INFORMED CONSENT

TITLE OF STUDY: Decreasing Postoperative Pain Following Endometrial Ablation: A Randomized Controlled Trial

PRINCIPAL INVESTIGATOR: Jordan Klebanoff, MD

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INTRODUCTION

You have been asked to take part in a clinical research study. For you to be able to decide to be part of this study or not, you should understand enough about its risks and benefits to make an informed decision. This process is known as informed consent. This consent form describes the purpose, procedures, possible benefits and risks of the study.

Your study doctor will discuss the clinical research study with you. Clinical research studies include only people who choose to take part. Please take your time to make your decision. Discuss it with your family and friends and health care team. Please read this document carefully and if you have any questions, you can ask your study doctor for further explanation.

You are being asked to take part in this study because you are undergoing a medical procedure to destroy the lining of the uterus because of bothersome bleeding, called an endometrial ablation.

The person responsible for this study at Christiana Care is Jordan Klebanoff, MD.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to assess whether or not women undergoing endometrial ablation may benefit from additional anesthesia at the completion of their procedure. The goal of the study is to reduce post-operative pain by using additional pain medication. This information is important to know because currently this additional anesthesia is sometimes given, exposing patients to potential risks without any proven benefit.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We expect to enroll 84 people in this trial.

WHAT IS INVOLVED IN THE STUDY?
If you qualify and agree to be in the study you will be asked to sign this consent form. On the day of your scheduled procedure you will be "randomized" into one of two study groups. Randomization means you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group:

- Group 1 will receive an injection of local anesthesia around the cervix after the procedure is finished
- Group 2 will receive an injection of normal saline solution around the cervix after the procedure is finished

You and your study doctor will not know which group you will be in. This is done to ensure the accuracy of the study results. Your pain will be measured according to the standard CCHS outpatient procedures. If you need additional pain medications, they will be provided to you.

Before leaving the surgical center you will be given two pieces of paper with a pain scale from 1-10 to rate your pain. We ask that you fill out these pain scales at home two times, the first 4 hours after your surgery and the second 8 hours after your surgery. The day following your surgery a study investigator will call you to obtain the scores you have recorded on the two pain scales. You will also be asked to state the number of pain tablets that you have remaining at this time.

Your involvement after discharge will include answering an additional phone call to fill out the two pain scales and to state the number of pain tablets you have.

HOW LONG WILL I BE IN THE STUDY?
You will be in the study from the time you sign this consent form until 1 day after the procedure.

CAN I STOP BEING IN THE STUDY?
You can stop being in the study at any time. The researcher also maintains the right to remove you from participation in the study at any time to protect your health and safety. Please tell the study doctor if you are thinking about stopping or if you decide to stop. If you decide to withdraw from the study, we will also ask you to complete an "Acknowledgement of Withdrawal Form".

WHAT ARE THE RISKS OF THE STUDY?
While on the study, you are at risk for some side effects. You should discuss these with the researcher and/or your regular doctor. There also may be other side effects that we cannot predict. Side effects may be mild or very serious. Other drugs or treatments may be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the intervention/drugs are stopped, but in some cases side effects can be serious or long-lasting or permanent. If side effects become severe, hospitalization may be necessary for treatment.

We do not anticipate any foreseeable risk to you as a participant of this study other than what your doctor discussed with you regarding risks when you signed your informed consent for this procedure. There are inherent risks of any surgical procedure some of which are unpredictable. There are risks associated with both general anesthesia as well as local anesthesia.

Patient Initials _____
Date _____

Some of the rare side effects of the local anesthetic that will be used in this study include: irregular heartbeats, cardiac arrest, liver damage, and death. Generally, these rare side effects are only encountered with injection of the anesthesia into a blood vessel which is not the intent for this study.

There is a risk of loss of confidentiality. We minimize this by assigning you a study ID number that is placed on all of the study forms so that your information is not readily available.

In the unlikely event that you experience any type of symptoms, side effects, or injuries due to your participation in the study, please let Dr. Klebanoff or the research staff know as soon as possible at 302-573-7413.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, it is possible that you may not benefit. The study doctors hope the information learned from this study will benefit other patients undergoing endometrial ablation in the future.

WHAT OTHER CHOICES ARE THERE IF I DO NOT TAKE PART IN THIS STUDY?
You do not have to take part in this research study in order to receive treatment. Your participation is voluntary. You may refuse to take part, or stop participating at any time without penalty, or jeopardizing your continued medical care at Christiana Care, or lose benefits you would otherwise be entitled to.

WHAT ABOUT CONFIDENTIALITY?
We need to collect information about you to conduct this study. Your personal health information is health information about you that could be used to identify you. This information may include demographics (such as your age, sex, height, weight), information about your health now and in the past, any surgeries that you may have had, and other facts about you collected for the purposes of this research study. The information that will be collected will be the minimum needed to meet the goals of this research study and will be used only for the study described in this consent. If you decide not to allow this use of your information, you may not take part or continue to take part in the research study, since the researcher needs this information to meet the study goals.

We try to keep your personal health information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law and it may be disclosed to others as described in this section. Individuals and organizations that may look at and/or copy your research records to conduct this research, assure quality of the data and analyze the data include:

- Members of the research team at Christiana Care;
- Medical staff who are directly or indirectly involved in your care related to this research;
- People who oversee or evaluate research and care activities at Christiana Care, including the Christiana Care Institutional Review Board, a committee that reviews research projects to help ensure that the rights of research participants are protected; and
- People from agencies and organizations that perform independent accreditation and oversight of research, such as the Department of Health and Human Services, Office for Human Research Protections.

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By signing this document, you are authorizing Christiana Care to use and release your health information for this research. Some of these groups listed above may not be required to protect your information. If permitted by law, they may be allowed to share it with others without your permission.

It is also possible that important information will be shared with your primary caregiver or other health care professionals as needed for your safety. If information from this study is presented or published at scientific meetings or journals, your name and other personal health information will not be used.

You have the right to see any medical information about yourself. However, during the research study you will not have access to all of the health information that is created or collected during the study. You do not have the right to review and/or copy records kept by associated with the study.

If you agree to participate in the study, you still have the right to withdraw at a later time. In addition, at the time you withdraw you have the right to refuse to allow future information about you to be collected and used for the research study. If you decide to withdraw from the study, you will be asked to tell a member of the research staff and sign a written notice (called an Acknowledgement of Withdrawal form) that you no longer allow the use of information for research purposes. If you withdraw from the study, your information that has already been collected may still be used and disclosed as described in this form for the research study but no new information about you will be collected.

It may be necessary to contact you at a future date regarding new information about the treatment you have received. For this reason, we ask that you notify the institution where you received treatment on this study of any changes in address. If you move, please provide your new address to the principal investigator or study staff.

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

WHAT ARE THE COSTS?
Taking part in this study may lead to added costs to you or your insurance company. You or your insurance company will be charged for continuing medical care and/or hospitalization. Please ask about any expected added costs or insurance problems.

Routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds will be offered to compensate you in the event of injury. However, by signing this document, you are not giving up any right you have to pursue legal remedies for injury resulting from participation in this study.

WILL I GET PAID FOR BEING IN THIS STUDY?
You will receive no payment for taking part in this study.

Patient Initials _____
Date _____

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide not to take part in the study, you will continue to receive the usual medical care appropriate for your condition. However, if you are thinking about stopping, we encourage you to talk to the researcher and your regular doctor first. They will tell you how to stop safely.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, contact the researcher Dr. Jordan Klebanoff at (302) 573-7413.

For questions about your rights as a research participant, contact the Christiana Care Institutional Review Board at (302) 623-4983.

You will be given a copy of this form.

SIGNATURE
You have read the information provided above. You voluntarily agree to take part in this study.

_____ _____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Christiana Care Institutional Review Board

RESEARCH PARTICIPANT BILL OF RIGHTS

As a participant in a research study or as someone who is asked to give consent on behalf of another person for such participation, you have certain rights and responsibilities. It is important that you fully understand the nature and purpose of the research and that your consent be offered willingly and with complete understanding. To aid in your understanding, you have the following **specific** rights:

1. To be informed of the nature and purpose of the research in which you are participating.
2. To be given an explanation of all procedures to be followed and of any drug or device to be used.
3. To be given a description of any risks or discomforts which can reasonably be expected to occur.
4. To be given an explanation of any benefits which may be expected by the subject as a result of this research.
5. To be informed of any appropriate alternative procedures, drugs, or devices that may be advantageous and of their relative risks and discomforts.
6. To be informed of any medical treatment which will be made available to the subject if complications should arise from this research.
7. To be given an opportunity and encouraged to ask any questions concerning the study or the procedures involved in this research.
8. To be made aware that consent to take part in the research may be withdrawn and that participation may be discontinued at any time without affecting continuity or quality of your medical care.
9. To be given a copy of the signed and dated written consent form.
10. To not be subjected to any element of force, fraud, deceit, duress, coercion, or any influence in reaching your decision to consent or to not consent to take part in the research.
11. Your signature on the Informed Consent does not waive any of your legal rights.

If you have any further questions or concerns about your rights as a research participant, please contact the Christiana Care Institutional Review Board at (302) 623-4983.

Patient Initials _____

Date _____