The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB17-1694 Name of Subject: _____
Medical History Number: _____

STUDY TITLE: MRI Derived Quantitative Risk Maps for Prostate Cancer Diagnosis Using Targeted Biopsy

Doctors Directing Research: Aytekin Oto, M.D.

Address: 5841 S. Maryland Avenue
Chicago, IL 60637
Telephone Number: (773) 702-8553
(773) 702-1860

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to test and validate an artificial intelligence-based Risk Map DSS tool that we have developed. This is a Decision Support System (DSS) image analysis software developed by our research group, for automated interpretation of prostate MR. This tool can potentially identify additional areas of cancer in your prostate that may have otherwise been missed. This research is being done because the Risk Map DSS tool has the potential to provide critical information to guide therapy and improve outcomes for prostate cancer patients.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 125 people will take part in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?
You are being asked to participate in this study because you are going to have a diagnostic MRI of your prostate to be followed by an MRI-guided fusion biopsy of the prostate as ordered by your doctor. You must meet all the requirements for the study.

You will be provided with routine instructions and precaution information prior to starting the MRI scan that your doctor has ordered. You will be asked to remain on the exam table for approximately 15

additional minutes to obtain the images for the research study. You will not be given any additional MRI contrast agents as part of this study.

You will then undergo an MRI-guided fusion biopsy of the prostate as ordered by your doctor. During this prostate MRI-guided fusion biopsy, we would like your permission to obtain tissue from up to two additional biopsy targets selected by the Risk Map DSS tool. Ultimately, the clinical radiologist will make the final decision on the targets to be biopsied.

During this study, Dr. Oto and his study team will collect information about you for the purposes of this research. These data include your name, address, telephone numbers, medical record number, demographic information (gender, birth date, race/ethnic background), your diagnosis, medical history, medications, medical test results, lab results, imaging results, pathology results and final diagnosis. This information is necessary for analysis of the MR images.

We would also like your permission to review your medical record, now and in the future, so that Dr. Oto and his research team can collect relevant information about you for the purposes of this research. If you give your consent, we will collect copies of your medical images and clinical records for the duration of the project, provided that you are still a patient at the University of Chicago Medical Center.

HOW LONG WILL I BE IN THE STUDY?
We think you will be in the study for 12 months. There is a one-time MRI and biopsy, and then we would like to follow your progress. However, your medical record and data may be accessed for future research indefinitely.

Dr. Oto may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study;
- Your medical condition changes;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?
A risk of the study would be that there is a chance that up to 2 targets suggested by the tool may not actually represent cancer and that may lead to unnecessary additional samples.

The only additional risk to you would be related to disclosure of your medical information to individuals not involved in this project. We will take care to avoid any loss of confidentiality.

There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue, this new information will be discussed with you.

Risks Associated with Transrectal or Transperineal Ultrasound-Guided Prostate Biopsy:
The risks will be those associated with standard MRI-guided fusion biopsy of the prostate, which you will undergo as ordered by your doctor. The research component (up to two additional biopsy targets) will cause a slightly increased risk of bleeding and infection. You may experience extreme discomfort

during these biopsies.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may or may not be any direct medical benefit to you. There will be a long-term benefit to society in general if this research leads to the development of a new technology that improves clinical practice.

WHAT OTHER OPTIONS ARE THERE?
You may choose not to participate in this study

The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

Clinical services provided during a clinical trial are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance.

There are no additional costs that are considered research-related for this study.

Usual medical care costs include any and all services that are considered medically necessary for your disease and would be done even if you were not part of this research study. This may include laboratory tests, physician visits, imaging, procedures, and other clinical services that your physician orders for your routine care. The cost of your routine MRI and the biopsy of your prostate will be the responsibility of you or your insurance. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance, and may include deductibles and co-payments. Similarly, this care will be subject to all the same requirements and restrictions of your insurance.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Aytekin Oto as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Aytekin Oto know right away.

If you have questions about whether specific clinical services are research related or usual medical care, please speak to your physician or research contact person.

WILL I BE PAID FOR MY PARTICIPATION?
You will not be paid for your participation in this study.

WHAT ABOUT CONFIDENTIALITY?
Study records that identify you will be kept confidential. Records will be kept locked and the database

will be stored in a password secured system.

The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

At times, the advancement of research or the development of healthcare devices is aided by the sharing of de-identified image data and clinical information with other organizations. De-identified copies of your image data and clinical information may be sent outside of The University of Chicago for such purposes, including as part of an image library. If this occurs, scientists outside of The University of Chicago will be unable to identify you from your medical images or from your clinical information, because all identifying information will have been removed from the images and records. Insurance agencies will not have access to your information.

Your PHI may be shared with governmental agencies, including the National Cancer Institute, for federally mandated reporting purposes.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

The results from tests and/or procedures performed as part of this study may become part of your medical record.

During your participation in this study, you will have access to your medical record. Dr. Oto is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

IS THERE ANYTHING ELSE I SHOULD KNOW?
Dr. Oto and Dr. Karczmar, a sub-investigator on the study, could potentially benefit from the image analysis software used in this clinical trial, which they developed. In addition, they have launched a start-up company, QMIS, LLC to ultimately commercialize this technology. Currently, the software is not licensed to a company and there is no financial benefit at this time, but there is potential for financial benefit if the study is successful. This is information we think you should know when you are making a decision whether or not to participate in this study. Study participants will not share in any financial benefits from this study. You should ask your doctor about this if you have any questions.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Oto in writing at the address on the first page. Dr. Oto may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
You have talked to _____ about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Oto at (773) 702-8553.

If you have a research related injury, you should immediately contact Dr. Oto at 773-702-8553.

In the event of an emergency, you should seek care at the nearest emergency room or call 911.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5841 S. Maryland Ave., MC7132, I-625, Chicago, IL 60637.

CONSENT

SUBJECT
The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT
I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:
Signature of Investigator/Physician _____
Date: _____ Time: _____ AM/PM (Circle)