EH21-338: Observational and Prospective Study on the Performance of Inherited Risk Assessment for Predicting Prostate Cancer from Prostate Biopsy

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Version 1

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CONSENT FORM

Observational and Prospective Study on the Performance of Inherited Risk Assessment for Predicting Prostate Cancer from Prostate Biopsy

Principal Investigator: Jianfeng Xu, MD, DrPH

Principal Investigator telephone number: (224) 364-7501

Sponsor: NorthShore University HealthSystem

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose**. The purpose of this research is to study how genetic testing can be used to improve practices to screen for prostate cancer.
- **Duration.** It is expected that your participation will last less than half an hour.
- **Procedures and Activities.** You will be asked to review and sign the consent form and provide a saliva sample.
- **Risks.** Some of the foreseeable risks or discomforts of your participation may include loss of genetic material confidentiality.
- **Benefits**. There is no direct benefit to you but the researchers hope to improve current screening methods for prostate cancer.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Detailed Information about this Study:

Introduction: You are being asked to volunteer for this research study because this research study because you have agreed to undergo a prostate biopsy (a procedure for taking a small sample of prostate tissue) for the purpose of detecting prostate cancer as part of your clinical care.

This Consent Form gives information about the study that you can talk about with your doctor and/or family. You are being given this information to help your decision. If you have any questions, you can ask the study doctor or staff.

Why is this Study Being Done?

The purpose of this research is to study how genetic testing can be used to improve the practices we use to screen for prostate cancer. This may help identify patients who inherited a higher risk for developing prostate cancer who would benefit by undergoing prostate biopsies. This may also help reduce the number of unnecessary biopsies for other patients who inherited a lower risk for developing prostate cancer.

Genetic testing is a useful tool that involves analyzing an individual's DNA for changes that may affect one's risk for developing certain diseases and medical conditions. DNA is made up of small molecules called nucleotides that are arranged in specific sequences. The arrangement of nucleotides in a sequence is important for the function of cells and for sustaining life. Certain nucleotide sequences are called genes, which play an important role in the creation of substances like proteins. Although the vast majority of DNA sequences between individuals are the same, some are different. Some of these differences are very rare and are only found within genes; these are called mutations. Other differences are more common and can happen outside of genes; these are called single nucleotide polymorphisms (SNPs).

The researchers are studying how mutations and SNPs can help identify patients who are at higher risk for developing prostate cancer. Combining information from genetic tests and prostate biopsies may help to better identify the patients who should undergo prostate biopsies due to having a higher genetic risk of developing the disease. The results of this research may improve how we currently screen for prostate cancer.

This study will include a total of 1000 subjects. Of those subjects, 334 will be from NorthShore University HealthSystem (NorthShore).

What Will Happen During the Study?

Your urologist has already determined that you need to undergo a prostate biopsy as part of routine preventive care. A prostate biopsy is performed by inserting a small needle into the prostate gland to extract a small sliver of tissue.

After agreeing to participate in the study, you will be asked to provide a small saliva sample (about 1-2 teaspoons) by spitting in a collection tube. You may not eat, drink, smoke or chew gum 30 minutes prior to providing your sample. We will collect your saliva sample only once for the duration of the study. Your sample will be given a unique study ID and will not labeled with any personal identifiers in order to protect your privacy. Your saliva sample will be processed in our lab at the Research Institute. Your DNA will be extracted from the sample and will be sequenced to detect the presence of any genetic mutations and SNPs that may increase your risk for prostate cancer. Information from your medical records will be collected at three different times- screening, after consent and after the biopsy pathology results has been resulted/concluded.

How Long Will I Be in the Study?

Your participation will last for as long as it takes to provide the saliva sample after the consenting. Sample collection should last no longer than 10 minutes. There are no follow-up visits required by this study.

What Other Choices Do I Have?

This is a research study and does not involve treatment. The alternative is not to participate.

Are There Benefits to Taking Part in the Study?

There will be no direct benefit to you if you decide to participate in this study. You may indirectly benefit by feeling that you are helping people in the future. You may find the study purpose to be interesting.

This study may allow doctors to learn more about prostate cancer screening. Knowledge gained in this study may help people in the future.

What Side Effects or Risks Can I Expect?

This study does not require you to have any additional procedures or treatments. Therefore, being in this study should not involve any risks that you would not face during your routine treatment. You may experience dry mouth during and after providing the saliva sample.

Genetic Material: Procedures are in place to keep your participation and all of your genetic results confidential. NorthShore University HealthSystem will not give genetic information to you, your family, your insurance company or your employer. Because there are no present established genetic markers for how to identify prostate biopsy candidates for prostate cancer screening, you will not be told the results of DNA genetic testing. DNA data will be kept under lock and key, and will be accessible only to authorized personnel.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study. Your research file can also be looked at by the NorthShore Institutional Review Board, other medical personnel at NorthShore who are involved in your care, or by the Food and Drug Administration (FDA).

Protected Health Information (PHI)

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "protected health information (PHI)." In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

What protected health information (PHI) will be used?

- Past, present and future medical records, including information housed in the Electronic Medical Record called "Epic," which is maintained by NorthShore University HealthSystem
- Information about research procedures, including research office visits, medical tests, procedures, interviews and questionnaires

Who may see, use and share my PHI and why may they need to do so?

- NorthShore research staff involved in this study
- Non-research staff within NorthShore who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)
- The NorthShore IRB board that oversees the research and the NorthShore research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US government bodies that oversee or review research)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside NorthShore, we cannot promise that it will remain private.

Do I have the right to withdraw permission for the use of my PHI?

You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. Once permission is withdrawn, you cannot continue to take part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

Do I have access to my health information?

You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right not to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

Genetic Material (Confidentiality):

You may be concerned that if people not involved in this research know your genetic information, problems with employment or insurance could occur. The likelihood that your participation in this genetic research will harm you is small. This is because procedures are in place to keep your participation and all of your genetic results confidential. NorthShore Genomic Core will not give genetic information to you, your family, your doctor, your insurance company or your employer. Because there are no present established genetic markers for how to identify prostate biopsy candidates for prostate cancer screening you will not be told the results of DNA genetic testing. The scientists studying the DNA genetic information at NorthShore will never receive any information that could link your name to your clinical DNA data. Likewise, scientists at NorthShore University HealthSystem will never receive any DNA data that could be linked to your name. DNA data will be kept under lock and key, and will be accessible only to authorized personnel.

A federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will generally protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information from this research.
- If health insurance companies and group health plans do somehow receive your genetic information from this research, they may not use it to make decisions about your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information from this research when making a decision to hire, promote or fire you or when setting the terms of your employment.

Be aware that this new law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance; nor does it protect you if you self-disclose any genetic information.

Will I Be Paid for Participating?

You will not be paid for being in this study.

The results of this research may be used to help develop new products in the future. However, you will not receive any reimbursements from the sale of these products.

Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study. You will still be responsible for all costs that you would normally incur as part of routine care.

Can I Withdraw from the Study?

Your participation in this research study is voluntary. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. You may stop participating in the study at any time.

You can change your mind at any time if you decide that you don't want your samples to be used for this research. Please contact the study investigator/research staff and let them know that you wish to withdraw from this study. Your saliva samples will be destroyed. However, any samples already in use for research previously will not be disposed.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at (224)-364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

Who Can I Call with Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Principal Investigator, Dr. Jianfeng Xu, at telephone: (224) 364-7501.

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INDIVIDUAL PROVIDING EXPLANATION:

The procedures and/or investigations described in the above paragraphs have been explained to you by:

Name of Person Explaining Study (Please PRINT)	
Signature of Person Explaining Study	
Date Study Was Explained	

CONSENT TO PARTICIPATE:

I understand that the Principal Investigator and study staff will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study doctor and/or staff. I have had enough time to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	