EFFECTIVE

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MCW IRB

Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

The Prevent Anal Cancer Study

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Definitions

Anal canal – the part of the body that starts at the opening of the anus and goes into the body for 1-2 inches.

DARE – A Digital Anal Rectal Exam is when a health care provider, like a nurse, views the skin around the opening of your anus to look for disease and then inserts a finger into your anus to feel for a problem in your anal canal.

Perianus – the skin around your anus.

Purpose

This project is being done to find out if single persons can do an anal self-exam (ASE) and if couples can do an anal companion exam (ACE).

Length

- You will be in this research project for about six months
- We would also like to keep in touch with you after your study activities are done if the health care provider found a problem with your anus. That way we will know what treatment you received and the treatment outcome.

Activities

In this study we'll give you education about your anus, teach you how to examine it so you can do an exam yourself, and ask you to complete questionnaires. A health care provider will collect an anal swab and examine your anus for cancer and other problems and give you the DARE results. After you get the results, we'll put you in one of two groups:

1) People in group one are asked to practice the ASE (or ACE) at home between Visit 1 and Visit 2.
2) People in group two are not asked to practice the exam at home.

List of visits:

- Visit 1
  - Total Number: 1
  - Total Time: 1 hour 15 minutes for individuals; 1 hour 30 minutes for couples.
- Visit 2 (six months after Visit 1)
  - Total Number: 1
  - Total Time: 1 hour for individuals; 1 hour 15 minutes for couples.

Activities that will occur at various visits:

Invasive Activities
- [Anal swab, DARE and ASE (or ACE)

Non-invasive Activities
- Questionnaires

Risks

This is a brief list of the most commonly seen risks The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Activity risks:

- Talking about the anus may make a person uncomfortable.
- Getting a DARE and an anal swab from a doctor or nurse may be embarrassing or slightly uncomfortable.
- Doing an ASE (or ACE) may make some persons embarrassed or uncomfortable.
- Some questions on the questionnaire may seem personal and make a person uncomfortable.

Benefits

This project may or may not help you, but we hope the information from this project will help us learn better ways to screen for anal cancer.

My Other Options

You do not have to join this project. You are free to say yes or no.

- Whether or not you join this project, you are free to seek services from this or other agencies.
- Whether or not you join this project, your usual medical services will not change.

If you have more questions about this project at any time, you can call Alan G. Nyitray, PhD at 414-805-3312.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because

- You are 25 years of age or older
- Acknowledge sex with men in the past five years or identify with a minority sexual or gender orientation
- Identify as male or a transgender person who has sex with men

A total of about 1000 people are expected to participate in this research nationally, including 400 in Houston.

The Director of the project is Alan Nyitray, PhD in the Center for AIDS Intervention Research and the Department of Psychiatry and Behavioral Health. A research team works with Dr Nyitray. You can ask who these people are.

The National Cancer Institute of the National Institutes of Health, a government agency, is funding the research.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A3. WHY IS THIS PROJECT BEING DONE?

This project is being done to try to find out if individual persons can do an anal self-exam (ASE) and if couples can do an anal companion exam (ACE). If persons can do the exams well, then it may help detect anal cancer earlier.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

You previously answered a few questions so we could learn if you're eligible for the study. The current consenting process is for you to decide if you want to be in the study. If you agree to be in the study and are able to take part in this study you will participate in the following activities:

Online (right after the consenting process)

- You will be sent a copy of the consent.
- We will set up a time and date for your Visit 1 to the clinic.
- You will take a short survey on your phone or PC (15 minutes).

Visit 1

- We will first check a photo ID to make sure you're the person who agreed to be a part of this study (any photo ID will do). Then, we will measure your weight, height, and waist size.

- Then we will tell you a little bit about anal anatomy and disease that can happen at the anal canal like anal cancer and anal warts.

- We will use mannequins so you can begin to learn how to do an ASE, or an ACE if you enroll as a couple. Both the ASE and ACE involve viewing the perianus and then inserting a finger in the anal canal to feel for something that's abnormal.

- We will also collect an anal canal cell sample using a swab (like a Q-tip). This sample will be shipped to the coordinating site, the Medical College of Wisconsin, where it will be stored and then possibly used in additional tests to help learn how to improve detection of anal cancer and other anal conditions. The sample will be stored with a study ID and will not contain any identifiers.

- Next, the health care provider will 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 health care provider will tell you the results later in the visit. It is possible that the PI or Study Coordinator will observe the health care provider who does your anal exam to help improve the quality of the research.

- If you enroll in the study as an individual, the health care provider will then leave you in private and you will perform the ASE on yourself just as you have been taught to do. When you're done, you will write down your results and give them to study staff. If you are here with your partner, your partner will perform an anal exam on you and you will perform an anal exam on your partner.

- Next, you'll take a post-exam survey (15 minutes).

- Then, we will give you the results of your DARE. If the health care provider found something that wasn't normal, then they will refer you for treatment, if any treatment is needed.

- After you get the results, we will randomly (like flipping a coin) put you into one of two groups:

    1) People in group one will be asked to practice the ASE (or ACE) at home between Visit 1 and Visit 2.
    2) People in group two will not be asked to practice the exam at home.

After you have completed the visit, the study team will schedule your Visit 2 for about six months later. If you're assigned to group 1, we'll contact you to remind you to practice the ASE (or ACE) between Visit 1 and Visit 2 and to get the results of your exam. We will also contact you before your second visit to remind you of the date and time. At that time, we'll also send you a link to complete a pre-exam survey on your computer or phone. Finally, we'll tell you about the study's referral program which provides incentives for referring friends and family to the study.

Visit 1 will take about 1 hour 15 minutes for individuals and 1 hour 30 minutes for couples.

Visit 2

At your second visit, the same procedures listed above will be performed again, except study staff will not train you again on how to perform the exams. In addition, we'll ask you to do the ASE/ACE at home just before you come back to the clinic rather than you performing it in the clinic as in visit 1. This will shorten your clinic visit to less than 1 hour for individuals and 1 hour 15 minutes for couples.

B2. HOW LONG WILL I BE IN THE PROJECT?

You will be in this research project for about six months.

We would also like to keep in touch with you if the health care provider found a problem with your anus. That way we will know what treatment you received and what happened with the problem. We will contact you by your preferred means of communication (telephone, text, or email) about one year after Visit 2 to ask about health issues related to your anus that may have happened in the prior year. If the health care provider found a problem with your anus during Visit 2, we will contact you after Visit 2 until the problem is taken care of.

B3. CAN I STOP BEING IN THE PROJECT?

You may stop at any time. If you decide to leave the project, please let the research team know.

The research director, Dr. Alan Nyitray, may stop your participation in the project at any time for any reason without your consent. He will tell you if this happens.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

We watch everyone in the project for unexpected problems. **You need to tell the research health care provider or a member of the research team immediately if you experience any problems or become too anxious.**

What about DARE and ASE/ACE Risks?

The health care provider (a doctor or a nurse) will perform an anal canal swabbing on you. The insertion of the swab may be slightly uncomfortable and he or she will rotate it gently to collect the sample. Talking about the anus or doing an ASE (or ACE) may make some persons embarrassed or uncomfortable.

What about Questionnaire Risks?

Some of the questions may seem personal and may make you feel uncomfortable. If you have any questions or concerns while answering these questions, please talk to a member of the study team. You may choose not to answer any question that makes you uncomfortable. A few questions we ask will be about COVID-19.

What about Confidentiality Risks?

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that

could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C2. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

This project may or may not help you, but we hope the information from this project will help us learn better ways to detect anal cancer. Possible benefits to you may include referrals to services if the health care provider believes there's a problem with your anus.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

There are no costs to you for any of the visits or services you receive in this project. If you have questions regarding costs, please contact Dr. Alan Nyitray. If you are billed for any study activities, do not pay it. Contact Dr. Nyitray if you get a bill for study activities.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

You will be paid $50 after Visit 1 and $80 after Visit 2 for your time in completing the study activities and the cost of parking or transportation. If you complete both visits, you will receive $130. If you joined as a couple, each person in the couple will receive these amounts.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no.

Whether or not you join this project, you are free to seek services from this or other agencies and your usual medical services will not change

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about DARE or anal self-exams that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

When research activities like anal exams are done, there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

In this study, you will be informed of any findings of possible clinical significance that may be discovered during review of results from your research DARE. The results of your research DARE may be placed in your medical record.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or

your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research clinician right away. Contact information: Derek Smith, Advance Practice Nurse Practitioner, 713-526-0005, Crofoot Research Center, 3701 Kirby Dr, Ste 1230, Houston, TX 77098.

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Dr. Alan G. Nyitray at 414-805-3312.
- You can also call Derek Smith, Advance Practice Nurse Practitioner, 713-526-0005, Crofoot Research Center, 3701 Kirby Dr, Ste 1230, Houston, TX 77098.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, or from forms we ask you to fill out, as described below. We will only collect and use information needed for the project.

The health information we will collect and use for this project is:

Health information collected during this project, such as, results of study-related procedures and questionnaires. This information includes name, address, date of birth, dates of study visits, study procedures, and telephone number. The information is collected to allow the study team to stay in contact with you and to monitor your progress in the study.

E2. Who will see the health information collected for this project?

The only people allowed to handle your health information are those on the research team at MCW/Froedtert Hospital, the Crofoot Research Center, Thomas Street Health Center, MD Anderson Cancer Center, The University of Texas Health Sciences Center in Houston, University of Chicago, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information and anal swabs, the information and swabs may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the research director about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Dr. Alan Nyitray, Medical College of Wisconsin, Clinical Cancer Center, Suite 5434, 8701 Watertown Plank Road, Milwaukee, WI 53226-3548. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the project. We may still use the information we have already collected.

E6. Audio recording

At the end of Visit 1, some participants will be asked to do an interview in the clinic with the study staff that will take up to about 15 minutes. The interview will ask questions about anxiety and the experience of the ASE or ACE.

All interviews will be recorded and transcribed. Both the recordings and transcripts will be saved on a secure server at MCW and University of Texas Health Sciences Center and analyzed by members of the research team.

Initial either 1 or 2 to let us know if this is okay:

1. _____I do not want to be audio recorded in this study. I understand I still can participate in other parts of the study.

2. _____I agree to be audio recorded in this study. I may ask that the recorder be turned off at any point during the interview if there is something that I do not want recorded.

E7. Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you, except the following:

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

F1. FOR MORE INFORMATION ABOUT THE PROJECT

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.

You can look up this project by referring to the ClinicalTrials.gov number NCT04090060 or by asking the research team for a printed copy.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it

where you can find it easily. It will help you remember what we discussed today.

Participant's Name *please print*	**Participant's Signature**	**Date/Time**