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[redacted]

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: A Phase 2 Randomized Discontinuation Trial in Patients with Hormone-Dependent Rising Prostate-Specific Antigen Progression After Local Therapy For Prostate Cancer Evaluating the Synergy of Metformin Plus Aspirin (PRIMA Trial)

Principal Investigator: [redacted]

[redacted] consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor, [redacted] or another member of the study team (an investigator) will also be asked to sign this informed consent form. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Supporter of the study:
The [redacted]
this study.

The costs that are usually covered include things such as research laboratory tests required by the study,

and the costs of collecting all of the information required by the study.

Why is this study being done?

Recent medical science suggests that two FDA approved medications metformin (used to treat diabetes) and aspirin (used to prevent heart attacks) may slow the growth of prostate cancer cells in the laboratory. We want to know if giving metformin and aspirin in people will slow the growth and possibly kill prostate cancer cells.

Why have you been asked to take part in this study?

You have been asked to participate in this study because you have prostate cancer and after completing prostate surgery or radiation, you have a rising prostate-specific antigen (PSA) level, which is a blood test used to monitor prostate cancer.

Who may take part in this study? And who may not?

You may take part in this study if:

- You are an adult male, 18 years of age or older, who has been diagnosed with prostate cancer and has a rising PSA level after you have previously received radiation therapy or had your prostate surgically removed for the initial treatment of your prostate cancer. A rising PSA is determined by three different measurements of PSA that is drawn at least 1 month apart.
- There is no evidence of any prostate cancer on CT scans or bone scans.

You may Not take part in this study if:

- Your prostate cancer has spread outside the prostate.
- You have another type of cancer.
- You are currently taking metformin for diabetes.
- You are currently taking aspirin for heart disease.
- You have already received some form of hormonal treatment for prostate cancer.
- You are taking warfarin or any blood thinner.
- You are taking a nonsteroidal anti-inflammatory drug (NSAID).
- You have a history of stomach bleeding or ulcers.

The study doctor and/or research team will also ask you other questions about your medical history in order to make sure you qualify to be in this study.

How long will the study take and how many subjects will participate?

The study will enroll approximately 66 patients. Patient participation is approximately 10 months.

All subjects will take part in this study at the [redacted].

What will you be asked to do if you take part in this research study?

[redacted]

Before starting treatment:
You will be asked to come to the clinic to have screening tests done to find out if you can be in the study. The results of these tests are used to determine if you are able to go on this study and are part of regular cancer care. The screening tests include the following:

Screening will consist of:

- Signing this informed consent form
- You will be asked about your health and medical history. You will also be asked about any medications you are taking.
- Physical examination including measurements of your height, weight, blood pressure as well as respiratory and heart rate.
- Blood Tests (about 2 teaspoons will be taken from your vein)
    - Complete blood count (CBC)
    - Chemistry tests to help determine how your kidneys and liver are functioning
    - PSA to monitor your disease status
- An MRI or CT scan of your body to monitor your disease status
    - A CT (Computed Tomography) scan is a study using x-rays to look at one part of your body.
    - An MRI (Magnetic Resonance Imaging) is imaging that uses a strong magnetic field to look at one part of your body
- Bone scan of your bone to monitor if the prostate cancer has spread to your bones

It is very important that you tell the study staff of all the medications you are taking. This includes both prescription and non-prescription (herbal products and over-the-counter medications). There are some medications that are not allowed while you are taking the study drugs. You should ask your study doctor any questions about other medications you want to take during the study.

During the study:
If you decide to participate on this study you will be asked to take two drugs, aspirin and metformin by mouth every day for four months. This is referred to as the **Run-In Stage** of the study.

You will take one (1) Aspirin 81 mg tablet daily with food. Metformin treatment will be started at one (1) 500 mg twice a day with food. If after two weeks, you do not have any bad side effects (i.e., nausea, vomiting) then it will be increased to 500 mg with breakfast and 1000 mg at bedtime daily.

You will be monitored with blood tests and physical exams every four weeks for the period you are taking the study drugs as described below. Most of these tests are routine and are part of the normal care of subjects with cancer such as yours.

- Before starting the study medications your PSA level will be checked. The PSA will also be

[redacted]

checked monthly while you are receiving study treatment.

- Physical examination
- Vital signs (blood pressure, heart rate, respiratory rate, oral temperature)
- Measure your height and weight
- Up to 3 teaspoons will be taken from your vein to measure how your kidneys and liver are functioning. These tests will also show whether your blood counts such as white blood cells, red blood cells and platelets are normal.
    - Blood samples may be taken to study drug levels or analyze biochemical markers
- Record any side effects you are having from the study medication

If a dose of the medication is missed, you will not need to take a "catch up" dose. If you realize you missed a dose within 4 hours of the time you were scheduled to take it, you may take the dose at that time and continue with the next regular scheduled dose. If it has been greater than 4 hours, skip the dose and continue with the next scheduled dose.

After completing 16 weeks of treatment, you will have a PSA level drawn to compare to the PSA level taken before you started the study treatment. Depending on the results you will either:

a) **Continue on the treatment with metformin and aspirin** because your PSA has decreased by more than 25% (decreased by one fourth, for instance the PSA has decreased from 10ng/mL to 7.5ng/mL) compared to the baseline value.
b) **Discontinue treatment as part of this study** because your PSA has increased by more than 50% compared to the baseline value. Your doctor will discuss other potential treatments with you if you discontinue treatment as part of this study.
c) **Continue treatment in the Randomization Stage of the study** because you have a PSA level that has remained stable, meaning that it has not decreased by more than 25% or increased by 50%.

In the Randomization Phase you will be assigned by chance to one of two arms described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the two arms; you have an equal chance of being assigned to arm 1 or arm 2. Neither you nor your doctor will not know if you are receiving active medicine or placebo (a pill without any active medication) during this portion of the study. This is referred to as a "double blind" study.

ARM 1: One (1) Aspirin 81mg tablet per day and metformin three 500mg tablets daily (one tablet in the morning and two tablets at bedtime).

ARM 2: One (1) placebo aspirin (a tablet that looks like aspirin) per day and placebo metformin (a tablet that looks like metformin) daily (one tablet in the morning and two tablets at night).

Treatment in the randomization phase will continue for up to 6 months. During this time your PSA will be checked monthly. Regardless of which arm you are in, if the PSA increases by more than 50% (for example it increases from 10ng/mL to 15ng/mL) then study treatment will be discontinued.

[redacted]

Additionally, if you have scans that show that the prostate cancer has spread to other parts of the body, then the study treatment will be discontinued.

At each visit, the study doctor or staff may do any or all of the following:

- Physical examination
- Vital signs (blood pressure, heart rate, respiratory rate, oral temperature)
- Measure your height and weight
- Check your PSA.
- Check routine blood tests including blood chemistry and measurement of the number of blood cells
- Blood samples may be taken to study drug levels, or analyze biochemical markers.
- Record any side-effects you are having from the study medication.
- Repeat CT or MRI scans if you have symptoms that your prostate cancer may have spread

After completing treatment you will have:

- Physical examination
- Vital signs (blood pressure, heart rate, respiratory rate, oral temperature)
- Up to 2 teaspoons of blood will be drawn for routine tests

What are the risks and/or discomforts you might experience if you take part in this study?
While on the study, you are at risk for the side effects described below. You should discuss these with the investigator and your doctor. There may also be other side effects that we cannot predict. You may receive other drugs to make side effects less serious and less uncomfortable. Many side effects go away shortly after chemotherapy is stopped, but in some cases, side effects can be serious or life threatening, long lasting or permanent or fatal.

Risks of metformin:

- Mild gastrointestinal symptoms (most common 1 out of 10):
  - Diarrhea
  - Nausea
  - Vomiting
  - Excessive gas

These symptoms are generally only present for a few days and resolve spontaneously during continued treatment. Gastrointestinal side effects can possibly be avoided if metformin is taken with meals. Occasionally, a dose reduction is needed. Occurrence of gastrointestinal symptoms, once you are stabilized on any dose of metformin, could be due to lactic acidosis or other serious disease (see below).

- Lactic acidosis is a very rare (< 1/10,000) but serious complication, that affects body chemistry and that can occur due to metformin accumulation during treatment. The presence of lactic acidosis can be determined with a blood test. The onset of lactic acidosis is may not be easily recognized by the patient since it initially causes symptoms similar to other common problems such as getting tired easily and wanting to sleep more, muscle aches, abdominal pain, diarrhea and difficulty breathing. In more advanced cases of lactic acidosis, there may be associated extreme weakness or tiredness,

[redacted]

confusion, strong muscle aches, low blood pressure, abnormalities in conduction in the heart in advanced stages of lactic acidosis. You and your doctor must be aware of the possible importance of such symptoms and you must notify the doctor immediately if they occur. Lactic acidosis is a medical emergency that must be treated in hospital. If you develop lactic acidosis Metformin should be discontinued immediately and permanently

- Fatigue (1 -10 out of 100 patients)
- Headache (1 -10 out of 100 patients)
- Metallic taste to food, occurring in approximately 3 out of 100 patients
- Skin redness, very rare

Risks of aspirin:

Rare and serious side effects

- Increased risk of bleeding is a rare but important side effect of aspirin. This is most often seen site of bleeding is in the gastrointestinal tract (stomach, esophagus) where it may be associated with damage to the lining of the stomach. Regular use of aspirin is estimated to cause 13 out of a total of 10,000 people to have serious bleeding in the stomach per year. Other factors such as your age, weight, use of cigarettes and may influence your risk of developing stomach bleeding.
- Damage to the lining of the stomach and esophagus without bleeding may occur rarely
- Increased risk of bleeding in the brain is a rare but important side effect of aspirin. Regular use of aspirin is estimated to cause 3 out of a total of 10,000 people to have serious bleeding in the brain per year.
- Reye's syndrome is a rare but serious condition that causes swelling in the liver and brain. Reye's syndrome most often affects children and teenagers recovering from a viral infection, most commonly the flu or chickenpox. Aspirin use has been linked with Reye's syndrome. Reye's syndrome in adults is very rare. Please inform your doctor if recently had chickenpox or the flu (influenza)

Rare and potentially serious side effects of aspirin are

- Stomach upset
- Diarrhea
- Constipation
- Rash and hives
- Allergic reactions with lip, face and throat swelling that may cause difficulty breathing

Rare side effects of aspirin seen with overdoses of apsirin or doses of aspirin higher than the dose used in this study are:

- Heart and blood vessels: irregular heartbeat, leg swelling, low blood pressure, fast heart rate
- Brain and nerves: Agitation, brain swelling, coma, confusion, dizziness, fatigue, headache, high body temperature, sleepiness
- Glands: high blood sugar, high blood potassium
- Gastrointestinal: stomach upset, stomach pain, nausea, vomiting

[redacted]

- Blood: low red blood cell counts (anemia), low platelets (needed to stop bleeding), skin brusing, inability to stop bleeding
- Liver: inflammation of the liver, damage to the liver, increase in levels of liver proteins in the blood
- Bone: bone destruction,
- Muscle: muscle breakdown causing kidney damage, weakness
- Hearing: hearing loss, ringing in the ears
- Kidney: decreased kidney function, inflammation in the kidney, kidney failure, kidney pain
- Lungs: wheezing, breathing fast, difficulty breathing
- Nose: runny nose

Risk of Blood Drawing:
You will have blood drawn during this study. Possible known side effects of having blood drawn include: feeling faint, redness of the vein, pain, bruising or bleeding at the site of the needle puncture. There is also a slight chance of a reaction. If you feel faint, notify one of the research staff immediately.

Risks of a CT scan:
You will be exposed to small amounts of radiation, which are equal to 3 years of exposure from the air around us. CT scans are typically performed with dye that is injected into your veins. The dye is used to improve the quality of the images of your body. If you have had any allergic reactions to any drugs, foods, or prior injections of dyes used in x-rays, you should also tell your study doctor about these reactions. The use of dyes in these x-rays may result in warmth and pain when it is given. Other side effects include: dizziness, lightheadedness, nausea, blurred vision, headaches and changes in taste. Tenderness and swelling at the injection site may also occur. Rarely, allergic reactions (some severe in the form of a heart attack or difficulty breathing) or decreased functioning of the kidneys have been reported as a result of the dye.

Risks of a MRI Scan:
You may feel claustrophobic or anxious or you may have discomfort and fatigue from lying in a confined space. There are no known effects from exposure to the magnetic fields. The contrast agent/dye will be injected into the vein and may cause you to experience nausea, headache, hot flashes, dizziness and irregular heartbeat.

Can you take other medicines while on this study?
You should not take any over-the-counter medicines, herbal products, vitamins or food supplements while taking part in this study, unless you tell the study doctor and get permission from the study doctor to go on taking these medicines. .

You should also tell the study doctor about all medicines that other doctors may have prescribed for you to take.

Are there any benefits for you if you choose to take part in this research study?
There may or may not be direct medical benefit to you from taking part in this study.

[redacted]

It is hoped that the information learned from this study will benefit other patients with prostate cancer in the future.

What are your alternatives if you don't want to take part in this study?
At this time, there is no universally accepted standard treatment for your type of prostate cancer. If you do not participate on this trial you may continue to be treated by the oncologists at the [redacted], or any other physician of your choosing. You may also be offered other additional standard or experimental treatments. These include hormonal therapy with Lupron or Zolodex (treatment to decrease the level of testosterone in your body or to interfere with the way your body uses testosterone), monitoring without treatment, or other clinical trials.

Talk to your doctor about your choices before you decide if you will take part in this study. You are under no obligation to take part in this research study. If you decide that you do not wish to take part in this study, you are free to leave the study at any time.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?
You and/or your insurance company will be billed for the costs of your treatment that are considered standard of care, as you would have received these services even if you were not participating in this study. These procedures include doctor/Advanced Practice Nurse (APN) visits, routine lab tests (complete blood counts, chemistries, and PSA), and restaging chest x-rays, bone and CT/MRI scans. You will be responsible for any co-payments due for office visits, co-insurances and deductibles due on any tests and/or procedures that are required and considered standard care.

The study drugs and research blood collections to monitor study drug (aspirin) levels will be paid for by the [redacted].

If you have any questions about insurance coverage, including any out of pocket expenses you might incur, or which laboratory or facilities you are allowed to have tests at, a financial counselor will be made available to you upon request.

Will you be paid to take part in this study?
You will not be paid for your participation in this research study.

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed.

Your personal health information, identifiers and research data are stored and kept in a secure area in the

[redacted]

[redacted]. Computer screens containing personal health identifiers are inaccessible to public view. Only the study doctor and research team will have direct access.

What will happen if you are injured during this study?
If you take part in this study, you will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment.

The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the [redacted] and no other type of assistance is available from the [redacted]

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in this study is voluntary. You may choose not to participate or you may change your mind at any time.

If you do not want to enter the study or decide to stop participating, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of your data, but you must do this in writing to Dr. Anna Ferrari(address provided on page 1).

[redacted] be withdrawn because there may not be any identifiers to link the data with you. We are required by the Food and Drug Administration however, to continue to report anything that relates to the safety of these drugs.

At any time, the study doctor can take you out of this study because it would not be in your best interest to stay in it. Your study doctor can stop treatment even if you are willing to stay in the study.

If you decide to withdraw from the study for any reason, you may be asked to return for at least one additional visit for safety reasons.

Also, you should understand that the Sponsor, in consultation with the study doctor, can withdraw you from the study at any time if you do not follow the instructions related to the study, if you need a different treatment, or if you have a study-related injury.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research

[redacted]

related injury, you can call the study doctor:

[redacted]

If you have any questions about your rights as a research subject, you can call:

IRB Director
[redacted]

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

Protected Health information
Protected Health Information (PHI) under HIPAA means any information that identifies an individual and relates to at least one of the following:

- The individual's past, present or future physical or mental health
- The provision of health care to the individual
- The past, present or future payment for health care

The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization (permission) and informed consent form as required or allowed by law. Because we are committed to protecting your health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form about what information we will collect about you, how we will use it, when or if it will be shared with others, and the measures we will take to protect your privacy and the confidentiality of your personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

Authorization to use your health information for research purposes
Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

Do you have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and receive any research related products. However, signing the form is not a condition for receiving any medical care outside the study.

[redacted]
Approval Date: 2/15/2018
Expiration Date: 2/14/2019

If you sign, can you revoke your authorization or withdraw your information later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing by contacting the study principal investigator.

What personal information will be used or disclosed?
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, information in your medical record such as certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examinations, x-rays, MRI's, etc. Your personal identity, that is your name, address, and other identifiers, will be kept confidential. You will have a code number and your actual name will not be used. Only your study doctor will be able to link the code number to your name.
Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential. The exception to this rule will be when there is a court order or when a law exists requiring the study doctor to report communicable diseases. In this case, you will be informed of the intent to disclose this information to the state agency. Such a law exists in New Jersey for diseases such as cancer, infectious diseases such as hepatitis, HIV, viruses and many others.

In applications for marketing authorization your data may be submitted to domestic and foreign drug regulatory agencies.

Your data may also be sent to domestic and foreign drug regulatory agencies if you should suffer a bad reaction to the study drug.

Who may use or disclose the information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- [redacted] (IRB-a committee that reviews research studies to protect people participating in research)
- [redacted])
- [redacted]

[redacted]

Who may receive/use the information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- U.S. Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS)

Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

When will your authorization expire?
Your authorization will expire six years after study completion. At this time the link between you and your study data will be destroyed.

Will access to your medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

Where can you get more information?
You may call the National Cancer Institute's Cancer Information Service at:
Voice: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/
For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

If you do not have access to a personal computer, you may access these websites and other information at a computer in the Resource and Learning Center on the second floor of the [redacted] at no cost to you.

Consent to Store Tissue and Health Information for Future Research Use:
The investigator is asking your permission to store any left-over blood specimens for future research studies. If you agree, the specimens will be kept and may be used to learn more about cancer. You may still participate in the main study even if you do not agree to allow your specimens to be stored for future research.

How and where will your tissue and health information be stored and by whom?
The samples will be kept until they are used up or destroyed. The samples are given a code to protect your privacy before they are used. Any related information given to researchers will also be coded.

[redacted]
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The samples and health information will be stored at the [redacted] Biorepository Service (BRS). BRS is a tissue bank owned and operated by the [redacted] and located at [redacted]

How will tissue and information be collected?
Your blood specimens and health information will be collected by the study doctors as part of the main study procedures. Any left-over samples will be processed and transferred to the BRS tissue bank. No additional blood specimens will be collected for storage and future use. Information from your medical record will be collected, but will not contain any personal information. Any related information given to researchers will be coded.

What are the risks of harm to you?
Use of Your Personal Information: The greatest risk to you is release of your information from your health records. To reduce this risk your name and personal information (such as date of birth or medical record number) will not be used. Your samples will be coded with a study identification number to protect your personal information. The databases developed for this project will be secured and only the study doctors and authorized personnel will have access to it. However, people may develop ways in the future that would allow someone to link your medical information back to you. It is also possible the computer systems can be hacked by unauthorized people. We will do our best to protect your personal information.

Risk of Genetic Testing: Your specimens will be used in the future to learn more about how to prevent, diagnose, treat cancer and may be used for genetic testing. The results from the testing will not be placed in your medical records and used for research only. You will not be contacted or receive the results from genetic testing.

Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. It may be possible that genetic information from them could be used to identify you. It may also be possible that genetic information from you could be used to help identify them.

New health information about genetic traits that might affect you or your blood relatives could be found during a research study. Very rarely health or genetic information could be misused by health providers, life insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information. The risk of misuse of your genetic information is very small. This is because the researchers has taken special steps to keep your information and results confidential. There are state and federal laws that protect against genetic discrimination.

Genetic Information Law: There is a federal law call the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health

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insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

There also may be other privacy risks that are unknown.

What are the benefits of participation?
You will not benefit personally from providing a sample. The research done on your samples may help investigators understand, prevent, or treat the diseases and conditions studied in the future.

How will information about you and your tissue samples be kept private and confidential?
Your samples will be given a code number. Information related to your age, sex, race, health condition and other important clinical information will also be given a code number. Your name, date of birth, address, or other personal identifying information, will not be linked with the samples you give.

Is there other important information to consider?

Cost
There is no cost to you if you agree to let us to store and use your tissue and information for future research.

You will not be paid for your samples and information. If any information from your tissue and information leads to making any drug, test or treatment, there is no plan to share any of the profits with you.

What are your rights if you agree to the storage and use of your tissue for future research?
You have the right to ask questions about any part of our storage and future research at any time. You should not sign this form unless you have a chance to ask questions and have been given answers to all of your questions. Your participation in storing tumor tissues in the BRS is voluntary. You do not have to participate. If you do, you can change your mind at any time.

What are the procedures for withdrawing consent?
We will keep records linking your identity with the tissue samples for a period of 10 years after the study has finished. If at any time you decide you no longer want your samples used for research, please write [redacted] You may also tell him to destroy any personal and private health information that you provided.

If your samples and information have already been used for research before your request; it will

[redacted]

not be possible to destroy them. However, any unused specimens will be destroyed. Your health information will no longer be used for research.

Permission to Store Tissue and Health Information for Future Research Use:
Please tell us if and how you wish your samples and information to be used for future research.
Initial next to ways you permit your samples and information to be used.

My samples **and** information may be stored and used for future research

_____ YES _____ NO
Initials Initials

AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

FOR NON-ENGLISH SPEAKING SUBJECTS:

Signature of Reader/Translator If the Subject Does Not Read English Well:

The person who has signed above, _____, does not read English well. You read English well and are fluent in _____ (*name of the language*), a language that the subject (his/her parent(s)/legal guardian) understands well. You understand the content of this consent form and you have translated for the subject (his/her parent(s)/legal guardian) the entire content of this form. To the best of your knowledge, the subject (his/her parent(s)/legal guardian) understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered (his/her parent(s)/legal guardian).

Reader/Translator Name:_____

Reader/Translator Signature:_____ Date:_____

Witness Name:_____

Witness Signature:_____ Date:_____

[redacted]

Signature of Investigator/Individual Obtaining Consent:

To the best of your ability, you have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date/Time: _____

[redacted]