THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Study Title: Prevalence of Anal Dysplasia and Anal Cancer in Women with Cervical, Vaginal and Vulvar Dysplasia and Cancer
2014-0021

Subtitle: MD Anderson and Harris Health System Consent

MD Anderson and Harris Health System Informed Consent

Protocol Number: **2014-0021**
Approval Date:
Expiration Date:
(Harris Health System)

Researcher at the Harris Health System: Kathleen Schmeler, MD

Researcher at MD Anderson: Kathleen Schmeler, MD

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

STUDY SUMMARY

The goal of this clinical research study is to learn how often high-grade dysplasia or invasive squamous cell carcinoma of the anus occurs in women with high-grade dysplasia invasive squamous cell carcinoma, invasive adenocarcinoma, or AIS of the cervix, vagina, or vulva.

This is an investigational study.

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If you are found to have HPV and/or pre-cancer or anal cancer, you may benefit by being diagnosed. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience pain and/or discomfort.

You can read a list of potential side effects below in the Possible Risks section of this consent.

Data related to HPV related dysplasia and cancer may be collected for up to 5 years. After that, your study participation will be over.

The anal pap test, anal HPV testing (including the research testing related to anal HPV), cervical/vaginal and rectal swabs, and a mouth rinse collection will be performed at no cost to you. You and/or your insurance provider will be responsible for the cost of any cervical/vaginal pap test, colposcopy, or surgery that your doctor performs as standard of care for the cervical, vaginal and/or vulvar dysplasia or cancer.

You may choose not to take part in this study.

1. STUDY DETAILS

Up to 500 women will take part in this study. Up to 250 will be enrolled at MD Anderson. Up to 250 will be enrolled at the Harris Health System.

Anal cancer as well as cervical, vaginal, vulvar, and oropharyngeal cancer (cancer in the throat) can be caused by an infection called human papillomavirus (HPV). Researchers do not know how often anal or oropharyngeal cancer and dysplasia occur together with cervical, vaginal or vulvar high-grade dysplasia, or invasive squamous cell carcinoma . All of these diseases are caused by the HPV virus and for this reason are thought to be related. Researchers also want to learn how to test for these diseases.

If you agree to take part in this study, the following tests and procedures will be performed either during your scheduled colposcopy as part of a clinic visit, or during your scheduled surgery. These tests are performed to test for pre-cancer of the anal canal.

During your scheduled pelvic exam, 3 cervical/vaginal swabs will be collected for research testing. Two (2) are for HPV research, and one is related to bacteria in the cervix/vagina.

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You will have an anal pap test. To perform this test, 12 small swab is placed in your anal canal to collect cells, similar to the pap test performed on your cervix/vagina. Three (3) additional samples will be collected, including 2 for HPV research, and 1 for research testing related to bacteria in the rectum.

Two (2) mouth rinse samples will be collected for research testing related to oral HPV. For each sample, you will swish with mouthwash for 15 seconds, gargle for 15 seconds, and spit into a sample cup.

If you have an abnormal test result, you will be referred for additional standard-of-care diagnostic procedures.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with your study doctor. The known side effects are listed in this form, but they will vary from person to person.

Side Effects of Cervical/Vaginal Swab, Anal Pap, and HPV Testing

• swelling	• pain/discomfort	• spotting and/or bleeding • redness

Side Effects of Mouth Rinse

• mouth/throat irritation	• taste changes

This study may involve unpredictable risks to the participants.

3. 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, MD at 713-745-3518 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

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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.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

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

4. You may ask the researcher (Dr. Kathleen Schmeler, MD, at 713-745-3518) 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 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. 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.

6. This study or your participation in it may be changed or stopped without your consent at any time by the researcher, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

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7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

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

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and the Harris Health System and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson and/or the Harris Health System may use any leftover samples that are stored at MD Anderson and/or the Harris Health System in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson and/or the Harris Health System, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson and/or the Harris Health System, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment.

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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

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

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, 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, MD (Phone: 713-745-3518, Fax: 713-792-7586), Address: Dan L. Duncan Building (CPB6.3227), 1515 Holcombe Blvd., Unit 1362, Houston, TX 77030. If you withdraw your authorization, the data collected about you 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.

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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

_____
PRINTED NAME OF PARTICIPANT

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

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2014-0021**.

_____ _____
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.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

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.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

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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

_____

PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION

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