The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB19-0525

Name of Subject: _____

Medical History Number: _____

STUDY TITLE: Determining the accuracy of self- and partner anal exams for detecting anal abnormalities

Doctors Directing Research: Aniruddha Hazra, MD

Address: 5841 South Maryland Avenue
MC 5065
Chicago, Illinois 60637

Telephone Number: 773-795-2016

KEY INFORMATION

We are asking you to choose whether or not to volunteer for a research study about self-screening for anal cancer (anal self-exam – ASE), and partnered-screening (partner anal exam – ACE). The study will question if the ASE or ACE can detect abnormalities and if they are more effective than less-frequent exams performed by a doctor. This section is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is above. Throughout this form, "you" will refer to you, your partner, or both.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this research study is to find ways to screen for anal cancer. This study will try to find out if single persons can do a self-anal exam, or perhaps the exam requires a partner, or if, in fact, the exam requires a doctor or nurse for reasons of safety, accuracy, or acceptability. An anal exam is also sometimes called a digital anal rectal exam (DARE). For this study, we will refer to an anal exam completed by an individual as an anal self-exam (ASE). We will refer to an anal exam completed with a partner as an anal companion exam (ACE).

You have been invited to join this research study because you are 25 years of age or older, identify as a gay or bisexual man, as a transwoman, or as a transman, have had sex with men, live in or near Chicago, and you are not currently diagnosed by a doctor as having anal cancer, anal warts, anal fissure, anal skin tags, or hemorrhoids.

By doing this study, we hope to learn if an ASE can be performed at home and maintain the same level of safety, accuracy, and acceptability as when completed by a nurse or doctor. Your participation in this research will last about six months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Your participation in this study may not directly benefit you. However, by participating you will be helping us better understand how ASE compares to ACE, or DARE completed by a clinician.

For a complete description of benefits, refer to the Detailed Consent Section below

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life. However, if the study tasks cause you to feel emotional distress, you may stop participating.

For a complete description of risks, and alternate options, refer to the Detailed Consent Section below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

You may choose not to participate at any time during the study. You will not lose any services, benefits or rights you would normally have if you choose to leave the study. The University of Chicago/University of Chicago Medical Center will not condition (withhold or refuse) treating you on whether you sign this Authorization or revoke your authorization at a later time. If you do not sign this form, you will not receive the research-related intervention(s).

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Hazra of the University of Chicago. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: 773-795-2016.

If you have a research related injury, you should immediately contact 773-795-2016**.**

For questions about your rights as a research subject, please contact the University of Chicago BSD IRB at 773-702-6505.

DETAILED CONSENT

WHAT IS INVOLVED IN THE STUDY?

About 400 people will take part in this study at the University of Chicago and about 800 people throughout the United States.

If you are eligible for this study and sign this consent form, you will participate in two study visits approximately six months apart. Each visit will last about 90 minutes.

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 training session and study interview. 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.

Visit 1 (Baseline)
At the first, Baseline visit, you will undergo the following procedures:

- The day before your in-person visit you will be sent a link to complete a survey about COVID-19 symptoms.
- You will take a short pre-test on paper or the computer, about 10 minutes. 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, we will first check a photo ID to make sure you're the person who agreed to take part in the study (any photo ID will do).
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- We will measure your weight, height, and waist size.
- Then we will tell you a little bit about disease that can happen at the anal canal like anal cancer and anal warts. We will show you photos of perianal tumors and lesions.
- 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 any abnormalities..
- There are four steps to an anal self-exam (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 doesn't seem normal, and then push in to the second knuckle and feel again
  4) (for anal self-exam) switch hands and repeat to feel 360° of the anal canal.
- We will also 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 molecular testing. The sample will be stored with a study code and will not contain any identifiers.

- Next, the doctor/nurse 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 doctor/nurse will later tell you the results. During initial appointments of the study, it is possible that the study's Principal Investigator, Dr. Hazra, will observe the doctor/nurse who does your anal exam.

- 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 are here with your 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 s/he did. If the doctor found something that wasn't normal, then s/he will refer you for treatment or help you find treatment

- Finally, we will ask you to participate in a quick survey, no more than 10 minutes. You may also be asked to participate in a 15-minute interview. A study team member will let you know if you are chosen for the interview. The interview will be audio-recorded in order to ensure that the information you provide during the interview is accurately recorded. We will not ask you about any information that can identify you in the interview, or which could identify anyone in your social network. Nevertheless, we will remind you 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 six months. We will call you before your second visit to remind you of the date and time. You will be asked to complete the ASE/ACE the day before this visit and text the result to the study staff. At that time, we'll also send you a link to complete a pre-exam survey on your computer or phone.

Randomization

After you participate in the Visit 1 activities, a computer will randomly assign you, like flipping a coin, to one of two study groups. If you are randomized to Group 1, the study team will call you to remind you to perform the ASE/ACE at home.

If you are randomized to Group 2, you will not receive phone calls about performing an ASE/ACE. You will not be required to complete a self-exam in between the two study visits. However you may still choose to perform an exam if you would like to.

Visit 2

The day before your in-person visit you will be sent a link to complete a survey about COVID-19 symptoms. At your second visit, the same procedures as listed above will be performed again, except the clinician will not give a demonstration of how to perform the ASE/ACE and you will have performed the ASE/ACE the day before the visit. You will be asked to complete a post-exam survey.

We will ask you to share an information card with a few of your friends who may be interested in taking part of this study.

Other Information
Your data collected during the study, such as results of exams or survey answers will be recorded into a database for the study. This database will be shared with other investigators at the Medical College of Wisconsin for analysis. They will receive your name, address, telephone number, and dates (such as date of birth or of appointments). They may contact you in the future if they have any safety concerns that they need to address directly with you. If you took part in the 15 minute interview, the responses given during the interview will be shared with researchers at the University of Texan Health. This interview data will be labeled with your study ID only and not any information that can identify you such as your name.

Your samples from the swabs collected during the study will be sent to Medical College of Wisconsin, who will store these samples indefinitely. The samples are labeled with a bar code and this bar code will link the sample to your study IDs. You may request that your samples are destroyed by writing to the address on the first page of this consent form. Any data collected from the samples prior to your request will be maintained.

In the future, identifiers associated with your data and/or specimens could be removed from the study database and specimens. The de-identified data and specimens could then be used for future research by our research team, MCW, or other researchers without notifying you or asking your permission for this use.

Dr. Hazra may decide to take you off of 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 indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

During your participation in this study, you are at risk for the side effects described in this section. You should discuss these with the study doctor. There may also be other side effects that we cannot predict.

DARE Risks
The doctor/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.

Loss of Confidentiality
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 "What about Confidentiality?" section below for more information.

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 your study doctor. You may choose not to answer any question that makes you uncomfortable.

Unknown Risks
There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue, this new information will be discussed with you.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot promise that you will benefit from participating in this study. The purpose of this study is to learn more about the difference in outcomes between ASE, ACE, and clinician DARE. However, possible benefits include a medical exam of the anus by a clinician and referrals to services should the results suggest an abnormal result.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate.

WHAT ARE THE COSTS?

Clinical services provided during a clinical research study are either research-related or considered part of the usual medical care for patients with your disease or condition. Tests, procedures, and activities that are ordered by your medical care team to monitor your disease or condition (whether you are participating in a clinical trial or not) are described as 'usual medical care'. 'Research-related' is the term used to describe any tests, procedures, or activities that you are being asked to undergo only because of your participation in this clinical trial.

All of the tests, procedures, and activities you will undergo as part of your participation in this clinical research study are considered research-related. You will not be responsible for the costs of tests or services that are being performed solely for the purposes of this study. However, this does not include visits or care received at the University of Chicago Medicine (or affiliate sites) that is not related to your participation in this clinical research study. You or your insurance will be financially responsible for the costs of your usual, ongoing medical care. Financial responsibilities from routine care may include deductibles and co-payments and this care will be subject to all the same requirements and restrictions of your insurance

If you have questions about whether specific clinical services are research related or part of your usual medical care, please speak to your physician or research contact person.

WHAT HAPPENS IF I HAVE AN INJURY?

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of

Chicago Medical Center at no cost to you. Costs of related non-emergency care for an unanticipated research injury will be covered if that care is provided at the University of Chicago Medical Center. You must notify Dr. Hazra as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure. If you think that you have suffered a research related injury, you must let Dr. Hazra know right away.

WILL I BE PAID FOR MY PARTICIPATION?

You will receive a $50 in cash for participating in the first study visit. You will receive an additional $80 in cash for participating in the second study visit. If you attend both study visits, you will receive a total of $130, paid in cash. If you refer a friend who enrolls in the study, you will receive $20 in cash. The amount you could receive for friend enrollment can vary from $0 to $100 in cash.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. Any research data will be stored in a locked drawer in a locked office and/or entered on a password-protected, HIPAA-compliant computer. Only study staff will have access to the data.

During this study, Dr. Hazra and his research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The information to be used on this study 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.

As part of the study, Dr. Hazra and his research team will share information about you as well as the results of your study-related procedures and tests with the coordinating site, Medical College of Wisconsin. Information from the study interview will be shared with University of Texas Health and will be labeled with a study ID only. We may also share the study data with other investigators in the future. These investigators may or may not be affiliated with the University of Chicago.

These include name, address, date of birth, telephone number, dates of study visits, as well as the results of research tests and procedures done as part of the study. This information is being sent to review the results of the study, to monitor the safety of participants, and to verify the accuracy of the study data.

Your PHI may be shared with governmental agencies, including the National Cancer Institute, for federally mandated reporting purposes.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). Representatives of the University of Chicago, including the Institutional Review Board (a committee that oversees the research) and the Office of Clinical Research may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

Once information is shared outside the University of Chicago, please note that your identifiable health information may be shared with someone else. The same laws that the University of Chicago must obey may not protect your health information.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team until completion of this study.

Data from this study may be used in medical publications or presentations. Your name and any other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

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.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Hazra in writing at the address on the first page. Dr. Hazra may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. Your authorization to use and disclose your health information does not have an expiration date.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____

Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____

Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician _____

Date: _____ Time: _____ AM/PM (Circle)