Capital Health

Consent Form Substitute Decision Maker

STUDY TITLE: Clinical Trial to evaluate the safety and clinical utility of 18F-FDG produced by the Molecular Imaging and Research Centre of Nova Scotia

CLINICAL STUDY REGISTRATION NUMBER: NCT01136720

PRINCIPAL INVESTIGATOR: Dr. Andrew Ross, Diagnostic Imaging
3rd Floor VG Hospital
1278 Tower Rd., Halifax, B3H 2Y9
Tel: 473-2825 fax: 473-6235 email aross@dal.ca

ASSOCIATE INVESTIGATORS: Antoun Bou Laouz, M.Sc
Radiochemist, C.D.H.A.
FUNDING AGENCY: Nova Scotia Department of Health
STUDY SPONSOR: Capital District Health Authority, QE2 HSC

PART A.
Clinical Studies – General Information

This study is being done to meet Health Canada requirements for licensing FDG in Halifax (the radioactive drug used for PET scanning a special body imaging procedure). Our FDG is the same chemical as that used elsewhere in Canada; however, Health Canada requires a clinical study to prove it is equally safe and effective. The government of Nova Scotia has funded us to produce FDG locally to be a more reliable and less expensive source.

1. Introduction

_____ has been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether _____ would wish to be in the study or not. Before you decide, you need to understand what the study is for, what risks their might be and what benefits there might be. This consent form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about it for a while. Mark anything you don't understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- Discuss the study with you
- Answer your questions
- Keep confidential any information which could identify you personally
- Be available during the study to deal with problems and answer questions

We do not know if taking part in this study will help. The study participant may feel better. On the other hand it might not help at all. It might even make the study participant feel worse. We will always give the study participant the best possible care no matter what happens.

If you decide not to have _____ take part or if you leave the study early, their usual care for their condition will not be affected.

PART B.

EXPLAINING THIS STUDY

2. What is the purpose of this study?

The purpose of this study is to collect information about the safety and usefulness of Halifax produced Flurodeoxyglucose (FDG), a radioactive compound that acts like sugar in the body and is used in PET scanning which is highly useful for cancer imaging. This scan will look at the use of sugar in your body and show changes that can help your doctor treat their condition.

3. What Is Being Tested?

FDG has been used safely in PET scanning for the last 25 years at many hospitals in Canada and elsewhere. We have used it in Halifax for the last two years safely in over 2,500 patients. We are now producing FDG in our Halifax facility and must make sure it is safe and like what has been shown elsewhere.

4. Why Is _____ Being Asked To Join This Study?

The study participant is being asked to join this study because the doctor requested a FDG PET scan to assist in managing the condition.

5. How Long Will _____ Be In The Study?

If you agree to allow the study participant to be involved they will be required to remain in the PET Centre for about 3 hours. This will include injection of the FDG, time for it to go through the body and the scanning time. Prior to leaving, you will fill in a brief questionnaire about whether anything bad happened from receiving the FDG. This will be the extent of the direct involvement.

6. How Many People Will Take Part In This Study?

It is expected 10,000 people from Atlantic Canada will participate in the study at CDHA over 5 years.

7. How Is The Study Being Done?

Patients in the study will have a routine FDG PET/CT scan. The only difference is where the FDG is made. The FDG made in Halifax has been shown to be the same chemical as that used elsewhere. The results of this procedure will be sent to the doctor to help guide treatment. During this study there will be no extra radiation procedures.

8. What Will Happen If _____ Takes Part In This Study?

You will be in the PET suite for about 3 hours. The technologist will check the blood sugar level with a small needle stick in the finger as diabetic people do. As long as the level is okay, the test will proceed. This will require an intravenous (a small needle put in a blood vessel in the arm) and injection of a small amount of FDG. The participant will then lie still for about one hour while the FDG goes through the body. The technologist will check to make sure there are no difficulties or concerns after the injection. The participant will be asked to go to the bathroom and empty the bladder and then be placed on the PET/CT scanner for up to 30 minutes. Once the technologist makes sure that the images are okay, you will be able to leave the department. You need not answer any question you are uncomfortable with. The study participant will need to drink some extra fluids after the study to help wash out the small amount of remaining radioactivity. The PET scan doctor will look at the images and a report will be sent to the doctor.

Prior to leaving you will fill in a brief questionnaire asking whether anything bad happened to you in the Centre which might be because of the FDG you received. You may find the questionnaire you receive at the end of the treatment upsetting or distressing. You may not like all the questions you will be asked. You do not have to answer all those questions you find too distressing.

9. What About Birth Control and Pregnancy?

The effects of this radioactive drug on an unborn baby are not known but generally radiation exposure is avoided if at all possible. Thus, if there is a chance the study participant is pregnant please let the technologist know. If there is a chance of pregnancy a pregnancy test will be performed to ensure the study participant is not pregnant before entering the trial.

10. Are There Risks To The Study?

There have been thousands of people injected with FDG through the world with no significant problems ever reported. There is a small amount of radioactivity as part of the FDG. It is given as an intravenous injection and so there may be some minimal pain and swelling at the injection site. Infection in the skin could occur so it should be kept clean. Bleeding at the intravenous site could happen when it is taken out but the technologist will watch for this. No other risks are expected. Some people find the PET scanner to be closed in and if the study participant is upset by small places it may cause some minimal discomfort.

11. Are There Other Choices?

The study participant does not have to be part of this trial. The doctor will continue to care for the study participant. The CDHA PET Centre uses the Halifax produced FDG available by joining this study. If the study participant decides not to be part of the study, a PET scan using FDG made in Montreal will be arranged.

12. What Happens at the End of the Study?

At the end of your time in the PET Centre the study participant's direct involvement in the study will end. The doctor will receive the report and use it to direct treatment.

13. What Are My Responsibilities?

- Follow the directions of the Principal Investigator
- Report all medications being taken
- Report any changes in health
- Report any problems experienced that you think might be related to participating in the study
- Report any problems experienced which you might believe to be related to the FDG (radioactive drug injected)
- Arrive at the PET Centre on time
- Let us know how the study participant feels throughout the time in the PET Centre and as well if you want us to stop

14. Can _____ Be Taken Out Of The Study Without My Consent?

Yes. The study participant may be taken out of the study by Health Canada, the Principal Investigator or the Research Ethics Board at any time, if:

- the study participant does not follow the directions of the Principal Investigator;
- in the opinion of the Principal Investigator the study participant is experiencing side effects that are harmful to their health or well-being;
- there is new information that shows that being in this study is not in the study participant's best interests;
- the participant is pregnant.

The study sponsor, the Capital Health Research Ethics Board, Health Canada or the Principal Investigator have the right to stop patient recruitment or cancel the study at any time.

The study participant and you will be told about the reasons why they might need to come out of the study.

15. Will It Cost Me Anything?

Compensation

You nor the study participant will be paid to be in the study.

Research Related Injury

If the study participant become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost. Your signature on this form only indicates that you have understood to your satisfaction the information regarding participation in the study and agree that _____ will participate in the study. In no way does this waive your legal rights nor release the Principal Investigator, the research team, the study sponsor or involved institutions from their legal and professional responsibilities.

16. What About My Privacy and Confidentiality?

Protecting privacy is an important part of this study. Every effort to protect the study participant's privacy will be made. As the PET scan is performed to help manage care, like an x-ray, the report and information from it will be available for use by the medical team. No other data from the study will be made available outside this health care facility. If the results of this study are presented to the public, nobody will be able to tell who was in the study.

However, complete privacy cannot be guaranteed. For example, the Investigator may be required by law to allow access to research records. A copy of this consent form will be put in the health record. The participant's doctor will be told that they are taking part in this study.

When you sign this consent form, you give us permission to:

- Collect information from you and the study participant
- Collect information from the study participant's health record
- Share information with the people conducting the study
- Share information with the people responsible for protecting the participant's safety while participating in this research

Access to Records

The study doctor and members of the research team will see health and study records that identify the study participant by name. Other people, during visits to this health care facility, may need to look at the health and study records that identify the study participant by name. These people might include:

- The Research Ethics Board and people working for or with the Research Ethics Board
- Health Canada

Use of Your Study Information

The research team will collect and use only the information they need to judge the safety and usefulness of the FDG.

You also allow the collection, reporting and transfer of your anonymous personal health information and data from the study to:

- Regulatory authorities within Canada

This information will include the study participant's
- month and year of birth
- male or female
- medical conditions
- medications
- the results of tests and procedures you had before and during the study
- information from the study interviews and questionnaires

The name and contact information will be kept secure by the research team in the PET electronic requisition and database system and the Radiology Research Offices, C.D.H.A. It will not be shared with others without your or the study participant's permission. Information will be kept for at least 25 years as required by law.

After the study participant's part in the study ends, we may continue to review health records for safety and data accuracy until the study is finished. Information collected and used by the research team will be stored in the PET electronic requisition and database system and the Radiology Research Offices, C.D.H.A. The Principle Investigator is the person responsible for keeping it secure.

The Research Ethics Board and people working for or with the Research Ethics Board may also contact you and/or the study participant personally for quality assurance purposes.

Your Access to Records

You may ask the study doctor to see the information that has been collected about the study participant. You may ask to make corrections to this information by talking with a member of the research team.

17. What If I Want To Quit The Study?

If you choose to participate and later decide to change your mind, you can say no and stop your and the study participant's participation in the research at any time. The health records may be examined in connection with this study or further analyses related to it up to the time of withdrawal. If you decide to withdraw from this study by providing notice to the study doctor, the health records

will only be made available as described above. However, the above agencies, including the sponsor, will only look at and use study related records up to the date of withdrawal from the study, except where it is necessary to ensure that the study is scientifically reliable and to report side effects associated with the study medication as required by regulatory authorities. A decision to stop participating in the study will not affect the participant's health care.

18. Declaration of Financial Interest

The PET/CT scan is funded by the Nova Scotia Department of Health to test the locally produced FDG and assist in the study participant's care. The Principle Investigator has no financial interest in conducting this research trial.

19. What About Questions or Problems?

For further information about the study call Dr. Andrew Ross. Dr. Ross is in charge of this study at this hospital (*he* is the "Principal Investigator"). Dr. Ross' work telephone number is (902) 473-2825.

If the study participant experiences any symptoms or possible side effects or other medical problems, please let the Principal Investigator know immediately.

If you can't reach the Principal Investigator, or it is after regular business hours, speak to the Nuclear Medicine Physician on call. The after hours number is **(902) 473-2222.** This doctor may not be the one you see while in this study. Please call the Principal Investigator the next business day to tell them about the possible side effects or other medical problems you experienced.

The Principal Investigator is Dr. Andrew Ross
Telephone: (902) 473-2825
Team Leader PET CT: Christina Kelly
Telephone: (902) 473-4377

20. What Are My Rights?

After you have signed this consent form you will be given a copy.

If you have any questions about your rights as a research participant, contact the **Patient Representative** at **(902) 473-2133**.

In the next part you will be asked if you agree (consent) to join this study. If the answer is "yes", you will need to sign the form.

Capital Health

PART C.
21. Consent Form Signature Page

I have reviewed all of the information in this consent form related to the trial called:

Clinical Trial to evaluate the safety and clinical utility of 18F-FDG produced by the Molecular Imaging and Research Centre of Nova Scotia

I have been given the opportunity to discuss this study. All of my questions have been answered to my satisfaction.

I agree that my personal health and study information may be used as described in this consent form.

This signature on this consent form means that I agree to allow _____ to take part in this study. I understand that I am free to withdraw at any time without affecting my future care.

_____	_____	____ / _____ / ___
Signature of Participant's Substitute Decision Maker	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Witness to Participant's Signature	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Investigator	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Person Conducting Consent Discussion	Name (Printed)	Year Month Day*

If the consent discussion has been conducted in a language other than English, please indicate:

_____
Language

_____	_____	____ / _____ / ___
Signature of Translator	Name (Printed)	Year Month Day*

Note: Please fill in the dates personally

I Will Be Given A Signed Copy Of This Consent Form