedure.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Dr. Alissa Conklin at alconkli@iu.edu. If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was

collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

PARTICIPANT'S CONSENT AND AUTHORIZATION

I agree to participate in this research study.

Participant's Printed Name: _____

Participant's Signature:_____**Date:**_____

Participant's Address:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____**Date:**_____