

**Study Title for Participants: Single Fraction Stereotactic Radiosurgery or Three to Five Fraction Stereotactic Radiosurgery in Treating Patients With Brain Metastasis That Has Been Removed By Surgery.**

**Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>: A071801, “Phase III Trial of Post-Surgical Single Fraction Stereotactic Radiosurgery (SRS) Compared with Fractionated SRS for Resected Metastatic Brain Disease,” (NCT04114981)**

## **Overview and Key Information**

### **What am I being asked to do?**

We are asking you to take part in a research study. This study has public funding from the National Cancer Institute (NCI), part of the National Institutes of Health (NIH) in the United States Department of Health and Human Services. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have cancer that has spread to the brain (also known as brain metastasis) and a brain metastasis has been resected (removed by surgery).

### **Taking part in this study is your choice.**

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make; you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It’s important that you have as much information as you need and that all your questions are answered. See the “Where can I get more information?” section for resources for more clinical trials and general cancer information.

This study is conducted by the Alliance for Clinical Trials in Oncology (the Alliance), a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

## **Why is this study being done?**

This study is being done to answer the following question: does fractionated (multiple treatment sessions) radiosurgery delivered to the surgical cavity in the brain (the part of the brain where the brain metastasis was resected) decrease the risk of tumor recurring in the surgical cavity compared to single fraction (single treatment session) radiosurgery?

## **What is the usual approach to my resected brain metastasis?**

The usual approach for patients who are not in a study is treatment with single fraction radiosurgery. These treatments can reduce symptoms and may stop the tumor from growing for a few months or longer.

Radiosurgery, despite its name, is a non-surgical procedure that delivers precisely-targeted radiation at much higher doses, in only a single (or few treatments) as compared to traditional radiation therapy. Radiosurgery utilizes immobilization (a head frame or a soft plastic mask that forms to the shape of your face that helps hold the head in place during treatment) during the procedure to allow very precise targeting of tumors. Radiosurgery is typically done as an outpatient procedure. For most patients, the actual time on the radiosurgery treatment machine is in the range of 20 to 90 minutes.

## **What are my choices if I decide not to take part in this study?**

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for your resected brain metastasis.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.

## **What will happen if I decide to take part in this study?**

If you decide to take part in this study, you will either get single fraction (single treatment session) radiosurgery with treatment delivered to the surgical cavity in the brain (the part of the brain where the brain metastasis was resected) in a single treatment, or you will get fractionated (multiple treatment sessions) radiosurgery to the surgical cavity in the brain for up to three or five daily treatments. In other words, the total dose of radiation is delivered in a single (single fraction) session or several (fractionated) treatment sessions. If you have other brain lesions outside of the resected brain metastasis, those will also be treated with radiation.

After you finish your radiosurgery, your doctor and study team will watch you for side effects for 2 years after treatment. They will check you at clinic visits at 3, 6, 9, 12, 16, and 24 months after treatment.

## **What are the risks and benefits of taking part in this study?**

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

### **Risks**

We want to make sure you know about a few key risks right now. We give you more information in the “What risks can I expect from taking part in this study?” section.

If you choose to take part in this study, there is a risk that the fractionated radiosurgery may not be as good as single fractionated radiosurgery at preventing your cancer from coming back in the surgical cavity.

There is also a risk that you could have side effects from the single fraction or fractionated radiosurgery. These side effects may be worse and may be different than you would get with the usual approach for your resected brain metastasis.

Some of the most common side effects that the study doctors know about are:

- Localized hair loss which may be permanent
- Swelling of the brain in the treated area, which may require steroids
- Severe local damage to or death of normal brain tissue, which may require surgery to remove

There may be some risks that the study doctors do not yet know about.

### **Benefits**

There is evidence that fractionated radiosurgery is effective in preventing your cancer from coming back in the surgical cavity. It is not possible to know if the fractionated radiosurgery will better prevent your cancer from coming back in the surgical cavity compared to the usual approach. This study will help the study doctors learn things that will help patients with brain metastases in the future.

## **If I decide to take part in this study, can I stop later?**

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your 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.

## **Are there other reasons why I might stop being in the study?**

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (the Alliance). The study sponsor is the organization who oversees the study.

**It is important that you understand the information in the informed consent before making your decision.** Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

## **What is the purpose of this study?**

The purpose of this study is to compare the usual treatment of single fraction radiosurgery to using fractionated radiosurgery. Fractionated radiosurgery could be more effective in preventing your cancer from coming back in the surgical cavity. But, it could also cause side effects, which are described in the risks section below.

This study will help the study doctors find out if this different approach is better than the usual approach. To decide if it is better, the study doctors will be looking to see if fractionated radiosurgery decreases the chances of cancer coming back in the area where you had your brain surgery by 17.4% at one year compared to the usual approach of single fraction radiosurgery.

## **What are the study groups?**

This study has a pre-registration step. Your doctor will perform a history and physical exam and review the results of your exams, tests, and procedures. If you are a female who is able to become pregnant, a urine or blood pregnancy test will be performed if not already done. Typically, a MRI scan of the brain is obtained after a brain metastasis has been removed, but if not available within 30 days of the pre-registration step, this will be needed as part of the pre-registration step. The purpose of this step is to make sure you are eligible for the study and the questionnaires have been completed.

This study has two groups. All study participants in each group will get radiosurgery.

**Group 1:** If you are in this group, you will get the usual approach to treat the surgical cavity with single fraction radiosurgery delivered in a single treatment.

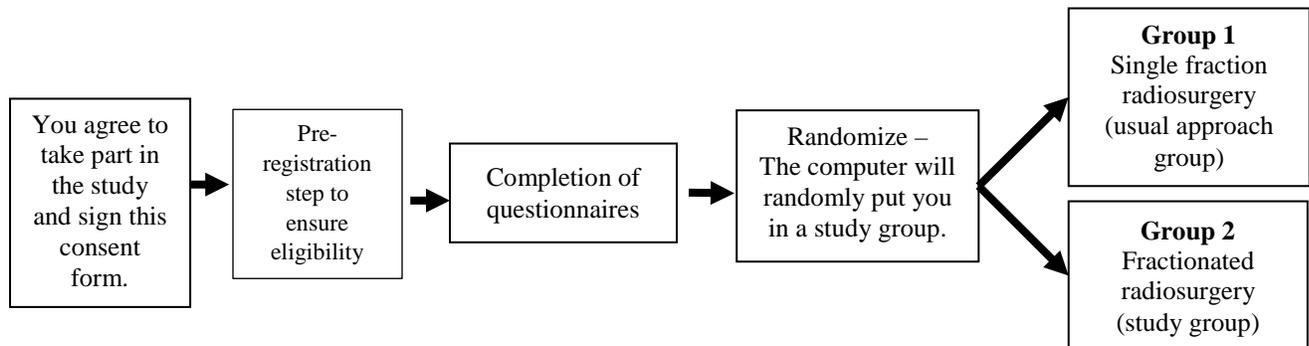
There will be about 104 people in this group.

**Group 2:** If you are in this group, you will get fractionated radiosurgery to the surgical cavity in three or five daily treatments, with smaller cavities treated with 3 daily fractions and larger cavities treated with 5 daily treatments.

There will be about 104 people in this group.

We will use a computer to assign you to one of the study groups. This process is called “randomization.” It means that your doctor will not choose and you cannot choose which study group you are in. You will be put into a group by chance. You will have an equal chance of being in Group 1 or Group 2. Both single fraction radiosurgery and fractionated radiosurgery are FDA approved.

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



### What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study. These include your doctor performing a history and physical exam and MRI scan of the brain. The MRI scan of the brain is obtained to determine if new brain metastases have developed or if cancer has grown back in the surgical cavity.

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

If you are an English, French, or Spanish speaker and choose to take part in this study, a questionnaire will be administered by a test administrator to see how the study is affecting your thinking abilities, such as memory, and you will be asked to fill out three forms with questions about your physical, emotional, and social well-being, fatigue, quality of life, and function. Researchers will use this information to learn more about how cancer and cancer treatment affects people. In total, all the forms will take about 15-20 minutes to complete.

Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns, please talk with your doctor or nurse right away.

There are also optional studies that include collecting the left over tissue from the resection of your brain metastasis and tissue from your biopsy or surgery from when you were diagnosed with cancer and/or taking blood samples. You can choose to take part in these optional studies and more information about these optional studies is provided later in the consent form.

**Questionnaires (Electronic Surveys):** For this study, you will be asked to complete the questionnaires on your personal smartphone or electronic device, which can be used to enter your answers to the questions. If you need help installing and/or using the questionnaire application (or “app”) on your phone or tablet, ask for help at your study site. Someone may help you enter your answers in the device if you need.

The use of your own electronic device on a cellular network may result in a small cost to your data plan. Regardless of the device you use, your answers and personal information will not be stored on the device.

Your survey answers will be sent to the research database and will be kept private as described in the section below called, “Who will see my medical information?” Your e-mail address will only be used for this survey and will not be used for mail or marketing purposes. The Alliance will not keep your email address.

If using your phone or a tablet is not possible or if you prefer to complete the questionnaires on paper, a paper survey will be provided.

You will be asked to fill out this form 7 times in total:

- Before radiosurgery, and at your on-study clinic visits 3, 6, 9, 12, 16, and 24 months after radiosurgery.

In total, all the forms will take about 15-20 minutes to complete. The forms will ask about things like fatigue. You don’t have to answer any questions that you do not want to answer.

## **What risks can I expect from taking part in this study?**

### **General Risks**

If you choose to take part in this study, there is a risk that the fractionated radiosurgery may not be as good as single fraction radiosurgery at preventing your cancer from coming back in the surgical cavity.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- May not be able to take part in future studies.

The radiosurgery used in this study could be very harmful to an unborn baby. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 3 months after you have completed the radiosurgery.

### **Side Effect Risks**

The radiosurgery used in this study may affect how different parts of your body work. The study doctor will assess you for side effects and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study radiosurgery.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.

**Possible Side Effects of Radiosurgery (Radiation)**

<p style="text-align: center;"><b>COMMON, SOME MAY BE SERIOUS</b></p> <p style="text-align: center;">In 100 people receiving radiation therapy, 20 to 100 may have:</p>
<ul style="list-style-type: none"><li>• If a head frame is used, temporary (short-term) pain from the head frame placement</li></ul>

<p style="text-align: center;"><b>OCCASIONAL, SOME MAY BE SERIOUS</b></p> <p style="text-align: center;">In 100 people receiving radiation therapy, 4 to 20 may have:</p>
<ul style="list-style-type: none"><li>• Headache</li><li>• Tiredness</li><li>• If a head frame is used, bleeding and/or infection around the head frame pin sites</li></ul>

<p style="text-align: center;"><b>RARE, SOME MAY BE SERIOUS</b></p> <p style="text-align: center;">In 100 people receiving radiation therapy, 3 or fewer may have:</p>
<ul style="list-style-type: none"><li>• Nausea</li><li>• Reddening of the skin</li><li>• Localized hair loss which may be permanent</li></ul>

<p style="text-align: center;"><b>RARE, AND SERIOUS</b></p> <p style="text-align: center;">In 100 people receiving radiation therapy, 3 or fewer may have:</p>
<ul style="list-style-type: none"><li>• Decreased brain function such as motor function (coordination/movement)</li><li>• Swelling of the brain in the treated area which may require steroids</li><li>• Severe local damage to or death of normal brain tissue, which may require surgery to remove</li><li>• Seizure</li></ul>

**What are my responsibilities in this study?**

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study.

**For women:** Do not get pregnant while taking part in this study. **For men:** Do not father a baby while taking part in this study and for up to 3 months after completing treatment. **For all:** Tell

your study doctor right away if you think that you or your partner have become pregnant during the study or within 3 months after completing treatment.

### **What are the costs of taking part in this study?**

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your resected metastatic brain disease. This includes:

- the costs of tests, exams including MRI brain scans, procedures including either the single fraction or fractionated radiosurgery, and drugs that you get during the study to monitor your safety, and prevent and treat side effects.
- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The questionnaire administered by a test administrator to see how the study is affecting your thinking abilities such as memory.
- The three forms you will be asked to fill out with questions about your physical, emotional, and social well-being, fatigue, quality of life, and function. If you complete these forms electronically, the use of your own electronic device on a cellular network may result in a small cost to your data plan. Regardless of the device you use, your answers and personal information will not be stored on the device.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

## **What happens if I am injured because I took part in this study?**

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. Contact information for your study doctor is listed on the consent cover page. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

No funds have been set aside to compensate you in the event of injury.

## **Who will see my medical information?**

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case.

However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at or receive copies of some of the information in your study records. Your health information in the research database may also be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- Montana Cancer Consortium
- The Alliance, the study sponsor.
- The NCI Central IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.

- NCI's National Clinical Trials Network and the groups it works with to conduct research including the Imaging and Radiation Oncology Core (IROC).

In addition to storing data in the study database, data from studies that are publicly funded may also be shared broadly for future research with protections for your privacy. The goal of this data sharing is to make more research possible that may improve people's health. Your study records may be stored and shared for future use in public databases. However, your name and other personal information will not be used.

Some types of future research may include looking at your information and information from other patients to see who had side effects across many studies or comparing new study data with other study data. However, right now we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

### **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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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 information for your study doctor is listed on the consent cover page.

For questions about your rights while in this study, call the Operations Office of the National Cancer Institute (NCI) Central Institutional Review Board (CIRB) at 888-657-3711.

## **Optional studies that 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. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people with your condition in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say “no” to any of these studies. There is no penalty for saying “no.” You and your insurance company will not be billed for these optional studies. If you sign up for, but cannot complete any of these studies for any reason, you can still take part in the main study.

Circle your choice of “yes” or “no” for the following studies.

## **Optional sample collections for storage for possible future studies**

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person’s response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

## **Unknown future studies**

If you choose to take part in this optional study, researchers will collect blood prior to treatment, at 3, 6, 9, and 12 months during your visits with your physician, and if your cancer progresses in your brain while you are still on study, and use a tissue sample from your prior surgeries or biopsies for research on brain metastases. These samples will be collected and stored. Storing samples for future studies is called “biobanking.” The biobank is being run by the Alliance and is supported by the NCI. This is a publicly funded study. Samples from publicly funded studies are required to be shared as broadly as possible. However, we will protect your privacy. The goal of this is to make more research possible that may improve people’s health.

The biobank is a public research resource. It has controlled access. This means that researchers who want to get samples and data from it must submit a specific research request. The request identifies who they are and what their planned research project is. Before getting the samples and data, the researchers must agree to keep the data private, only use it for their planned research project, and never use it to try to identify you.

Right now, we don't know what research may be done in the future using your tissue samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

Unknown future research studies may include sequencing of all or part of your DNA. This is called genomic sequencing. Sequencing allows researchers to identify your genetic code. Changes in your genetic code may just be in your tumor tissue. These are called somatic changes. Changes may also be in your normal tissue and passed down through your family. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down. These are called germline changes.

If only tumor tissue is sequenced, we will not know if a genetic change in your tumor is also in your normal tissue. This is why sometimes both normal tissue and tumor tissue are sequenced. This helps researchers understand if a genetic change happened only in your cancer tissue, or in your normal tissue as well.

### **What is involved in this optional sample collection?**

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 treatment, at 3, 6, 9, and 12 months after randomization, and if your cancer progresses in your brain while you are still on study. A sample from the tissue that was collected at the time of surgery will be sent to the biobank.
2. Your sample will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

### **What are the risks in this optional sample collection?**

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.

- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: <https://www.genome.gov/10002328/>

### **How will information about me be kept private?**

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

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

### **What are the benefits to taking part in this optional sample collection?**

You will not benefit from taking part in the optional sample collection.

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 to this optional sample collection?**

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

### **What if I change my mind about this optional sample collection?**

If you decide you no longer want your samples to be used, you can call the study doctor, who will let the biobank know. Contact information for your study doctor is listed on the consent cover page. Then, any sample that remains in the biobank will be destroyed or returned to your

study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

**What if I have questions about this optional sample collection?**

If you have questions about the use of your samples for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

Please circle your answer below to show if you would or would not like to take part in each optional study:

**Samples for known future studies:**

1) I agree that my samples and related health information may be used for the laboratory study described above.

YES                      NO

**Samples for unknown future studies:**

2) I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES                      NO

**Optional MRI study for future known and unknown studies**

Researchers are trying to better understand how tumors look on MRI when there is an inflammatory reaction in the brain called radionecrosis. This can look very similar to a tumor recurrence on MRI and thus, can be quite challenging in making a diagnosis. By studying MRI's further, we can better differentiate recurrence from radionecrosis and can treat patients more appropriately. This does not require additional MRI studies and just studies the standard MRI brain scans you will obtain as part of standard care and as part of this study.

**Known future studies**

If you choose to take part in this optional study, researchers will have access to your MRI's that are obtained during the course of the trial. They will examine these MRI's to identify patterns which may differentiate radionecrosis from tumor recurrence.

### **Unknown future studies**

If you choose to take part in this study, your MRI's may be used for further studies. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

We don't know what research may be done in the future using your MRI's. This means that:

- You will not be asked if you agree to take part in the future research studies
- You and your study doctor will not be told when or what type of research will be done
- You will not get reports or other information about any research that is done using your MRI's

### **How will information about me be kept private?**

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

1. They will remove identifiers, such as your initials, from your MRI's and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the MRI's and information.
2. Researchers who study your MRI's and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

### **What are the benefits to taking part in this optional study?**

You will not benefit from taking part in this optional study.

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

### **Are there any costs or payments to this optional study?**

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

### **What if I change my mind about this optional study?**

If you decide you no longer want your MRI's to be used, you can call the study doctor, who will let the researchers know. Contact information for your study doctor is listed on the consent cover page.

**What if I have questions about this optional study?**

If you have questions about the use of your MRI's for research, contact the study doctor. Contact information for your study doctor is listed on the consent cover page.

Please circle your answer below to show if you would or would not like to take part in each optional study:

**MRI images for known future studies:**

1) I agree that my MRI's and related health information may be used for the imaging study described above.

YES                  NO

**MRI images for unknown future studies:**

2) I agree that my MRI's and related health information may be used in future health research.

YES                  NO

**Contact for Future Research**

3) I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES                  NO

**This is the end of the section about optional studies.**

**My signature agreeing to take part in the 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 and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled “yes”.

Participant Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Person Obtaining Consent: \_\_\_\_\_

Date: \_\_\_\_\_

Time of consent: \_\_\_\_\_ (AM) (PM)

(Required for initial consent only)