

Office for the Protection
of Research Subjects

Northwestern University
750 North Lake Shore Drive
Suite 700
Chicago, Illinois 60611
irb@northwestern.edu
Phone 312-503-9338
Fax 312-503-0555



NORTHWESTERN
UNIVERSITY

October 15, 2009

William Catalona, PhD
Department of Urology
675 North St. Clair Street
Galter Pavilion - Suite 20-150
Chicago Campus
wcatalona@nmff.org

IRB Project Number: 1327-004
Approval Period: 10/14/2009 - 10/13/2010
Study Sites: Northwestern University, Northwestern Memorial Hospital, Clinical Research Unit, Northwestern Medical Faculty Foundation

Project Title: Genetics of Prostate Cancer Urological Foundation (#650 52620000 60017072)

Submission Accession Number: 200907-0148

Submission(s) Considered: Periodic Review

Revision: Increase in subject number from 3000 to 5000; conversion to the combined consent form/HIPAA authorization template;

Status: APPROVED

Project Expiration: 10/13/2010


On 10/14/2009 a member of the Institutional Review Board considered and approved your submission referenced above for a one year period ending 10/13/2010. IRB approval includes approval of the protocol and consent forms(s) listed below.

Version Date: 09/28/2009 Consent Form and Authorization for Research

IRB approval is granted with the understanding that the investigator will:

- Change neither the procedures nor the consent form without prior IRB review and approval of those changes.
- Changes in the approved research may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. Proposed changes must be submitted to the IRB as a Revision.
- Promptly report any unanticipated problems involving risks to subjects or others to the IRB. (See OPRS website, <http://www.northwestern.edu/research/OPRS/irb>, for additional guidance on reporting of UPIRSOS)
- Submit a Continuing Review of Research Form 4-6 weeks prior to the expiration of this approval. If IRB renewal is not obtained by the indicated expiration date, the protocol will be closed.
- Send a copy of the final approved consent form and a copy of this approval letter to the Office of Sponsored Research (OSR) if this is a sponsored project. Additionally, OSR must be contacted if any amendments are made to this project that may affect the award.

Sincerely,


Debra Gibson Tice, BS, CIP, CCRC
Co-Interim Director

CC: CRU
NMH

Northwestern University
Department of Urology

CONSENT FORM AND AUTHORIZATION FOR RESEARCH

Project Title: *Genetics of Prostate Cancer*

Principal Investigator or Faculty Advisor: *William J. Catalona, M.D.*

Supported by [or Funded by]: *Urological Research Foundation*

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 participate in a research study for William J. Catalona, M.D. on the Genetics of Prostate Cancer.

You are being asked to participate in this study because you have been either diagnosed with prostate cancer, have a family history of prostate cancer, are a healthy male or are at risk for developing prostate cancer. The purpose is to study genetic causes of prostate cancer. To further study this question, we are recording family histories of men who are diagnosed with prostate cancer, who have a family history of prostate cancer, or are at risk for developing prostate cancer, and their female relatives. The specimen (blood sample or tissue removed at surgery or biopsy or urine, if applicable) will be collected and may be stored for a long time. They will be analyzed by the research team and other researchers, based on specific study questions designed to discover the causes of prostate cancer and how it is passed down in families in the future. Any future research done will have to be first approved by the researcher's Institutional Review Board (these are research oversight agencies whose function is to protect the rights of research subjects and to oversee ethical issues).

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

Your participation in this study will last until the study is completed. Your participation will involve: having up to 50-ml of your blood drawn (10 teaspoons), donate 6-8 teaspoons of urine and completing family history questionnaires (baseline and follow-ups) and clinical follow-up questionnaires, if applicable. If you are already having blood drawn that day for clinical purposes, additional blood will be collected at the same time. If you come to clinic for research purposes, a trained clinical staff member will draw your blood for this research study. You may be asked to come to Clinical Research Unit (CRU) to get blood drawn. Additionally, if it is not convenient for you to come to our clinic, we can send you a blood drawing kit, and you will be able to get blood drawn at a clinic of your choice and mail back the blood sample.

It will take about 20 to 40 minutes to complete the questionnaire. In the case that your family history suggests familial prostate cancer, Dr. Catalona may want your family members to participate in the study as well. You may be asked to contact your relative(s) about the study. We will follow up with a Family History Follow-up Questionnaire annually, which takes 15 to 30 minutes to finish, to update the file. If you develop prostate cancer, we will want you to fill out a clinical follow-up questionnaire about prostate cancer and follow you up with the questionnaire annually as well, which takes 10 minutes to finish.

In addition, we may request up to 20 follow-up blood samples of 10 to 20 ml (2-4 teaspoons) and urine samples (6-8 teaspoons) from you at a later date. These may be requested at 6-12 month intervals for up to 10 years, depending on the evolving needs of the study. These sample collections may be coordinated with clinical visits if you are a patient of Dr. Catalona or one of his collaborators. If you are not a patient of Dr. Catalona or one of his collaborators, you may provide follow-up samples via return visits or mailed blood kits, as requested by the Primary Investigator. You may refuse to provide these follow-up blood samples without affecting your participation in this study.

The blood sample(s) will be saved for future analysis. If you have undergone or plan to undergo any type of procedure during which prostate tissue was/is removed, you may be asked to provide some of this tissue. You might need to sign a medical release form for the tissue removed at surgery or biopsy (if any) from the hospital where the surgery was performed. Please be aware that our studies may require the use of all of the tissue removed at surgery or biopsy, though ordinarily this specimen is not used for any clinical purposes after surgery.

In addition to your tissue, this research requires information from your health record' obtain. . This information may be also obtained from Dr. Catalona's patient registry and/or other studies if you have been enrolled for these studies. Donation of tissue along with your health information helps researchers to discover relationships between health history and specific characteristics of prostate cancer. Your information may be used for other studies in which you have been enrolled. At the end of this consent form, you may

choose how your blood sample and/or tissue will be used and whether we may contact you regarding future studies. The future studies include the follow-up, behavior of the disease in the population, cause, diagnosis, treatment, chemical aspects of the development and progression and genetics of prostate cancer, as well as other forms of cancer. The purpose of future studies will be to discover the underlying fundamental mechanisms of prostate cancer and other cancers in human beings.

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

Your participation in this study may involve the following risks: The discomfort associated with the blood draw, that might include slight pain and bruising at the puncture site, redness/swelling of the vein and infection. Care will be taken to avoid these complications.

You might find it embarrassing to discuss your cancer and your family's medical history with members of the research team. Certain genetic research may reveal that you are a carrier of a genetic disorder. This could mean that you or members of your extended family may have an increased likelihood of developing prostate cancer or other diseases or may be carriers.

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

There may be no direct benefit to you by your participation in this research study.

The potential benefits to society from participation in this study may include: Your participation in this study may aid in our understanding of prostate cancer or other diseases in our society that might lead to a means of detecting prostate cancer in the early stages and to new treatments of prostate cancer. By agreeing to participate, you authorize the use of your tissue for research that may benefit others. The study of your tissue may one day result in new tests or treatments or may help to prevent or cure prostate cancer or other disease.

What other procedures or courses of treatment might be available to me?

You have the alternative to choose not to participate or withdraw your consent at any time in this research study. If you later change your mind and choose to withdraw from the study, the DNA from your blood sample will be destroyed or transferred, using appropriate safety precautions, upon your request.

Are there any financial costs to being in this study?

You will not be charged for any study-related procedures. The study sponsor will pay for all procedures that are directly associated with this research study.

You will not be paid for your participation in this study. Allowing for the storage and future testing of tissue and blood samples will involve no cost to you. Your tissue will be used only for research and will not be sold. The research done with your tissue and blood 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.

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

Further information regarding this study may be obtained by contacting William J. Catalona, M.D. (Principal Investigator), at telephone number (312) 695-4471. For problems arising evenings or weekends, you may call (312) 695-4471.

What are my rights as a research subject?

Your participation in this study is voluntary and you are free to withdraw at any time. Choosing not to participate or withdrawing from this study will not affect your present or future medical treatment. Any new findings developed during the course of this research that may affect your willingness to continue will be provided to you.

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.

The following personal contact and personal health information will be collected, used for this research study and may be disclosed or released during your involvement with this research study:

- Name
- Address
- SSN
- Date of birth

- Race/ethnicity
- Telephone number, e-mail address, FAX number
- Internist/Urologist
- Background information (demographics)
- Work history
- Experience with tobacco
- Medical history and diagnoses
- Current and past medications and therapies
- PSA (Prostate Specific Antigen) level and other clinical testing results
- Pathology
- Family history questionnaire (including any pertinent medical history)
- DNA, obtained from your blood sample and/or tissue
- Genetic Testing Information
- Pathologic Specimen (if applicable)

In this study, you will be asked about illegal activities (use of marijuana, “crack”/cocaine or “poppers”/amyl nitrate). The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, courts have subpoenaed research records.

The following individuals and organizations within Northwestern University may use or disclose your personal health information for this research project:

- The Principal Investigator and the Investigator’s study team (other University staff and collaborators 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).

As part of the study the Principal Investigator, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to the following:

- Other researchers associated with the study (e.g., the Principal Investigator’s collaborators)
- Other health care providers who are part of the study (e.g., laboratories who perform tests)
- Other health care providers who are not part of the study but who may be involved in treating you
- Government agencies and public health authorities for the public health activities and matters over which they have official authority, such as the Food and Drug Administration in the United States and other countries
- Study monitors and auditors who are responsible for overseeing the quality and integrity of the study

The personal information of yours that is disclosed in connection with the study may no longer be protected by the federal privacy protection regulations.

In all disclosures outside of Northwestern University, you will not be identified by name, social security number, address, telephone 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 Investigator's office].

Results of this study may be used for teaching, research, publications, or presentations at scientific meetings. If your individual results are discussed, your identity will be protected by using a code number rather than your name or other identifying information. Examples of identifying information include medical record number, Social Security number, and address.

Research results will not be available to you or your physician except under extraordinary circumstances. These are situations in which a life-threatening medical disorder is discovered for which medical treatment is available to prevent or alleviate long-term medical complications. If such a situation should occur, we will contact you via phone, email or mail.

The results of your samples will be collected in a centralized computer or data registry at Dr. Catalona's research facility at 676 N. Saint Clair St. in Chicago, Illinois. The results will be stored by identifiers. There are many protections in place for privacy of records including secure building, secure network, protected password computer, locked cabinet, locked suite and locked office. Access is limited to the research team. Laboratories and other collaborators only get the information without identifiers. Information disclosed will not be shared with family members.

After specimens are collected for study they will be identified by a study number and not by your name or identifying information. Every effort will be made to protect your research data; there is, however, always the unlikely possibility of a breach of confidentiality, even though it is rare.

Your participation and results from this study will not be recorded in your medical records.

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:
William J. Catalona, M.D.
Northwestern University Feinberg School of Medicine
Department of Urology
675 N. St. Clair St.
Galter 20-150
(312) 695-4471
- 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.

Optional Consent:

Please read each sentence below and think about your choice. After reading each sentence, initial one line for each statement below, indicating your decision. No matter what you decide, it will not affect the quality of your care.

_____ I agree that my blood/urine/tissue may be kept for use to learn about, prevent, treat, or cure prostate cancer.

_____ I do not agree that my blood/urine/tissue may be kept for use to learn about, prevent, treat, or cure prostate cancer.

_____ I agree that my blood/urine/tissue may be kept for use for research about other health problems.

_____ I do not agree that my blood/urine/tissue may be kept for use for research about other health problems.

_____ I agree that a member of the research team may contact me to invite my participation in future research studies.

_____ I do not agree that a member of the research team may contact me to invite my participation in future research studies.

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 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

Signature of Legally Authorized Individual

Date

Northwestern University
Institutional Review Board
IRB #: 1327-004
Approved to consent subjects
through: 10/13/2010