THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Texas State HPV Self-Collection Pilot Study
2019-0182

Subtitle: Project Self - Pilot Study

Study Chair: Surendranath S. Shastri

_____ _____
Participant's Name Medical Record Number or Study ID

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.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this research study (called Project Self) is to learn if providing self-collection kits, education, counseling, and navigation can help to improve cervical cancer screening rates in Hispanic and African-American women in Houston, Texas.

This is an investigational study.

Taking part in this study may help you to learn more about cervical cancer screening and some of the possible benefits and risks of engaging in screening. People in the future may benefit from what is learned on this study. 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 time commitment.

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

Your total participation time on this study will be about 4 weeks.

There is no cost to you for taking part in this research study.

You may choose not to take part in this study. You may choose to learn about cancer screening on your own or with the help of a doctor or other health care professional.

1. STUDY DETAILS

Up to 40 participants will be enrolled in this study. All will take part at MD Anderson.

Baseline Visit

If you are eligible and agree to take part in this study, the following will occur when you start the study (also called a baseline visit):

- You will complete questionnaires about yourself, cancer screening, and your health. These should take about 30-40 minutes to complete.
- You will take part in a health education session within your community or surrounding community setting (such as a community center). During the health education session, the research staff will give a 10-minute presentation and have a discussion with you and other women about cervical cancer screening. Your participation in the health education session may take up to 15 minutes.
- At the end of the health education session, you will complete a questionnaire that includes questions about your knowledge of cervical cancer screening/prevention and attitudes. This questionnaire will be similar to the one you completed before participating in the health education session and may take about 15-20 minutes to complete.
- At the end of your baseline visit, you will receive a HPV self-collection kit, including instructions on how to complete the kit procedures, as well as how to pack and return the kit to the lab/research staff member.

Your baseline visit may take up to 1 – 1½ hours to complete.

Weeks 1-2

You will be contacted by phone and/or text by a study staff member or Community Health Worker (CHW) during weeks 1 and 2 of the study:

- **Week 1** (from your baseline visit): you will receive a call and/or text reminding you to complete the HPV self-collection procedures and/or confirming that you have completed the self-collection.
- **Week 2** (from your baseline visit): you will receive a call and/or text reminding you to return the HPV self-collection kit to the lab, scheduling a date/time to return it to a research staff member, and/or confirming your kit return.

Test Results

You will receive your results from the lab within 2 weeks of returning your completed self-collection kit (by mail or in-person). You will receive your self-

collection results through an email, text, and/or letter from the lab. Project Self study staff will ask you for your test results. Your test results will be used for study purposes only and will be kept confidential.

Women who test positive by HPV self-collection test will be navigated to the nearest community clinic and/or federally qualified health clinic (FQHC) for diagnosis.

Follow-Up

About 1 month after your baseline visit, you will complete questionnaires in person or over the phone that include questions about your experience(s) with completing the HPV self-collection kit procedures. This should take about 20-30 minutes to complete.

Your participation on this study will be over after you have completed your Follow-Up assessment.

2. POSSIBLE RISKS

You should discuss the risks of questionnaires, health education, and self-collection procedures with the study chair. The known risks are listed in this form, but they will vary from person to person.

Some questions in the questionnaires and the content that will be discussed during the health education session may make you feel uncomfortable and may be sensitive in nature. You may refuse to discuss any topic or answer any question that makes you feel uncomfortable. Your name will not be used in the health education sessions. If you have concerns after completing the questionnaires, participating in the health education session, and/or completing the HPV self-collection procedures, you are encouraged to contact the study chair or study staff.

Your data will be used for research purposes only. Your responses will not be shared with your doctor. If you feel you need a doctor's opinion about anything that is asked about in the questionnaires (such as mental or emotional difficulties or symptoms), please contact either your personal doctor or the study chair.

However, if stress is suspected from you completing the questionnaires, you may be contacted by study staff. Possible outcomes of this contact could include referral to your primary care physician, other physician, and/or other mental health providers.

This study may involve unpredictable risks to the participants.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, the study staff may contact you to ask if you want to take part in other research studies in the future.

There are no benefits to you for taking part in the optional procedure. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.

Optional Procedure Risks

There are no known risks for taking part in this optional procedure.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

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

Optional Procedure #1: Do you agree to allow the study staff to contact you about taking part in future research studies?

YES NO

3. COSTS AND COMPENSATION

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 for this injury. 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.

Unless otherwise stated in this consent form, all of the costs linked with this study, which are not covered by other payers (health maintenance organization [HMO], health insurance company, etc.), will be your responsibility.

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.

As compensation for your time and effort, you may receive up to $35 total in department store gift cards. You will receive a $25 department store gift card after completing the health education session and questionnaires at the Baseline Visit, and you will receive a $10 department store gift card after completing the questionnaires at the Follow-Up Visit. The gift card(s) will be given to you in person at the visit and/or sent to you by certified mail within 2 business days after completing the visit.

Participants who make a good faith effort to complete the study activity will receive compensation.

Additional Information

4. You may ask the study chair (Dr. Surendranath S. Shastri, at 713-745-2682) 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 withdraw from this study, you can still choose to be treated at MD Anderson.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair 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 may benefit from your participation and/or what is learned in this study.

Future Research

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

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or 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 samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or 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, MD Anderson will not have oversight of any data and/or samples.

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

A. During the course of this study, MD Anderson may be collecting and using your PHI. For legal, ethical, research, and safety-related reasons, the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - 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 if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible according to state and federal law. However, in some situations, health authorities 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 in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, 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 study chair 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

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2019-0182**.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) 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 STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION