Informed Consent/Authorization for Participation in Research

Title of Research Study: The Effect of the Prostate Cancer Foundation Screening Guidelines for Black Men on Intention to Screen in Faith-based Communities

Study Number: 2024-1312

Principal Investigator: Matthew Smith

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

Key Information

The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

You are invited to take part in a research study because you identify as Black/African American man, and you are part of a faith-based community.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The goal of this research study is to learn about barriers to prostate cancer screening in Black, faith-based communities. Researchers will use the information collected in this study

to create a prostate cancer education program that is relevant to Black men within the church and improve prostate cancer screening.

How long will the research last and what will I need to do?

You will be asked to take part in a focus group and share your views on barriers to prostate cancer screening in Black, faith-based communities. Your participation in this study will be over after you complete the focus group.

More detailed information about the study procedures can be found under ***"What happens if I agree to be in this research?"***

Is there any way being in this study could be bad for me?

Focus groups may include questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

You will learn about prostate cancer during the focus group and may be better informed to speak with your doctor. Future patients may benefit from what is learned. However, it cannot be promised that there will be any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of your regular benefits.

Your alternative to participating in this research study is to not participate. Instead of taking part in this study, you may learn about prostate cancer and your risk of developing prostate cancer from your primary care doctor.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

Who can I talk to if I have questions or concerns?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team].

This research has been reviewed and approved by the MD Anderson Institutional Review Board ("IRB" - an ethics committee that reviews research studies). You may talk to them at 713-792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be in this study?

It is expected that about 24 people will be enrolled in this part of the research study at MD Anderson.

What happens if I agree to be in this research?

If you agree to take part in this study, you will take part in a focus group. You will be asked about your views and personal opinions on barriers of prostate cancer screening in the Black community, with a specific focus on Black men in church. You will also watch an educational video about prostate cancer and review specialized prostate cancer guidelines for Black men and will be asked to provide feedback about these materials.

The focus group will take about 2 hours to complete and will be led by the study chair and a research coordinator. A member of the research team will also take notes during the focus group, and the discussion will also be audio recorded and transcribed (written down word for word).

Additionally, your demographic information will be collected (such as your age).

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for the following:

- Follow study directions.
- Come to all study appointments (or contact the study team to reschedule).

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. You may withdraw from participation in this study without any penalty or loss of benefits.

If you decide you want to stop taking part in the study, tell the study doctor.

If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me? (Detailed Risks)

Focus groups may include 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 focus group, you are encouraged to contact the study chair.

There is a small risk that you **feel stress or worry** from learning about prostate cancer and possibly increased chances of having prostate cancer. If you are feeling distressed and the study staff or doctor thinks it is needed, you will be referred to another doctor or therapist for additional help.

Your voice may be identifiable in **audio recordings**.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

You will be told about any new information that may affect your choice to stay in the research.

Will it cost anything to be in this study? Will I be paid to be in this study?

There is no cost to you to take part in this study.

As compensation for your time and effort, you will receive $100 for completing the focus group.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who need to review this information. Complete secrecy cannot be promised. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

A participant study number will be assigned to you once you have been enrolled in the study. This participant study number will be used to identify your data in the study report and when reporting any data from the study.

Any personal information that could identify you will be removed or changed before data are shared with other researchers or results are made public.

Federal law provides additional protections of your medical records and related health information. These are described below.

Will my data be used for future research?

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

In some cases, all of your identifying information may not be removed before your data is used for future research. If future research is performed at MD Anderson, the researchers must get approval from the MD Anderson IRB before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or shared with another researcher for future research studies without your additional informed consent.

Some of your genetic and/or health information might also be placed into one or more external publicly accessible scientific databases. Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information.

Can I be removed from the research study without my permission?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include if you are unable to follow

study directions or if the study is stopped.

What happens if I get hurt from being in this study?

This is a minimal risk study. It is unlikely you will get hurt from taking part in this study. You may contact the MD Anderson 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.

What else do I need to know?

This research is being funded by [Insert sponsor/supporter name].

MD Anderson may benefit from your participation and/or what is learned in this study.

Your information (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

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

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your study records. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - The Office for Human Research Protections (OHRP)
   - The IRB and officials of MD Anderson
   - [List any other entities that may see PHI]
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Some of your information will be kept in a central research database. However, your name and contact information will not be put in the database. The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

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 do its best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it may be released to others. If

this happens, your information may no longer be protected by federal law.

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 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.

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

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