Official Study Title: METHIONINE PET/CT STUDIES IN PATIENTS WITH CANCER

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Informed Consent for Research (Non-therapeutic)

METHIONINE PET/CT STUDIES IN PATIENTS WITH CANCER

NOTE: *When we say "you" throughout this document, we mean "you or your child."*

We are asking you to take part in a research study that your doctor thinks may be useful for your care. This consent form gives you information about the study, which will be discussed with you. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

Before you learn about the study, it is important that you know the following:

- Whether or not you take part in this study is entirely up to you.
- If you decide not to be in the study, or to withdraw from the study at any time, you will not lose the benefits of routine medical care.
- This study is being sponsored by St. Jude Children's Research Hospital.
- The Principal Investigator (researcher) of this study is Dr. Barry Shulkin, who can be reached at 901/595-2887.

Why is this study being done?

The purpose of this study is to perform imaging studies using radiolabeled methionine in the evaluation of children and young adults with tumor(s). Methionine is a naturally occurring amino acid, which is a part of proteins which are essential to life. When labeled with carbon-11 ([C-11], a radioactive isotope [chemical element] of the naturally occurring carbon-12), we can take images of how much methionine your tumor takes up using a PET camera. This is the same camera that we use for PET studies. C-11 methionine (MET) has been shown valuable in studying and evaluating a large number of tumors.
MET is not FDA approved or commercially available, it is considered investigational and will be produced at St Jude under an IND (Investigational New Drug) granted by the FDA (Food and Drug Administration).

The study has the following goal:

To provide PET scans using methionine in order to find tumors at the time of diagnosis or during or after therapy. This study will continue to evaluate the safety of methionine.

How many people will take part in the study?

About 50 patients will take part in the open-access part of this study. All participants who have a tumor or who are suspected of having a tumor, and who are under the care of a St. Jude physician are eligible for participation.

What is involved in this study?

The METPET examinations will require about 1-1.5 hours and can be ordered up to 6 times. We will perform no more than 6 scans.

The research study has the following parts:

1. *Pre-Study Evaluations*
   You will complete all evaluations according to your St. Jude treatment plan.

   Females cannot be pregnant or breast feeding. If you are a female and having periods, you will have a pregnancy test before the scan is done.

   You will not eat or drink for at least 4 hours before the PET CT.

2. *Off –Study Evaluations*
   If receiving a dose of carbon-11 methionine poses a medical risk for you or you become too sick to have imaging studies, then you may be removed from the study at the request of the study doctor or your physician.

3. *Long-Term Follow-up Evaluations*
   You will continue to follow your treatment plan and follow-up evaluation schedule according to your physician. After 6 scans or if your doctor decides not to order 6 scans, you'll be placed in the follow-up phase for one year.

How long will I be in the study?

You will remain on the study for follow-up scans and data collection until you or your physician request that you be withdrawn from the study or until one year after your last METPET scan.

Can I be taken out of the study without my consent?

You may be taken out of the study without your consent for the following reasons:

- You, your parent, or legal guardian request that you be taken off the study.
- Study requirements create a medical risk for you. Removal from the study will occur at the request of the study doctor or your physician.
- If you are female and found to be pregnant or if you are breast feeding at the time of planned imaging.
- The METPET study is closed.

What are the consequences of withdrawing from this study?

You may choose to stop the study at any time. The study is voluntary. If you withdraw from the study, you will still have access to the same services and care that you would otherwise receive.

What are the risks of the study?

The main risk(s) of this study are:

The major risk from participating in this study is related to the exposure to a small dose of ionizing radiation. METPET uses radioactivity for tracking methionine used by tumors. This radiation dose is in addition to any radiation you may have received as part of your routine care. The radioactivity disappears very quickly and is nearly gone by the time the scan is over. We are constantly exposed to naturally occurring radiation from everywhere in the environment, including the earth, sun, air, and food. The amount of radioactivity in a METPET scan is about twice the average radiation dose people in the U.S. receive from natural background radiation sources each year. When compared with the risk of your disease and the possible complication of therapy, the risk of harm from METPET radiation is minimal and too low for any observable effects even should you receive six exams.

Reproductive Risks:
The risks of this treatment to an unborn or nursing child are thought to be very low. Female participants must not be breast feeding when entering the study and should not get pregnant during the study. Your doctor can discuss birth control methods to prevent pregnancy. If you think you may have become pregnant during the study, you must notify your doctor immediately. If you become pregnant, you will be taken out of the study.

If you are a girl who has started having menstrual periods, we will need to obtain a small amount of your urine or blood to do a test to make sure that you are not pregnant prior to the METPET scan. Urine pregnancy testing is allowed only if IV access is not available and we cannot obtain a blood test.

Sedation: Another risk could be related to possible side effects from anesthesia. If sedation is required to help you hold still during the METPET scans, a member of the sedation team will explain the possible side effects and you will be asked to sign a separate consent form. We will try to perform the METPET scans at the same time you will have another scan, such as a MRI or CT, to reduce the number of times you need to be sedated. However, this is not always possible. Sometimes you may need to have the METPET scans separate from the other scans, which may require you to have additional sedation.

The side effects from anesthesia/sedation include vomiting, sore throat, headache or backache, muscle pains, shivering, sleepiness, confusion and/or problems with urinating.

With any anesthetic/sedation procedure, there may be serious risks or problems that cannot be prevented, and are not known about ahead of time. These may be allergic reaction, nerve

damage, low blood pressure, spasms in the throat, voice box or breathing tubes, problems breathing, slow breathing, heart attack, brain damage, numbness that does not go away, loss of movement, seizures, unusual reactions, or rarely, death.

Some anesthetics require medical devices around or in the mouth and nose. There may be soreness and bruising in the mouth, nose and throat. Sometimes, but not often, teeth my get knocked loose, chipped or damaged.

Anesthesia risks following the use of sedation and/or anesthetic drugs involve primarily the respiratory system e.g. brief halt in breathing, decreased oxygen saturation, airway obstruction, and possible use of airway devices. Other possible adverse effects include low blood pressure, slowed heart rate, fast heart rate, low body temperature, and possibly delayed awakening.

Clinical procedure: The screening interview that was part of your routine medical care contains data that would be useful in our study. With your permission, we will use this data in our research.

Breach of confidentiality: Very rarely, data from your records could be accidentally released that might embarrass you or affect your ability to get insurance. We take several steps to prevent this from happening, including:

- Storing records separately from names or other personal information
- Limiting access to members of the study team
- Storing electronic data only on password-protected computers
- Reporting study results on the whole group and never identifying individuals in any reports

What are the benefits of the study?

We expect that this test will be useful in the management of many patients who undergo METPET scanning. It may or may not help you directly. It may help find additional sites of disease not discovered by other tests, it may more accurately determine the adequacy of treatment, and in patients whose disease recurs, it may detect tumor(s) earlier. Each of these benefits could benefit you. We hope to develop better ways to diagnose tumors.

What about new information?

We will tell you anything we learn during the study that we think might cause you to change your mind about staying in the study.

What about confidentiality?

We will keep your medical records private to the degree allowed by law. We will not give information from your medical records to anyone outside the hospital unless we are required by law to do so. We will not identify you personally in any publication about this study.

Government agencies oversee research studies involving people. Your medical records may be

reviewed by such agencies if you take part in this research study. These agencies may include the Food and Drug Administration (FDA) and the National Cancer Institute (NCI).

It may be necessary to check parts of your medical record to be sure that the study data are correct and complete. Such a check might be done by the following groups:

1. Clinical research monitors and auditors.
2. St. Jude Children's Research Hospital Institutional Biosafety Committee (IBC), a committee that oversees all aspects of investigational biologic products, including the manufacturing (making) of the product, as well as all laboratory and clinical related safety issues.
3. St. Jude Radiation Safety Committee, a committee that oversees research that involves radiation.

No information other than what is needed for the study is recorded.

How will I find out the results of this study?

The investigator or your physician will share with you available information regarding the overall results of this study. Whether you will know your personal test results will be discussed elsewhere in this document. St. Jude researchers share information with research participants in many ways, including:

- articles on www.StJude.org
- in newsletters,
- in medical or scientific journals
- in the media

Published research results will only describe groups of participants. Information that identifies individuals will not appear in research journals or other reports.

SUMMARY OF RESEARCH AND PRIVACY RIGHTS
NON-THERAPEUTIC AND MINIMAL RISK RESEARCH

The following statement describes your rights as a research participant in this study:

1) You may refuse to be in this research study or stop at any time. This decision will not affect your care or your relationship with your doctor or St. Jude. If available, you may receive routine medical care at St. Jude Children's Research Hospital.

2) You will not be charged for being in this research study.

3) Your samples and information may be used to develop a new product or medical test, which may be sold. If this happens, you will not receive any payments for these new products.

4) If you have any questions about this study or if you are injured as a result of this study, contact Dr. Barry Shulkin**,** at 901-595-3300, immediately. If you're injured from being in this research study, St. Jude will provide reasonable and necessary care for that injury. If you need more care than St. Jude is able to provide, we will help you find medical care somewhere else. It is not the hospital's policy to provide payment if you are injured from being in this study; however, you are not giving up any of your rights by signing this consent form.

5) A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most the Website will include a summary of the results. You can search this Website at any time.

6) A decision to take part in this research means that you agree to let the research team use and share your health information, also called Protected Health Information (PHI), for the study explained above. This information will be kept indefinitely. You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. However, research information may not be seen until the end of the study.

7) When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI may be used or given to someone outside the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. You can find it at the bottom of every page on the St. Jude Internet website: *www.stjude.org*.

8) Federal agencies such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP) or the National Institutes of Health (NIH), St. Jude Children's Research Hospital Institutional Review Board (IRB), your insurance company (if charges are billed to insurance), as well as other regulatory agencies, committees, or persons involved in overseeing research studies may review your research and medical record.

9) Information about you that may be given out includes your complete medical records,

including details about diagnosis, illness, treatment, and information that may be recorded about past diagnosis or treatment and information taken as a part of this research study as explained in this informed consent.

10) After your records are given to or used by others, St. Jude Children's Research Hospital cannot promise that information will not be given out again. Also, the information given out may no longer be protected by federal privacy laws.

11) St. Jude uses reasonable safeguards and means to protect your private information. However, St. Jude cannot guarantee the security and confidentiality of e-mail, text messages, fax communications or mail.

12) Your permission to use and give out your child's protected health information will end when your child turns 18 years of age. At that time, we may contact your child for his or her permission to continue using it.

13) You may take back permission for your records to be used or given out at any time, for any reason, except when that information has already been given out or used for the study based on your permission. To take back your permission, please fill out a form called a Revocation of Release of Authorization. You may ask for this form by calling the St. Jude Privacy Officer at 901-595-6141. You must mail the form or hand it to:

    HIPAA Privacy Officer
    St. Jude Children's Research Hospital
    262 Danny Thomas Place
    Memphis, TN 38105

14) You can get more details about your rights as a research participant by calling the St. Jude Institutional Review Board at 901-595-4357 or the Research Participant Advocate at 901-595-4644. If you are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE IRB).

15) The St. Jude Research Participant Advocate is an individual who is not part of the research study team and is available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team. You can reach the Advocate by calling 901-595-4644, or if you are outside of the Memphis area, call toll free at 1-866-583-3472 (1-866-JUDE-IRB).

16) You will be given a copy of this <u>signed</u> consent form.

PARENT/GUARDIAN STATEMENT (Required for participants younger than 18 years):
I have read this document or it was read to me. I have been encouraged to ask questions and all my questions have been answered. I give permission for my child to be in this research study.

_____	_____	_____ AM/PM
Parent/Legal Guardian Signature	Date	Time (circle one)

ASSENT DISCUSSION (Required for participants 7–13 years old)

☐ The research was explained to the minor participant in age-appropriate terms and the minor verbally agreed to take part in the study.

☐ An assent discussion was not initiated with the minor for the following reason(s):
- ☐ Minor is under 7 years of age.
- ☐ Minor is incapacitated.
- ☐ Minor refused to take part in the discussion.
- ☐ Minor declined to take part in the study. The minor declined for the following reason(s):

_____

- ☐ Other _____

RESEARCH PARTICIPANT STATEMENT (14–17 years old and Adult Participants 18 years and older):
I have read this document or it was read to me. I have been encouraged to ask questions and all my questions were answered. I agree to take part in this research study.

_____	_____	_____ AM/PM
Research Participant Signature	Date	Time (circle one)

RESEARCHER/DESIGNEE STATEMENT: I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant was encouraged to ask questions and all questions were answered to their satisfaction. A copy of this form has been given to the participant or his/her representative.

_____	_____	_____ AM/PM
Researcher/Designee Signature	Date	Time (circle one)

_____
Print Name

In case of questions or emergencies in reference to this protocol, please contact:
St. Jude Children's Research Hospital
262 Danny Thomas Place
Memphis, TN 38105-2794
(901) 595-3300

PLEASE FAX CONSENT FORM TO PROTOCOL OFFICE # (901) 595-6265