Protocol Title: A Phase 2 Study of Nivolumab in Patients with High-Risk Biochemically Recurrent Prostate Cancer

DF/HCC Principal Research Doctor / Institution:

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A. INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have prostate cancer that has recurred after surgery and/or radiation but is detectable only in blood tests (Prostate-Specific Antigen, PSA) and not on scans. This is known as biochemically recurrent (BCR) prostate cancer. This research study is studying an immune-based cancer drug as a possible treatment for this diagnosis.

The name of the study drug involved in this study is:

- Nivolumab

For purposes of this research, you will be referred to as a "participant".

It is expected that about 34 people will take part in this research study.

Beth Israel Deaconess is the sponsor of this study. Bristol-Myers Squibb, a pharmaceutical company, is supporting this research by providing funding for the research study and the study drug.
This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this

research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future.

Dana-Farber Cancer Institute has a financial interest in the investigational compound used in this trial, Nivolumab. This financial interest could be affected by the outcome of this research. Additional information is available in the Patient Information Sheet available to participants.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Phase II clinical trial. Phase II clinical trials test the safety and effectiveness of an investigational drug to learn whether the drug works in treating a specific disease. "Investigational" means that the drug is being studied.

The FDA (the U.S. Food and Drug Administration) has not approved nivolumab for your specific disease but it has been approved for other uses. Nivolumab is an antibody inhibitor of the programmed death-1 (PD-1) pathway. By blocking PD-1, this medication may allow the immune system to recognize and fight cancer.

In this research study, we are investigating whether nivolumab has any activity in patients who have a rising PSA (prostate specific antigen) after previously undergoing surgery or radiation for prostate cancer. Although nivolumab was previously not found to have significant effect in advanced prostate cancer after all other therapies had failed, based on new research, we are testing whether nivolumab could have a greater effect earlier in the disease course and before patients receive hormone therapies.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options, which may include the following:

- Observation, meaning checking blood tests (PSA) and evaluating symptoms on a scheduled basis.

- Receive standard treatment including androgen deprivation therapy (ADT), continuously or intermittently.
- Take part in another research study.
- Receive no therapy specific to your cancer.
- Comfort care, also called palliative care. This type of care may help to reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to treat the symptoms.

Please talk to the research doctor about your options before you decide whether you will take part in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

- This study will begin by assessing your tumor for the PD-L1 marker. If you are receiving this consent form, then your tumor has been found to have the PD-L1 marker.
- Then, we will go over eligibility criteria. You may be asked to undergo scans (CT scan or MRI plus bone scan) if you have not done so recently.
- If you are found to be eligible for the trial, you will begin receiving nivolumab. Nivolumab is given through an IV in your arm once every 4 weeks (28 days). This is called a "cycle."
- If you are found to be eligible for the trial and you consent, and have a female partner who is of reproductive potential, then you will be advised to utilize contraception during the study period.
- Many side effects can be managed with supportive medications or delaying doses of medication. In rare circumstances, steroids or other immune-suppressive medications may be needed for more severe side effects. If you had severe side effects, you would not receive further nivolumab. The study team would continue to follow you to make sure that side effects resolved.
- You will have blood drawn to assess PSAs every cycle, but you will continue receiving nivolumab regardless of PSA level for at least 3 cycles. After 3 cycles, you will have repeat imaging done to look for any new tumors. If any new tumors are seen, you will be removed from the study. So long as you remain on study, you will have PSAs drawn every cycle and imaging performed every 3 cycles.

Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study.

Before the research starts (screening):
After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

- **A medical history,** which includes questions about your health, current medications, and any allergies.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Physical examination**, including vital signs (height, weight, pulse, blood pressure, temperature).
- **An assessment of your tumor** by the following standard assessment tools: CT (Computerized Tomography) scan or MRI (Magnetic Resonance Imaging), plus bone scan
- **Blood tests.** Approximately 2 ½ tablespoons of blood will be collected to measure your blood chemistry, including kidney and liver function, count your red and white blood cells and platelets, and test your thyroid function.
  i. **Biobanking:** Biological specimens (such as blood, tissue) will be collected and shared with an outside lab or collaborator for analysis. The specimens will not be identifiable. The specimens will be banked for future use.

If these tests show that you are eligible to participate in the research study, you may begin receiving the study drug. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Study Overview:

- **Infused Study Drug(s):** You will be given the study drug once every 4 weeks into your vein (by intravenous infusion) over about 30 minutes. This will continue for up to two years.

Study Visit: Cycle 1 day 1

This visit will involve the following:

- **Clinical Exams:** During this visit you will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Blood tests**, including research blood samples at specified visits (see chart below). Standard labs involve approximately 2 ½ tablespoons of blood.
    - **½ tablespoon of blood will be collected for research purposes**
    - **Approximately 2½ tablespoons of blood will be collected for research purposes**
- **An assessment of your tumor** by the following standard assessment tools: CT (Computerized Tomography) scan or MRI (Magnetic Resonance Imaging), plus bone scan, to be performed every three cycles
- **Study drug infusion:** nivolumab

Study Visit: Cycle 2 day 1

This visit will involve the following:

- **Clinical Exams:** During this visit you will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Blood tests**, including research blood samples at specified visits (see chart below). Standard labs involve approximately 2 ½ tablespoons of blood. When research blood samples are being collected during the first two cycles, an additional approximately 2 ½ tablespoons of blood will be collected (plus blood for standard labs).
    - **Approximately 2½ tablespoons of blood will be collected for for research purposes**
- **An assessment of your tumor** by the following standard assessment tools: CT (Computerized Tomography) scan or MRI (Magnetic Resonance Imaging), plus bone scan, to be performed every three cycles

Study drug infusion: nivolumab

Study Visit: Cycle 5 day 1 and every four cycles beyond (cycle 9 day 1, cycle 13 day 1, etc.)

This visit will involve the following:

- **Clinical Exams:** During this visit you will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Blood tests**, including research blood samples at specified visits (see chart below). Standard labs involve approximately 2 ½ tablespoons of blood. When research blood samples are being collected during the first two cycles, an additional approximately 2 ½ tablespoons of blood will be collected (plus blood for standard labs). If you are still on the study after cycle four, an additional 5 1/3 tablespoons of blood will be collected every four cycles (plus blood for standard labs).
    - **3½ tablespoons of blood will be collected for banking for assessment of cell responsiveness to antigens**
    - **Approximately 2½ tablespoons of blood will be collected for for research purposes plus for banking**
- **An assessment of your tumor** by the following standard assessment tools: CT (Computerized Tomography) scan or MRI (Magnetic Resonance Imaging), plus bone scan, to be performed every three cycles

Study drug infusion: nivolumab

Study Visit: End-of-study

This visit at approximately 30 days after last dose of nivolumab, will involve the following:

- **Clinical Exams:** During this visit you will have a physical exam and you will be asked questions about your general health and specific questions about any problems that you might be having and any medications you may be taking.
- **Performance status**, which evaluates how you are able to carry on with your usual activities.
- **Blood tests**, including research blood samples involving approximately 2 ½ tablespoons of blood (plus blood for standard labs).

Study Contact: Three month follow-up

This contact at approximately 100 days after the last dose of nivolumab will involve the following:

- **Phone call or email (depending on your preference)** for the study team to ask about any side effects have occurred during this time.

In addition, you should notify the study team about any side effects that occur before this contact as they occur.

Research Study Plan:

Event	Screening	On Study (28-day cycles)	End of Study	Follow-Up
	≤ 28 days prior to enrollment	**Day 1**	**Within 30 days of last dose**	**Every 3 months until metastatic cancer**
Tissue pre-screening	Prior to this informed consent and the screening period			
Informed consent and consent for sequencing of tumor	X			
Medical history	X		X	X
Physical examination	X	X	X	
ECOG performance status	X	X	X	
Concomitant medication review	X	X	X	
Adverse Event review	X	X	X	X (100 days after last nivolumab dose)
Standard blood tests	X	X		
Prostate-specific antigen	X	X	X	
Research blood samples		Cycles 1 and 2; q4 cycles beyond cycle 4 (C5, C9, etc.)	X	
Radionuclide bone scan and CT of abdomen/pelvis with contrast or MRI (or advanced imaging such as fluciclovine PET if you have had this recently)	X	X (Prior to cycle 4 and every 3rd cycle thereafter)		
Nivolumab infusion		X		

Planned Follow-up:

We would like to keep track of your medical condition. We would like to do this by looking at your medical record, calling you on the telephone, or emailing you every three months to see how you are doing. Keeping in touch with you and checking your condition helps us look at the long-term effects of the research study.

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will receive the study drug for up to two years and will be followed for up to 10 years.

You may be taken off the research study of nivolumab for many reasons including if:

- It is considered to be in your best interest
- The study drug or procedures are found to be unsafe or ineffective
- There is any problem with following study infusions and procedures
- Your condition worsens
- A decision is made to close the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

If you are removed from the research study, the research doctor will explain to you why you were removed. The research doctor and research team will help arrange for your continued care. If you are removed from the research study, you may be followed for up to ten years.

In addition, you can stop participating in the research study at any time, however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. One risk is that you may get a study drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All cancer treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great deal of variability among side effects of different cancer treatments and between

individuals. In a research study, all of the risks or side effects may not be known before you start the study. **You need to tell your doctor or a member of the study team immediately if you experience any side effects.**

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild; but others can be long lasting and may never go away. Some may be life-threatening or fatal.

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Risks Associated with nivolumab:

More Common (greater than or equal to 20% chance that this will happen):

- Feeling tired
- Pain in the muscles and/or joints
- Cough
- Nausea
- Rash
- Shortness of breath
- Diarrhea
- Constipation
- Decreased appetite
- Back pain
- Fever
- Itchy skin
- Upper respiratory tract infection
- Weakness

Common (up to a 10% chance that this will occur)

- Allergic reaction: reactions related to the infusion of the medicine
- High blood pressure (hypertension)
- Dry eyes

Serious side effects associated with nivolumab:
Nivolumab can cause your immune system to attack normal organs and tissues in many areas of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death. These problems may happen anytime during the study or even after your study drug has ended. Getting medical treatment right away may keep these problems from becoming more serious.

Call your study doctor right away if you develop any symptoms of the following problems or if these symptoms get worse:

- Lung problems (pneumonitis). Symptoms of pneumonitis may include: new or worsening cough; chest pain; and shortness of breath.
- Intestinal problems (colitis) that can lead to tears or holes in your intestine. Signs and symptoms of colitis may include: diarrhea (loose stools) or more bowel movements than usual; blood in your stools or dark, tarry, sticky stools; and severe stomach area (abdomen) pain or tenderness.
- Liver problems (hepatitis). Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); drowsiness; dark urine (tea colored); bleeding or bruising more easily than normal; and feeling less hungry than usual.
- Hormone gland problems (especially the thyroid, pituitary, adrenal glands, and pancreas). Signs and symptoms that your hormone glands are not working properly may include: headaches that will not go away or unusual headaches; extreme tiredness; weight gain or weight loss; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness; hair loss; feeling cold; constipation; voice gets deeper; and excessive thirst or lots of urine.
- Kidney problems, including nephritis and kidney failure. Signs of kidney problems may include: decrease in the amount of urine; blood in your urine; swelling in your ankles; and loss of appetite.
- Skin problems. Signs of these problems may include: rash; itching; skin blistering; and ulcers in the mouth or other mucous membranes.

- Inflammation of the brain (encephalitis). Signs and symptoms of encephalitis may include: headache; fever; tiredness or weakness; confusion; memory problems; sleepiness; seeing or hearing things that are not really there (hallucinations); seizures; and stiff neck.
- Problems in other organs. Signs of these problems may include: changes in eyesight; severe or persistent muscle or joint pains; and severe muscle weakness.
- Severe infusion reactions. Tell your doctor or nurse right away if you get these symptoms during an infusion of nivolumab: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever; or feeling like passing out.

These are not all the possible side effects of nivolumab. If you would like more information about nivolumab, talk with your study doctor. You can ask your study doctor for information about nivolumab that is written for health professionals.

Radiation Risks Associated with Scans and X-Rays:
While you are in this research study, CT scans and Bone Scans utilizing radioactivity may be used to evaluate your disease. *[If applicable, please include:]* In the long term, over many years, there is a very low risk of developing a new cancer as a result of the radiological evaluation and treatment for your cancer.

Risks Associated with MRI Scans:
When having an MRI (Magnetic Resonance Imaging) scan, you will lie still on a table that slides into a tunnel slightly wider than your body. People who feel uncomfortable in confined spaces (claustrophobia) may feel uncomfortable in the narrow cylinder. If you feel uncomfortable in confined spaces, please tell your research doctor. Your doctor may give you a medication to make you feel more comfortable. As images are taken, a loud banging noise will be produced. Earplugs or headphones will be available if needed. The MRI can be stopped at any time at your request, but the scan may not be complete.

Reproductive Risks:
The drug used in this research study may affect a fetus. While participating in this research study, you should not father a baby. We can provide counseling about preventing pregnancy for either male or female study participants. Male participants should use birth control for 7 months after the last dose of nivolumab. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

In the event that your partner becomes pregnant, it may be critical to share information regarding your participation in this research study with that person. Your research doctor should also be told if this happens. The study sponsor may want to collect data on your partner's pregnancy.

Non-Physical Risks:
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

We do not know if taking part in this study will help you. This study may help researchers learn information that could help people in the future.

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the nivolumab. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

I. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for participating in this study.

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

J. WHAT ARE THE COSTS?

Taking part in this research study might lead to added costs to you or your insurance company.
You will not be charged for nivolumab.

You or your insurance company will be charged for portions of your care during this research study that are considered standard care. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Beth Israel Deaconess Medical Center: (617) 667-5661
- Dana-Farber Cancer Institute: (617) 632-3455

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

K. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments will be billed to your insurance company. You will be responsible for deductibles and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

L. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of a DF/HCC research database.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

As participation in this study involves providing a specimen of your tissue, please know that if the research doctor leaves the institution, the research and the tissue might remain at the DF/HCC or might be transferred to another institution.

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health, and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health, and enable people to take part in research studies such as this without fear that their DNA information might be used against them by health insurers or their workplace. This protection does not extend to disability or life insurance. Additional information can be found at http://www.genome.gov/10002328.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As part of this study, your de-identified specimens or genetic data may be placed into one or more publicly-accessible scientific databases, such as the National Institutes of Health's Database for Genotypes and Phenotypes (dbGaP). Through such databases, researchers from around the world will have access to de-identified samples or data for future research.

M. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Beth Israel Deaconess Medical Center
- David J. Einstein, MD: (617) 667-2100

24-hour contact: David J. Einstein, MD at (617) 667-2100 or page at (617) 667-7000 beeper 95240. Nights and weekends, please ask for the Hematology/Oncology fellow on call to be paged.

Dana-Farber Cancer Institute
- Xiao Wei, MD MAS: (617) 632-4524
- **24-hour contact:** Xiao Wei, MD MAS at (617) 632-4524 or call (617) 632-3352 beeper 40468.

Dana-Farber Cancer Institute-Londonderry
- Frederick Briccetti, MD: (603) 552-9100
- **24-hour contact:** Frederick Briccetti, MD at (603) 552-9100

Dana-Farber Cancer Institute-St Elizabeth's
- Olga Kozyreva, MD: (617) 789-3031
- **24-hour contact:** Olga Kozyreva, MD at (617) 789-3000

Dana-Farber Cancer Institute-South Shore
- Thomas O'Connor, MD: (781) 624-4800
- **24-hour contact:** Thomas O'Connor, MD at (781) 624-4800

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

N. FUTURE USE OF DATA AND SPECIMENS

Your personal information and/or biospecimens collected during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify and destroy them.

Investigators, including investigators from collaborating institutions, can request this data and samples for new research. Samples and data may also be shared with outside non-profit academic investigators as well as with for-profit pharmaceutical investigators or commercial entities, with whom we collaborate.

You will not be asked to provide additional informed consent for the use of your de-identified information or samples in future research.
Future research studies may include genetic research. Your genes are unique to you. At this time, you cannot be identified through this research. There is a risk that you might be reidentified in the future as genetic research progresses

O. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.

- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).

- The supporter of the study, its subcontractors, representatives, business partners, and its agent(s): Bristol-Myers Squibb
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information,

please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

Optional Study #1:

We may be able to detect early signs of immune cells responding to the study drug, which could help in the future to identify which patients are most likely to benefit or not benefit from the study drug. Therefore, we are asking for an optional blood collection (2 tablespoons) approximately one week after the first study drug administration. The collection can occur at a time that is convenient for you and does not require any visits with the nurse or doctor. You would not otherwise be having blood collected at this time.

Please indicate whether or not you want to take part in this optional research study.

□ Yes _____Initials _____Date

□ No _____ Initials _____Date

P. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

_____ _____

Signature of Participant Date
or Legally Authorized Representative

Relationship of Legally Authorized Representative to Participant

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate