RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Phase II Study to Evaluate Axumin PET/CT for Risk Stratification for Laser Focal Therapy of Intermediate Risk Localized Prostate Cancer

PROTOCOL NO.: DMI Axumin-001
WIRB® Protocol #20171334

SPONSOR: Desert Positron Imaging Center, LLC

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STUDY-RELATED PHONE NUMBER(S): Bernadette M. Greenwood, BSc, RT(R)(MR)
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John F. Feller, MD
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SUMMARY

You are being asked to participate in this research study because you are considering treatment for prostate cancer. Before you receive one of the possible methods of treatment for prostate cancer, you are being asked to receive an experimental scan of your prostate gland and your body. The purpose of this scan is to see if any evidence of prostate cancer can be seen in the images that are generated, and if so, where in your body the prostate cancer is found. The results will help determine what treatments for prostate cancer might be most appropriate for you.

The purpose of this consent form is to help you decide if you want to receive this experimental scan.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.

- Other parts of this study may involve experimental (investigational) drugs or procedures that are being tested for a certain condition or illness. An investigational drug, such as the fluciclovine used F-18 in this study, is one that has not been approved by the U.S. Food & Drug Administration (FDA) for the type of disease that you have.
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

PURPOSE OF THE STUDY

Prostate cancer is one of the most common cancers in men. Some of the ways that a doctor can detect prostate cancer is by measuring PSA levels in your blood, or by removing samples of the prostate to see if signs of the disease are found in the samples (this is called a biopsy). Imaging tests, like a bone scan, MRI (magnetic resonance imaging) or CT (computed tomography), are often performed to help the doctor determine where or how much cancer there is, and how best to treat the cancer.

If the disease is limited to the prostate only, and has not spread to your lymph nodes or other parts of your body, you may have treatment options that are not available to you if the disease has spread. The purpose of this experimental study is to use an imaging agent known as fluciclovine F 18 to help determine where in the body your cancer is located. Fluciclovine F 18 is a radioactive tracer has been approved by the FDA for the detection of recurrent prostate cancer in men (in other words, men who have already been treated for prostate cancer, and now have signs that the disease has returned). However, fluciclovine F 18 use is experimental when used to image prostate cancer that has not yet been treated. Fluciclovine 18 is used in combination with a CT scan. When a radioactive tracer is used in combination with a CT scan, the procedure is called a PET/CT (PET = positron emission tomography).

PROCEDURES

Your participation for this study will consist of 2 visits: screening (today), and the day of the fluciclovine F 18 PET/CT scan.

<u>Screening Visit (up to 30 days before the scan)</u>

Before the study starts, you will be asked to sign this informed consent form, and a member of the Study Staff will ask you about your general health history, treatments you have had for prostate cancer, if you take any over-the-counter or prescription medicines, vitamins, or herbs, and if you have any drug allergies. The Study Staff will also record information from your medical records including previous blood test results, procedures, treatments, and plans for your prostate cancer treatment.

The Study Staff may do some tests as part of the study at this visit. If these tests are not done at this visit then they will be done on the day of the scan before you have the scan. These tests include:

- Assessment of vital signs (blood pressure and heart rate)
- Routine blood tests

If you agree to participate in the study and you qualify for the study, then you will be scheduled for the fluciclovine F 18 PET/CT scan within 30 days.

The Study Staff will tell you when and where the PET/CT scan will be performed. You should not exercise the day before the scan and until the scan is finished. Do not eat or drink for at least 4 hours before the scan; sips of water to take medication are permitted.

Day of the PET/CT Scan

Before the fluciclovine F 18 dosing and PET/CT scan, a member of the Study Staff will ask you questions about your general health and medications.

The Study Staff will place an IV catheter (long, thin tube) into a vein in your arm. You will receive the fluciclovine F 18 injection through the catheter in your arm immediately before the scan. During the scan, you will lie on your back on the scanning bed. The bed will move slowly through the PET/CT scanner. The CT portion of the scan usually takes about 1 minute, and sends X-rays through the body that are measured by the CT camera. The PET portion of the scan begins about four minutes after the injection and usually takes about 30 minutes.

After the Scan

After the scan, the images will be read. If there are features in the image that indicate that your prostate cancer is not localized in the prostate, you may no longer be eligible for certain forms of therapy.

You will be asked to remain at the scanning site for 2 more hours to make sure that you have no delayed reactions to the scan. The whole visit for the scan and the follow up should take approximately 3-4 hours.

RISKS AND DISCOMFORTS

To date, at least 2000 people have received a fluciclovine F-18 injection. Side effects are generally uncommon, however people have experienced the following: Injection site pain (less than 0.1%), change in taste sensation in the mouth (less than 0.1%), and headache (less than 0.1%). Allergic and similar type reactions, including life-threatening ones, may occur.

Tell your doctor if you have a side effect or feel unwell. **Contact the Study Staff immediately** if you:

- Have a side effect that concerns you, or
- Are unable to perform your daily functions.

Risks Related to Radiation

This study involves exposure to a small amount of radiation. Radiation is part of our natural environment. We are exposed to background radiation from materials in the earth itself, from

naturally occurring radon in the air, from outer space, and from inside our own bodies (as a result of the food and water we consume). The level of radioactivity you are exposed to during this study is equivalent to the background radiation you would be exposed to during approximately 2 ½ years. The main risk associated with all radiation exposure is the possibility of developing a radiation-induced cancer later in life. At these exposure levels, the risk is small.

Risks Related to Other Study Procedures
On the day of the scan you will have an intravenous catheter placed in your arm. Like blood draws, there is a risk of bruising, discomfort and pain, and in rare cases a chance of infection.

There is the risk that the PET/CT scan may provide a false positive image (giving the appearance of cancer) in sites where it is not present, due to other events in the body such as inflammation or a false negative result (failing to detect cancer). If your treatment plan is altered due to false-positive results, you may undergo unnecessary biopsies or treatment. If the PET/CT scan provides false-negative results, you may not be offered adequate treatment for your cancer.

In a small percentage of men scanned with fluciclovine F 18, the PET/CT scan has detected other (non-prostate cancers) which were not suspected at the time of scanning. This could provide useful information, but may also result in additional stress or anxiety.

Reproductive Risks
Animal reproduction studies have not been conducted with fluciclovine F 18. It is not known whether fluciclovine F 18can cause fetal harm when administered to a pregnant woman or affects male fertility. You will be slightly radioactive for up to 24 hours after the injection and should avoid close contact with women who are able to have children, and with children, for 24 hours after the scan.

Other Risks
There may be risk of infection or hematoma (blood accumulation) at the site of injection.

There may be side effects that are not known at this time.

BENEFITS
The fluciclovine F 18 PET/CT scan may provide further information regarding your prostate cancer disease status and your doctor may be able to offer you a more suitable treatment plan based on this information, however there is no guarantee of this. You should also be aware that you may derive no benefit from this treatment. However, it is hoped that the information gained from the study will help in the treatment of future patients with prostate cancer. If the PET/CT scan shows evidence of disease outside of your prostate, this finding will indicate that local treatments to the prostate bed might not be effective, because they do not treat the disease that is found outside of the prostate gland.

ALTERNATIVE TREATMENT
If you decide not to enter this study, there are other choices available. These include: Following the treatment and management plan that would be part of standard of care for your prostate cancer, including other imaging options, such as MRI or choline C PET Scan. Ask the Study Doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

NEW INFORMATION
You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

COSTS
The study sponsor will provide the fluciclovine F 18 PET/CT scan free of charge.

You or your insurance company may be billed for any imaging services (approximately $1,500) or standard medical care given during a research study. These are costs that you would normally have if you were being treated for your disease.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you may be billed for those charges.

You might have unexpected expenses from being in this study. Ask the Study Staff to discuss the costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

PAYMENT FOR PARTICIPATION
If you take part in this study you will not be paid for your participation.

COMPENSATION FOR STUDY-RELATED INJURY
If you are injured or get sick as a direct result of the fluciclovine F 18 PET/CT scan or other study-related procedure, you will receive medical care for the immediate treatment of the illness or injury. If your injury or illness was caused by fluciclovine F 18, the PET/CT or another study procedure, the Sponsor will pay any charges that your insurance does not cover. No other compensation or payment will be offered to you, including lost wages.

Please be aware that some insurance plans may not pay for research-related injuries. You should contact your insurance company for more information.

If you experience an injury or side effects, you should contact the Study Doctor at the phone number(s) listed on the first page of this form. You do not waive any rights to compensation by signing this informed consent.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the Study Doctor or the Sponsor without your consent for any reason, including:

- If it is in your best interest
- If you do not consent to continue in the study after being told of changes in the research that may affect you
- You require a medication that is not allowed while participating in the study
- You develop a condition which may negatively affect your health
- You do not follow the study instructions given by the Study Staff

- You withdraw your consent to participate
- The Sponsor decides to suspend or terminate (end) the study or the participation of this site in the study
- Other unanticipated circumstances

If you decide to withdraw from this study, please inform your Study Doctor right away.

CONTACT FOR QUESTIONS
If you have any side effects during this study, report them to the Study Doctor or the Study Staff. Also contact the Study Doctor or Study Staff if you have any questions, complaints, or concerns regarding any part of this study.

John F. Feller, MD (Principal Investigator)
760-776-8989

Bernadette M. Greenwood, BSc, RT(R)(MR)(ARRT) (Sub-Investigator)
760-766-2047
262-269-8764 (24 hrs.)

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact Western Institutional Review Board, the IRB for this study:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who independently review research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the Study Staff cannot be reached or if you wish to talk to someone other than the Study Staff.

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.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

SOURCE OF FUNDING FOR THE STUDY
The company that developed the imaging agent fluciclovine F 18, Blue Earth Diagnostics, Ltd., is paying for the imaging agent used in the study. The reminder of the funding for the study is being paid for by each patient (approximately $1,500) if insurance does not cover the imaging component of the examination.

CONFIDENTIALITY

By signing this informed consent document, you allow access to your medical records to the Study Doctors and their staff, the Sponsor or its representative, representatives of the IRB and representatives from the US FDA, or other regulatory agencies and representatives from Blue Earth Diagnostics. Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. However, all recipients of any information pertaining to your participation in this research study will treat the information as confidentially as possible based on applicable laws and regulations.

The results of this study may be reported or published. However, you will never be identified by name nor will other personal identifying information about you be released.

CONSENT
I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

I authorize the release of my medical and research records for the purpose of this study.

By signing this consent form, I have not given up any of my legal rights.

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Signature of Participant **Date**

_____

Printed Name of Participant

I certify that the information provided was given in language that was understandable to the participant.

_____

Signature of Person Obtaining Consent **Date**

_____

Printed Name of Person Obtaining Consent

_____

Signature of Study Doctor **Date**

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The Study Doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

Who may use and give out information about you?
The Study Doctor and the Study Staff.

Who might get this information?
The Sponsor of this research. "Sponsor" means

- Any representatives from Desert Medical Imaging.
- People who are working for or with the sponsor, or
- Owned by the Sponsor.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- Western Institutional Review Board® (WIRB®).
- Representatives from Blue Earth Diagnostics.
- California Cancer Registry

Why will this information be used and/or given to others?

- To do the research,
- To study the results, and
- To see if the research was done right.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until January 1, 2020.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the Study Doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
Although your study information does not use your name or other personal identification, there is a risk that your information will be given to others without your permission.

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Signature of Participant **Date**

_____

Printed Name of Participant