Sunnybrook
HEALTH SCIENCES CENTRE

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: 18F-FET-PET/MRI versus Standard MRI alone for Stereotactic Radiotherapy Planning for High Grade Brain Gliomas: A Pilot Study (FETSMaRT)

Principal Investigator: Amit Singnurkar, Nuclear Medicine, (416) 480-6100 ext. 83787

Sponsor: Sunnybrook Research Institute

Study Funding Source: Sunnybrook Research Institute

INFORMED CONSENT

You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood.

This form explains the purpose of this research study, provides information about the study, the tests and procedures involved, possible risks and benefits, and the rights of participants.

Please ask the study staff or one of the investigator(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study. If you wish, someone may be available to verbally translate this form into your preferred language.

Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time.

INTRODUCTION

You are being asked to consider participating in this study because you have recently been diagnosed with high grade brain glioma and are planned to undergo radiation therapy.

High grade gliomas represent the most common cancer of the brain in adults. Survival is poor, partly because we don't have a reliable way to see the entire tumor or tell if patients have any cancer left after treatment. In this study, we will use an imaging technology call positron emission tomography (PET) to see cancer cells that take up amino acids, the building blocks of proteins, by using a radioactive drug called FET (0-(2-^{18}F-Fluoroethyl)-L-Tyrosine). We think that PET will help us see the cancer better and eventually help doctors treat the cancer better, improve the health of patients, and develop better treatments.

Health Canada has not approved FET for use or sale for imaging high grade glioma, although they have allowed its use in this research study.

WHAT IS THE USUAL TREATMENT?

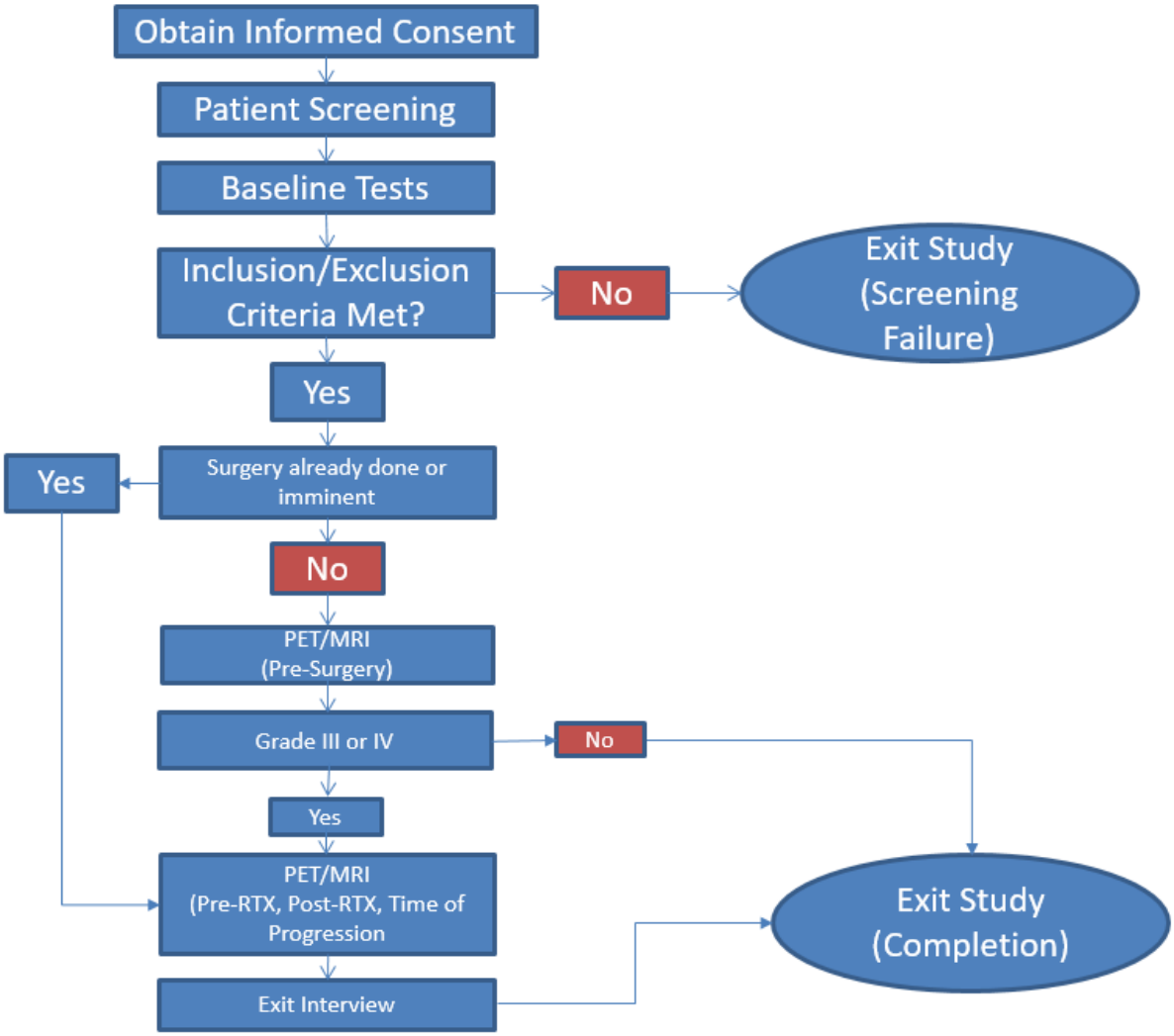
MRI is the standard of care to monitor patients after surgery or radiation therapy for high grade gliomas. Patients enrolled in this study will still obtain the standard of care MRI as prescribed by their care team along with additional imaging with FET-PET/MRI.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to understand whether the addition of FET-PET to standard of care MRI results in a significant change in how doctors think patients with high grade glioma could be treated.

WHAT WILL HAPPEN DURING THIS STUDY?

An examination will be performed on a camera that can perform both PET and MRI imaging (PET/MRI scanner) after injection of the FET imaging agent. This is in addition to MRI as prescribed by your care team. If study participants are recruited prior to surgery, they will be offered the opportunity to undergo PET/MRI imaging prior to this procedure. This is not a requirement. All patients will undergo PET/MRI before radiation therapy, after radiation therapy, and if there is suspicion of recurrent cancer after completing therapy up to 12 months after the post radiation scan. The following flowchart will give you some idea of what procedures are involved in the study:



HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is expected that 30 patients will participate in this study at Sunnybrook and they will be followed for 12 months after the post-radiation scan. The entire study is expected to take about 2 years to complete and results should be known in 3 years.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you decide to participate in this study you will be asked to do the following:

Visit 1 [Screening]:
In addition to the routine medical assessment at the neurology clinic, you will undergo blood tests to ensure eligibility for the study. Results of the testing may make you ineligible to participate. If you agree to join the study prior to surgery, you will undergo baseline PET/MRI imaging (Visit 2). (If you do not, you will proceed to "Visit 3" explained below.)

Visit 2 (Baseline scan):
This is a 1 hour appointment which involved lying flat and still in a PET/MRI scanner for 45 minutes. Prior to the examination, you will be greeted by a nuclear medicine technologist who will collect basic information before starting as well starting an intravenous access. The intravenous access will be used to inject FET at the start of the examination, while MRI contrast (Gadolinium) will be injected in the latter part of the study. You will be asked to complete a 5 minute survey on your health status.

Visit 3 (Pre-radiation therapy scan): This is a 1 hour appointment which involved lying flat and still in a PET/MRI scanner for 45 minutes. Prior to the examination, you will be greeted by a nuclear medicine technologist who will collect basic information before starting as well starting an intravenous access. The intravenous access will be used to inject FET at the start of the examination. You will be asked to complete a 5 minute survey on your health status.

Visit 4 (Post-radiation therapy scan): This is a 1 hour appointment which involved lying flat and still in a PET/MRI scanner for 45 minutes. Prior to the examination, you will be greeted by a nuclear medicine technologist who will collect basic information before starting as well starting an intravenous access. The intravenous access will be used to inject FET at the start of the examination. You will be asked to complete a 5 minute survey on your health status.

Visit 5 (Time of progression scan): If at any time during routine follow-up there is suspicion of recurrent disease, PET/MRI will be performed. This is a 1 hour appointment which involved lying flat and still in a PET/MRI scanner for 45 minutes. Prior to the examination, you will be greeted by a nuclear medicine technologist who will collect basic information before starting as well starting an intravenous access. The intravenous access will be used to inject FET at the start of the examination. You will be asked to complete a 5 minute survey on your health status.

Visit 6 (Exit Interview): After 12 month period following the post-radiation therapy scan, you will be contacted by a research associate to collect basic information about your health status.

Assessment	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
	Screening	Pre-Sx Scan (Optional)	Pre – RTx	Post-RTx	Time of Progression	12 Month Exit Interview
Informed Consent	x					
Medical History	x					
Physical Examination	x					
Blood Tests	x					
PET/MRI		x	x	x	x	
Exit Interview						x

The research done with your medical images may or may not help develop commercial (for profit) products or tests. There are no plans to provide payment to you if this happens.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You are not expected to experience any side effects from participating in this study. There are no know side effects resulting from administration of the FET imaging agent. Still, the study procedures may involve unforeseeable risks to the participants. If you decide to take part in this study, you should contact Regis Manorajah, (Sunnybrook Research Institute, (416) 480-6100 ext. 83787) about any side effects or study-related injuries that you experience.

FET is a radioactive substance which may increase the risk of future malignancies. The risk is considered very low. The potential risk is lower than that associated with standard CT imaging.

The effects or discomforts of tests/procedures that are part of this study but are part of your normal clinical care will be reviewed by your treating doctor.

The effects of 0-(2-18F-Fluoroethyl)-L-Tyrosine (FET) on unborn babies or sperm are unknown. You should not take part in this study if you are pregnant or planning pregnancy. If you and your partner are of childbearing potential (physically able to have children) and you are sexually active, it is important that you practice an acceptable method of birth control during this study. Clinically acceptable methods of birth control for this study include intrauterine devices (IUD), birth control pills, hormonal implants, injectable contraceptives, and using barrier methods such as condoms, vaginal diaphragm with spermicide, or sponge.

The medicine a mother takes while breast-feeding can also pass into a nursing child through the breast milk. In this case, there is a possibility of causing harmful side effects to the child. The safety of 0-(2-18F-Fluoroethyl)-L-Tyrosine (FET) during breast-feeding is not known. For this reason, if you are breast-feeding, you cannot take part in this study.

If you become pregnant during this study, you are requested to notify your study doctor immediately, in addition to the research coordinator and principal investigator. It is also recommended that you tell the doctor who will be taking care of your partner during the pregnancy that you took part in this study.

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may or may not benefit directly from participating in this study. Your participation may or may not help other people with high grade gliomas in the future.

WHAT OTHER CHOICES ARE THERE?

If you decide not to participate in this study, you will still undergo standard of care imaging and treatment.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The sponsor may decide to end the study at any time and for any reason.

The investigator may decide to remove you from this study without your consent for any of the following reasons:

- The investigator decides that continuing in this study would be harmful to you.
- You plan to become pregnant, plan to discontinue acceptable birth control, or become pregnant.

- You are unable or unwilling to follow the study procedures.
- If is not in your best interest to carry on as planned.

If you are removed from this study, the investigator will discuss the reasons with you.

You can also choose to end your participation at any time without having to provide a reason. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care.
If you withdraw voluntarily from the study, you are encouraged to contact Regis Manorajah (Sunnybrook Research Institute, (416) 480-6100 ext. 83787).

If you withdraw your consent, the information about you and your imaging tests that were collected before you left the study will still be used. No new information about you will be collected without your permission.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?

Participation in this study will not involve any additional costs to you.

WHAT HAPPENS IF I HAVE A RESEARCH RELATED INJURY?

If you become sick or injured as a direct result of your participation in this study, your medical care will be provided. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available.

By signing this consent form, you do not give up any of your legal rights.

ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?

You will not be paid to participate in this study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

You have the right to have any information about you and your health that is collected, used or disclosed for this study to be handled in a confidential manner.

If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. “Personal health information” is health information about you that could identify you because it includes information such as your:

- Name, address, telephone number, date of birth, new and existing medical records, or the types, dates and results of various tests and procedures.

You have the right to access, review and request changes to your personal health information.

The following people may come to the hospital to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre or the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook; and
- Representatives of Health Canada, group of people who oversee the use of drugs in research in Canada.

Access to your personal health information will take place under the supervision of the Principal Investigator.

“Study data" is health information about you that is collected for the study, but that does not directly identify you.

Any study data about you that is sent outside of the hospital will have a code and will not contain your name or address, or any information that directly identifies you. Study data that is sent outside of the hospital will be used for the research purposes explained in this consent form.

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. Any information sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection may not be as strict as in Canada. However, any information will be transferred in compliance with all relevant Canadian privacy laws.

The Principal Investigator will keep any personal health information about you in a secure and confidential location for 25 years and then destroy it according to Health Canada regulations.

When the results of this study are published, your identity will not be disclosed.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please provide your name, address and telephone number to Regis Manorajah (Sunnybrook Research Institute, fetsmart@sunnybrook.ca).

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*. 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.

ARE THERE ANY CONFLICTS OF INTEREST/RELATIONSHIPS?

The principal investigator, Amit Singnurkar, is a sponsored speaker for Isologic Innovative Radiopharmaceuticals, the supplier of the FET imaging agent used in this study

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to ask questions and to receive answers throughout this study.

If you have any questions about this study you may contact the person in charge of this study (Principal Investigator) **Amit Singnurkar, Sunnybrook Research Institute, (416) 480-6100 ext. 83787**.

The Sunnybrook Research Ethics Board has reviewed this study. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the **Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.**

DOCUMENTATION OF INFORMED CONSENT

You will be given a copy of this informed consent form after it has been signed and dated by you and the study staff.

Full Study Title: 18F-FET-PET/MRI versus Standard MRI alone for Stereotactic Radiotherapy Planning for High Grade Brain Gliomas: A Pilot Study (FETSMaRT)

Name of Participant: _____

Participant

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I authorize access to my personal health information, medical record and research study data as explained in this form
- I have agreed, or agree to allow the person I am responsible for, to participate in this research study

- I understand that my family doctor may be informed of my participation in this research study
- This informed consent document may be placed in my medical records

Name of participant (print)	Signature	Date

ASSISTANCE DECLARATION

Was the participant assisted during the consent process? ☐ Yes ☐ No

☐ 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.

☐ The person signing below acted as a translator for the participant during the consent process. He/she attests that they have accurately translated the information for the participant, and believe that that participant has understood the information translated.

Name of Person Assisting (Print)	Signature	Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

Name of Person obtaining consent (print)	Signature	Date

Statement of Investigator

I acknowledge my responsibility for the care and well-being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

Name of Investigator (print)	Signature	Date