RAD 0003
FACTORS PREDICTIVE OF URINARY RETENTION AFTER PROSTATE BRACHYTHERAPY

INVESTIGATOR: John Fiveash, M.D.

SPONSOR: The Departments of Radiation and Urology

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to identify factors that may predict patients who are at high risk for developing urinary retention after brachytherapy.

EXPLANATION OF PROCEDURES

Prostate brachytherapy is the insertion of radioactive seeds or pellets into the prostate. This technique has been utilized to treat prostate cancer since the 1970’s, but new techniques including transrectal ultrasound guidance, transperineal seed implantation and more advanced treatment planning systems have contributed to the recent popularity of the treatment.

Difficulty with urination is the major side effect from prostate brachytherapy. Eligible patients who choose brachytherapy as their treatment option will be asked to participate in this study. If you consent, you will be asked to complete a 7-item questionnaire (American Urological Association Score), obtain a urine flow rate and have post-void residual urine. Patients will have these studies performed before brachytherapy and 1 month postop.

To obtain a flow rate you will come to clinic with a full bladder and void into a special container and a graph will print out. Ultrasound gel will be placed on your lower abdomen, a probe will placed on your abdomen, a picture will be taken of your bladder. This will tell the doctors how well you empty your bladder.

RISKS AND DISCOMFORTS

There are no additional risks to you if you participate in this study. These same tests are sometimes needed to evaluate patients who have difficulty with urination after brachytherapy. The most common side effects from prostate brachytherapy are urinary frequency, urgency and urinary retention.

BENEFITS

You may not directly benefit from this study. It will help identify patients in the future who are at risk for developing urinary retention. Furthermore, results will be communicated to referring physicians.

UAB – IRB
Consent Form Approval 10-13-05
Expiration Date 10-13-06

Participant’s Initials
ALTERNATIVES

Alternative treatments for prostate cancer include Watchful Waiting, Radical Prostatectomy, External Radiation Therapy and Hormonal Therapy. Your doctor can provide detailed information about your disease and the benefits of the various treatments available. You have been told that you should feel free to discuss your disease and your prognosis with your doctor. Your physician involved in your care will be available to answer any questions you have concerning this program.

CONFIDENTIALITY

Records of participation in this study will be kept confidential so far as permitted by law. However, the UAB Institutional Review Board for Human Use may review the research records for auditing purposes. Any publication of the data will not identify you. This study is not a group sponsored study.

Information relating to this study, including your name, medical record number, date of birth and social security number may be shared with the billing offices of UAB and UAB Health System-affiliated entities so that claims may be submitted for payment to your insurance company for standard care, non-study related clinical services and procedures provided to you during the course of this study. A copy of this consent form will be placed in your medical record if you receive services at University Hospital as part of this study.

WITHDRAWAL FROM STUDY

You may withdraw your consent and discontinue participation in the project at any time without prejudice. You are free to seek care from a physician of your choice at any time. If you do not take part in or withdraw from this study, you will continue to receive care.

COSTS TO PARTICIPANT

There will be no additional cost to you because of your participation in the study. The costs of regular care will be billed to your insurer in the regular manner.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

PAYMENT FOR PARTICIPATION IN THE RESEARCH

You will receive no compensation for participating in this research study.
PAYMENTS FOR INJURY

UAB has made no provision for monetary compensation in the event of injury resulting from the research, and in the event of such injury, treatment is provided, but is not free of charge.

SIGNIFICANT NEW FINDINGS

Significant new findings developed during the course of the research, which may relate to your willingness to continue participation, will be provided to you by Dr. Fiveash.

QUESTIONS

If you have any questions about the research or research-related injuries, you may contact the principal investigator, Dr. John Fiveash at (205) 975-0224.

If you have any questions regarding your rights as a research participant, you may call Ms. Sheila Moore, Director of the Office of Institutional Review Board for Human Use (IRB). Ms. Moore can be reached at (205) 934-3789 or 1-800-822-8816, press the option for an operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday.

LEGAL RIGHTS

You are not waiving any of your legal rights by signing this form.

SIGNATURES

You have read all of the above, discussed any questions that you may have had, and agree to participate in this program. You will receive a signed copy of this consent form.

Signature of Participant

Date

Signature of Physician or Investigator

Date

Signature of Witness

Date

Signature of Person Obtaining Consent

Date
What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research.

Participant name: ____________________________ UAB IRB Protocol Number: X000914006
Research Protocol: Factors Predictive of Urinary Retention After Prostate Brachytherapy Principal Investigator: John B.菲维什, MD
Sponsor: Department of Radiation Oncology & Department of Urology

What health information do the researchers want to use? All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.

Why do the researchers want my health information? The researchers want to use your health information as part of the research protocol listed above and described to you in the Informed Consent document.

Who will disclose, use and/or receive my health information? The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, The Children’s Hospital of Alabama, Callahan Eye Foundation Hospital and the Jefferson County Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies, such as the Food and Drug Administration.

How will my health information be protected once it is given to others? Your health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel the Authorization? You may cancel this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the health information that was provided before you cancelled your authorization.

Can I see my health information? You have a right to request to see your health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: ____________________________ Date: ________
or participants’ legally authorized representative: ____________________________ Date: ________
Printed Name of participant’s representative: ____________________________ Relationship to the participant: ____________________________