THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent
Date of Consent Activation: 09/25/2018

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Study Title: Conservative surgery for women with low-risk, early stage cervical cancer
2008-0118

Subtitle: MD Anderson and Harris Health System Consent

MD Anderson and Harris Health System Informed Consent

Protocol Number:
Approval Date:
Expiration Date:
(Harris Health System)

Researcher at the Harris Health System: Kathleen Schmeler

Researcher at MD Anderson: Kathleen Schmeler

Participant's Name _____ Medical Record Number _____

This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. You may choose not to take part in this study.

1. DESCRIPTION OF STUDY

The goal of this surgical research study is to learn if "conservative surgery" is a safe and feasible option for women with low-risk cervical cancer (stage IA2 or IB1, Grade 1 or 2).

This is an investigational study. Up to 195 patients will take part in this multicenter study. Up to 40 participants will be enrolled at MD Anderson and the Harris Health System.

2. STUDY PROCEDURES

Stage IA2 or IB1 cervical cancer is currently treated by a radical hysterectomy (removal of the uterus, cervix, and the parametrium) or radical trachelectomy (removal of the cervix and the parametrium). The parametrium is the tissue next to the uterus and cervix that holds these organs in place. Pelvic lymph nodes and possibly para-aortic lymph nodes (near the aorta in the abdomen) are also removed. This procedure is called a pelvic and para-aortic lymphadenectomy. While these surgeries are very effective, significant side effects can occur, such as bladder, bowel, and/or sexual dysfunction.

Conservative surgery involves the removal of the pelvic lymph nodes (pelvic lymphadenectomy) and/or lymphatic mapping with sentinel lymph node biopsy. The cervix and parametrium are left intact. During surgery, for women no longer wanting children, a simple hysterectomy (removal of the uterus with or without removal of the fallopian tubes and ovaries) can also be performed. In this study, participants will have conservative surgery.

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. You will have "screening tests" to help the doctor decide if you are eligible to take part in this study. The following tests and procedures will be performed:

You will have a cervical cone biopsy and endocervical curettage (ECC) performed. A cone biopsy is surgery to remove a cone-shaped piece of tissue from the cervix and cervical canal. It is used to diagnose cervical cancer and also to learn how extensive the disease is. An ECC is a procedure using a curette, a spoon-shaped instrument, that is used to scrape the mucus membrane of the endocervical canal (passageway between cervix and uterus) in order to get a tissue sample.

The tissue taken from both of these procedures will be reviewed by a pathologist from MDAnderson.

If your tissue samples are negative for invasive cancer or adenocarcinoma-in-situ (AIS), you will be eligible for conservative surgery.

If your tissue samples are positive for invasive cancer and/or AIS, you may have the cervical cone biopsy and ECC repeated. If the tissue samples are negative after the second procedure, you will be eligible for conservative surgery. If your tissue samples from the second procedure are positive, you will be removed from study and other treatment options will be offered.

Conservative Surgery

If you are found to be eligible to take part in this study, you will have conservative surgery. You will be taken to the operating room where you will be put to sleep using general anesthesia. You will have your pelvic lymph nodes removed by pelvic lymph node dissection and/or lymphatic mapping with sentinel lymph node biopsy, however, the parametrium is left intact. If you no longer want to have children, you can have a simple hysterectomy. Removal of the pelvic lymph nodes takes about 1-2 hours. If you also decide to have a simple hysterectomy, this procedure will take about 2 hours.
You will sign a separate consent for this surgery/procedure, which will discuss the risks in more detail.

Study Procedures

If you agree to take part in this study, the following information will be collected from your medical record and/or you will be asked for this information when you enroll in the study:

- Age at the time of the cancer diagnosis
- Race
- Height and weight to determine body mass index (BMI)
- Menopausal status
- Symptoms
- History of sexually transmitted diseases
- Smoking history
- Child bearing history

The following information will be collected from your medical record and/or you will be asked for this information after surgery:

- How long the surgery took to complete
- What procedures were performed during the surgery
- How long you were in the hospital
- If there was any blood loss before or after surgery
- If blood transfusions were performed before or after surgery
- What complications, if any, happened that were related to the surgery

Starting 3 months after your first visit after surgery, you will have study visits every 3 months for 2 years. At these visits, the following tests and procedures will be performed:

- You will have a physical exam.
- You will have a pelvic exam.
- You will have a pap smear.

You will be contacted by telephone or by mail every year for 3 years. You will be asked if the cancer has returned, when you last saw your doctor, and any complications or problems you may be having. If you are called, the call will take less than 10 minutes.

Length of Study
You may remain on study for 5 years after surgery. You will be taken off study early if either the lymph nodes or cervix (if a simple hysterectomy was performed) removed during surgery contain cancer.

3. POSSIBLE RISKS

While on this study, you are at risk for side effects. These will vary from person to person. You should discuss these with the study doctor. Many side effects go away shortly after the procedure is over, but in some cases side effects may be serious, long-lasting or permanent, and may even cause death.

Cervical cancer can spread into the parametrium. Several studies have shown that the chance of cancer spreading to this area in patients with certain types of stage IA2 or IB1 disease is small. However, the only way to know for sure whether or not cancer is in the parametrium is by removing this area, along with the uterus and cervix (radical hysterectomy), and examining the tissue under a microscope. Participants in this study will have **"conservative surgery"** which does not involve the removal of parametrium. Because the parametrium is not removed there is a risk that cancer cells may be left behind.

The cervical cone biopsy and ECC may cause abdominal pain or cramping, bleeding, and/or discomfort.

Simple hysterectomy may cause discomfort, pain, and/or bleeding. You may need blood transfusions. Your body may go into shock, which is a serious condition where not enough blood flow reaches the body tissues. You may have damage to other organs, such as the intestines, bladder, and ureter (the tube that carries urine from the kidney to the bladder). This damage may require additional surgery to repair. Blood clots may form in the large veins that pass into the lungs. This may cause breathing failure.

A simple hysterectomy may cause damage to the nerves in the abdomen, which may cause numbness of the abdominal area and/or loss of function of the area of the abdomen that is linked to the damaged nerves. The incision sites and body organs around the surgical area may become infected and require treatment.

Electrocautery (the electric tool used to remove tissues) that is used during the simple hysterectomy may damage the skin.

After a simple hysterectomy, you will no longer be able to become pregnant.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant or breastfeed a baby while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: Women who have a pelvic lymph node dissection should use an effective method of birth control for 6 months following this procedure.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant may result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

If you agree, you will complete 5 questionnaires that ask about your health and well-being, sexual functioning, symptoms, and satisfaction with healthcare decisions. The 5 questionnaires will take a total of about 15 minutes to complete. These questionnaires will be completed at the following timepoints:

- Within 4 weeks before your scheduled surgery
- Three (3) months after your first visit after surgery (+/- 1 month)
- Six (6) months after your first visit after surgery (+/- 1 month)
- One (1) year after your first visit after surgery (+/- 1 month)
- Two (2) years after your first visit after surgery (+/- 1 month)

There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks:
Some questions in the **questionnaires** may be sensitive in nature. You may refuse to answer any questions that make you feel uncomfortable. If you have concerns after completing the questionnaire, you are encouraged to contact your doctor or the study chair.

Optional Procedure Benefits:
There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned.

Optional Procedure Alternatives:
You do not have to agree to take part in the optional procedures in order to receive treatment on this study. You may withdraw from the optional procedures at any time.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Do you agree to complete 5 questionnaires about your health and well-being, sexual functioning, symptoms, and satisfaction with your healthcare decisions as an optional procedure?

YES NO

4. POTENTIAL BENEFITS

Conservative surgery may help reduce side effects after surgery. Future patients may benefit from what is learned. There may be no benefits for you in this study.

5. OTHER PROCEDURES OR TREATMENT OPTIONS

You may have a radical hysterectomy or radical trachelectomy. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

6. COSTS AND COMPENSATION

Payment for Injury for Harris Health System participants
In the event of injury resulting from this research, MD Anderson and/or the Harris Health System are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You should report any injury to Kathleen Schmeler at 713-745-0307 and to the MD Anderson IRB at 713-792-2933. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Payment for Injury for MD Anderson participants
If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson, or the study sponsor for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your health care plan and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your health care plan and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your health care plan may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

ADDITIONAL INFORMATION

7. You may ask the researchers (Dr. Kathleen Schmeler, at 713-745-0307) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-2933 with any questions that have to do with this study or your rights as a study participant.

8. Your participation in this research study is strictly voluntary. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson and the Harris Health System.

9. This study or your participation in it may be changed or stopped at any time by the study doctor, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

10. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

11. MD Anderson and the Harris Health System may benefit from your participation and/or what is learned in this study.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson and the Harris Health System will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Officials at the Harris Health System and the Harris Health System Research and Sponsored Programs Department
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson and the Harris Health System will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson and the Harris Health System, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization by sending or faxing your request in writing. For MD Anderson participants, instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP). You may contact the Chief Privacy Officer of MD Anderson at 713-745-6636 with questions about how to find the NPP. For Harris Health participants, send or fax your request in writing to: Kathleen Schmeler (phone: 713-745-0307, FAX: 713-792-7586, Address: 1155 Pressler St., Unit 1362, Houston, Texas 77030). If you withdraw your authorization, the data collected up to that point can be used and included in data analysis, but no further information about you will be collected.

E. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the researcher permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT DATE

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)
The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SIGNATURE OF LAR DATE

RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT
I was present during the explanation of the research to be performed under Protocol **2008-0118**.

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR RESEARCHER) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

PERSON OBTAINING CONSENT
I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

SIGNATURE OF RESEARCHER OR PERSON AUTHORIZED TO OBTAIN CONSENT DATE

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR RESEARCHER)	DATE