

**MRI - Magnetic Resonance Imaging** - uses powerful magnets and radio waves linked to a computer to create cross-sectional images of the body that are very clear and detailed.

**Gadolinium (also called a contrast agent)** - This study will use a contrast agent called **gadolinium**, a liquid-like dye liquid substance that goes into the body to help doctors better see and gain more information about your tumor.

**PET - Positron Emission Tomography** - a nuclear medicine imaging scan that produces a 3-D images that provide information about cell function and show the difference between healthy tissue and diseased tissue. In this study, a PET scan will take pictures of your brain to see how much oxygen is getting into the brain tumor.

**FMISO - F-fluoromisonidazole (also called a radiotracer)** - the agent used in this study is a molecule holding a radioactive substance. FMISO gives off a low dose of radiation from inside the body that will show up as color on PET scan images. Doctors can then see whether oxygen is getting to different areas of the tumor. The amount of radiation to the patient is low and it is short-lived. It is not enough to affect the normal body processes.

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*“The ultimate goal in glioblastoma research is to learn how to successfully treat the disease so that we cannot ever remember what it was like when it could not be treated. Continued research is needed to find treatments, and hopefully cures, for this terrible disease. This trial represents a crucial opportunity to learn more about the behavior of glioblastomas that may ultimately lead to more effective therapies. The additional MRI and PET scans required for this trial support a research effort that could possibly help thousands upon thousands of patients with glioblastoma in the future.”*

**Neal Levitan**  
ACRIN Patient Advocate

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*“FMISO PET has estimated tissue oxygen levels in patients with various types of cancer. If the oxygen data provided by FMISO PET in this study are connected with the tumor characteristics found by the MRI, the stage will be set for future research using oxygen imaging to show associations between oxygen levels and treatment selection and evaluation of response.”*

**David A. Mankoff, MD**  
ACRIN 6684 Co-principal Investigator

*“Better therapies are desperately needed for the patients diagnosed with glioblastoma each year. By combining the information provided by MRI with the data provided by PET using FMISO, we hope to see whether a change in the amount of oxygen to tissues as a result of treatment will predict a response to therapy for glioblastoma and eventually the development of more effective, patient-specific therapies.”*

**A Gregory Sorensen, MD**  
ACRIN 6684 Principal Investigator

For questions please contact:

## A Study for Glioblastoma Patients

Helping us find answers to brain cancer's toughest questions



**ACRIN**<sup>™</sup>  
AMERICAN COLLEGE OF  
RADIOLOGY  
IMAGING NETWORK

Funded by the National Cancer Institute

Every year, one million Americans take part in clinical trials to help researchers gather important information about the benefits and risks of new drugs and treatment methods. Many participants said they received excellent care and saw their involvement as a positive experience. Thanks to patients who take part in clinical trials, researchers have been able to find new and effective treatments for many types of cancer. These treatments have the potential to become the new standard of care offered to future patients.

## ACRIN Study Participation

You are being asked to take part in this study because you have recently been diagnosed with a form of brain cancer called "glioblastoma". This study involves taking pictures of the brain with two types of imaging scans: MRI, which is used during regular treatment for glioblastoma, and PET. The study will be carried out at 6 to 10 centers nationwide and will add important information about whether advanced MRI and PET scans can help doctors decide how best to treat people with brain cancer. (Please see the "Learning about MRI, PET, and FMISO" section of this brochure for more information.)

## Evaluating Tumor Oxygen Level

This study will use an advanced MRI technique to increase doctors' knowledge about how a tumor's lack of oxygen (called "hypoxia") is related to cancer treatment. The MRI will show doctors changes in blood flow, blood volume, and blood vessel size. Researchers hope that by understanding blood circulation and oxygen levels in glioblastoma tumors they can find better treatment for people with the tumors.

## PET Scans with FMISO

This study will evaluate whether the new radiotracer, FMISO, which is used during PET scans, can help doctors

see whether or not a tumor is getting enough oxygen for treatment to effectively destroy it. FMISO has recently shown hopeful results in other research studies.

FMISO is not yet approved by the US Food and Drug Administration (FDA) for routine use in people with brain cancer. The results of this study will add evidence for the FDA to make a decision about approving FMISO.

## Your role in the study

Your doctor or nurse research coordinator will give you detailed information about the study. You will be asked to read and sign an informed consent form that outlines the study procedures and possible risks and benefits.

As part of your regular cancer care, you will receive a cancer-fighting drug (chemotherapy) called "temozolomide," radiation therapy, and an MRI scan before treatment has begun and another after treatment is finished. As part of this study, you will undergo the following additional procedures:

- Three PET scans with FMISO
  - 2 weeks before your treatment begins (at the time of your MRI)
  - During week 3 of your treatment
  - 3 to 5 weeks after your treatment is finished (at the time of your MRI)
- One additional MRI scan during week 4 your treatment (along with your 2nd PET scan)
- Blood samples will be taken at each scanning visit
- 15 participants will be asked to undergo a fourth PET scan 1 week before treatment starts

A diagram outlining how the PET scans will fit into your regular treatment and scanning program will be given to you by the doctor or nurse working on this study.

## Who can join this study?

You may be eligible for this study if:

- You are at least 18 years old
- You have been newly diagnosed with glioblastoma (World Health Organization grade IV)
- The tumor remaining after surgery is the size specified in the study
- You are scheduled to receive standard radiation therapy
- You are scheduled to receive the drug "temozolomide"

## Who cannot join this study?

You cannot join this study if:

- If you are pregnant or breastfeeding
- You are scheduled to receive treatment with any drug other than temozolomide
- You are not able to undergo an MRI or PET scan
- You have a history of allergic reactions to compounds similar to FMISO such as Flagyl
- You have had treatment with implanted radiotherapy or chemotherapy sources
- You cannot receive 100% oxygen for up to 10 minutes (e.g., a history of COPD, chronic obstructive pulmonary disease)

## Why should I participate in this study?

Although you will not receive treatment benefits by taking part in this study, you will be part of an effort that may help future brain cancer patients. The information gained from this study may help doctors decide on the best treatment for certain types of brain cancer or to help treatments work better for brain cancers that are hard to treat. The study team of doctors, nurses, and research staff will work together to guide you through the scheduling of scans and answer questions about the study process, to help make your study involvement as comfortable and easy as possible.

## How long do the scanning procedures last?

The FMISO PET scan procedure will take three hours from the time of the FMISO injection. MRI scans take 90 minutes.

## How long will I be in this study?

You will be involved with the study's imaging procedures for about 12 weeks. Your doctor will continue to forward information about your health and cancer status to the study doctors for up to three years.

## Are there possible side effects?

Side effects are similar to those for routine MRIs and PET scans. Many side effects go away shortly after the scan is finished. Your doctor or nurse will discuss side effects more with you during your initial consultation.

## Will it cost me anything to be in this study?

No. Taking part in this study will not add any costs to you or your insurance company. The cost of taking blood samples at each scanning visit, the three or four PET scans with FMISO, and the one additional MRI scan are covered by the study.

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

Taking part in this study is voluntary, and you may choose to stop at any time. Leaving the study or choosing to not participate will not affect your medical care.-