NRG ONCOLOGY

NRG-BN001

(ClinicalTrials.gov NCT #: **02179086***)*

RANDOMIZED PHASE II TRIAL OF HYPOFRACTIONATED DOSE-ESCALEATED PHOTON IMRT OR PROTON BEAM THERAPY VERSUS CONVENTIONAL PHOTON IRRADIATION WITH CONCOMITANT AND ADJUVANT TEMOZOLOMIDE IN PATIENTS WITH NEWLY DIAGNOSED GLIOBLASTOMA

Amendment 1: August 31, 2021

Study Title for Study Participants: Comparing Higher-Dose Radiotherapy To Standard-Dose Radiotherapy To Treat Patients With Glioblastoma Brain Tumors

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma (NCT 02179086) (19-NOV-2019)

What is the usual approach to my brain tumor*?*

You are being asked to take part in this study because you have a brain tumor called a glioblastoma. People who are not in a study are usually treated with radiation and temozolomide followed by temozolomide alone. For patients who receive the usual approach for this cancer, about 4 out of 100 are free of cancer growth at five years.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available
- or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

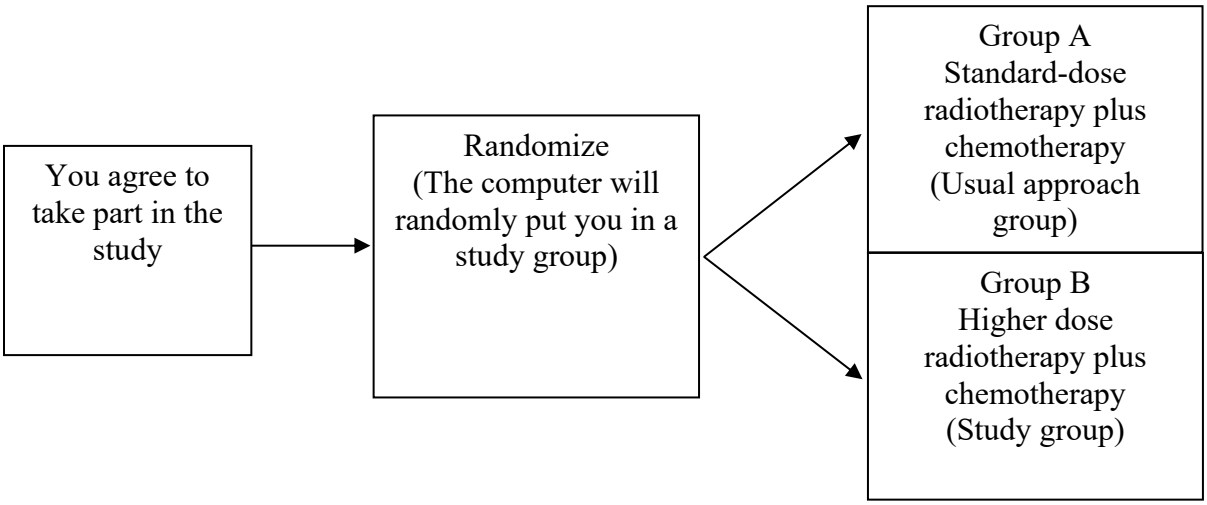
Why is this study being done? (19-NOV-2019)

The purpose of this study is to compare a different radiation therapy schedule and higher radiation dose [higher dose group] to the standard dose of radiation therapy [standard dose group]. Both groups will receive usual chemotherapy, temozolomide. The higher radiotherapy dose could shrink your cancer, but it could also cause side effects. This study will allow the researchers to know whether this higher dose is better, the same, or worse than the usual approach. To be better, the study should increase life by six months or more compared to the usual approach. Two methods of giving radiation therapy will also be compared. They are proton beam radiation and intensity-modulated radiation. There will be about 569 people taking part in this study.

What are the study groups? (2/16/17)

This study has two study groups. Group A will receive the standard radiotherapy dose along with the usual chemotherapy and Group B will receive a higher radiotherapy dose along with the usual chemotherapy.
A computer will by chance assign you to treatment groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the other. You will have about a 2 in 3 chance of being placed in Group B and about a 1 in 3 chance of being placed in Group A. You are 2 times as likely to receive the experimental treatment (Group B) in this study.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



If you are assigned to Group A, you will receive standard of care radiotherapy. This may include intensity-modulated radiotherapy, but will not include proton beam therapy.

If you are assigned to Group B, you will receive experimental radiotherapy. This will be either intensity-modulated radiotherapy or proton beam therapy, depending on the center where you receive your treatment.

How long will I be in this study? (2/16/17)

You will receive the radiation and temozolomide for about 6 weeks. Temozolomide will be taken by mouth once per day during this period. Approximately one month after you complete radiation, you will begin maintenance temozolomide which will be taken for five consecutive days every 4 weeks (3 weeks of no drug) for up to 12 months. During weekdays with radiotherapy (Monday through Friday) temozolomide should be taken each day before or after each session of radiotherapy, as best tolerated by the patient . During weekends (Saturday and Sunday) without radiotherapy, temozolomide should be taken in the morning. Post radiotherapy, temozolomide should be taken at night. You will give the temozolomide capsules to yourself on an empty stomach with a glass of water according to this schedule. To help record the amount of temozolomide you take and when you take it, you will be asked to complete a pill diary which is to be given to the research staff at the completion of each cycle of treatment. After you finish all treatment, your doctor will continue to watch you for side effects and follow your condition indefinitely.

What extra tests and procedures will I have if I take part in this study? (31-AUG-2021)

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra tests that you will need to have if you take part in this study.

Before you begin the study, you will need to have the following extra test:

Small pieces of cancer tissue removed at the time of your surgery will be taken for the study before you begin treatment on this study. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study. Your study doctor will need to send this tissue to a central pathology site. There, a pathologist will confirm that the tumor is a glioblastoma and will determine whether

there is adequate tumor tissue to perform the analysis for genetic (molecular) profile. If the tumor is not a glioblastoma and/or if the tissue is not adequate for performing the molecular analysis, you will not be able to continue on the study. If any of the tissue is left over and you chose to give your consent, it will be stored for biobanking. Biobanking will be discussed in the section on optional studies.

Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information.

Neither you nor your health care plan/insurance carrier will be billed for the collection of the tissue that will be used for this study.

Additional Required Sub-Study for patients enrolling as of April 25, 2017,to sites not able to treat with proton beam therapy: **(Advanced imaging sub-study closed to accrual)**

About Advanced Imaging in the Study

In addition to the standard imaging you are being asked to undergo in the main part of the study, you will participate in an advanced MRI study. A total of 40 eligible patients will be included in the advanced imaging portion of the study.

Researchers hope that the advanced MRI will help them learn more about how blood is supplied to the cancer and the tumor's response to treatment. The advanced MRI will take about 5 more minutes to complete than the regular MRI examinations. A regular MRI examination takes between 30 and 45 minutes. You will receive 1 additional MRI for a total of 4 exams instead of the standard 3 exams.

Advanced imaging will take place at 4 time points and the second MRI listed below is the extra exam:

Before you start treatment with chemoradiation

↓

After you have been receiving chemoradiation for about 3 weeks

↓

About 1 week before you begin treatment with chemotherapy alone

↓

After you have been receiving chemotherapy alone for about 3 months

MRI examinations require that you lie flat in the MR scanner while imaging is performed. During this time, you will receive an intravenous (through a tube placed in a vein in your arm) medication, called gadolinium that helps doctors see the tumor.

Risks

MRI. For most patients, there are no specific risks associated with MRI scanning, but some may experience anxiety, stress, claustrophobia, or discomfort. You will not be allowed to have an MRI scan if you have certain types of metallic or electrical devices (such as a pacemaker or certain aneurysm clips) placed in your body. If you had previous surgery to your heart or brain, doctors will determine whether the MRI is safe for you. You will not be allowed to have an MRI if you have any metal pieces in your brain, spinal cord, or eyes. If your job has ever placed you at risk for exposure to metallic fragments (such as metal working or welding), doctors will perform an x-ray of your eyes prior to the study to determine that MRI is safe for you.

Benefits

You will not directly benefit from the results of the advanced imaging study, but we hope that the results will help other people with brain cancer in the future. The results of the advanced MRI central reviews will not be sent to you or your doctor and will not be used to determine your treatment.

Costs and Payments

You or your insurance company may be charged for MRI scans that are considered standard of care.

You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

What possible risks can I expect from taking part in this study? (19-NOV-2019)

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- The research radiation approach may not be better, and could possibly be worse, than the usual approach for your cancer.

The radiation and chemotherapy used in this study may affect how different parts of your body work such as your liver and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the radiation and chemotherapy.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study radiotherapy or drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Study Groups A and B- Possible side effects of temozolomide, which is the usual chemotherapy for this type of cancer:

Possible Side Effects of Temozolomide (Table Version Date: September 28, 2018)

COMMON, SOME MAY BE SERIOUS In 100 people receiving Temozolomide, more than 20 and up to 100 may have:
• Headache, seizure • Constipation, nausea, vomiting, diarrhea • Trouble with memory • Difficulty sleeping • Muscle weakness, paralysis, difficulty walking • Dizziness • Tiredness • Hair loss

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Temozolomide, from 4 to 20 may have:
• Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may cause tiredness, or may require transfusions • Severe skin rash with blisters and can involve inside of mouth and other parts of the body • Rash

RARE, AND SERIOUS In 100 people receiving Temozolomide, 3 or fewer may have:
• Cough, damage to the lungs which may cause shortness of breath • Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require blood transfusions • Liver damage which may cause yellowing of eyes and skin, swelling • A new cancer including leukemia resulting from treatment of a prior cancer

Study Group A

Possible Side of Effects of Standard Radiation Therapy (Standard-Dose Radiation Therapy), which is the usual approach for this type of cancer:

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, more than 20 and up to 100 may have:
• Reddening, tanning, or peeling of the skin • Hair loss, which may be temporary or permanent • Tiredness • Lethargy • Ear/ear canal reactions, possibly resulting in a short-term hearing loss • Temporary aggravation of brain tumor symptoms such as headaches, seizures, or weakness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Mental slowing • Permanent hearing loss • Cataracts • Behavioral change • Nausea • Vomiting • Temporary worsening of existing neurologic deficits, such as decreased vision, drowsiness, and weakness of your arms and legs • Endocrine problems causing abnormalities in the level of some hormones related to changes to the pituitary gland • Dry mouth or altered taste

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Severe local damage to normal brain tissue, a condition called necrosis (tissue deterioration). Radiation necrosis can mimic recurrent brain tumor and may require surgery for diagnosis and treatment. • Injury to the eyes with the possibility of blindness • Development of other tumors (either benign or malignant)

Study Group B

Possible Side Effects of Research Radiation Therapy (Higher-Dose Radiation Therapy) Using Either Intensity-Modulated Radiotherapy or Proton Beam Therapy

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, more than 20 and up to 100 may have:
• Reddening, tanning, or peeling of the skin • Hair loss, which may be temporary or permanent • Tiredness • Lethargy • Ear/ear canal reactions, possibly resulting in a short-term hearing loss • Temporary aggravation of brain tumor symptoms such as headaches, seizures, or weakness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Mental slowing • Permanent hearing loss • Cataracts • Behavioral change • Nausea • Vomiting • Temporary worsening of existing neurologic deficits, such as decreased vision, drowsiness, and weakness of your arms and legs • Endocrine problems causing abnormalities in the level of some hormones related to changes to the pituitary gland • Dry mouth or altered taste

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Severe local damage to normal brain tissue, a condition called necrosis (tissue deterioration). Radiation necrosis can mimic recurrent brain tumor and may require surgery for diagnosis and treatment. • Injury to the eyes with the possibility of blindness • Development of other tumors (either benign or malignant)

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study. The chemotherapy and radiation therapy used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if the study approach is better than the usual approach so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to pay for the temozolomide, radiation therapy, and all of the other costs of treating your cancer while in this study, including the cost of managing any side effects. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information? (8/7/15)

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, NRG Oncology
- American College of Radiology (ACR), for the collection of digital data
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

ADDITIONAL STUDIES SECTION

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading these optional studies hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

1. Optional Quality of Life/Neurocognitive Function Study

If you choose to take part in this study, you will be asked to fill out two forms with questions about (*symptoms* such as fatigue, your physical and emotional well-being). You will also be asked to complete a neurocognitive assessment. Researchers will use this information to better understand how patients feel during treatments and what effects the treatments are having.

You will be asked to complete the neurocognitive assessment and fill out these forms at three times: Before you start treatment, while you are receiving treatment, and when you have completed treatment. You will complete these measures during your regular office visits for this study. Each of these visits will take about 30 minutes to complete all measures. The questionnaires will ask about things like (*e*.g., fatigue, quality of life, memory). You may feel uncomfortable answering some of the questions, and you can skip any you do not want to answer.

Please circle your answer: I choose to take part in the Quality of Life/Neurocognitive Function study and will complete these forms:

YES NO

2. Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies (2/16/17)

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

Laboratory Study
If you choose to take part in this study, the study doctor for the main study would like to collect a sample of tissue that is left over from the molecular analysis described in the main part of the study. The left-over tissue will be used to see if there are other genes, like the one used in this study, that may provide information about how the tumor will respond to treatment.

Biobanking for Possible Future Studies
If you choose to take part, a sample of tissue from your previous surgery will be collected, and a sample of blood and urine taken before you start treatment will be collected. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of study tests and medicines you are given) for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by NRG Oncology and supported by the National Cancer Institute

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) About *2* tablespoons of blood will be collected from a vein in your arm before you start treatment at the same time that blood is collected as part of your pre-treatment evaluation for the main part of this study.
2) About 2 tablespoons of urine will be collected before you start treatment at the same time that is urine is collected as part of your pre-treatment evaluation for the main part of this study.
3) Tissue remaining from the sample sent for central pathology review as part of your participation on the main part of this study will be sent to the Biobank.
4) Your sample and some related health information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
5) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
6) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
7) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) The most common risks related to drawing blood from your arm are brief pain and possibly a bruise
2) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
3) There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives.

Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information.

Many states have laws to protect against genetic discrimination *[list appropriate state information if your state or locality has such laws]*. Additionally, a federal law called the Genetic Information Non-Discrimination Act, or GINA, is in effect. This law prohibits health insurer or employer discrimination. The law does not include other types of misuse by life insurance, disability, or long term care insurance. To learn more about the GINA Law, please ask *[Note to local investigator: Contact information for patient representatives or other individuals in a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can be listed here.]*.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only. The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and NRG Oncology staff with access to the list must sign an agreement to keep your identity confidential.
2) Researchers to whom NRG Oncology sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
3) Information that identifies you will not be given to anyone, unless required by law.
4) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no

longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option (*include only applicable questions)*:

SAMPLES FOR THE LABORATORY STUDY: (2/16/17)

I agree to have my left-over tumor tissue from my study entry biopsy submission collected and I agree that my left-over tumor tissue and related information may be used for the laboratory study described above.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to learn about results from this study.

YES NO

SAMPLES FOR FUTURE RESEARCH STUDIES:

My samples and related information may be kept in a Biobank for use in future health research.

YES NO

I agree that my study doctor, or his/her representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

3. Optional Advanced Imaging Sub-Study (31-AUG-2021)

(Advanced imaging sub-study closed to accrual)

[LIMITED INSTITUTIONS: For:

- *Potential advanced imaging sub-study participants at advanced imaging–qualified institutions **enrolling to study Group 2** as of April 25, 2017 .*
- *Advanced imaging sub-study participants at advanced imaging–qualified institutions **enrolled to study Groups 1 or 2** before April 25, 2017*

[Institutions not participating in the optional advanced imaging sub-study may remove this portion of the sample consent.]

About Advanced Imaging in the Study (2/16/17)

In addition to the standard imaging you are being asked to undergo in the main part of the study, you are being asked to participate in an advanced MRI study. A total of 40 eligible patients will be included in the advanced imaging portion of the study.

Researchers hope that the advanced MRI will help them learn more about how blood is supplied to the cancer and the tumor's response to treatment. The advanced MRI will take about 5 more minutes to complete than the regular MRI examinations. A regular MRI examination takes between 30 and 45 minutes. If you take part in the advanced MRI study, you will receive 1 additional MRI for a total of 4 exams instead of the standard 3 exams.

Advanced imaging will take place at 4 time points and the second MRI listed below is the extra exam:

Before you start treatment with chemoradiation

↓

After you have been receiving chemoradiation for about 3 weeks

↓

About 1 week before you begin treatment with chemotherapy alone

↓

After you have been receiving chemotherapy alone for about 3 months

MRI examinations require that you lie flat in the MR scanner while imaging is performed. During this time, you will receive an intravenous (through a tube placed in a vein in your arm) medication, called gadolinium that helps doctors see the tumor.

Risks

MRI. For most patients, there are no specific risks associated with MRI scanning, but some may experience anxiety, stress, claustrophobia, or discomfort. You will not be allowed to have an MRI scan if you have certain types of metallic or electrical devices (such as a pacemaker or certain aneurysm clips) placed in your body. If you had previous surgery to your heart or brain, doctors will determine whether the MRI is safe for you. You will not be allowed to have an MRI if you have any metal pieces in your brain, spinal cord, or eyes. If your job has ever placed you at risk for exposure to metallic fragments (such as metal working or welding), doctors will perform an x-ray of your eyes prior to the study to determine that MRI is safe for you.

Benefits

You will not directly benefit from the results of the advanced imaging study, but we hope that the results will help other people with brain cancer in the future. The results of the advanced MRI central reviews will not be sent to you or your doctor and will not be used to determine your treatment.

Costs and Payments (2/16/17)

You or your insurance company may be charged for MRI scans that are considered standard of care.

You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

Making Your Choice

If you decide to participate in the study, these advanced images will be part of the study. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot

guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Records of your progress while on the study will be kept in a confidential form at this institution and in a computer file at the headquarters of the American College of Radiology (ACR) in Philadelphia, PA. Copies of your MR images will be permanently kept on file with the ACR. This information will be used for research purposes only. All identifying information will be taken off of the films to maintain confidentiality. Future research studies may be conducted on other aspects of the data collected during the study. At this time it is not known what type of studies may be conducted. Some possibilities may be issues affecting patient care or future studies of a medical or non-medical nature.

Please circle your answer.

I choose to take part in the advanced MRI study that is being done for research as a part of the main treatment study.

Yes **No**

This is the end of the section about optional studies.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study *and any additional studies where I circled 'yes'. (Note to protocol authors – remove italicized text if not applicable. Remove italics, if the text does apply.)*

Participant's signature_____

Date of signature_____

(The following signature and date lines for the person(s) conducting the discussion may be included at the discretion of the study sponsor.)

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____