Thomas Jefferson University
Adult Informed Consent Document for Human Subjects Research

Department: Department of Medical Oncology
Principal Investigators: Charnita Zeigler Johnson, PhD, MPH
Amy E. Leader, DrPH, MPH

Study Title: A Neighborhood Based Intervention to Reduce Prostate Cancer Disparities

What Is Informed Consent?
You are being asked to take part in an educational research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a University committee that reviews, approves and monitors research involving humans. Before you can make a knowledgeable decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form. If you don't understand something about the study or if you have questions, you should ask for an explanation before signing this form;
- Being given a copy of the signed and dated consent form to keep for your own records.

What is the purpose of this study?
The purpose of the study is to understand the knowledge, attitudes, and beliefs about factors that may increase a man's chances of getting prostate cancer. We will also talk about the role that a man's neighborhood environment has on his health.

How many people will participate in the study and how long will the study last?
We will conduct 4 focus groups, each with up to 10 men in each group. Therefore, up to 40 men will be able to participate. We expect to conduct all of the focus groups over the course of 3 months.

What will I have to do during the study?
You will be asked to complete a short, one-page survey about your health history, focusing on your risk of prostate cancer. Then, you will participate in an informal discussion about men's health, particularly as it relates to prostate cancer risk. Members of the research team will be recording what is said during the discussion, but no videos will be made of the discussion.

What are the risks or discomforts involved?
You may become uncomfortable or anxious when talking about your own health or your health experiences. The research staff will do everything that they can to minimize this risk. Questions or concerns can be addressed by the research staff member who is attending the discussion.

Are there alternatives to being in the study?
Your alternative is to not participate in the research study.

How will privacy and confidentiality (identity) be protected?
Federal regulations require that certain information about individuals be kept confidential. This information is called "protected health information" (PHI). PHI includes information that identifies you personally such as name, address and social security number, or any medical or mental health record, or test result, that may have this sort of information on it. The laws state that you may see and review your TJU or Thomas Jefferson University Hospital medical records at any time. However, in a research study, you may not see the study results or other data about the study until after the research is completed unless the study doctor decides otherwise.

If you join this study, the following individuals or entities may have access to your PHI and by law must protect it. These include investigators listed on this consent form and other personnel at Thomas Jefferson University, Jefferson University Physicians and Thomas Jefferson University Hospitals, Inc. involved in this specific study, the University's Division of Human Subjects Protection, the Institutional Review Board (IRB) the Department of Defense, and collaborating investigators and personnel at the University of Pennsylvania involved in this specific study

Your PHI may also be shared with the following entities that, while not obligated by law to protect PHI, will protect it to the best of their ability:

- With any person or agency required by law.

The following information will be provided to the entities noted above:

- Study data for analysis: questionnaire results, decision sessions.
- Demographic data: name, date of birth, contact information including phone and address, race and ethnicity, level of education, and marital status.

You may quit the study and revoke permission to use and share your PHI at any time by contacting the principal investigator, Dr. Amy Leader, in writing, at 834 Chestnut Street, Suite 314, Philadelphia, PA 19107. If you quit the study further collection of PHI will be stopped, but PHI that has already been collected may still be used.

The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.
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, this Web site will include a summary of the results. You can search this Web site at any time.

Will I benefit from being in this study?
You may or may not receive a direct benefit however; it is hoped that participants will improve their knowledge of prostate cancer.

Will I be paid for being in this study?
You will receive $50 at the end of the focus group. This is compensation for taking the time to be a part of this important research project.

Who is sponsoring or paying for the study?
Researchers from Thomas Jefferson University are conducting this study with funding from the U.S. Department of Defense. Nothing from this study will be reported to your health insurance company, or your doctor.

Are there costs related to being in this study?
There is no charge for you to participate in this study. Neither you, nor your insurance provider, will be charged for participating in this study which includes completing a short survey and being part of a focus group.

Can I be removed from the study or quit the study?
Being in this study is voluntary. Anyone who takes part in the study can stop being in it at any time. There will be no change to your usual medical care if you decide not to be in the study or decide to stop being in the study. Your participation in this research project may be stopped by a study team member without your consent for any reason that he/she feels is appropriate.

CONTACT INFORMATION

Telephone number for questions about your rights as a research participant	Jefferson Institutional Review Board	215-503-8966
For questions, concerns or complaints about the research, or if you suspect a research-related injury	Principal Investigator, Dr. Amy Leader	215-955-7739
If you have difficulty contacting the study staff	Call the Jefferson Office of Human Research during working hours	215-503-0203

Non-Waiver of Legal Rights Statement

- ✓ **By your agreement to participate in this study, and by signing this consent form, you are not waiving any of your legal rights.**
- ✓ **In order to be in this research study, you must sign this consent.**
- ✓ **You affirm that you have read all pages of this consent form. You have been told that you will receive a copy.**

SIGNATURES

Your Name	Your Signature	Date
Name of **Person Conducting Consent Interview**	Signature of **Person Conducting Consent Interview**	Date
Name of **Investigator or Co-Investigator**	Signature of **Investigator or Co-Investigator**	Date

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/LAR**

***

Your Name **(if Minor)**	Your Signature **(if Minor)**	Date

(If subject is a minor and this document is being used both as consent and assent form.)

Name of **Witness**	Signature of **Witness**	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

As per University Counsel - Do not sign this consent form after 5/11/17