Consent to Take Part in a Clinical Trial

TITLE: 18F -Fluorodeoxyglucose in Positron Emission Tomography

PROTOCOL TITLE/NUMBER: 18F-Fluorodeoxyglucose in Positron Emission Tomography, Control # 244190

STUDY DOCTORS: Dr. Jeffery Flemming **Phone number:** 709-777-1133

SPONSOR: Eastern Health Regional Health Authority

Part A: General information

Introduction

You have been invited to take part in a clinical study. Taking part in this study is voluntary. You may choose to take part or you may choose not to take part in this study. You also may change your mind at any time. If you decide to not participate in the study, your study doctor will discuss other options with you. Whatever you choose it will not affect your ability to receive treatment and you will not lose any benefits to which you are entitled.

This consent form has important information to help you make your choice. Please ask the study staff to explain anything that you do not understand. It is important that you have as much information as you need and that all your questions are answered. Please take as much time as you need to think about your decision to participate or not, and ask questions about anything that is not clear. You may find it helpful to discuss it with your friends and family.

1. Why am I being asked to join this study?

This research is being conducted to study the use of a radioactive tracer for an imaging test in patients who have or are suspected of having one of the following conditions: cancer, dementia, neurological disease, cardiac disease, infection, or an inflammation process. You are being asked to take part in this study because you have or may have one of these conditions. The imaging test is called a Positron Emission Tomography (PET) scan and the radioactive tracer is called 18F-Fluorodeoxyglucose (FDG or FDG), a radioactive form of sugar that aids in diagnosis.

2. What is being tested?

FDG PET/CT has been approved by Health Canada for several years. This study is being done as a requirement from Health Canada to allow our site to produce FDG. This is standard practice for any site just starting to produce FDG. We have done PET scans at the Nuclear and Molecular Medicine Facility since September 2017 using FDG made in other provinces. Now we are making FDG here at the Nuclear and Molecular Medicine Facility at the Health Sciences Centre and we are doing this study to show that the radioactive tracer (FDG) made here at this facility is effective and safe in people with your condition.

3. How many people will take part in this study?

This study will take place at the Nuclear and Molecular Medicine Facility at the Health Sciences Centre in St. John's, Newfoundland. This study will enroll approximately 10,000 people.

4. How long will I be in the study?

If you take part in this study, you will have one PET scan performed during one visit to the Nuclear and Molecular Medicine Facility at the Health Sciences Center. The duration of your appointment will be approximately 3-4 hours in total. Once you leave the hospital, your participation in the study is over.

5. What are the study groups?

This study has one study group. All participants who get a PET scan performed and receive the FDG made at the Nuclear and Molecular Medicine Facility at the Health Sciences Centre in St. John's will be entered into the study**.**

6. What will happen if I take part in this study?

You will have one PET scan performed at one visit to the Nuclear and Molecular Medicine Facility. Please refer to the Positron Emission Tomography- Computed Tomography (FDG PET/CT) Patient Information and Preparation for a detailed explanation of the entire process of the FDG PET/CT scan.

7. Are there risks to taking part in this study?

FDG PET/CT scans are considered very safe with few risks. The amount of radiation exposure from the PET scan is close to the amount from other Nuclear Medicine scans and other imaging tests such as CT scans. There is no evidence that the radiation exposure from FDG PET/CT scan has caused any harmful effects in people. There are no known adverse events associated with FDG and no side effects are anticipated, however you will be monitored by research staff during your time in the department. It should be noted that FDG has never been studied in pregnancy.

The FDG produced at our facility will undergo the same rigorous quality assurance process prior to being administered as any other FDG produced in Canada. This includes testing the whether the product is sterile, pure, and without any contaminants.

You may experience discomfort during the insertion and removal of the IV catheter. This will be very similar to having a needle for a routine blood test; you may develop a small bruise. A larger amount of bleeding is possible, but very rare. Infection at the IV site is possible but very rare.

Risk of confidentiality breach is present. Identifiable data, such as your name and MCP number, will be kept and stored in a PET database on a secure, password protected computer system that has many safeguards in place including 2 firewalls. Any paper forms, such as your consent form will be stored in a locked filing cabinet in a secure office. Although very unlikely, it is possible that someone from outside the research team could gain access to your information. However, if this was to happen, you would be notified immediately.

An additional risk is the risk that data cannot be withdrawn. Once you consent to the study and have the FDG PET/CT scan complete, you will not be able to withdraw from the study and your data will not be destroyed. This is done to preserve the study's scientific integrity/validity.

8. What about pregnancy and breast feeding?

If you are pregnant, you cannot participate in this study. A pregnancy test may be required prior to your scan. Once your scan is completed, there are no known risks to becoming pregnant.

If you are breastfeeding, you will be required to discontinue for 12 hours after the FDG PET/CT scan.

9. What are the possible benefits of participating in this study?

There are no expected benefits from participating in this study other than the benefits related to having the PET scan. Prior to this study, however, our facility was getting FDG shipped from other provinces and at times, appointments have been canceled due to issues with manufacturing of the FDG or with shipping of the FDG. Therefore, having easy access to our locally made FDG will limit the amount of appointments needed to be rescheduled and hopefully allow us to provide more PET scans to the people of this province.

10. Are there other choices?

If you choose not to participate in the study, unfortunately, it is not currently possible to obtain FDG from outside the province as we have done in the past. Other options such as CT scan, MRI, and ultrasound are available and will be offered if considered beneficial in your case. If an FDG PET/CT scan is considered essential and you do not wish to participate in the study, you can discuss the option of travelling outside of the province with your referring doctor.

You do not have to participate in this study to receive treatment for your condition. You and your doctor will continue your treatment and your medical care based on the available information without the PET scan.

Please talk to your regular doctor about all your treatment options.

11. What happens at the end of the study?

After your participation in the study, you can request the results of your FDG PET/CT scan from your physician who requested the FDG PET/CT scan to be completed.

Additionally if the study is successful, the radioactive tracer made at the Nuclear and Molecular Medicine Facility at the Health Sciences Centre will be approved by Health Canada and used for all patients requiring a FDG PET/CT scan in this province in the future.

12. What are my responsibilities?

If you take part in this study you will be expected to:

- Register in the Nuclear Medicine Department 30 minutes prior to your scheduled appointment
- Follow the directions for preparation as detailed in the PET information pamphlet

- Report any diabetic medications you are taking prior to your scan
- Report any changes in your health, including side effects
- Report any problems you think might be related to taking part in the study including anxiety with previous PET, CT, or MRI scan
- Tell the study doctor about your current medical conditions
- Tell the study doctor if you are pregnant/breastfeeding prior to scan
- Tell the study staff if you change your mind about being in this study

13. If I decide to take part in this study, can I stop later?

It is your choice to take part in this study, participation is voluntary. You can change your mind and withdraw from the study at any time before or even during your appointment for your FDG PET/CT scan. Once you have been injected with 18F-FDG, you will not be able to withdraw from the study. This means that your data will still be kept, and includes answering follow-up questions to ensure you do not experience any adverse events from the injection. The reason for this is to ensure your safety, and to protect the study's scientific integrity.

If you do decide to withdraw, the study team may ask why you are withdrawing for reporting purposes, but you do not need to give a reason if you do not want to. Withdrawal from the study will not have any effect on the care you (or your family, if applicable) will receive. If you decide to leave the study, you can contact the study doctor or a member of the study team to let them know. The study doctor will discuss other options with you.

14. Are there other reasons why I might stop being in the study?

The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- Your referring physician or study doctor no longer feels this is in your best interest.

- New information becomes available and the study is no longer in your best interest.
- You are unable to complete all required study procedures
- If you are pregnant
- The study is stopped by Eastern Health, the Health Research Ethics Board (HREB), Health Canada, or your study doctor.

If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision. If your participation in the study is stopped, your study doctor will provide information about what you should do next. If this happens, it may mean that you would not receive the FDG or FDG PET/CT scan, as described in this consent form. Your study doctor will arrange for you to continue your care outside of the study.

15. What about new information?

It is extremely unlikely that new information on the safety or efficacy of FDG will become available to you during your participation in this study, given that your participation is only for the duration of your appointment today. In the extremely unlikely event that new information does become available during your participation, you will be notified in a timely manner and can decide whether or not you wish to continue for the remainder of your appointment.

A description of this clinical trial will be available on *clinicaltrials.gov* as required by local and international laws and regulations. This website will not include information that can identify you. You can search this website at any time.

16. Will it cost me anything?

You will not be paid or reimbursed for any expenses related to being in this study.

Research related injury

If you become ill or injured as a direct result of taking part in this study, medical care will be available at no additional cost to you.

Other costs

The costs of your medical treatment will be paid for by your provincial medical plan to the extent that coverage is available. All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you.

The study drug/agent will be given to you free of charge as long as you are in the study.

17. What about my privacy and confidentiality?

Protecting your privacy is an important part of this study. If you decide to participate in this study, the study doctors and study staff will collect and use information from your medical records. They will only collect and use the information they need for this study, including:

- Name
- Gender
- MCP
- date of birth (DD/MM/YY)
- Address/Telephone Number
- new or existing medical tests or procedures and medical conditions
- medications
- information from study interviews and questionnaires

The personal health information with your identifying information (i.e. name, MCP) collected for this study will not be available to anyone outside of the immediate research team, including other Eastern Health personnel.
Study information collected during the study will be kept at the Nuclear and Molecular Medicine Facility and stored in a secure, locked place that only the study staff will be able to access. After the study closes, study information will be kept as long as required by law, which could be 25 years or more. Any paper documents will be stored in locked filing cabinets in the offices and/or storage rooms of the Nuclear and Molecular Medicine Department at the Health Sciences Center. . The Research Registered Nurse Coordinator, is the person responsible for keeping it secure.

Study information sent to the sponsor, and companies working for the sponsor, will be stored in a secure central database. When the results of this study are published or presented at scientific meetings, your name and other personal information will not be used in the publication.

All information that identifies you will be kept confidential, and to the extent permitted by applicable laws, will not be disclosed or made publicly available, except as described in this consent document. Every effort to protect your privacy will be made. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. If there is a breach of your privacy resulting from your participation in this study you will be notified.

Your participation in this study will be noted in your hospital or clinic chart. This is recommended to ensure your safety so that any treating physician will know that you are participating in a research study.

18. Who will see my medical information?

Representatives from the following organizations may come to the hospital/clinic to look at your personal health information under the supervision of the study staff to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Eastern Regional Integrated Health Authority which is the sponsor of this clinical trial and the organization that makes the radioactive tracer
- Representatives of the Health Research Ethics Board,
- Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada

We may continue to review your health records that you have consented for the study to access for a period of time after your last study visit in order to check that the information we collected is correct.

Your access to records

- You have the right to see the information that has been collected about you for this study. If you wish to do so, please contact your study doctor.

19. What are my rights when participating in a research study?

You have the right to receive all information that could help you make a decision about participating in this study, in a timely manner. You also have the right to ask questions about this study at any time and to have them answered to your satisfaction.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

Signing this form gives us your consent to be in this study. It tells us that you understand the information about the research study. When you sign this form you do not give up any of your legal rights against the study doctor, sponsor or involved institutions for compensation, nor does this form relieve the study doctor, sponsor or their agents of their legal and professional responsibilities.

You have the right to be informed of the results of this study once the entire study is complete. A report of the results of your FDG PET/CT scan will be forwarded to your doctor, and can be available to you from your doctor.

You will be given a copy of this signed and dated consent form prior to participating in this study.

20. Declaration of financial interest, if applicable

There are no conflicts of interest to declare related to this study.

21. What about questions or problems?

If you suffer a research-related injury or if you have any questions about taking part in this study, you can talk to your study doctor or study nurse (777-1133). You can also meet with the study doctor who is in charge of the study. That person is:

Dr. Jeffery Flemming, Clinical Chief of Nuclear and Molecular Medicine

You can also talk to someone who is not involved with the study at all. They can tell you about your rights as a participant in a research study. This person can be reached through:

Research Ethics Office at 709-777-6974
Email: info@hrea.ca

Signature Page

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- 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, without having to give a reason, and that this will not change the quality of care that I receive.
- I understand that it is my choice to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of participating in this study.
- I do not give up any of my legal rights by signing this consent form.
- I understand that all of the information collected will be kept confidential and that the results will only be used for the purposes described in this consent form.
- I allow access to health records and transfer of specimens and related personal health information as explained in this consent form.
- I understand that my family doctor or specialist may be be informed of my study participation
- I agree, or agree to allow the person I am responsible for, to take part in this study

Signature of participant	Printed name	Day Month Year
Signature of person authorized substitute decision maker **[If applicable]**	Printed name	Day Month Year

Participant Initials: _____

Consent Version Date: August 19, 2022

Signature Page for Parent/Guardian

My signature on this consent form means:

- I have had enough time to think about the information provided and ask for advice if needed.
- All of my questions have been answered and I understand the information within this consent form.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse for my child/ward to participate or to withdraw from this study at any time, without having to give a reason, and that this will not change the quality of care that my child/ward receives.
- I understand that it is my choice for my child/ward to be in the study and there is no guarantee that this study will provide any benefits to me.
- I am aware of the risks of my child/ward participating in this study.
- I do not give up any of my my child/ward's legal rights by signing this consent form,
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I allow access to my child/ward's medical records and transfer of specimens and related personal health information as explained in this consent form.
- I understand that my child/ward's family doctor or specialist will/may be informed of my study participation

I consent for my child/ward _____ to take part in this study.

_____

Signature of parent/guardian Name printed Day Month Year

_____

Signature of witness **[If applicable]** Name printed Day Month Year

Participant Initials: _____

Consent Version Date: August 19, 2022

Participant Assistance

Complete the following declaration only if the participant is <u>unable to read</u>:

- The informed consent form was accurately explained to, and apparently understood by, the participant, and
- Informed consent was freely given by the participant

Signature of Impartial Witness	Printed Name	Day Month Year

Complete the following declaration only if the participant has limited proficiency in the language in which the consent form is written and interpretation was provided as follows:

- The informed consent discussion was interpreted by an interpreter and
- A sight translation of this document was provided by the interpreter as directed by the research staff conducting the consent.

Interpreter Declaration and Signature:

By signing the consent form I attest that I provided a faithful interpretation for any discussion that took place in my presence, and provided a sight translation of this document as directed by the research staff conducting the consent.

Signature of Interpreter	Printed Name	Day Month Year

To be signed by the person conducting the consent discussion:

I have explained this study to the best of my ability. I invited questions and given answers where applicable. I believe that the participant/substitute decision maker fully understands what is involved in being in the study, any potential risks of the study and that he or she has freely chosen to be in the study. I have offered for the participant to speak with the Investigator/Physician who is on site and responsible for the clinical trial today.

Signature of Research Staff completing consent discussion	Name printed	Day Month Year

To be signed by the Investigator on-site:

I have been available today to speak with any participant that has wished to speak with me regarding the clinical trial and any questions/concerns they have had. If a participant has requested to speak with me, I have done so and addressed their questions and/or concerns.

Signature of investigator	Name Printed	Day Month Year