**Medical Research Informed Consent**

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## Purpose

You are being asked to be in a research study about positron emission tomography (PET) scans because you have cancer. This study is being conducted at Wayne State University (WSU), the Detroit Medical Center (DMC), Children's Hospital of Michigan (PET scans are performed here), Karmanos Cancer Institute (KCI) and McLaren Health Care (MHC) sites. The estimated number of study participants to be enrolled at WSU, KCI, KCI at McLaren Bloomfield Hills, KCI at McLaren Clarkston and KCI at McLaren Macomb is about 80. **Please read this form and ask any questions you may have before agreeing to be in the study.**

In this research study, we will study the changes within your tumor cells which may improve understanding of how tumors grow and how they respond to various treatments. These changes may be compared with results of the physical examination and scans (CT and MRI) that are done as part of routine clinical care. Another purpose of this study is to analyze tumor genes and chemical form of FLT (3'-deoxy 3'-fluorothymidine) obtained at biopsy to compare the imaging results. Pictures (images) will be made showing the distribution throughout your body of substances containing a small amount of radioactive material. This procedure is called a PET Scan. The radioactive substances (tracer compounds) in this study are [F-18] FLT. [F-18]-FLT is approved as an investigational new drug under the FDA. Small blood samples will be taken to measure the levels of the tracer compound in your blood. From this study, we aim to gain knowledge about how to best diagnose and treat tumors, how tumors affect normal tissue and how treatment of tumors with radiation therapy and chemotherapy affect tumors.

## Study Procedures

If you agree to take part in this research study, you will have your PET scans done at Children's Hospital of Michigan. The Department of Defense will be funding the scans for select (lung cancer) subjects. Your imaging scans will be done on a PET scanner. Two different types of PET scanners may be used; one is a dedicated PET scanner alone and the other includes a CT scanner (PET/CT). You may be imaged on the PET scanner, the PET/CT scanner, or both. The procedure will require up to one half day of your time, including waiting and imaging time. These studies may be repeated up to four times, requiring an additional one half day of your time for each scan. For each PET session, small tubes will be inserted into one of your veins (a numbing medicine will be used). The tubes are necessary for injection of tracer compounds and for withdrawals of some small blood samples that allow measurements of the tracer compound in your blood. You will lie on a comfortable table for 1 to 2 hours at a time while your head or body sits in the opening of a large doughnut-shaped detection device (PET device). The PET device contains crystals which pick up small radiation signals from

tracer chemicals in your body. It is able to localize the region of your brain or body from which the signals arise. With the help of computers, the signals are added up and provide a picture of the location of the tracer in the brain regions, and other organs or tumors.

The majority of participants will have PET studies as follows: The tracer compound [F-18] FLT will be injected as described above into your veins in a small volume of normal saline solution. The PET scan data collection is started immediately and is continued for 2 hours. This procedure will measure tumor growth within your body. Blood may be withdrawn (through the catheters) up to a total volume of 30 milliliters (or 2 tablespoons) for each scan. A urine sample may be collected at the end of the imaging of the tracer compound to analyze its breakdown products.

The venous catheter will be removed at the end of the PET studies.

Genes and their expression in your tumor cells may also be analyzed. This will be done only when frozen or fixed specimens biopsy samples to the tumor and normal nearby tissues are already available. Analysis of these specimens may include DNA/RNA methods which can measure thousands of genes at one time. Analysis may include assays of the metabolic pathways and protein levels in the specimens. For some participants these results may determine if you will receive a PET scan. Some participants who have already had their first FLT PET scan may receive another FLT injection just prior to previously planned surgery. A portion of the tumor removed at surgery will then be analyzed to study the chemical form of FLT in the body.

It will take approximately up to one half day of your time for each scan. This will include time for parking, getting to the PET Center, check in paperwork, placement of IV, restroom use, getting on the scanner and the scan itself.

**Benefits**

The possible benefits to you for taking part in this research study are the benefits from the use of PET imaging, which may define the extent of your tumor. PET may also help to evaluate your response to treatment. If the results of this study show this test to be useful scientific information, another possible benefit is that you will contribute to the better management of cancer patients in the future.

**Risks**

All of the possible side effects of this procedure are not known, but previous studies have shown the more common side effects to be:

You may feel a mild discomfort with placement of the catheters in the vein of your arm. Numbing medication (lidocaine) may be administered to reduce this discomfort and may itself be temporarily painful. While it is rare, you may experience an allergic reaction to the lidocaine. There is a slight risk of infection at the site, but sterile technique reduces this risk nearly completely. A possible risk from blood sampling is bleeding. You may also experience claustrophobia from the imaging ring apparatus.

The amount of radiation exposure you will receive from this procedure is equal to a uniform whole-body exposure of approximately 11.5mSv (a measure of radiation exposure) for each PET scan. If

you have an attenuation scan (used to determine the density of your body), you will be exposed to an additional 0.2 mSv. Furthermore, if you have a PET/CT scan, the additional amount of radiation exposure is 3 mSv. The risk from this level of radiation exposure is small when compared with other everyday risks. The annual allowable amount of radiation exposure for radiation workers (X-ray technicians) is 50mSv.

[F-18]-FLT: For the dose of FLT used in this study there are no anticipated side effects.

For pre-study evaluations, blood samples will be obtained from your veins. Blood obtained during PET scans will be obtained through the catheters in your arms. Possible side effects of obtaining blood samples are pain, bruising, bleeding, or infection at the blood draw site. Occasionally, nausea, lightheadedness or fainting may occur.

There may be unknown risks to women who are or may become pregnant, to unborn babies, and to nursing infants. Therefore, to take part in this study, a medically acceptable form of birth control is required—for both male and female participants. Medically acceptable birth control may include the following methods: barrier protection—such as condoms, intrauterine devices (IUD), abstinence (not having sex), etc. Oral contraceptives may be used but should not be the only means of protection. No birth control method completely eliminates the risk of pregnancy. You should inform the study doctor (PI) immediately if you or your partner intends to get pregnant, or if you or your partner should become pregnant while participating in this research study, so that your choices and options can be explored and discussed.

If you are a female of child bearing age, you will be required to have a negative result from a serum (blood) pregnancy test prior to your participation in this study. This will require approximately two teaspoons of blood to be drawn in order to test for pregnancy. If you are pregnant or nursing, you will not be able to participate in this study. A serum pregnancy test may be repeated up to 4 times if you are unable to confirm your pregnancy status.

There could be unknown side effects, and you will be closely monitored by your physician. Although the side effects listed above have been seen before, there are chances that other side effects may occur which have not been previously seen. You may experience some drug side effects or complications, including serious or life threatening side effects that at this time are unknown and are therefore unforeseeable.

**Alternatives**

The alternative to this study is to choose not to participate.

**Study Costs**

The FLT PET scans will be provided at no charge to you and/or your insurance company.

You and/or your insurance company will be responsible for those procedures that are considered routine care for your disease. These include CT/MRI scans, clinic, hospital, and doctors' services, labs, the cost and administration of other medications to treat your disease, and the treatment of side effects. Some insurance plans will not pay for these services for people taking part in research

studies. You will be responsible for any charges that your insurance does not cover including co-payments, co-insurance, and deductibles.

For more information on clinical trials, you can visit the National Cancer Institute's (NCI) web site at http://www.cancer.gov/aboutnci/organization/clinical-center-fact-sheet

To learn more information about paying for clinical trials and insurance, you can visit the NCI web site at:

- http://www.cancer.gov/clinicaltrials/learningabout/payingfor
- http://www.cancer.gov/clinicaltrials/learningabout/payingfor/insurance-coverage

Another way to get information is to call the NCI at 1-800-4-CANCER (1-800-422-6237) and talk to an Information Specialist, Monday-Friday 8am-8pm EST. You can request free information to be sent to you, such as the Cancer Clinical Trials Fact Sheet.

**Compensation**

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

**Research Related Injuries**

In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University, Detroit Medical Center, Karmanos Cancer Institute, McLaren Health Care, University Physician Group, Children's Hospital of Michigan, sponsor, and any other facility involved with this study. If you think that you have suffered a research related injury, contact the PI right away at (313) 576-8735.

**Confidentiality**

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, Detroit Medical Center, Karmanos Cancer Institute (KCI), McLaren Health Care Corporation, the Institutional Review Board (IRB) at McLaren Health Care (MHC), the McLaren Health Care Office of Research Compliance and Quality Improvement, other McLaren sites involved in this study or federal agencies with appropriate regulatory oversight e.g., Food and Drug Administration (FDA), Department of Defense, Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc. may review your records.

If you have signed a consent form and are participating in another research study to evaluate and treat your cancer, the sponsor of that study may also review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity.

**Voluntary Participation/Withdrawal**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

The PI may stop your participation in this study without your consent. If you have any side effects that are very serious or if you become ill during the course of the research study you may have to drop out, even if you would like to continue. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because it is part of the research plan that people who develop certain conditions or do not follow the instructions from the study doctor may not continue to participate.

While taking part in this study you will be told of any important new findings that may change your willingness to continue to take part in the research.

**Questions**

If you have any questions about this study now or in the future, you may contact Dr. Shields or one of his research team members at the following phone number (313) 576-8735. If you have questions or concerns about your rights as a research participant, the Chair of the Human Investigation Committee can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

If you are a McLaren patient and have questions about your rights while taking part in this study, if the study staff cannot be reached, or if you have questions, complaints or concerns about the research that you do not feel you can discuss with your study team, contact the McLaren Health Care Human Research Protections Program at (248) 484-4950, Fax (248) 276-9732, or e-mail hrpp@mclaren.org or regular mail at 2701 Cambridge Court, Suite 110; Auburn Hills, MI 48326.

**Consent to Participate in a Research Study**

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

| | | |
|---|---|---|
| _____ | _____ | |
| Signature of participant / Legally authorized representative | | Date |
| _____ | _____ | |
| Printed name of participant / Legally authorized representative * | | Time |
| _____ | _____ | |
| Signature of witness** | | Date |
| _____ | _____ | |
| Printed of witness** | | Time |
| _____ | _____ | |
| Signature of person obtaining consent | | Date |
| _____ | _____ | |
| Printed name of person obtaining consent | | Time |

*Remove LAR reference if you don't intend to consent participants that have or may have LAR.

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

IRB#052009MP2F(M)
08/20/2025 - 08/19/2026
**APPROVAL PERIOD**
WAYNE STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

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| _____ | _____ | |
| Signature of translator | | Date |
| _____ | _____ | |
| Printed name of translator | | Time |

**Continue to HIPAA Authorization on next page**

**HIPAA Authorization**

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place any time during the study or after the study has ended.

**The PHI that will be "USED"** for this research includes the following: name, address (street address, city, state and zip code), elements of dates, telephone numbers, fax numbers, social security number, medical record number, health insurance number, and any unique identifying numbers or characteristics or code.

**The PHI that will be "DISCLOSED"** or shared with others for this research includes the following: patient initials, elements of dates, and any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of WSU, DMC, KCI and MHC associated with the research project
- WSU's IRB and the Institutional Review Boards (IRB)
- Authorized members of KCI's, DMC's, WSU's, and McLaren Health Care Corporation's workforce who may need to access your information in the performance of their duties.
- The McLaren Health Care (MHC) Institutional Review Board
- The McLaren Health Care Office of Research Compliance and Quality Improvement
- KCI at McLaren Bloomfield Hills
- KCI at McLaren Clarkston
- KCI at McLaren Macomb
- The study Sponsor or representative, including companies it hires to provide study related services, which include: KCI and the Department of Defense (DoD)
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at anytime, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center, the Karmanos Cancer Institute and/or the WSU School of Medicine Practice Plans and/or McLaren Health Care.

**Authorization to use and disclose PHI**

- ❖ By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____

Signature of participant Date

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Printed name of participant

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- ❖ For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

_____ _____

Signature of authorized representative Date

_____ _____

Printed name of authorized representative Relationship to the participant

_____ _____

Signature of person obtaining Authorization Date

_____ _____

Printed name of person obtaining Authorization Time



_____

Participant's Initials



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08/20/2025
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INSTITUTIONAL REVIEW BOARD