THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

**Informed Consent**

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

# Investigation of Serial Advanced Magnetic Resonance Imaging (MRI) and Biofluid Biomarkers Predictive of Neurocognitive Decline following Brain Radiation
PA18-0719

**Study Chair: Caroline Chung**

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

## STUDY SUMMARY

The goal of this laboratory research study is to learn if repeated MRI scans, along with questionnaires and research blood tests, can be used by researchers to predict changes in a person's mental functions that result from radiation exposure to the brain.

This study is investigational.

Taking part in this study will let researchers monitor your responses to treatment and the disease better and possibly make changes to your treatment, if needed. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment. Your parking costs may be higher than usual due to longer study visits.

You can read a full list of potential risks below in the Possible Risks section of this consent.

Your participation in this study will be over after your last MRI is performed at 24 months after the end of treatment.

The research blood tests will be provided at no cost to you. There will be no cost to you for taking part in this study.

You may choose to receive chemotherapy and/or radiation therapy without taking part in this study.

## 1. STUDY DETAILS

**Imaging Scans**

If you agree to take part in this study, you will have up to 6 extra MRI scans performed along with the standard imaging scans that are part of your routine care and follow-up. Some of the scans will involve an injection of a contrast agent (a chemical that helps the doctor see your blood vessels better during the scan). These imaging scans are being performed to check the status of the disease and to study the effect of treatment on the brain. The research-only scans will be completed within 1 hour, at the time points are noted below.

You will have MRI scans with a contrast agent:

- Before treatment begins
- During Week 3 of treatment (research only), only if you are still receiving treatment
- At 1, 3, 6, 12, and 24 months after treatment

You will also have research-only MRI scans without a contrast agent during Weeks 1, 2, 4, 5, and 6 of treatment. These scans may be done at all or only some of these timepoints based on how long you receive treatment. For example, if you receive 1 week of treatment, these scans will be done at only Week 1.

Copies of your imaging scans and information from your medical record will also be collected as part of this study. To protect your identity, the collected information will be labeled only with your participant code, which may include your initials. The study staff will have a list that links your participant code to your personal identifying information.

After you have completed radiation therapy and the last MRI has been performed, you will continue to have follow-up visits (which may include additional MRI scans) as part of your standard care. If you have imaging scans performed as part of your routine care after your last MRI, the results of these scans will be collected from that point forward.

**Questionnaires**

Before starting treatment, and then at 1, 3, 6, 12, and 24 months after finishing treatment, you will be asked to fill out questionnaires about any symptoms you may have and your quality of life. At these times, you will also be asked to complete neurocognitive exam (tests to check your memory and thinking abilities, for example) that will check your attention span, thinking speed, and memory. A member of the study staff will help you complete the tests and questionnaires on paper and with a tablet computer. It should take about 70 minutes to complete the thinking tests.

At the end of each week during treatment, you will be asked to complete the thinking test on the computer tablet. This should take about 20 minutes to complete each time

**Biomarker Testing**

As part of this study, blood (about 4 teaspoons each time) will be drawn for biomarker testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug.

Blood for these biomarker samples will be collected before you begin treatment; at Week 1 of treatment; at Weeks 2, 3, 4, 5, and 6 of treatment if you are still receiving treatment; and then at 1, 3, 6, 12, and 24 months after the end of treatment. The blood sample collected before treatment begins will be used to check for a genetic biomarker called ApoE that may be related to cognitive side effects on the brain after radiation therapy.

Up to 50 participants will be enrolled in this study. All will take part at MD Anderson.

## 2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel “closed in” and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

**Questionnaires** may contain questions that are sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns about completing the questionnaire, you are encouraged to contact your doctor or the study chair.

**Blood draws** may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

**Genetic Research**

Samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

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**OPTIONAL PROCEDURES FOR THE STUDY**

**Optional Procedure #1:** If you agree, you will have an fMRI at the screening and the 6-month visits. An fMRI is a non-contrast MRI that can give the study doctor information about your memory and thinking ability.

You do not have to agree to the optional procedure in order to take part in this study. There are no benefits to you for taking part in the optional procedure. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedure.

**Optional Procedure Risks**

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel "closed in" and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

**CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES**

**Circle your choice of "yes" or "no" for each of the following optional procedures:**

**Optional Procedure #1:** Do you agree to have an fMRI at the screening and 6-month visits?

**YES** **NO**

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**3. COSTS AND COMPENSATION**

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or National Aeronautics and Space Administration (NASA) for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

**Additional Information**

4. You may ask the study chair (Dr. Caroline Chung, at 713-563-2300) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped at any time by the

study chair, National Aeronautics and Space Administration (NASA), or the IRB of MD Anderson.

7. MD Anderson may benefit from your participation and/or what is learned in this study.

8. This study is sponsored and/or supported by: National Aeronautics and Space Administration (NASA).

9. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

**Future Research**

Your personal information and/or samples are being collected as part of this study. These data and/or samples may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

Before being shared for future research, every effort will be made to remove your identifying information from any data and/or samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or samples are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If you do not want your samples or data to be used for future research, tell the study doctor. You may withdraw your samples at any time by telling your study team. If you decide to withdraw your samples, they will be returned to the lab they came from or destroyed. However, the data and test results already collected from your samples will be kept and may be used.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

**Authorization for Use and Disclosure of Protected Health Information (PHI):**

A. During the course of this study, MD Anderson will be collecting and using PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- National Aeronautics and Space Administration (NASA), who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

To protect your identity, the data and samples collected from you will be labeled with a unique number instead of your name or other identifying information. Only the study doctor or study staff will have access to the code that can link you to your data and samples. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. 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.

## CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____

SIGNATURE OF PARTICIPANT DATE

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PRINTED NAME OF PARTICIPANT

## PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____

PERSON OBTAINING CONSENT DATE

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PRINTED NAME OF PERSON OBTAINING CONSENT