VA Consent Document

STUDY SUMMARY

The study doctor wants to know if you would like to be part of a research study. Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. This summary will give you important information and the consent will provide you a full explanation of the study.

Researchers want to find out more about a test called Test 1. The main purpose of this study is to see if the Test 1 test can help doctors make decisions about how to treat men with prostate cancer. It is planned that about 1,500 men with prostate cancer will be in this study.

The Test 1 test is what is known as an “assay.” This assay measures how fast the cells in your tumor are dividing or in other words it measures the expression of certain genes during the cycle of a cell. Because all prostate cancers are not the same, getting a Test 1 result may tell your doctor additional information about your cancer. This will help determine how aggressive your cancer is and help you and your doctor make decisions about your treatment. The Test 1 assay is not regulated by the FDA because it is a laboratory test and therefore has not been approved by the FDA.

There are two parts of this study. If you decide to be in this study and the study doctor says you can be in the study, participation in Part 1 will last about 6 months. After 6 months, if you are eligible to continue in the study, you will begin Part 2. Participation in Part 2 will last about 5 years. The doctor will send your samples to be tested with Test 1. You and your doctor will receive those results and determine your treatment regimen. Part 1 will also include questionnaires. Part 2 will include the review of medical records. All the study procedures will be described later in this document.

Risks of this study are minimal and include the loss of confidentiality. The test may help you and your doctor make decisions about your care but being in the study may not help you. A full description of risks and benefits will be described later in this document.

You do not have to be in this study to get help for your prostate cancer. If you decide not to take part in this study your regular doctor will decide on a treatment for you using standard of care methods. You should discuss your alternatives to participating in this research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider.

If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

CONFLICT OF INTEREST
A company called [Sponsor Name], the sponsor of the study, is paying for this study to be conducted at the Salt Lake City VA Medical Center.

STUDY PROCEDURES
This study will have two parts. You will visit the study center to have the procedures and tests described in this form. Ask the study doctor or study staff about your study visit schedule.

Part 1
Your study doctor will discuss the study and your treatment options with you based on standard treatment guidelines. If you decide you want to take part in the study and sign this consent form, the study doctor will send samples of your tumor to the sponsor for genomic testing with Test 1. The results of the genomic testing will be returned to your study doctor, and you will be informed of your genomic testing results either over the phone or at a VA urology clinic visit, whichever you prefer and your regular doctor will once again discuss your treatment regimen. You and your regular doctor will make a final decision about your treatment regimen.

Six months after the results are returned, your study doctor will complete a questionnaire about your treatment regimen.

The purpose of Part 1 is to determine how much the genomic testing results influenced you and your regular doctor’s decision about your treatment regimen. During Part 1, the study doctor or study staff will do the things listed below. If you would like more information about when the tests and procedures occur, ask the study doctor or study staff.

- Demographic Questions: Collect your personal information, such as your name, date of birth, race, ethnicity, address, and phone number.
- Health and Treatment Questions: Ask you questions about your health and your treatment for your prostate cancer.
- Height, Weight: See how tall you are, and see how much you weigh.
- Tissue samples: The study doctor will use a portion of a tissue sample from your tumor in order to do tests. You will not have to have a new biopsy to participate in this study.
- Test 1 test: Your study doctor will send some of your biopsy samples for evaluation with the Test 1 test.
- You will be phoned with the results of the testing or you can discuss the results of the testing at your next VA urology clinic visit, whichever you prefer. During the phone call or during your VA urology clinic visit, you can discuss with the study doctor what the genetic test results may mean to you. The test results will be put in your regular medical records.

Part 2
• Part 2 of this study will begin after Part 1. If you are still eligible for the study, your health records will be reviewed every six months for five years to see if your cancer came back, got worse, or if you had any additional treatment.
• The purpose of Part 2 is to determine how well the genomic testing predicted the actual aggressiveness of your prostate cancer.

The tumor sample will only be used for study purposes. At the close of the study, any left-over tissue will be returned to the site, except for one tumor slide which [Laboratory Name] will keep to meet certain federal laboratory requirements.

The Test 1 test does not measure any inherited changes in the DNA or any type of genetic changes in the DNA referred to as “Germline Mutations” nor does it measure any permanent changes in the DNA sequence that make up a gene called “Genomic Mutations”. There will be no whole genome or whole exome sequencing. This means that the researchers have no plans to look at or try to “read,” the protein information that makes up your genes (DNA) from your sample.

RISKS
Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

The risks of the research are as follows: There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the study doctor or study staff if you would like to know more about how your information will be protected while you are in this study.

You may experience stress or anxiety as a result of receiving your Test 1 test results. If this happens we can refer you to the Genetic Counselors here at the VA Hospital for further discussion and help with any issues.

BENEFITS
We cannot promise any benefits to you from being in the study. However, the Test 1 test may help you and your regular doctor make a decision about your treatment for prostate cancer, but there is no guarantee that being in this study will help you. Your prostate cancer might not get better or may even get worse while you are in this study. Information from this study might help researchers to better understand prostate cancer or come up with new tests or medications to help others in the future.

CONFIDENTIALITY
Your identity will be protected as required by law and according to any policies the VA or sponsor may have. Be aware that your study records (which include your medical records, your signed consent form, and other information) will be shared as needed for the study. For example, the Office for Human Research Protections (OHRP), the Centers for Medicare and Medicaid Services through the Clinical Laboratory Improvement Amendments (CLIA), the Office of Research Oversight, the VA Office of the Inspector General (OIG), the sponsor and an institutional review board (a group of people who review research studies to protect the rights and welfare of research participants) may look at your study and medical records.

The test requisition form that we send to [Laboratory Name] (so they can run the Test 1 test on your biopsy samples) does contain your full name and date of birth. The reason that your name and date of birth are used on the test requisition form is so the lab has written orders from the study physician to perform the Test 1 test on your biopsy samples. Also, when the test report results are returned to the study physician, there will be no question that these are your results.

However, your biopsy samples will not be labeled with your name or other directly identifying information. Your samples will have a code instead. The list that matches the code with your name will be stored separately from your samples.

Your information and samples collected in this study will not be used for future research studies.

PERSON TO CONTACT
If you have questions, complaints or concerns about this study, you can contact [Contact Name] at [Phone Number]. If you think you may have been injured from being in this study, please call [Contact Name] at [Phone Number]. The Urology Resident on call can be reached at this number [Phone Number], 24 hours a day.

INSTITUTIONAL REVIEW BOARD
Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

MEDICAL TREATMENT OR COMPENSATION FOR INJURY
The VA has the authority to provide medical treatment to participants injured by participation in a VA study. If you are injured as a result of being in this study, the VA will provide the necessary medical treatment in accordance with federal law. If you want to make a legal claim against the VA or anyone who works for the VA, special laws may apply. The Federal Tort Claims Act (28 U.S.C. 1346(b), 2671-2680) is a federal law that controls when and how a person can bring a claim against the U.S.
Government. If you sign this document you’re not giving up your right to make a legal claim against the United States.

This is an observational study. No additional procedures will be prescribed as part of your visit outside of those normally conducted as part of your standard care. As such, there is no potential for research related injury. You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

**VOLUNTARY PARTICIPATION**

You do not have to be in this study to get help for your prostate cancer. If you decide not to take part in this study your regular doctor will decide on a treatment for you using standard of care methods.

You should discuss your alternatives to participating in this research with the study doctor or study staff. In addition, you may discuss your options with your regular health care provider. It is possible that the study doctor is your regular health care provider.

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won’t lose any benefits to which you are otherwise entitled. If you don’t take part, you can still receive all usual care that is available to you. Your decision will not affect the relationship you have with your regular doctor, study doctor, or study staff, and it will not decrease the standard of care that you receive as a patient. If you want to stop being in the study, tell the study doctor or study staff.

**RIGHT OF INVESTIGATOR TO WITHDRAW**

The study doctor or study staff or sponsor can remove you from the study at any time, even if you want to stay in the study. This could happen if:

• The study doctor or study staff believes it is best for you to stop being in the study.

• The sponsor stops the study for any reason.

If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected. If you change your mind later, tell the study doctor or study staff and they will destroy your samples.

**COSTS TO PARTICIPANTS AND COMPENSATION**

A veteran participant will not be required to pay for care and services (treatment) received as a subject in a VA research project. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

You will not be paid for participating in this study.

Commented [UUIRB18]: For studies conducted at the VA, the statement that the VA will provide treatment for the research related injury is required.

Commented [UUIRB19]: Is there a statement that participation is voluntary? Yes.

Commented [UUIRB20]: Is there a statement that individuals may refuse to participate or discontinue participation without penalty or loss of benefits? Yes.

Commented [UUIRB21]: Is there a description of anticipated circumstances under which the investigator may terminate participation? Yes. This is an additional element of consent. Generally, this element is not required for studies that are no more than minimal risk.

Commented [UUIRB22]: When appropriate, is there a statement that informs VA subjects that insurance will not be charged for costs related to the research? Yes. This is an additional element required by the VA.
Samples obtained from you in this research may be used to make a discovery that could be patented or licensed to an individual or a private entity. There are no plans to provide financial compensation to you should this occur. However, should the VA ever provide your samples for research or commercial use, it will do so in such a way as to protect your privacy and confidentiality as stated in the last paragraph of the confidentiality section above.

NEW INFORMATION
If the study doctor or study staff learns any new information that might change your mind about continuing in the study, the study doctor or study staff will tell you about it.

NUMBER OF PARTICIPANTS
We expect to enroll approximately 150 participants at the VA Salt Lake City Health Care System (VSLHC). We also expect to enroll approximately 1500 participants at other medical centers.

CONSENT
I confirm that I have read this consent document and have had the opportunity to ask questions. I will be given a signed copy of the consent form to keep. I agree to participate in this research study as you have explained in this document.

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