Protocol Title: A Phase II Study of M6620 (VX-970) in Selected Solid Tumors

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Translational Lead-In Informed Consent Form

A. INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have an advanced solid tumor. This research study is studying a drug called M6620 as a possible treatment for this diagnosis.

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

It is expected that about 223 people will take part in this research study.

EMD Serono, a pharmaceutical company, is supporting this study by providing the study drug and funding for the study procedures.

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.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

This study is made up of two phases: a Translational Lead-In Phase and a Phase II. These two phases serve different functions. The translational lead-in phase is designed to test the drug on a small number of patients in efforts to gain information on two research questions:

- If M6620 has an anti-cancer effect on participants
- If M6620 research findings that were discovered in laboratory studies are also found in human research studies.

Phase II is a much larger study to determine if M6620 has an anti-cancer effect in different groups of patients.

You are being invited to participate in the translational lead-in phase of study.

The FDA (the U.S. Food and Drug Administration) has not approved M6620 as a treatment for any disease.

ATR is an enzyme in cells that is responsible for multiple functions including repairing damaged DNA, helping cells that are stressed during the DNA copying process, and working to maintain the ends of chromosomes. In cancer cells, active ATR enzymes protect the cancer by helping the cells repair damage, stay alive, and maintain health. M6620 is a drug designed to inhibit the ATR enzyme. Inhibiting ATR may block how cancers repair their naturally damaged DNA, handle cancer cell stress, and maintain cancer cell life and health. Administration of M6620 may therefore assist in the slowing of growth or destruction of some cancers.

In this research study, we are...

- Gathering initial data on the anti-cancer activity of M6620 when given alone to participants within selected cancer populations
- Determining if there are changes in the biological components in your body that may be associated with damaged DNA repair.

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:

- Receive standard treatment including chemotherapy and/or immunotherapy, depending on your disease.
- 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?

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 demographics, health, current medications, and any allergies. At future visits, this will be abbreviated and you will be asked about any changes in your health or symptoms you may have recently experienced.
- **A physical exam,** which examines the health of your various body systems.
- **Your vital signs will be measured,** which may include your pulse, oxygen level, respiratory rate, temperature, and blood pressure. This may include measuring your height and/or weight as well.

- **Performance status,** which evaluates how you are able to carry on with your usual activities.
- **Blood tests,** totaling up to approximately 5 tablespoons at any one visit, to:
  - Measure your chemistry results, which provide information the health of various body systems
  - Assess your pregnancy status if you are a woman who is able to become pregnant
  - Take a baseline germline sample for analysis. Germline samples are used to look for genetic mutations that are inherited and may increase the risk and likelihood of the cancer you have.
  - To try to detect circulating free tumor DNA, for Cohort T1 only (approximately 1 tablespoon)
- An **electrocardiogram (ECG)**, which measures the electrical activity of your heart
- **An assessment of your tumor** by one or more of the following standard assessment tools: CT (Computerized Tomography) scan, or MRI (Magnetic Resonance Imaging) scans.
  - If clinically necessary, your doctor may also request additional scans as medically appropriate:
    - x-ray
    - FDG-PET (fluorodeoxyglucose-positron emission tomography
    - PET-CT (Positron emission tomography–computed tomography)
    - MIBG(Metaiodobenzylguanidine).
- Review of your tissue to determine your eligibility to participate in this study:
  - **Your previously collected and stored tissue (archival tissue) will be obtained for tests**. Reviewing your archival tissue is mandatory for entering into this study.
  - **A new biopsy will be performed** to collect a sample of your tumor tissue. Performing a new biopsy is mandatory for entering into this study. This biopsy serves an important function in this study, as it will help researchers assess the anti-tumor effects of the treatment. This is required for Cohorts T1-T3 and optional for T4.

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

Study Treatment Overview:

- **Infused Study Drug:** One treatment cycle is 28 days long. You will be given M6620 twice weekly into your vein (by intravenous infusion) over about 60 minutes. After 16 weeks (4 Cycles) of treatment, your doctor may give you the option of switching to a once weekly infusion schedule if it is medically appropriate for you. Either way, study drug administration will continue as long as you do not have any unmanageable side effects and your disease doesn't get worse.

Study Visit: On treatment

You will have regularly scheduled appointments to infuse the study drug. While you are receiving the infusion twice weekly, those infusions will occur on Cycle Days 1, 4, 8, 11, 15, 18, 22, and 25. If you are able and decide to switch to the once weekly treatment (after 4 Cycles), that will occur on Cycle Days 1, 8, 15, and 22.

The study visits may involve any of the procedures described in the screening section above, as well as the following:

- Infused Study Drug
- Blood tests:
    - Take a pharmacokinetic (PK) sample for analysis. PK samples are used to analyze the various components in your blood and body. Sometimes this sample will be drawn after your dose of the study drug has been administered, to see how your body absorbs and metabolizes the drug.

Research Study Plan:

	Screening	Cycle 1			Cycles 2 and Beyond[a]				Off Treatment
		Days 1 and 15	Day 4, 11, 18, and 25	Day 8 and 22	Day 1	Days 4, 11, 18, 25	Day 8 and 22	Day 15	
Medical History	X	X	X	X	X	X	X	X	X
Physical Exam	X	X		X	X			X	X
Vital Signs	X	X	X	X	X	X	X	X	X
Performance Status	X	X			X				X
Blood Test	X	X	X	X	X		X	X	X
ECG	X	Only if clinically indicated							
Tumor Assessment Scan(s)	X	Every 8 Weeks							X
Archival Tissue Review	X								
Tumor Biopsy	X[b]	X[c]							X[d]
M6620 Administration		X	X	X	X	X	X	X	

[a] If you switch to a once weekly infusion schedule, you will only have visits on Cycle Days 1, 8, 15, and 22
[b] Screening biopsy required for Cohorts T1-3. Optional for T4.
[c] On treatment tumor biopsy on Cycle 1 Day 15. This is optional for T4
[d] There is an optional biopsy for participants whose disease progresses

Study Visit: Off Treatment
You will have one visit when you go off treatment. Procedures and tests for this visit are described above in the Research Study Plan.

Planned Follow-up:
We would like to keep track of your medical condition. We would like to do this by following your condition for 30 days after you stop taking the study drug. This is to assess if you have any side effects after the treatment.

When you leave the study, information from your chart will be collected about your cancer and wellbeing. The study team may also call you on the telephone if they have any questions or need to speak to you to hear about how you are doing. If the study team finds you have remaining side effects from the treatment, your condition will be followed until the side effects resolve, and the doctor may ask you to come in for a visit as well

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 be in this research study as long as you do not have any unmanageable side effects and your disease does not get worse.

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

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- You are a female and become pregnant or plan to become pregnant
- 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.

There may be an opportunity for you to continue on the study treatment even if you are removed from the study. Your doctor will discuss this with you if that is the case.

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 M6620:

Likely (At least a 15% chance that this will happen)

- Nausea
- Vomiting
- Diarrhea
- Fatigue
- Urinary Tract Infection
- Changes in liver tests that may indicate liver inflammation.
- Changes in blood tests (creatinine) that may indicate kidney dysfunction. Kidney dysfunction may mean your body can't filter out waste properly, leading to waste build up in your blood that causes swelling in the arms and legs, tiredness, and weakness.
- Hyperglycemia, or high blood sugar. This may cause increased thirst, headaches, trouble concentrating, blurred vision, frequent need to urinate, fatigue, and weight loss.
- Worsening of cancer pain
- Anemia, or low red blood cell count. This may cause tiredness and shortness of breath.
- Flushing or redness of the skin
- Headache

- Dizziness
- Infusion related reaction where your body has a negative reaction to the drugs being administered. Symptoms may include dizziness, fainting, flushing of the skin, fever, shortness of breath, nausea, vomiting, or pain at the site of the infusion.

An episode of delayed allergic reaction has occurred, which was possibly related to M6620. Delayed allergic reaction may include a rash, hives, fever, difficulty breathing, and low blood pressure. Although usually reversible with treatment, it can be severe or life threatening.

An episode of febrile neutropenia has occurred, which was probably related to M6620. Symptoms of this condition include fever and an abnormally low level of a type of white blood cell called neutrophils.

During an infusion, one episode of moderate phlebitis, or inflammation of the veins causing discomfort, pain, and swelling, occurred once for a patient that did not have a port. The patient had a port placement completed and the event has not recurred.

Cancer research often includes biopsies, scans, x-rays that are also provided as routine care. The following describes the side effects of procedures done only for the purposes of research.

Risks Associated with Biopsies:
Biopsies are normally performed under the guidance of an imaging technique. Each procedure requires a separate consent prior to the biopsy. The risks may include:

- Pain and discomfort. The amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site.
- Tenderness at the biopsy site.
- Scarring at the biopsy site.
- Rarely, an infection at the biopsy site.

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

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 become pregnant or father a baby, and should not nurse a baby. We can provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

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 drug. In some cases, the abrupt stopping of a drug can have risks in itself. 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 M6620.

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
- Boston Children's Hospital: (617) 355-7188
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485
- Dana-Farber Cancer Institute: (617) 632-3455
- Massachusetts General Hospital: (617) 726-2191

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 your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database.

As part of the research, your deidentified samples may be shared with outside laboratories or institutions for analysis.

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.

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.

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:

Massachusetts General Hospital
- Gregory Cote, MD, PhD: (617) 724-4000

Dana-Farber Cancer Institute
- Geoffrey Shapiro, MD, PhD: (617) 632-3000

Beth Israel Deaconess Medical Center
- Andrea Bullock, MD MPH: (617) 667-2100

Dana-Farber Cancer Institute(DFCI)/Boston Children's Hospital(BCH)
- Katherine Janeway, MD (617) 632-4994

24-hour contact at Massachusetts General Hospital, Dana-Farber, and Beth Israel: Please call the number of your facility above and ask to speak to your study doctor, or for your study doctor to be paged.

24-hour contact at DFCI/BCH: please page the Pediatric Oncology Fellow on call by calling the page operator at (617) 632-3352.

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.

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 sponsor of the study, its subcontractors, representatives, business partners, and its agents: DF/HCC
- The supporting pharmaceutical company of the study, its subcontractors, representatives, business partners, and its agents: EMD Serono. The support company may send study data outside of the U.S.
- 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?”

P. OPTIONAL RESEARCH STUDIES:

You are being asked to participate in some optional studies. If you decide not to participate in any of the optional studies, you can still participate in the main research study. Please take your time to make your decision and discuss it with others and your primary care physician.

Your participation in this optional research study is voluntary, and you will not be penalized or lose any benefits if you refuse to participate or decide to stop.

Optional Study #1: Optional Biopsy upon Disease Progression

The study team would like perform an additional tumor biopsy if your disease progresses while you are on the study treatment. The purpose of this optional biopsy is to look at your tumor tissue and research how it may or may not have responded to the study drug.
Please indicate whether or not you want to take part in this optional research study.

☐ Yes _____ Initials _____ Date

☐ No _____ Initials _____ Date

Optional Study #2: Optional Research on Collected Samples

If you undergo an additional procedure, for clinical (non-research) reasons, that results in the collection of tumor tissue (e.g. biopsy, surgery, fluid collection) the study team would like to take a sample for research. The purpose of this optional collection is to look at your tumor tissue and research how it may or may not have responded to the study drug.

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

☐ Yes _____ Initials _____ Date

☐ No _____ Initials _____ Date

Optional Study #3: Optional Screening Biopsy (For T4 Only)

The study team would like to perform an additional biopsy during screening. The purpose of this optional biopsy is to look at your tumor tissue and research how it may or may not have responded to the study drug.

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

☐ Yes _____Initials _____Date

☐ No _____ Initials _____Date

Optional Study #4: Optional On-Treatment Biopsy (For T4 Only)

The study team would like to perform a biopsy on Cycle 1 Day 15. The purpose of this optional biopsy is to look at your tumor tissue and research how it may or may not have responded to the study drug.

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

☐ Yes _____Initials _____Date

☐ No _____ Initials _____Date

Q. DOCUMENTATION OF ASSENT

Signature of participant between age of 10 and 18: The person doing this research study has explained what will happen to me if I take part in this research study. My signature below means that I want to be in this research study. I can decide not to take part in this research study if I do not want to and nothing will happen to me if I decide I do not want to participate.

_____ _____
Signature of Participant Date

To be completed by person obtaining assent:

The assent discussion was initiated on _____ (date).

☐ The information was presented in age-appropriate terms. The minor:
- ☐ Agreed to take part in the study
- ☐ Did not agree to take part in the study

☐ An assent discussion was not initiated with the minor for the following reason(s):
- ☐ Minor is incapacitated
- ☐ Minor is under 10 years of age
- ☐ Other_____

_____

Signature of Individual obtaining assent: _____

Printed name of above: _____

Date: _____

R. 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 or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

Research Consent Form for Biomedical Research
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

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

DFCI Protocol Number: 18-274	Approved Date (DFCI IRB Approval): 03/16/2020
Date Posted for Use: 03/19/2020	

To be completed by person obtaining consent:

Minor 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, or, where the participant is a minor, the participant's parent or legal guardian.

☐ 1) The parent or legally authorized representative gave permission for the minor to participate.

☐ 1a) Parent 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) Parent or legally authorized representative 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 parent or legally authorized representative who was given the opportunity to ask questions and who communicated agreement for the minor to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 1c) The parent or legally authorized representative did not give permission for the minor to participate