[18F]-Fluoro-Deoxy-Glucose (18F-FDG) Positron Emission Tomography / Computed Tomography (PET/CT) Imaging in Cardiac Sarcoidosis

Dear Potential Study Participant,

The purpose of this letter is to let you know about a research study that you are eligible to participate in called: “[18F]-Fluoro-Deoxy-Glucose (18F-FDG) Positron Emission Tomography / Computed Tomography (PET/CT) imaging in Cardiac Sarcoidosis”. The research study involves a special type of scan to look at your heart because your cardiologist believes that a special scan might provide additional information about whether or not you have cardiac sarcoidosis.

The imaging procedure that will be used in this study is called a positron emission / computed tomography (PET/CT) scan and this scan is available at the BC Cancer Agency (BCCA). You are not being offered participation in this study because your doctor suspects you have cancer. PET/CT scans are only available for this study at the BC Cancer Agency – Vancouver Centre and this is why the BCCA is providing you with information about the study.

A complete description of this study is included with this letter entitled: “Subject Information and Consent Form”. This consent form is included for your information and will be fully explained to you by your referring cardiologist. This form will need to be signed at a later date, if you decide you would like to participate in the study.

This is a clinical trial, which is a type of research study. Research studies only include people who choose to take part. Your participation is completely voluntary, so it is up to you to decide whether or not to take part. If you decide you do not want to participate in this study, you will still continue to receive the best available treatment by your cardiology team.

Please do not hesitate to contact the chief PET/CT Technologist at the BCCA, Tina Alden, if you have any questions about the study or if you do not wish to participate in the study. You can reach Tina Alden at the Functional Imaging Department at 604-707-5951.

Sincerely yours,

Don Wilson MD, FRCPC
Medical Director, Functional Imaging
BC Cancer Agency, Vancouver Centre
SUBJECT INFORMATION AND CONSENT FORM

[18F]-Fluoro-Deoxy-Glucose (18F-FDG) Positron Emission Tomography / Computed Tomography (PET/CT) Imaging in Cardiac Sarcoidosis

Principal Investigators:  
Dr. Don Wilson, MD, FRCPC  
Medical Director, Functional Imaging, BC Cancer Agency  
Phone: 604-707-5979

Dr. Andrew Ignaszewski, MD, FRCPC  
Head, Heart Function Clinic and Providence Healthcare Division of Cardiology  
Phone: 604-806-8605

Emergency Contact Number (24 hours / 7 days a week):  
For emergencies only: You can call St. Paul’s Hospital and ask for your Cardiologist, or if he/she is not available, the Cardiologist on-call.

St. Paul’s Hospital  
(604) 682-2344

Sponsor:  British Columbia Cancer Agency (BCCA)

Non-Emergency contact numbers are noted at the end of this document under the section heading “Contact”.

INVITATION  
You are being invited to participate in this research study because you are suspected of having cardiac sarcoidosis (CS) and your cardiologist has determined that you require a specific type of scan to provide additional information that may help make a diagnosis.

YOUR PARTICIPATION IS VOLUNTARY  
Participation in this study is voluntary. You may decide not to participate or to withdraw at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

Before you give your consent to participate in this study, please take time to read carefully and consider the following information which describes the purpose and procedures, the possible risks and benefits, and other information about the study.

You also need to know that there are important differences between being in a research study and being cared for by your doctor. When you participate in a research study, the main goal is to learn things to help other patients in the future. Outside a research study, your doctor’s sole
goal is to care for your health. The researchers have a duty of care to all subjects and will inform you of any information that may affect your willingness to remain in the study.

If you wish to participate in this study, you will be asked to sign this form to indicate your consent.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

**WHO IS CONDUCTING THE STUDY?**
This study is being conducted by St. Paul’s Hospital and the BC Cancer Agency.

**BACKGROUND**
You are being invited to participate in this clinical trial because you are suspected of having CS and your doctor has determined that you require a scan to provide additional information. If you agree to participate in this research study, you will undergo a Positron Emission Tomography / Computed Tomography (PET/CT) scan, using a radio-labeled tracer called $^{18}$F-Deoxy-Glucose ($^{18}$F-FDG). This type of scan combines both a CT scan and a PET scan done on the same machine during one procedure. For the purposes of the rest of this consent form, we will refer to this combined scan (PET and CT using the $^{18}$F-FDG radio-labeled tracer) as an FDG PET scan.

The treatment of CS depends on the accurate and early diagnosis of the disease, however, diagnosis can be challenging. When diagnosed, treatment of CS can be initiated and is directed at minimizing the inflammation in heart tissues associated with the disease. Generally corticosteroid therapy is utilized for treatment. Currently, the standard of care for diagnosing CS is a combination of imaging techniques or a biopsy of the heart. Heart biopsies can be very difficult because sometimes it is hard to see where the suspected site of disease is, or it is difficult to access the site with the needle for a biopsy. Conventional imaging methods such as computed tomography (CT) and magnetic resonance imaging (MRI) face some technical limitations which make it difficult to detect CS. FDG PET scanning may more accurately identify the sites of CS compared with CT or MRI. The accurate information that is obtained from FDG PET may have an impact on the treatment management of some patients with CS as it may allow the appropriate type of therapy to be initiated earlier.

If you meet the clinical criteria for a diagnosis of cardiac sarcoidosis, as determined by your cardiologist, you will be eligible to participate in this study. We anticipate that it will take 3 years to enroll 30 – 45 participants to complete this study.

**WHAT IS THE PURPOSE OF THIS STUDY?**
This study is called an expanded access study. The purpose of an expanded access study is to make FDG PET imaging available to people who may benefit from the scan’s findings when other methods to detect a disease have failed. Another purpose of an expanded access study is to collect further data on the effectiveness and safety of FDG PET in patients suspected of having CS. You are not being investigated for possible cancer at the BC Cancer Agency. The FDG PET scan will be performed at the BC Cancer Agency – Vancouver Centre because this is the only available location for FDG PET scans for this study.
WHO CAN PARTICIPATE IN THIS STUDY?
You may participate in this study if:

- You have provided written informed consent.
- You are 19 years or older.
- You have a clinical suspicion of cardiac sarcoidosis (ex. symptoms of heart failure, an arrhythmia)
- Routine tests for cardiac sarcoidosis (electrocardiogram, 24-hour Holter monitor, MRI) are inconclusive.
- Other imaging methods are unavailable due to a pre-existing condition (because you have a pacemaker or renal dysfunction).
- You will be able to tolerate the physical / logistical requirements for completing an FDG PET scan including lying flat for 45 – 60 minutes and tolerating intra-venous (IV) injection of the FDG radioactive tracer.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?
You cannot participate in this study if:

- Your blood glucose is greater than 11.1 mmol/L (200 mg/dL) measured immediately prior to scan.
- You are pregnant.
- You have been previously diagnosed with diabetes.
- You are unable to comply with the dietary modifications or prolonged fasting period required as part of the trial.
- Your doctor or the clinical trials staff assess that you are medically unstable (you are in acute cardiac or respiratory distress, or hypotensive).
- You exceed the safe medical weight limit of the PET bed (204.5 kg) or you cannot fit through the PET machine (diameter 70 cm).

WHAT DOES THE STUDY INVOLVE?
If you agree to participate in this study, you will undergo the following:

Prior to the procedure:
- If you are breastfeeding you will be pre-instructed to withhold breastfeeding for 24 hours after the scan to avoid radiation exposure to the infant.
- You will be instructed to fast for a minimum of 12 hours prior to your FDG PET scan and to consume a high protein and low carbohydrate diet the day before your scan. When your appointment time is booked, the PET staff will make sure you understand when you have to start fasting and they will ensure you understand the diet modification sheet for the high protein / low carbohydrate diet. You may drink water and take any usual medications prior to your scan.
- If you are a pre-menopausal woman who cannot state with certainty that you are not pregnant, a urine pregnancy test will be performed.

When you arrive for the procedure:
- The clinical trials doctor and/or other PET staff will meet with you to answer questions.
- You will complete a short dietary questionnaire prior to your PET/CT scan describing your food consumption the day prior to your PET/CT scan.
- You will be weighed and vital signs will be measured (blood pressure, heart rate and blood oxygen saturation).
During the Procedure:
- You will have an intravenous (IV) catheter inserted into a vein in your arm so the FDG can be administered. At the same time, a small amount of blood will be taken with a hand-held glucometer to measure your blood glucose level.
- You will receive an IV dose of FDG in a dose determined by your weight. The injection volume will be very small and it will only take a few seconds to administer through your IV.
- You will rest in a private quiet room for 45 to 60 minutes, to enable the FDG to circulate throughout your body.
- You will undergo the FDG PET scan, which will take about 30 minutes. You will need to lie still on the scanner bed during the scan.
- During the scan, the PET staff will monitor you by direct vision, by video camera and with pulse oximetry (a small clamp that attaches to a finger and measures blood oxygen saturation and heart rate).

After the Procedure:
After the scan is completed, you will be free to leave the BCCA and will be encouraged to drink 3 to 4 extra glasses of water by the end of the day to promote further clearance of the remaining $^{18}$F-FDG tracer from your body. If there are any concerns that your health status has changed during the FDG PET scan then a physician will provide a more in-depth assessment, but we do not expect that any subjects will experience any side effects.

Your FDG PET scan will be reviewed by a BCCA doctor specialized in PET. The results will be sent to your referring cardiologist who will contact you about the results.

In total, the FDG PET scan appointment will require 2.25 hours of time from you that is above and beyond the time needed if you were not participating in this study.

WHAT ARE THE POSSIBLE HARMs AND DISCOMFORTs?
FDG PET scans are considered very safe procedures with few associated risks. No serious side effects have been reported to date in the literature that is attributed to the FDG tracer. However, it is possible that not all side-effects are known. You might experience some minor discomfort associated with the insertion of the IV catheter into your arm. This will be very similar to having a needle for a routine blood test. You may develop a small bruise following the injection, however significant bleeding is extremely rare.

This research study involves exposure to radiation from one radiopharmaceutical which is intravenously injected into your arm before your PET/CT scan. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you will receive from the scan is about 9.14 mSv. This radiation exposure is approximately equivalent to the whole body exposure you would receive from 3.05 years of exposure to natural background radiation, the radiation present in your natural environment. The effects of exposure to such low levels of radiation are expected to be minimal. The main potential risk from exposure to radiation is cancer. This could appear decades from now. This risk is thought to be related to the total radiation exposure you may incur during your entire life. The increased risk associated with your participation in this study is felt to be very low and acceptable for these kinds of studies. It has been estimated that in 2004, about 1,000,000 PET procedures were safely performed in the US. Since 2005, more than 22,000 FDG PET scans have been safely performed at the BC Cancer Agency alone.
WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?
There is no guarantee that you will benefit from participating in this clinical trial. FDG PET scans may or may not more accurately characterize cardiac sarcoidosis. Your FDG PET scan may help your doctor to offer more appropriate and timely treatment for you. Finally, your participation in this clinical trial may allow the investigators to gain valuable knowledge that may benefit others in the future.

WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?
This is a clinical trial and participation is strictly voluntary. If you decide you do not want to participate, your doctor will continue to use the standard diagnostic tests available and treat you to the best of their ability. Participation in this clinical trial will not make you ineligible for other clinical trials.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?
If you choose to enter this study and at a later date a more effective procedure becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study.

WHAT IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?
You may withdraw from this study at any time without giving reasons.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis. It is a legal requirement that these data cannot be destroyed.

CAN I BE ASKED TO LEAVE THE STUDY?
If you are not able to follow the requirements of the study or for any other reason, the study doctor may withdraw you from the study and will arrange for your care to continue. On receiving new information about the FDG PET your research doctor might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?
Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his/her designate by representatives of Health Canada and the UBC BCCA Research Ethics Board for the purposes of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.
Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also give you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

**SPECIALIST NOTIFICATION**
The cardiologist involved in your care will be sent a copy of your FDG PET scan result so that this may be taken into consideration when providing your medical care. Your family physician will also be notified of your participation in the study so he/she is aware of the reason for the FDG PET scan.

**AFTER THE STUDY IS FINISHED**
You may not be able to receive additional FDG PET scans once the clinical trial is complete. Possible reasons for this include: the FDG PET may not turn out to be effective or safe; the FDG may not be approved for use in Canada; your doctor may not feel it is the best option for you; coverage may not remain available for this treatment in British Columbia and you may decide it is too expensive to purchase on your own.

**WHAT HAPPENS IF SOMETHING GOES WRONG?**
Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else, and you do not release the study doctors or participating institutions from their legal and professional responsibilities.

**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 which are needed as part of the study. However, taking part in this study may result in added costs to you, such as travel expenses, parking and meal costs while away from home.

**Compensation:**
If you are injured as a consequence of participation in the study due to the administration of the study drug or study procedures, your medical condition will be evaluated and medical care will be provided by one of the investigators or you will be referred for appropriate treatment. If you are injured as a result of participating in this study, the costs of your medical treatment will be paid for by your provincial medical plan to the extent that it is available.

No additional funds have been set aside to compensate you in the event of injury or illness related to study treatment or procedures.

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 clinical trial. In addition, St. Paul’s Hospital, the BC Cancer Agency or any of the investigators / staff conducting this clinical trial will not receive any direct financial benefit from conducting this clinical trial.
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 side effects, you can contact the cardiologist at St. Paul’s Hospital:

Dr. Andrew Ignaszewski: 604-806-8605,

Or you may call the radiologist interpreting your FDG PET scan:

Dr. Don Wilson: 604-707-5979
SUBJECT CONSENT TO PARTICIPATE

[18F]-fluorodeoxyglucose (18F-FDG) Positron Emission Tomography (PET) in Cardiac Sarcoidosis

My signature on this consent form means:
- I have read and understood the subject information and consent form.
- I have had the opportunity to ask questions and received satisfactory responses.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I authorize access to my health record as described in this consent form.
- I understand I am not waiving any of my legal rights by signing this consent form.

I will receive a signed copy of this consent form including all attachments, for my own records.

_________________________   ___________________________   __________
Subject'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 a translator, indicate:

Language:__________________________

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

☐ Yes  ☐ No  [Note: For typical situations where the person conducting the consent discussion simply reads the consent with the subject to ensure that informed consent is properly obtained, check "no".]

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

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

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

_________________________   ___________________________   __________
Signature of Person Assisting in Consent Discussion  Printed Name  Date
PET/CT Scan Patient Preparation Instructions

Follow these instructions for your PET/CT Scan:

One day before your scan
Date:________________

- Avoid heavy exercise (jogging, weight lifting) as this can affect your test results
- Eat a high protein / low carbohydrate diet (see table below for foods allowed and not allowed)
- Do not eat anything after 8pm

On the day of your scan
Date:_______________

- Avoid heavy exercise
- Do not eat anything
- Do not chew gum, or take cough syrup or cough drops
- Take your prescribed medications on an empty stomach (water is okay) if you can. If not, bring your medication with you to take after the scan with food

2 hours before your scan

- Drink 4 glasses of plain water
- Complete the attached questionnaire and give it to the technologist before your scan

High Protein / Low Carbohydrate Diet

<table>
<thead>
<tr>
<th>FOODS</th>
<th>DO NOT EAT</th>
<th>YOU MAY EAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meats and Alternates</td>
<td>• Beans / lentils&lt;br&gt;• Tofu</td>
<td>• Beef, pork, lamb, chicken, turkey, fish, eggs&lt;br&gt;• Nuts / seeds</td>
</tr>
<tr>
<td>Breads and Cereals</td>
<td>• Anything made with flour or grains&lt;br&gt;• Rice, pasta, noodles, breads, cereals, buns, crackers&lt;br&gt;• Snack bars</td>
<td>• Avoid all foods in this category</td>
</tr>
<tr>
<td>Fruits</td>
<td>• Avoid all fruit except those listed in the next column</td>
<td>• Apple, avocado, banana, orange, berries, pear, plum&lt;br&gt;• Only have a total of ½ cup of fruit in the whole day</td>
</tr>
<tr>
<td>Vegetables</td>
<td>• Potatoes, sweet potatoes, yams</td>
<td>• All other vegetables&lt;br&gt;• Only have a total of 4 cups of</td>
</tr>
<tr>
<td>FOODS</td>
<td>DO NOT EAT</td>
<td>YOU MAY EAT</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>Dairy Products</td>
<td>• Yogurt, milk, soymilk, cottage cheese, rice milk</td>
<td>• Hard cheese</td>
</tr>
<tr>
<td>Drinks</td>
<td>• Alcohol, soft drinks, all fruit / vegetable juices, flavoured water, sports / energy drinks, nutritional drinks (Ensure, Boost)</td>
<td>• Plain coffee and tea (no sugar, cream or milk)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Water</td>
</tr>
<tr>
<td>Other foods</td>
<td>• Jams, jellies, honey, chips, candy, cakes, cookies, chocolates, Jello, puddings</td>
<td></td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>• Salad dressings, sauces, ketchup, rice vinegar, balsamic vinegar, Splenda</td>
<td>• Butter, oils</td>
</tr>
</tbody>
</table>

Meal suggestions:
- Cheese omelet with vegetables
- Grilled meat, chicken or fish with a salad
- Chicken vegetable soup (no rice, pasta or beans)
- Chili with meat and vegetables (no beans)
- Stir-fried chicken or beef with vegetables (no rice, or noodles)
- Tuna salad (little mayonnaise) with raw vegetables
- Salmon with roasted vegetables

Please call the Functional Imaging Department at 604-707-5951 if you have any questions.
Modified Diet and Fasting Questionnaire

Questionnaire

It is important for us to know if you were able to follow all of the instructions for your scan. Please fill out this questionnaire as best as you can and hand it in to the technologist before your scan. Thank you.

1) Were you able to follow the instructions before your scan (circle one)?
   YES       NO

2) When did you last eat?  Last night at ____________ or, today at ____________

3) YESTERDAY, DID YOU HAVE ANY? YES NO WHAT DID YOU EAT?

<table>
<thead>
<tr>
<th>ALCOHOL OR CAFFEINE</th>
<th>YES</th>
<th>NO</th>
<th>WHAT DID YOU EAT?</th>
</tr>
</thead>
<tbody>
<tr>
<td>BREAKFAST:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BREAD OR BUNS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAKES, COOKIES OR MUFFINS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POTATOES (including potato chips or fries)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PASTA OR RICE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BEANS OR LENTILS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BREAKFAST CEREALS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>YOGURT OR MILK</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JAMS, JELLIES OR HONEY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CHEWING GUM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SOFT DRINKS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FRUIT OR VEGETABLE JUICE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DRESSINGS, KETCHUP OR SAUCES</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LUNCH:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNACKS:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DINNER:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4) Did you take any medications today (circle one)?  YES NO

If yes, please list them:

5) Did you exercise yesterday or today (circle one)?  YES NO

If yes, when?

What type of exercise?

Total duration of exercise?