Participant Information and Consent Form

^{18}F-DCFPyL Positron Emission Tomography / Computed Tomography (PET/CT) for Assessment of Recurrent Prostate Cancer

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Sponsor:	**BC Cancer – Functional Imaging Department** 600 West 10th Avenue Vancouver, BC, V5Z 4E6
Funding Support:	**BC Cancer Foundation**

For emergencies, 24 hours a day/ 7 days a week: Call your local hospital or the cancer centre nearest you and ask for your usual oncologist or, if he or she is not available, the oncologist on-call.

Vancouver Centre	(604) 877-6000
Vancouver Island Centre	(250) 370-8000
Fraser Valley Centre	(604) 581-2211
Centre for the Southern Interior	(250) 862-4000
Abbotsford Centre	(604) 851-4710
Centre for the North	(250) 565-2000

For non-emergency, contact number: 604-877-8000 ext.2818

1. INVITATION

You are being invited to participate in this research study because your doctor is trying to determine if the prostate cancer has returned. Before consenting to participate in this study, please take time to carefully read the following information which describes the purpose and procedures, the possible risks and benefits, and other information about the study. Please discuss any questions you have with your treating doctor (doctor currently treating your cancer) and research staff. You may also discuss this study with your family, friends, and family doctor.

2. YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. Please take as much time as you need to decide. If you do not wish to participate in this study, you will continue your cancer management with your doctor as you normally would. Other imaging tests may be available to you if you decide not to participate, including: MRI, CT, and bone scan.

Health Canada has not approved the use of ^{18}F-DCFPyL PET/CT for the assessment of recurrent prostate cancer, but has allowed its use in this clinical study.

Please review the consent document carefully when deciding whether you wish to be part of the research. If you wish to participate, you will be asked to sign this form at the time of your scan.

3. WHO IS CONDUCTING THE STUDY?

This study is being sponsored by BC Cancer – Functional Imaging Department and funded by the BC Cancer Foundation. This means that BC Cancer has received funding to do the study. However, none of the study doctors or staff will receive any personal payments.

4. BACKGROUND

Most patients with prostate cancer will be successfully treated with surgery or radiation therapy, a small proportion of patients will develop recurrence of disease at some time in their life. The prostate-specific antigen (PSA) is measured from a blood test and used to monitor the status of the cancer. When there is an unexpected and persistent rise in the PSA, this raises concern that the cancer may have returned. Knowing if and where the cancer has returned in the body might be useful for your treating doctor to decide the best course of treatment. Imaging studies like magnetic resonance imaging (MRI), computerized tomography (CT) or bone scans are commonly performed for this purpose but may not always be able to detect cancer cells, especially when it is in the early stages.

This study is investigating the usefulness of an alternative test with a positron emission tomography/computerized tomography (PET/CT) scan using a radioactive tracer called ^{18}F-DCFPyL. ^{18}F-DCFPyL is an agent that binds to a special protein in the human body called prostate specific membrane antigen (PSMA). Studies have shown that PSMA is found in many prostate cancer cells, especially when the cancer comes back after treatment. The purpose of this study is to determine how accurate an ^{18}F-DCFPyL PET/CT scan is in detecting prostate cancer recurrence.

^{18}F-DCFPyL will be made at the BC Cancer - Vancouver. It is considered investigational but has been used safely in preliminary human research studies without serious undesirable effects.

5. PURPOSE

The purpose of this study is to evaluate the proportion of participants with biochemical recurrence (increased PSA) of prostate cancer in which ^{18}F-DCFPyL PET/CT scans can detect and localize recurrent disease, when standard imaging studies are negative or equivocal, as well as determine how the use of ^{18}F-DCFPyL PET/CT scans improve your doctor's decision making and treatment planning. A total of 2,244 participants will take part in this study at BC Cancer – Vancouver, Victoria and Kelowna.

6. WHO CAN PARTICIPATE IN THE STUDY?

You may participate in this study if:

- You have had your prostate removed and your treating doctor has concern that your prostate cancer may have returned because of an unexpected and persistent rise in your PSA level.
- You have had recent imaging (CT, x-ray, MRI, bone scan) that may indicate that the cancer has spread but the imaging is not certain.
- You have had treatment (ex: radiation therapy) and your treating doctor has concern that your prostate cancer may have returned because of an unexpected and persistent rise in your PSA level.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

You cannot participate in this study if:

- You are too unwell, or participating in this study would not be in your interest, in the opinion of the study doctor.
- You are not able to tolerate the physical and logistical requirements of completing one PET/CT scan, including have an IV injection of the radioactive tracer into a vein in your arm and lying flat for 30 minutes.

- You are unable to provide written informed consent.
- You weigh over 204.5kg or are unable to fit through the scanner opening (diameter 70cm).

8. WHAT DOES THE STUDY INVOLVE?

If you agree to join this study, you will receive an ^{18}F-DCFPyL PET/CT scan which will be performed at one of the following BC Cancer locations; Vancouver, Victoria, or Kelowna. This scan will be scheduled with the study coordinator. You may also receive other diagnostic imaging tests at a later date if your treating doctor feels more information is required, and/or a tissue biopsy to clarify the nature of an abnormal finding on the PET/CT scan. The investigators will collect information from such tests to find out whether the PET/CT scan provided an accurate result. Such tests and procedures will be decided by your doctor and yourself in your best interest, and are not mandatory or part this research study. You will be followed on this study for up to 3 years after completion of your PET/CT scan.

9. WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT YOU?

During the study the researchers may learn something about you that they didn't expect. It is possible that the doctor may find other abnormalities not related to prostate cancer. For example, as with any medical imaging examination, it is possible that unsuspected abnormalities could be identified on the PET/CT images. If this happens, this information will be included in an examination report that will be provided to the doctor that referred you to participate in this study and this will be included in your medical record. It is possible that such abnormalities could lead your doctor to suggest additional investigations or procedures.

10. STUDY PROCEDURES

Screening questions will need to be completed to make sure you are eligible to take part. Reasons that you may be excluded are listed in Section 7. If you agree to join this study you will receive an ^{18}F-DCFPyL PET/CT scan for the purposes of this study. The PET/CT scan will be performed at BC Cancer.

Before completing any study procedures, you will meet the study coordinator who will answer all your questions about the study, and obtain your signature for the consent.

^{18}F-DCFPyL PET/CT scan:

Prior to the procedure

- You may take your usual medications as prescribed
- Please do not have anything to eat within the 4 hours before your PET/CT scan.
- Please drink 3 to 4 glasses of water within the 2 hours before your PET/CT scan.

When you arrive for the procedure

- The study doctor and/or a technologist will meet with you to answer any questions.
- You will be weighed and your height will be measured.

During the Procedure

- You will have an IV needle inserted into your arm and you will receive a dose of ^{18}F-DCFPyL. The injection volume will be very small and it will only take a few seconds to give.
- There is a waiting period of 1- 2 hours so the tracer can circulate throughout your body.

- The technologist will let you know if you can leave the department to get something to eat (if you wish) and exactly when to return, or if your scan will take place immediately after the 1 hour period.
- You will be taken to a designated washroom and asked to void prior to being scanned in order to clear excreted ^{18}F-DCFPyL from the urinary tract.
- You will undergo the PET/CT scan, which will take about 30 minutes. You will need to lie still on the scanner bed during this time.
- During the scan, a technologist monitors you by direct vision or by video camera.
- If you feel anxious at any time during the scan it can be stopped and you will be brought out of the scanner immediately.

After the Procedure:
- After the scan is complete, you can leave the PET scan department. You will be encouraged to drink 3 to 4 extra glasses of water by the end of the day.
- A doctor will provide a more in-depth assessment if there are any concerns that your health status has changed during the PET/CT scan. We do not expect that any participants will experience any side effects.
- Your PET/CT scan will be reviewed by a BC Cancer doctor specialized in PET/CT. The results of the scan will be sent to your referring doctor.
- Your PET/CT scan will also be reviewed by central readers for study purposes only and this information will not be available to you or your referring doctor. No personal information will be transferred to the central readers and you will only be identified by your unique study code.
- Your treating doctor will be asked to complete a follow-up questionnaire asking how your diagnosis and treatment plan has changed, if at all, based on your PET/CT scan results.

Optional Delayed Images:
Your participation in this part of the study is optional and you can still participate in the main part of the study even if you choose not to participate in the optional part. If you decide not to take part in the optional part, your care will not be affected.

^{18}F-DCFPyL is removed by the kidney by the elimination of urine. It sometimes can be difficult for the physicians interpreting your images to know if the collection of the ^{18}F-DCFPyL is due to activity in the urine or to cancer right next to the urinary excretion pathways. Allowing more time for the radiotracer to leave your urinary tract could help physicians interpret the images more accurately.

After you complete your study scan it may be determined that the addition of delayed images might be helpful to interpret your images. You will be given the option to wait in the PET department for 30 – 60 minutes to allow the remaining ^{18}F-DCFPyL to leave your urinary system and have additional images taken of your pelvis; the additional scan will take 10 minutes.

24-hour phone call:
- You will be given the clinic's contact information and asked to phone the clinic <u>within a 24 hour time period</u>, if you feel that you experienced or are experiencing any undesirable effects following the administration of the ^{18}F-DCFPyL.

Follow-up Visits:

A study team member will call you to complete up to three follow ups. These calls would occur at 12, 24 and 36 months after the date of your ^{18}F-DCFPyL PET/CT scan and inquire about any symptoms you may have and any treatments you may have undergone. Your medical chart will be reviewed to compare your PET/CT scan results to other imaging, as well as any clinical and laboratory tests to evaluate the accuracy of the PET/CT scan.

Possible additional procedures:

Other imaging procedure:

After a minimum period of 6 months, and up to 36 months following the initial ^{18}F-DCFPyL PET/CT scan, it is possible that a repeat ^{18}F-DCFPyL imaging study may be requested for the following reasons:

- To assess for progressive disease to confirm the results of your initial ^{18}F-DCFPyL PET/CT.
- To assess the response to treatment you may have undergone.
- To assess progression of unconfirmed ^{18}F-DCFPyL PET/CT findings (no other imaging or biopsy has been completed).

An additional ^{18}F-DCFPyL PET/CT scan is available as part of this study for each participant. If an additional ^{18}F-DCFPyL PET/CT scan is requested, you will have the options to accept, or decline the follow-up examination without compromising your participation in this study or your clinical care. If you decline the additional study, follow-up clinical evaluations will continue as described above in "Follow-up Visits".

Your treating doctor may decide that you require another scan with a CT or MRI after your PET/CT scan. This could occur if the PET/CT scan shows results that require further clarification. If a CT or MRI is requested by your treating doctor, the procedures will be carried out according to the normal practices of BC Cancer.

Tissue biopsy:

After your PET/CT scan, your treating doctor may decide to organize a biopsy of an abnormal finding on the PET/CT scan. A biopsy is not a part of this study and is not required as part of this study. However, your doctor may feel that it will help to better determine whether you have cancer.

Time:

The PET/CT scan will take about 3 - 4 hours of your time. Up to three follow-up phone calls, at 12, 24 and 36 months after your PET/CT, will take 15 minutes per phone call. In total, there will be about 4.5 to 5 hours of extra time required of you to participate in this study.
If you choose to participate in the optional delayed images portion of the study it will take approximately 40 – 70 minutes including the time to allow the ^{18}F-DCFPyL to leave your body and the additional scan time.

Optional Studies:
You may also be asked to participate in an optional study (called a 'sub-study'), which will be offered to a small number of study participants. You can take part in the main study and not take part in the optional studies. If you decide not to take part in the optional study, your care will not be affected. If you are interested in participating in a sub-study, you will be provided with a separate consent form that describes the details of the additional procedures. You will be required to sign the separate consent form if you wish to participate in the sub-study.

11. WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?

The ^{18}F-DCFPyL PET/CT scan is considered safe with few associated risks. There have never been any reported serious side effects from the ^{18}F-DCFPyL radiotracer. Over 1000 people have received ^{18}F-DCFPyL at BC Cancer. You might experience some minor pain when the IV is inserted into your arm. This will be very similar to having a needle for a routine blood test. You may develop a small

bruise, but significant bleeding is extremely rare. Some people feel anxious in the narrow PET/CT scanner. If necessary, your doctor can prescribe you medication to manage this anxiety.

^{18}F-DCFPyL is a radioactive tracer. This means that it emits a small quantity of radiation that is used to create the PET image. The amount of radiation you will be exposed to in this study is comparable to that of other diagnostic tests that are used in the standard of care for your type of cancer.

Medical imaging examples in mSv (a millisievert is a radioprotection unit measuring the radiation dose received from a radioactive source);

- ^{18}F-FDG PET/CT – 8.6 –11.6 mSv
- CT scan of the abdomen and pelvis – 10 mSv
- Bone scan – 3 – 4 mSv

The amounts of radiation exposure from the extra scan performed as part of this study are within the guidelines issued by Health Canada for such research studies. The effects of exposure to low levels of radiation are expected to be minimal, as your risk level is calculated over your entire lifetime. The main potential risk from exposure to radiation is cancer, and this risk is extremely low for the radiation exposure from this study. This would appear decades from now, if it were to happen at all.

Everyone is exposed to natural radiation occurring in the environment. The radiation comes from radioactive products in natural elements, present in earth's crust, gases in soil and bedrock, in food and water, as well as from cosmic rays to which we are exposed. Radiation exposure is measured in units of milliSievert (mSv). As a reference value, the average radiation exposure in the world is approximately 2.4 mSv per year. In Canada, this ranges from 1.3 mSv (Vancouver) to 4.1 mSv (Winnipeg).

The additional radiation exposure will range from 8.8 to 16.4 mSv. The radiation exposure is also similar to the amount an average person would receive from 3.5 to 7 years of exposure to naturally occurring radiation from everyday life.

If you chose to participate in the optional delayed images portion, you will be exposed to a small dose of additional radiation from the CT portion of the additional scan.

12. WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study. We hope that the information learned from this study can be used in the future to benefit other people with a similar disease. One of the possible benefits of participating in the study is that the ^{18}F-DCFPyL PET/CT scan that you will have access to, may be more able to see cancer in your cells compared to other types of scans currently available in BC. The increased detection ability may lead to improved treatment planning. .

13. WHAT ARE THE ALTERNATIVES TO THE STUDY DIAGNOSTIC PROCEDURE?

If you choose not to participate in this study or to withdraw at a later date, the standard diagnostic scans are still available to you and may be offered to you by your doctor. Those tests include (but are not limited to):

- Bone scan
- Contrast-enhanced CT
- MRI

14. WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

If you choose to enter this study and a more effective scanning method becomes available, your doctor will talk with you about it. You will also be told if any new information becomes available that may affect your willingness to stay in this study.

15. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

You can leave the study at any time without giving reasons. If you choose to enter the study and then decide to withdraw later, all information about you collected up to the point of your withdrawal including, where applicable, information obtained from your biological samples will be kept for analysis in order to protect the integrity of the research, which may benefit future research participants and patients. However, no further information will be collected.

16. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Federal and provincial privacy laws give safeguards for privacy, security, and authorized access to information. We will not give information that identifies you to anyone without your permission, except as required by law.

However, there is a risk that someone could get access to the information we have stored about you, it could be revealed inappropriately or accidentally, and the risk of someone identifying you may increase in the future as people find new ways of tracing information. Depending on the nature of the information, such a release could upset or embarrass you, or be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. There are laws against this kind of misuse in Canada, but they may not give full protection, and laws in other countries may not be as strict as those in Canada, so when your information and samples are sent to places outside of Canada, you may not be afforded the same rights. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data is very important to us, and we will make every effort to protect these as described below.

Study-related data and coding:

- All information gathered for use in the study is referred to as the 'study-related data'. This data may include parts of your medical records, medical images such as PET/CT, MRI or CT scans, completed questionnaires and/or diaries, etc. The study-related data will be transformed into datasets that can be analyzed. You will be assigned a unique code that will be used to track your study-related data. This unique code does not include any personal information that could identify you, and will be used on all study-related data that leave BC Cancer unless otherwise specified in this form (this is referred to as 'coded data').
- Coded data from this study may be pooled and shared with researchers from around the world for future studies that are unknown at this time. It may also be added to public databases, published, or presented at scientific meetings. The aim of these future studies is to benefit people by improving our understanding of health conditions like cancer.

Who will know I participated?

- Your referring doctor (for example: your urologist, oncologist, family doctor) will know that you are taking part in this study so that your study doctor and referring doctor can provide the proper medical care.
- If required by law, your medical information may also need to be given out. If this should happen, the study doctors and staff will do their best to make sure that information that is shared will not directly identify you.

Using email:
We are asking study participants to provide a personal email address so that we can communicate with them about the study and their participation. Before you provide your consent, please carefully consider whether this email account is secure, whether other people have access to it or whether you have concerns about the security of any information sent to this account. We will only send your personal information to the email address you have provided to us, and all of the information which you provide to us will be kept confidential by the research team. However, you should be aware that some webmail services (e.g. Gmail, Hotmail, etc.) may store the contents of your email account outside of Canada (for example, in the United States), where privacy and data security standards may be different than they are in Canada. The security of information sent over the internet can also not be guaranteed. The email communications we exchange with you may contain some of your personal information (your name, health information, etc.). Under the *Freedom of Information and Protection of Privacy Act* (British Columbia), we require your consent in order to send your personal information outside of Canada. By providing your email address, you are voluntarily providing your consent for the study team to communicate with you using your email account.

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.

17. WHO WILL HAVE ACCESS TO MY STUDY RELATED DATA?

Your signed consent form will be included in your study-related data, and in any electronic medical record(s). Your healthcare team will also be alerted that you are on a study to ensure they can treat you safely according to the study protocol.

Your study-related data will be reviewed by the sponsor of this study, or their representatives at BC Cancer. The BC Cancer Research Ethics Board or regulatory authorities and auditors may also look at your study-related data for the purpose of overseeing the conduct of the study. By signing this form you are authorizing such access. Table 1 sets out the organizations that may access your study-related data and for what purposes. Please also see Appendix A for more information.

Table 1: Access to your study-related data

WHO	WHAT	WHERE	PURPOSE
Health Canada	Study-related records and data (including your medical records) that include information that can identify you	Canada	Oversight of the use of drugs in Canada

18. WHAT WILL THE STUDY COST ME?

Reimbursement:

You will not be paid for participating in this study. There will be no costs to you during the study for medical services or laboratory tests that are needed for the study. However, taking part in the study may result in added costs to you, such as travel, parking and meal costs while away from home.

Compensation:

No funds have been set aside as part of this study to compensate you in the event of injury or illness related to study treatment or procedures. However, you do not waive any of your legal rights to compensation by signing this consent form.

The investigators conducting this clinical trial will not receive any personal payments for conducting this study. In addition, neither the BC Cancer, any of the investigators, or any staff conducting this study will receive any direct financial benefit from conducting this study.

19. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information with respect to this clinical trial, or if you experience any adverse side effects, you can contact the study doctor, Dr. François Bénard, at telephone number 604-707-5979.

If it is after hours, call the main BC Cancer number at (604) 877-6000, and ask to speak to Dr. Bénard or one of the study investigators named at the beginning of this document. If they are not available, please request the oncologist on call.

Or, you can speak to the Head of the Functional Imaging Program of the BC Cancer - Vancouver, Dr. Don Wilson. That person can be reached at (604) 877-6000.

20. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A PARTICIPANT?

If you have any concerns or complaints about your rights as a research participant or your experiences while participating in this study, contact the Research Participant Complaint Line at the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number H16-01551 when contacting the Complaint Line so the staff can better assist you.

21. SIGNATURES

^{18}F-DCFPyL Positron Emission Tomography / Computed Tomography (PET/CT) for Assessment of Recurrent Prostate Cancer
Patient Consent

My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I will receive a signed copy of this consent form for my own records.
- I consent to participate in this study.

_____	_____	_____
Participant's Signature	Printed name	Date

_____	_____	_____	_____
Signature of Person Obtaining Consent	Printed name	Study Role	Date

If this consent process has been done in a language other than that on this written form, with the assistance of an interpreter/translator, indicate:

Language: _____

Was the participant assisted during the consent process in one of ways listed below?

☐ Yes ☐ No

If yes, please check the relevant box and complete the signature space below:

☐ The consent form was read to the participant, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant (**please check if participant is unable to read**).

☐ The person signing below acted as an interpreter/translator for the participant, during the consent process (**please check if an interpreter/translator assisted during the consent process**).

_____	_____	_____
Signature of Person Assisting in the Consent Discussion	Printed Name	Date