# CONSENT FOR CANCER RESEARCH

**Project Title:** Sentinel Lymph Node Mapping for Endometrial Cancer

**Principal Investigator**: Chad Michener, MD, Cleveland Clinic
216-445-0226
**Sponsor:** None

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Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at Cleveland Clinic.

## 1. Introduction

We are asking you to participate in a research study. The purpose of this document is to summarize your discussion with the research team and provide you with written information to help you decide whether you want to participate in research. Your decision is completely voluntary.

Your treating doctor may also be an investigator on this research study. If so, your doctor will have an interest in both your welfare and in the research study. You are not required to take part in this research study offered by your doctor. You may ask for a second opinion from another doctor who is not linked to this study. If you choose not to be in this study, the quality of your regular medical care will not be affected.

Please ask any questions you may have about the study or this consent form before signing it. Please take your time to make your decision. You will be given a copy of this form to keep.

## 2. Purpose

### Why Are You Being Asked To Take Part In This Research?

You are being asked to participate in this research study because you will be having surgery for your endometrial (uterine) cancer that includes removing some of your pelvic lymph nodes (pelvic lymphadenectomy).

### Why Is This Study Being Done?

The purpose of this study is to investigate the usefulness of sentinel lymph node biopsy for endometrial cancer.

Lymph nodes are small glands which help to fight infection. Cancer cells can sometimes spread to lymph nodes. During cancer surgery some of your lymph nodes will be removed to see if the cancer has spread to them. In this study researchers will be using a procedure called a sentinel lymph node biopsy which will help to find the sentinel lymph node, the first lymph node that cancer would usually spread to.

During your surgery while you are asleep (under anesthesia) doctors will use a small needle to inject a dye into your pelvic area. The dye will then travel to the sentinel lymph node. The doctor will then remove that lymph node and send it to the pathologist for examination. The doctors will then complete your surgery as planned and explained to you before surgery.

Researchers will use the information they receive from your surgery and pathology reports to help determine the usefulness of sentinel lymph node biopsy for endometrial cancer.

**How Many People Will Take Part In The Study?**

Approximately 200 people will take part in this study. About 100 patients will be enrolled at Cleveland Clinic.

## 3. Study Procedures

You will have 3 routine visits for this study. All of these visits will be done even if you are not entered into the study. There are not any additional tests, visits, or examinations that are required specifically for this study. The table below explains what will happen at your visits.

| Visit | Intervention | What procedures/tests that will be done at this visit? |
|---|---|---|
| **Visit 1**<br><br>Within one month before surgery | Pre-operative evaluation | • Routine pre-operative labs<br>• Routine pre-operative examination<br>• Sign consent |
| **Visit 2** | Operation | • Cancer procedure with sentinel lymph node biopsies |

| | | |
|---|---|---|
| **Visit 3**<br>2-4 weeks after surgery | Post-operative evaluation | • Routine post-operative examination |

Your participation in the study will end after your post operative evaluation (visit 3).

**4. Risks**

The surgery you are having is not part of the study. Your doctor(s) will explain the risks and benefits of your surgery and you will sign a separate permission form for that.

The main risk to this study is that you may have some additional lymph nodes removed if you participate in the study. This study requires a pelvic lymph node dissection. If you were not participating in this study, your doctor may or may not decide to perform a pelvic lymph node dissection. By removing these lymph nodes, we will be able to tell you whether or not they have cancer in them. However, there is a small risk of lymphedema (approximately 5-10%), which causes swelling of the legs post-operatively.

The only other additional risk to the study is the very low risk of a sensitivity reaction to one of the dyes used to identify a sentinel lymph node. A sensitivity reaction may include shortness of breath, wheezing, a fast heart rate and low blood pressure. If this kind of reaction occurs during surgery you will be given medicine to help with these symptoms. There is less than a 2% risk of this type of reaction.

**5. Benefits**

There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

**6. Alternatives to Participation**

The alternative to participation in this study is to receive the standard surgical treatment for your disease, or to receive no treatment at all.

**7. Costs and Compensation**

There are no additional costs to you for participation in this research study. The cost for routine tests and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider.

You will not be paid for participating in this study.

**8. Research-Related Injury**

It is important that you tell your study doctor or nurse if you feel that you have been injured because of taking part in this study.

If injury occurs as a result of your involvement in this research, medical treatment is available from Cleveland Clinic and another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you weren't in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research-related injury. To help avoid injury, it is very important to follow all study directions.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

Further information about research-related injuries is available by contacting the Cleveland Clinic Institutional Review Board at (216) 444-2924.

**9. Privacy and Confidentiality**

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to **Chad Michener, MD or Kimberly Levinson, MD,** the research staff at Cleveland Clinic and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition..

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board, the Case Comprehensive Cancer Center Protocol Review

and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- The Food and Drug Administration*;*
- The Department of Health and Human Services;

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to **Chad Michener, MD or Kimberly Levinson, MD, Cleveland Clinic at 9500 Euclid Ave., A-81, Cleveland, Ohio 44195**, **(216) 445-0226.**

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board (IRB) assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are agreeing to the use of your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

**10. Voluntary Participation**

Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

If new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

**11. Questions About the Research**

If you have any questions, you can ask the Principal Investigators and/or research staff by writing or calling: **Chad Michener, MD or Kimberly Levinson, MD, Cleveland Clinic, 9500 Euclid Ave., Desk A-81, Cleveland, Ohio 44195**, **216-445-0226.**

**Emergency and After-hours Contact Information**

Main campus patients should contact the page operator at (216) 444-2200 or toll free at (800) 223-2273, and ask for the oncologist (cancer doctor) that is on call.

If you are a Cleveland Clinic-Fairview participant, please call (216) 476-7540.

If you are a Cleveland Clinic-Hillcrest participant, please call (440) 312-5560.

If you have questions about your rights as a research subject, you may contact the Institutional Review Board (IRB) at Cleveland Clinic IRB 216-444-2924.

**Where Can I Get More Information?**

You may call the National Cancer Institute's Cancer Information Services at:
1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI website at http://cancer.gov
For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials
For NCI's general information about cancer, go to http://cancer.gov/cancerinfo

You will get a copy of this form. If you want more information about this study, ask your study doctor.

**US National Institutes of Health (NIH) Clinical Trial Database**

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.

**12. Signature**

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or

sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

| _____ | _____ | _____ |
|---|---|---|
| ***Signature of Participant*** | ***Date*** | ***Printed Name of Participant*** |

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

| _____ | _____ |
|---|---|
| ***Signature of Person Obtaining Consent*** | ***Date*** |

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***Printed Name of Person Obtaining Consent***