Northwestern University
Robert H Lurie Comprehensive Cancer Center

CONSENT FORM AND AUTHORIZATION FOR RESEARCH

Title: NCI 01X2 (EH01-129): Specialized Program of Research Excellence (SPORE) in Prostate Cancer: Tissue Resource Core

Principal Investigator: Ximing Yang, MD, PhD

Supported by: National Institutes of Health, National Cancer Institute

Introduction

You are being asked to take part in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we (i.e., Northwestern University) would like to use information about you and your health.

What is the reason for doing this study?

You are being asked to take part in this project because your doctor would like to collect an extra portion of your prostate tissue or other specimens for future research. The Specialized Program of Research Excellence (SPORE) of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University is a tissue and specimen collection facility funded by the National Cancer Institute. The purpose of this facility is to collect prostate tissue for cancer research while maintaining that patient confidentiality and patient care are not affected in any way. The tissue will be made available to researchers worldwide through a strict request process.

What you will do if you choose to be in this study

You are being asked for consent to allow the SPORE to collect some of your biological samples and medical information. Only tissue or fluid in excess of that required for clinical decision making will be collected. Specimens to be collected include:

Tissue from prostate biopsy as well as from surgical resection: If you are scheduled to have a prostate biopsy or surgery, you may be asked to provide some of the tissue. It is normal for several core biopsies to be taken at the time of a prostate biopsy. If you agree to provide some prostate tissue, two extra biopsy cores along with two tumor blocks that are kept at your hospital storage will be taken and stored for future studies.

Blood: You may be asked to donate blood. This blood will be spun to separate it into different parts and will be frozen for future studies. If you are having treatment for prostate cancer, 1-10 teaspoons (5-50 ml) of venous blood may be drawn from you before, during and after treatment. Blood will

be drawn from existing intravenous lines if possible. Additionally, blood samples of 1-10 teaspoons (5-50 ml) may be collected from you if you have a normal prostate, benign disease, prostatic intraepithelial neoplasia (PIN), or prostate cancer when you are seen for prostate needle biopsy, treatment or follow up at any of the participating sites. The study team may also contact you or your physician in the future to request that you provide additional blood samples of 1-10 teaspoons (5-50 ml) during follow up visits. You may agree to or refuse these future requests for blood. Your choice will not affect your medical care or other aspects of this study.

Urine: You may be asked to donate 6-8 teaspoons of urine. This urine will be collected and frozen for future studies.

Tissue from prostate removal: If you are scheduled to have your prostate removed, you may be asked to donate some of this tissue for research purposes. Only tissue that is not needed for medical purposes will be taken and frozen for future research.

Prostate fluid: If you are scheduled for a digital rectal exam of your prostate (in which the doctor feels the surface of your prostate with a gloved finger, feeling for irregularities which may be suspicious for cancer.), you may be asked to donate prostate fluid. As your doctor massages your prostate, fluid is released through your urethra, which is the tube running through your penis that excretes urine and other fluids. About 1 teaspoon (5 ml) of fluid will be collected.

The study will also collect information about your medical history, your family's medical history, and your current health status on an ongoing basis from your medical record. If we are unable to collect complete information from your medical record, a member of the study staff may contact you annually at one of your physicians' follow-up visits, telephone, mail, email, or using any other contact information provided by you. A member of the study staff may also contact your physician if we are unable to reach you directly.

What are some of the risks and discomforts that may happen to people who are in this study?

Your involvement in this study may involve the following risks. In addition, there is always the risk of very uncommon or previously unknown side effects.

Digital Rectal Examination and Prostate Fluid Collection may involve some discomfort. There are also rare risks, which may include tearing in the lining of the rectum and/or bleeding.

Blood withdrawal may cause pain, bleeding, bruising and pain at the site of vein puncture, inflammation of the vein and infection; care will be taken to avoid these complications.

What are some of the benefits that are likely to come from my being in this study?

You will not benefit by allowing collection of your specimens and family health history for research. However, use of these samples and information may contribute to our understanding of the mechanisms of disease.

Are there any financial costs to being in this study*?*

Allowing for the storage and future testing of your tissue and blood samples will involve no cost to you. Your samples will be used only for research and will not be sold. The research done with your tissue and blood sample may lead to the development of new products in the future. No compensation will be given to you now or in the future for the use of these samples. You will not be paid for your participation in this study.

If I have questions or concerns about this research study, whom can I call?

The Office for the Protection of Research Subjects of Northwestern University, at telephone number (312) 503-9338, can provide further information about your rights as a research subject.

Further information regarding this project may be obtained from the study coordinator at (312) 695-4168.

What are my rights as a research subject?

Your participation in the project is voluntary and you are free to request that your samples be discarded at any time. Participation or withdrawal will not affect any rights to which you are entitled. If you do not take part in this project or request withdrawal of your samples, you will continue to receive care as determined by your regular doctor.

What about my confidentiality and privacy rights?

We are committed to respect your privacy and to keep your personal information confidential.

When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number.

Your health information we may collect and use for this research includes:

- all information in a medical record
- results of physical examinations
- medical history
- lab tests
- family medical history
- personal medical history

You are also giving permission to the following groups of people to give information about you (described above) to the researchers for this study:

- The Principal Investigator and the Investigator's Study team (other University staff associated with the Study)
- The Northwestern University Institutional Review Boards (the committees charged with overseeing research on human subjects)

- The Northwestern University Office for the Protection of Research Subjects (the office which monitors research studies)
- Authorized members of the Northwestern University workforce who may need to access your information in the performance of their duties (for example: to make sure the research is being done correctly).

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is required by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office]

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office of Research, and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study),

- Other University research centers or healthcare providers and their contractors who are also working on the study

- Study monitors and auditors who make sure that the study is being done properly,

- National Cancer Institute (NCI) who is sponsoring the study and their associates

- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

- Other health care providers who are not part of the Study but who may be involved in treating you

- Researchers worldwide who are given access to specific data and sample sets by the study Disbursement Committee

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for publications and presentations at scientific meetings.

Please note that:

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.
- You may change your mind and "take back" (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was

obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to:

Prostate SPORE Study Coordinator
Northwestern University Department of Pathology
676 N Saint Clair Street, Suite 1200
Chicago, IL 60611
(312) 695-4168

- Unless you revoke your consent, it will not expire.
- If you "take back" (revoke) your consent to use any blood or tissue taken for the study, the Principal Investigator will make sure that these specimens are destroyed or will make sure that all information that could identify you is removed from these samples.

Consent Summary:

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above.

A copy of this consent form will be provided to me after I sign it. A copy of this signed consent document, information about this study and the results of any test or procedure done may be included in my medical record and may be seen by my insurance company.

_____ _____
Subject's Name (printed) and Signature Date

_____ _____
Name (printed) and Signature of Person Obtaining Consent Date