THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

Comprehensive Evaluation of Tumor Oxygenation, Metabolism and Blood Supply of High Grade Glioma and Cervical Cancers Using Dynamic ^{18}F-FAZA PET and Multiparametric MRI
2020-0285

Study Chair: Caroline Chung, MD

_____ _____
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

Hypoxia (a low level of oxygen in the blood) may cause both 1) certain treatments to not be effective, and 2) tumors to be more aggressive.

The goal of this research study is to learn if imaging scans can be used to check the oxygen level of the tumor area.

This is an investigational study. The imaging scans in this study are performed using FDA-approved and commercially available methods. The radioactive tracer (^{18}F-FAZA) used with the PET imaging that is being used to check your oxygen levels is not FDA approved and is being used for research purposes only. The study doctor can explain how the tracer and imaging scans are designed to work.

Future patients may benefit from what is learned on this study. There are 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 side effects, potential expenses, and time commitment.

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

You will have 1 or 2 imaging scans on this study. Your active participation will be over after the last scan.

This study will be performed at no cost to you.

You may choose not to take part in this study.

1. STUDY DETAILS

Signing this consent form does not mean you will be able to take part in this study. If you can become pregnant, blood (about 1 teaspoon) or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

If you agree to take part in this study and you were diagnosed with a glioma, you will be scheduled to have a PET/MRI scan within the next 2 weeks. Before the PET/MRI scan, you will be injected with a small amount (less than a teaspoon) of a radioactive tracer called ^{18}F-FAZA. This tracer is used to help the study team see what areas of the body have lower oxygen levels. The PET/MRI scan should take about 50 minutes.

If you agree to take part in this study and you were diagnosed with a cervical cancer, you will have 1 or 2 imaging scans within the next 2 weeks:

- You will have 1 scan if you are scheduled to have a PET/MRI scan. Before the PET/MRI scan, you will be injected with a small amount (less than a teaspoon) of a radioactive tracer called ^{18}F-FAZA. This tracer is used to help the study team see what areas of the body have lower oxygen levels. The PET/MRI scan should take about 50 minutes.
- You will have 2 scans if you are scheduled to have a PET/CT scan and a separate MRI scan, which combined will take a little over 2 hours. Before the PET/CT scan, you will be injected with a small amount (less than a teaspoon) of a radioactive tracer called ^{18}F-FAZA. This tracer is used to help the study team see what areas of the body have lower oxygen levels. If possible, the 2 scans will be scheduled to be performed on the same day.

If you were diagnosed with a glioma or cervical cancer and are having a surgery or biopsy procedure at MD Anderson, you will be asked to have a piece of your tumor collected and used for biomarker testing in this study (see “Optional Procedures for the Study” section below for more information and to consent to this procedure).

After you have completed the imaging scans, you may be contacted by phone to learn how you are doing and to complete a symptom questionnaire about 24 hours

after the injection or the next business day, then about 30 days after the injection. If you are called, this call should last about 5-10 minutes. During these calls, you will be asked if you have had any side effects related to the ^{18}F-FAZA injection.

Your participation in this study will be over after the 30-day ^{18}FAZA-PET tracer injection.

Up to 20 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.

A **PET/MRI or PET/CT scan** may cause you to feel “closed in” while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.

The PET/MRI or PET/CT scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

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.

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**.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant or breastfeed a baby while on this study. You must use birth control during the study if you are sexually active and can become pregnant.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away. If this happens before or between scans, you will be removed from the study.

OPTIONAL PROCEDURES FOR THE STUDY

You do not have to agree to the optional procedures in order to take part in this study. There are no benefits to you for taking part in the optional procedures. 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 procedures.

Optional Procedure #1: If you are scheduled to have surgery or biopsy and you agree, tumor samples removed as part of the surgery/biopsy will be collected and used for biomarker testing. Biomarkers are found in the blood and tissue and may be related to the status of the disease. Tumor tissue that has been removed may be scanned using a 3-dimensional MRI.

Optional Procedure #2: Your personal information and/or samples are being collected as part of this study. If you agree, your data and/or samples will be stored in a research bank at MD Anderson and may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research related to cancer and/or other diseases.

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

You may withdraw your data and/or samples at any time by telling the study doctor.

If you decide to withdraw your data, the data will no longer be collected for storage. If you decide to withdraw your samples, any samples in the bank will no longer be used for research and will be removed from the bank and destroyed. However, if any of your de-identified data or samples were already released for research purposes before you withdraw consent, MD Anderson will not be able to delete the data or destroy the samples, and the data and test results already collected from the samples will be kept and may be used.

Optional Procedure Risks

There are no additional risks to having these samples collected, as they would be removed as part of your surgery/biopsy. Therefore, there are no added risks to the **surgery/biopsy**.

MD Anderson and others can learn about cancer and other diseases from your **banked data and/or samples**. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy but cannot guarantee complete privacy.

Samples may 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).

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.

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 tumor samples collected during your surgery or biopsy for use in biomarker testing?

YES **NO**

Optional Procedure #2: Do you agree that your data and/or samples collected as part of this study may be stored in a research bank at MD Anderson for use in future research as described above?

YES **NO**

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 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- 745-5422) 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 decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

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

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

A. During the course of this study, MD Anderson will be collecting and using your 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
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form
   - Any future sponsors and/or licensees of the study technology

   To protect your identity, the data and/or samples collected from you will be de-identified and labeled with a unique patient identifier instead of your name or other identifying information. Data will be stored on a password- and firewall-protected computer. Paper records (data forms, list of patient names and unique identifiers,

and so on) will be maintained in a locked file cabinet, and only the study investigators and research staff will have access. Only the study doctor and study staff will have access to patient information, and only information relevant to this study will be examined. All protected health information will be de-identified before releasing the results of the study outside the research team.

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 or receive study-related treatment 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 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

_____
PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2020-0285.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

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

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION DATE
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

_____
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION