Northwestern University
Department of Urology

CONSENT FORM AND AUTHORIZATION FOR RESEARCH

Title: *Follow-Up Study of Northwestern University Prostate Cancer Patients of William J. Catalona, M.D.*

Principal Investigator: *William J. Catalona, MD*

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

Introduction/Purpose:

You are being asked to participate in this study because you are a patient of Dr. Catalona at Northwestern University, and you have been diagnosed with prostate cancer and will be or have been treated with radical retropubic prostatectomy (RRP) by Dr. Catalona.

What is the reason for doing this study?

The overall purpose of this research study is to carefully record the postoperative course after surgery for localized prostate cancer, including how well the cancer is controlled and the side effects of treatments.

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

As a participant in this study, researchers will access your medical records for information concerning your care, including preoperative clinical and pathological information about your tumor, information about your surgical treatment and any adjuvant therapy, postoperative pathology information, and/or follow-up information after your surgery. If you have already been enrolled in Dr. Catalona's patient registry study and/or any other of his studies, this information may be also obtained from these studies.

We will follow you annually with a brief follow-up questionnaire that takes approximately 10 minutes to fill out and covers your prostate specific antigen (PSA) level, whether there has been a recurrence of the cancer, additional treatments, medical condition, medications, urinary and sexual functioning since surgery, and contact information for your private physician. PSA level and relevant follow-up information may also be obtained from the patient registry and/or medical records. You may need to sign the medical release form to allow us to obtain follow-up information if you see your private physician outside of Northwestern University for follow-up. We may contact you to obtain or verify the above information via phone, fax, mail, e-mail or personal interview, if you come to Northwestern University**.**

We will follow you once a year for up to 15 years or as long as possible. The data may be used for completing Dr. Catalona's patient registry and any other studies in which you have been enrolled. The data collected may be used to complete your medical records. At the end of this consent form, you may choose whether to be contacted about future studies. The future studies include the

epidemiology, etiology, diagnosis, treatment, molecular biology and genetics of prostate cancer or other forms of cancer.

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:

There is no physical risk to you because there is no intervention in this study.

The psychological risks include potential embarrassment with regard to questionnaire items dealing with sensitive topics (i.e., sexual and urinary functions). It is possible that some of the questions may be upsetting, since they may remind you of unpleasant aspects of your health.

Every effort will be made to protect your research data; there is, however, always the possibility of a breach of confidentiality.

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

There will be no direct benefit to you for your study participation.

The potential benefits to society from participation in this study may include increased knowledge about prostate cancer, its prognosis, treatment effectiveness and complications and quality of life after surgery and other secondary treatments. The potential benefits to society also include the possibility to aid in the diagnosis, prevention of prostate cancer in future generations and adding information which may allow accurate prediction of the nature or course of the disease in you or others.

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

You will not be charged for any study-related procedures. Any procedures or drugs that are considered standard of care will be the responsibility of you or your insurance company.
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?

You may call us with your questions or concerns. If you have any illness or injury during your time on this study, you should call us promptly. Dr. William J. Catalona is the person in charge of this research study. You can call him at 312-695-4471, Monday through Friday, from 8am to 5pm. You can also call Dr. Catalona's research office at 312-695-0195, Monday-Friday, from 8 am to 5 pm with questions about this research study. For problems arising evenings or weekends, you may call the Department of Urology at 312-695-8146, and your call will be directed to the physician on call.

What are my rights as a research subject?

If you choose to be in this study, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop participating in the study. You are free to choose to stop being in the study at any time.

Choosing not to participate in this study or to stop participating in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to participate in this study will not negatively affect your right to any present or future medical treatment to which you are otherwise entitled.

If you want to speak with someone who is not directly involved in this research, or have questions about your rights as a research subject, please contact the Office for the Protection of Research Subjects. You can call them at 312-503-9338.

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, or certain health information indicating or relating to a particular condition as well diaries and questionnaires,
- records about study medication or drugs,
- records about study devices.

You are also giving permission to the following groups of people to give information about you (described above) to the researchers for this study:
All current and previous health care providers, including but not limited to Northwestern Medical Faculty Foundation (NMFF), Northwestern Memorial Hospital (NMH).
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 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 that is responsible for the ethical oversight of the study)

- Other research centers and University contractors who are also working on the study
- Study monitors and auditors who make sure that the study is being conducted properly
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

- Research registries or other research-related databases
- Selected collaborators designated by Dr. Catalona
- Other health care providers who are not part of the study but who may be involved in treating you

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 teaching, publications, or presentations at scientific meetings. If your individual results are discussed , your identity will be protected by using a study code number rather than your name or other identifying information.

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, MD
  Department of Urology
  675 N. St. Clair Street
  Suite 20-150
  Chicago, IL 60611

- Unless you revoke your consent, it will not expire

Optional Study Elements:

Please initial one line below, indicating your decision to be contacted about future studies.

_____Yes, I agree to be contacted about future research studies.

_____No, I do not want to be contacted about future research studies.

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

_____ _____ _____
Authorized subject representative **[print]** Authorized subject representative **[Signature]** Date

My authority to sign as the subject's authorized representative.

- ☐ **Parent**
- ☐ **Spouse**
- ☐ **Legal Guardian**
- ☐ **Authorized Agent (e.g., Health Care Power of Attorney)**