THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR
PARTICIPATION IN RESEARCH

THE PREVENT ANAL CANCER (PAC) PALPATION STUDY

2021-0094

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 Harris Health System: Elizabeth Y Chiao

Researcher at MD Anderson: Elizabeth Y Chiao

_____ _____
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 research study is to learn about different ways to screen for anal cancer. Researchers want to learn if single persons can do a self-anal exam, or if the exam requires a partner, or if the exam requires a doctor or nurse for safety, accuracy, and acceptability.

An anal exam is also sometimes called a digital anal rectal exam (DARE). For this study, an anal exam completed by an individual will be called an anal self-exam (ASE). An anal exam completed with a partner will be called an anal companion exam (ACE).

This is an investigational study.

Future patients may benefit from what is learned. There may be no benefits to you on 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.

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

Your participation in this study will last about 6 months.

There are no costs to you for any of the visits or services you receive in this study.

You may choose not to take part in this study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study.

1. STUDY DETAILS

Up to 800 participants will be enrolled in this multicenter study. Up to 250 people will take part in this study at The Harris Health System (Thomas Street Clinic).

If you agree to take part in this study, you will have 2 study visits about 6 months apart. Each visit will last about 90 minutes.

Visit 1

At this first visit, you will have the following tests and procedures:

- You will take a short pre-test on paper or computer that should take about 10 minutes. This will ask you about your demographic information (such as age, sex, sexual orientation) and any diseases that you may have.
    - If you enroll in the study over the phone or by video conference, you will be asked to complete this survey on your phone or a computer before the baseline visit.
    - If you enroll in the study over the phone or by video conference, you will also need to show a photo ID to help the study staff make sure you are the person who agreed to take part in the study (any photo ID will do).
- Your weight, height, and waist size will be measured.

The study staff will then provide you with information about anal warts and anal cancer. They will show you pictures.

The study staff will then use a model to show you how to perform an anal exam. There are 4 steps to an anal exam for single men (3 steps for partners):

1) put on exam gloves and lube a finger,
2) touch the anal opening and feel for something that doesn't seem normal - like a lump

3) put a finger in the anus to the first knuckle, and feel all around the anus (360°) for anything that does not seem normal, and then push in to the second knuckle and feel again
4) (for single men) switch hands and repeat to feel 360° of the anal canal.

The staff will ask you (or your partner, if you enroll as a couple) to demonstrate on the model what you have been taught.

The study staff will collect an anal canal cell sample. The clinician will insert a swab into the anus and twirl it, slowly removing the swab, counting slowly to ten, and applying pressure to the anal canal walls. This sample will be shipped to the coordinating site, the Medical College of Wisconsin, where it will be stored for possible future testing to help develop and test better methods for diagnosing anal cancer. The sample will be stored with a study code and will not contain any identifiers (meaning the sample will not be linked to you).

The doctor/nurse will then give you an anal exam, which will include looking at your anus for disease and gently inserting an index finger to find out if you have anything abnormal in your anal canal. The doctor/nurse will later tell you the results.

If you enroll in the study as an individual, the doctor/nurse will then leave you in private and you will perform the ASE on yourself just as you have been taught to do. When you are done, you will write down your results. If you enroll with a partner, your partner will perform an ACE on you and then you will switch.

Then, the doctor/nurse will come back in and give you the results of the anal exam that they did. If the doctor found something that wasn't normal, then the doctor/nurse will refer you for treatment or help you find treatment.

After you receive the results, you will complete a questionnaire about the experiences with the exam/study. The questionnaire should take no more than 10 minutes.

You may also be asked to take part in a 15-minute interview in which you will be asked about your feelings about the exam and any anxiety you may have or have had. A study team member will let you know if you are chosen for the interview. The interview will be audio-recorded. The study staff will not ask you about any information that can identify you in the interview, or which could identify anyone in your social network. You will be reminded not to say anything that could identify you or your social network in order to keep the interviews confidential. At the end of the study, the audio-recordings will be destroyed.

After you have completed the visit, the study team will schedule your Visit 2 in about 6 months. You will also then be randomly assigned (as in the flip of a coin) to 1 of 2 groups.

- If you are in Group 1, you will be called 2 and 4 months after Visit 1 and reminded to perform anal exams at home. You will also be given a diary in which you can record your results.
- If you are in Group 2, you will not be called and will not receive a diary.

Visit 2

Two (2) weeks before your scheduled visit, the study staff will contact you to confirm the Visit 2 appointment time, give instructions for the pre-visit anal exam, and how to report the result.

You will complete the Visit 2 pre-exam computer-assisted self-interview before coming to the clinic for Visit 2. You will be asked to do the anal exam at home within 24 hours before the Visit 2 in-clinic visit.

At your second visit, the same procedures from Visit 1 will be performed (except the ASE/ACE). You may again be asked to participate in a 15-minute interview. A study team member will let you know if you are chosen for the interview.

Other Information

The doctor in charge of this study, Dr. Elizabeth Chiao, may decide to take you off the study without your consent if:

- You are unable to meet the requirements of the study or your medical condition changes;
- New information becomes available that shows that participation in this study is not in your best interest; or
- If the study is stopped.

After you sign consent, a staff member from Medical College of Wisconsin (MCW), the coordinating center for the study, may attend one of the study visits. The MCW staff member may assist with taking body measurements and will observe the training session and study interviews. This would be for training purposes. You may choose that the MCW staff member does not attend the visit, or that he/she leaves the visit at any point.

2. POSSIBLE RISKS

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

The doctor/nurse will perform an **anal canal swabbing** on you. The insertion of the swab may be slightly uncomfortable, and he/she will rotate it gently to collect the sample.

You may also feel uncomfortable during the **ASE/ACE**.

Questionnaires may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

Any time information is collected about you there is a potential risk for **loss of confidentiality**. However, the researchers will make every effort to keep your information confidential. Please see the "Authorization for Use and Disclosure of Protected Health Information (PHI)" section below for more information.

This research is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The researchers with this CoC may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this CoC cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below).

The CoC cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation. You should understand that a CoC does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The CoC will not be used to prevent disclosure for any purpose you have consented to.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

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 Dr. Elizabeth Y. Chiao at 713-792-1860 and to the MD Anderson IRB at 713-792-6477. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 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 a $50 gift card for participating in the first study visit. You will receive an additional $80 gift card for participating in the second study visit. If you attend both study visits, you will receive a total of $130, paid in gift cards.

Additional Information

4. You may ask the researchers (Dr. Elizabeth Y Chiao, at 713-792-1860 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, National Cancer Institute, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

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.

9. This study is sponsored and/or supported by: National Cancer Institute.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data

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

Samples

Anal canal cell samples will be collected from you as part of this study. Researchers at MD Anderson, the Medical College of Wisconsin, the Harris Health System, and/or the National Cancer Institute, may be used 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 and/or the Harris Health System 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. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you.

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
   - National Cancer Institute, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - The National Institute of Health (NIH)
   - Medical College of Wisconsin, University of Texas Health Science Center, University of Chicago
   - 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.

   The anal canal cell sample will be shipped to the coordinating site, the Medical College of Wisconsin, where it will be stored for possible future molecular testing. The sample will be stored with a study code and will not contain any identifiers.

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:

   Fax: (713) 873-4141

Mailing Address: 2015 Thomas St, Houston, TX, 77009.

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.

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 2021-0094.

_____ _____
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

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 DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR RESEARCHER)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION