



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

¹⁸F-fluciclovine PET-CT as an indicator of therapeutic response in metastatic prostate carcinoma (M1PCa)
2019-0030

Study Chair: Gregory Ravizzini

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.

STUDY SUMMARY

The goal of this clinical research study is to learn if a radioactive imaging agent called ¹⁸F-fluciclovine used during a PET-CT scan can further help measure changes in tumor size. The results of these scans will be compared to standard of care imaging scans.

This is an investigational study. ¹⁸F-fluciclovine is an FDA-approved and commercially available radioactive imaging agent for PET/CT scans in adult males with suspected prostate cancer. The PET-CT scans are performed using FDA approved and commercially available methods. The use of ¹⁸F-fluciclovine to measure changes in tumor size in this study is investigational.

Future patients may benefit from what is learned from your participation in this study. There are no direct 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. If you take part in this study, you may experience pain or redness at the injection site or a change in taste.

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

Your active participation in this study will be over after the post-treatment ^{18}F -fluciclovine PET-CT scan.

The ^{18}F -fluciclovine PET-CT scans will be provided at no cost to you while taking part in this study.

You may choose not to take part in this study.

1. STUDY DETAILS

If you agree to take part in this study, you will have two (2) ^{18}F -fluciclovine PET-CT scans in addition to some of the standard of care tests, procedures, bone scans, CT scans, and PET-CT scans without ^{18}F -fluciclovine.

For the ^{18}F -fluciclovine PET-CT scans, you will receive an injection of the imaging agent ^{18}F -fluciclovine into a vein through a standard catheter while you lie in the scanner. The ^{18}F -fluciclovine PET-CT scan will last about 30 minutes.

Within 30 days before and then 22-28 weeks after starting systemic therapy, you may have some of the standard of care imaging scans listed above and a research ^{18}F -fluciclovine PET-CT scan.

Up to 45 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.

^{18}F -fluciclovine may cause a feeling of warmth or pain at the injection site. It may cause headache and dizziness. It may cause hypersensitivity reactions which may cause breathing and/or skin problems (rash, redness, blisters, itching, and/or local swellings) and may appear either immediately or up to a few days after the injection. It may cause anaphylactic shock (a severe allergic reaction that can cause breathing difficulty and/or a drop in blood pressure). It may cause changes in the way you move or changes in your senses.

A **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-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.

This study may involve unpredictable risks to participants.

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 Blue Earth Diagnostics 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.

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. Gregory Ravizzini, at 713-745-5721) 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.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Blue Earth Diagnostics, 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. Results of ^{18}F -fluciclovine PET/CT scans and all of your standard tests performed as part of this research will be available to you and recorded on the electronic medical records. 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.
9. This study is sponsored and/or supported by: Blue Earth Diagnostics.
10. 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 is being collected as part of this study. This information, or data, may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research.

Before being shared for future research, every effort will be made to remove your identifying information from any data. 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 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 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.

Conflict of Interest

Dr. Brian Chapin (Collaborator) has received compensation from Blue Earth Diagnostics as a Consultant. The financial interests are within the limits of the conflict of interest policy.

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
 - Blue Earth Diagnostics, 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.

- 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

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SIGNATURE OF LAR

DATE

PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2019-0030.

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
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,
OR STUDY CHAIR)

DATE

PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION