Memorial Sloan-Kettering Cancer Center
IRB Protocol#: 13-199 A(3)

INFORMED CONSENT FOR CLINICAL RESEARCH

^{18}F-Fluorocholine (^{18}F-FCH) to Distinguish Necrosis from Recurrence in Brain Metastases

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

Stereotactic radiosurgery (SRS) is a very accurate form of radiation that targets tumors in the brain. After SRS, metastatic brain tumors may re-grow or sometimes the brain is damaged by the radiation (radiation necrosis). Both recurrent tumor and radiation necrosis (scarring) can cause progressive brain lesions. It is hard to tell the difference between tumor regrowth and radiation necrosis with MRI or other standard radiology studies such as FDG (glucose) PET (positron emission tomography) scans. ^{18}F Fluorocholine is a radioactive tracer used in PET scans (a scan using an investigational type of tracer). This type of marker may be able to distinguish tumor regrowth from radiation necrosis more accurately than MRI or standard FDG PET scans, because ^{18}F-FCH may be a better marker for tumors that grow back. However the exact way this tracer is absorbed by the body is not yet known. ^{18}F-FCH has been used in humans; however this tracer has not been used for distinguishing active tumor from necrosis in patients with brain metastasis.

The main purpose of this study is to determine the distribution of ^{18}F Fluorocholine (^{18}F-FCH) in the brain which can help distinguishing radiation-induced scarring from tumor regrowth. In addition, the study will measure levels of ^{18}F-FCH in your blood and (if applicable) in the brain lesion tissue that is removed as part of your planned brain surgery.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You are being asked to take part in this study because you have surgery planned to remove an expanding lesion that has changed after your stereotactic radiosurgery for brain metastasis.

How many people will take part in the study?

About 30 people will take part in this study at MSKCC.

What will happen if I take part in this research study?

Before you begin the study …

- We will discuss the details of the study with you. If you decide to participate, we will obtain your written consent.
- You will have a neurological/physical examination. These tests may include:
  - Testing your muscle strength
  - Testing how well you speak and understand language
- You will need to have a brain MRI to show that the lesion has grown or changed from an older scan. This scan was already going to happen as per standard of care.
- Pregnancy test- if you are a woman of child bearing potential

During the study…

^{18}F Fluorocholine PET scans produce images of your body after IV injection of a tracer called ^{18}F Fluorocholine. The tracer is a radioactive form of fluorocholine. This scan is not standard and will not be offered if you do not participate in this study.

If you choose to take part, you will undergo an ^{18}F-FCH PET study 1 to 7 days before your scheduled surgery. During the pre-operative study:

- Two IVs will be placed in your arms (one in each arm). The ^{18}F Fluorocholine tracer will be injected through one of the IVs and the research blood samples will be drawn from the other.
- After your injection you will be asked to sit quietly for 15-20 minutes before you have your scan.
- You will then lie down on the PET/CT scanner
- At about 1, 4, 10 and 30 minutes after the injection about 1 tablespoon of blood will be drawn from the IV
- The PET/CT scan will take approximately 40 minutes to complete.

After your scan, the study team will contact you about whether you experienced any side effects.

You will then proceed to have surgery as planned (prior to enrollment, regardless of scan results).

If your ^{18}F-FCH PET scan results (that you have before surgery) show that you are more likely to have tumor regrowth, rather than radiation necrosis (scarring), you will be given a 2nd IV injection at a lower dose at the time of your scheduled surgery for removal of the progressive lesion in your brain. This 2nd dose is given in the operating room to confirm the areas with uptake suggesting recurrent cancer. Five to ten samples of your brain tumor will be taken during the surgery to see how ^{18}F-FCH correlates with the sample. This will help determine how sensitive the ^{18}F Fluorocholine is at picking up small areas with recurrent cancer.

About 1-3 days after each injection, someone from the research team will contact you to see if you experienced any side effects related to the ^{18}F Fluorocholine scan.

After the study…

There are no additional scans and surgery done after the above described ^{18}F Fluorocholine PET scans. Your doctors will care for you and follow you routinely as they would for any other patient with a treated brain metastasis.

How long will I be in the study?

If you agree to participate in the study, there will an ^{18}F-Fluorocholine PET/CT scan 1-7 days before your surgery. The result of the scan will be given to you before your surgery. If the first scan is negative, then your participation will be complete 3 days after the first scan. If the scan is positive, then you will have the second ^{18}F-Fluorocholine injection during your surgery and your participation will be complete 3 days after surgery is complete.

You will be on the study for up to 10 days.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

PET (positron emission tomography) is a safe technique that involves a very small amount of radiation risk. The radiation dose is within typical doses for imaging cancer patients.

There are no major risks associated with this study. However, even low levels of radiation are associated with a very low, unknown risk of causing cancer later in your life. Each year millions of patients have similar tests and are exposed to similar radiation levels without any known short- or long-term effects.

Although no toxicity has been previously reported following ^{18}F-FCH administration, you will be contacted 1-3 days after the scan and asked whether you have experienced any adverse effects. The following are minor risks associated with the injection of the ^{18}F Fluorocholine. Placement of a catheter involves sticking a small needle into a vein in your arm. This may cause some discomfort when the needle breaks the skin. There is a small chance you may also get an infection or bruising at the injection site. Standard medical care will be taken to minimize these risks.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. We do know that the information from this study will help doctors learn more about ^{18}F Fluorocholine PET scans as imaging tools for patients with brain metastases treated with radiation. This information could help future cancer patients.
There are no direct benefits to you from the study. But what we learn may help others in the future.

Will I receive the results from the study?

The results from this study will be available approximately 6 months after the last patient is enrolled. Requests for summary results (e.g., abstracts) will be honored as available.

You may obtain the official readings of your ^{18}F Fluorocholine PET/CT scan by contacting your physician. These are usually completed 1-2 days after the scan was performed.

Do I have to take part in this study?

The choice to take part in this study or not is yours. Make your choice based on what we have explained to you and what you have read about the study

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

A description of this clinical trial may 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.

What are the costs of taking part in this study?

You and/or your insurance company will be billed for any procedures that are standard medical care. This includes:

- Surgery
- Pre-surgical testing
- Blood tests and scans (ie: MRI, FDG PET/CT) that are not for research purposes
- Tissue samples taken for diagnostic purposes (if applicable)

You and/or your insurance company will not be charged for the following:

- Administration of ^{18}F Fluorocholine and the corresponding ^{18}F Fluorocholine PET/CT

scan

- The intraoperative administration of ^{18}F Fluorocholine (if this scan is done).
- Blood draws for research purposes
- Tissue samples taken for research purposes (if applicable)

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for the medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor Kathryn Beal, M.D. at 212-639-5159.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

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RESEARCH AUTHORIZATION

$^{18F\text{-}Fluorocholine}$ ($^{18F\text{-}FCH}$) to Distinguish Necrosis from Recurrence in Brain Metastases

Research Participant Name: _____

Research Participant MRN : _____

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- The people in charge of the study and their assistants and support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, Data Safety Monitoring Board, and the Quality Assurance Committee.
- Members and staff of the hospital's Institutional Review Board and Privacy Board.
- The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- The following sponsor(s) of this research: Memorial Sloan-Kettering Cancer Center

The following information will be used and/or disclosed for this research:

- Your entire research record.
- HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses or AIDS, or any information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.
- HIV-related information collected during this study if you choose to disclose it when talking to any of the staff.
- Your medical records from the hospital
- The following information:
  - Blood and tissue taken for research purposes
  - ^{18}F-Fluorocholine scan results

If you sign this form, it means you are giving us permission to share your protected health information. We can only share it with the people or organizations describe above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also the right to withdraw it at any time. If you withdraw it, we cannot use or share anymore of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization, write to: Kathryn Beal, MD at the Department of Radiation Oncology Memorial Sloan-Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights (888) 392-3644
- New York City Commission of Human Rights (212) 306-7500

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand.		
YES	**NO**	**N/A (Adult or Child <7)**
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

Non-English Speaking Participant Witness and/or Interpreter: I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

Other: I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.