

**NORTHWESTERN UNIVERSITY**  
The Robert H. Lurie Comprehensive Cancer Center

*Tissue Banking Consent Form*

**NCI 01X2: Specialized Program of Research Excellence  
(SPORE) in Prostate Cancer: Tissue Resource Core**

***Principal Investigator: Michael Pins, M.D.***  
***Sponsor: National Cancer Institute (NCI)***

**INTRODUCTION/PURPOSE:** 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 Northwestern University researchers and SPORE programs at other Universities nationwide.

**PROCEDURES:** You are being asked for consent to allow the SPORE to collect some of your biological samples. 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:** If you are scheduled to have a prostate biopsy, you may be asked to donate tissue from the biopsy. It is normal for several core biopsies to be taken at the time of a prostate biopsy. If you agree to donate some prostate tissue, two extra biopsy cores will be taken and frozen 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 surgery, 1-2 teaspoons (5-10 ml) of venous blood may be drawn from you before, during and after surgery. Blood will be drawn from existing intravenous lines if possible. Additionally, blood samples of 1-2 teaspoons (5-10 ml) may be collected from you if you have benign disease, prostatic intraepithelial neoplasia (PIN), and advanced prostate cancer when you are seen for prostate needle biopsy, treatment or follow up at any of the participating sites.

**Urine:** You may also 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.

All future requests for samples will be reviewed by a multi-institutional committee, which includes statisticians and board-certified pathologists and oncologists.

The study will also collect information about your medical history and your family's medical history from your medical record. Additionally on an ongoing basis, follow-up information about your health will be collected from your medical record. If you no longer visit Northwestern Memorial Hospital, a member of the study staff will contact you by telephone (about 10-15 minutes) once a year to collect information about your current health status.

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

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.

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

Prostate biopsy may be a somewhat uncomfortable procedure and can cause bleeding in the urine or rectum, or blood-tinged ejaculate (body fluid released by the prostate during sexual intercourse). There is also a risk of a temporary inability to urinate or infection.

**BENEFITS:** There will be no direct benefit to you by allowing collection of your specimens for research. However, use of these samples may contribute to our understanding of the mechanisms of disease.

**ALTERNATIVES:** You have the alternative to choose not to participate in this research study.

**CONFIDENTIALITY:** Participation in this research study may result in a loss of privacy, since persons other than the investigator(s) might view your study records. However, your research tissue or fluid will not be directly linked to your identity. After tissues are collected for study they will be identified by a serial number and not by your name or medical record number. Unless required by law, only the study investigator, members of the investigator's staff, members of the SPORE, the Northwestern University Institutional Review Board, and representatives from the National Cancer Institute (NCI), will have authority to review your study records. The principal investigator has

obtained a Certificate of Confidentiality from the federal government. Your study records cannot be subpoenaed (released to courts at their request), and we will only release your study records if you ask us in writing. Reports will be coded so that your confidentiality is protected. All materials and information obtained will be kept within a password protected electronic system. Only authorized individuals in the SPORE will have access to this system. Also, your collected sample will not be used for commercial purposes.

**FINANCIAL INFORMATION:** Participation in this project is at no cost to you. You will not be paid for your participation in this study.

**SUBJECTS' RIGHTS:** 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.

**CONTACT PERSONS:** 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 and is where any research-related injury should be reported.

Further information regarding this project may be obtained from the project director, Dr. Michael Pins, 312-908-9595.

**CONSENT:** I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered to my satisfaction. If I have additional questions, I have been told who to contact. I agree to participate in the research study described above and will receive a copy of this consent form. I will receive a copy of this consent form after I sign it.

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Subject's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date