Protocol Title:

Sponsor Protocol Number:

NWH Principal Research Doctor / Institution:

NWH Site-Responsible Research Doctor(s)/Institution(s):

Study Population:

[The study title for participants may be entered here.]

[Insert NCI Model Consent Document]

[THIS SECTION SHOULD BE ADDED TO THE END OF THE RISK SECTION OF THE MODEL CONSENT] NWH RADIATION RISK INFORMATION

[Include the following paragraph if the study involves research scans or x-rays.] Cancer research often includes, 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.

Radiation Risks Associated with Scans and X-Rays:
[This language will be reviewed by the appropriate Radiation Safety Offices and should be consistent with the Radiation Safety Screening Form. Only include if the scans are not standard of care.] While you are in this research study, CT scans, PET/CT scans, Bone Scans, x-rays, mammograms, and/or other scans utilizing radioactivity *[Include only those scans/x-rays that are applicable.]* may be used to evaluate your disease. The frequency of these exams is slightly greater than what you would receive as standard care. In the long term, over many years, there is a very low risk of developing a new cancer as a result of the

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radiological evaluation and treatment for your cancer. *[Include if appropriate:]* Certain types of drugs or combinations of these drugs with radiation may further slightly increase the risk of developing a new cancer. This risk is described above, in the section about the risks associated with *[study drug(s)]*.

Risks Associated with Mammograms:

[For studies that involve ONLY mammograms that are more frequent than standard of care, you may use the following language. For studies that involve mammograms and other radioactive agents, please add this language to the previous section, "Risks Associated with Radiological Scans and X-Rays."]

While you are in this research study, mammograms may be used to evaluate your disease. *[If scans are for research purposes state:* The frequency of these exams is greater than what you would receive as standard care. *But if scans are NOT for research purposes state:* The frequency of these exams is about the same as what you would receive as standard care.*]* There is thought to be a low but increased risk of cancers associated with radiation in the long term over many years.

[If done for screening purposes only, please include the following:] In addition, there is a chance of having an abnormal mammogram. This could require further testing with a breast biopsy and possible other tests. If you have an abnormal mammogram, this could result in your needing a breast biopsy you would not otherwise get. An abnormal mammogram may cause you to feel upset, worried, or depressed. If you are upset, you may speak with the research doctor or ask to be referred for additional emotional support.

[Include only if appropriate:]

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.

[Include only if appropriate:]

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Risks Associated with Contrast Agents Used During Scans:

[Include only if appropriate:] There is a small risk with using a contrast agent that is injected into a vein during the _____ *[indicate type of scan, eg. CT scan or MRI]*. The contrast agent is a special dye that highlights organs, blood vessels or tissue to make them more visible. Depending on the type of contrast agent that is used, it may cause decreased kidney function or worsen kidney function in people who already have decreased kidney function. Therefore, we will monitor your kidney function closely while you participate in this study. If there is any change in your kidney function, we may have to remove you from the study.

[Include only if appropriate:] Uncommonly, some people have allergic reactions (such as hives and itching) to the contrast agent. Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare.

[THIS SECTION SHOULD BE INSERTED FOLLOWING THE WHAT ARE THE COSTS SECTION OF THE MODEL CONSENT] NWH FINANCIAL INFORMATION

Taking part in this research study might lead to added costs to you or your insurance company.

[NOTE: Please state whether the cost of the study drug will be covered. Please do not list who will cover payment for costs for procedures because they might conflict with the billing grids.]

[If appropriate, include the following] You will not be charged for ____ *[insert drugs]. [If appropriate, include the following]* It is possible that ____ *[insert drugs] may not continue to be supplied free for some reason. If this would occur, your research doctor will talk with you about your options.*

[If this applies to your study, add this statement:] You or your insurance company will be charged for portions of your care during this research study that are considered standard care, *[if applicable, add "including the following study drugs…."]*. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

*[For drugs that are **commercially available, but used off label**, please include the following language if applicable (e.g., peer reviewed publications supporting the off-label use). Please contact your clinical trials billing department if you*

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have questions: [Drug name] is commercially available which means that the FDA has approved it for use in patients with another type of cancer. Because there is evidence that supports using this drug in patients with your type of cancer, you or your insurance company will be billed for the cost of _____*[drug name].]*

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: *[include only the relevant institutional numbers]*

- Massachusetts General Hospital/Newton-Wellesley Hospital Vernon Cancer Center: (617) 243-6392

[THIS SECTION SHOULD BE INSERTED FOLLOWING THE WHAT HAPPENS IF I AM INJURED SECTION OF THE MODEL CONSENT] NWH INJURY LANGUAGE

[Include only what applies to the study. If there is sponsor-specific injury language to include, please include it, but avoid redundancy and do not include any exculpatory language, i.e., language that suggests to participants that they are giving up rights or benefits.

NWH will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but as noted earlier you may also be responsible for some of them.

[THIS SECTION SHOULD REPLACE THE INFORMATION IN THE WHO CAN ANSWER QUESTIONS ABOUT THE STUDY SECTION OF THE MODEL CONSENT

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

Type of Question	Role	Contact Person	Contact Phone No.
About study procedures, risks, benefits, alternatives	Study doctor/Investigator	*[insert name]*	*[insert phone number]*
About changing an appointment or	Research Nurse or study coordinator	*[insert name]*	*[insert phone number]*

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parking			
About your rights as a participant in the research study or complaints	Institutional Review Board	Manager, Office of Research	617-243-6493

For questions about your rights as a research participant, please contact a representative of the NWH Office of Research at (617) 243-6493 or 243-6211. 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.

[THIS SECTION SHOULD BE INSERTED FOLLOWING THE WHO CAN ANSWER QUESTIONS ABOUT THE STUDY SECTION OF THE MODEL CONSENT] NWH PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Newton-Wellesley Hospital 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

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- 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 for the purpose of this or other research relating the study drug and its use in cancer; 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?

- NWH and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other NWH or Partners Health Services 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 NWH 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 NWH and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, and its agent(s): ____ *[enter name of sponsor]*
- Other research doctors and medical centers participating in this research, including: *[enter name(s) of other research doctors and/or medical centers]*
- 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.

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- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable
- Other, ____ *[please specify]*

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 NWH 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: “NWH Investigator Contact Information”
- 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 study doctor/investigator listed above in the section: “Who Can Answer my Questions about the Study.”

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To be completed by person obtaining consent:

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 illiterate

The consent form was read to the participant who was given the opportunity to ask questions.

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

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