The Ohio State University Consent to Participate in Research

Study Title:	Feasibility Assessment of Next-generation PET Technology and Procedures
Principal Investigator:	Michael V. Knopp, MD, PhD
Research Project:	RP0506

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the 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 usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

This study is being performed as a way of exploring positron emission tomography (PET) imaging beyond current standard of care/insurance reimbursable procedures in regard to the medical ailment for which you may be seeking diagnosis and/or treatment. This imaging study will not replace any standard of care imaging and tests. It may lead to additional insights into your ailment and/or disease state. Any findings of this research study may only be considered as investigational and supplemental information to standard of care imaging. In addition to standard of care imaging and tests, we are interested in seeing if the information from a PET study can provide additional insight for a variety of diseases and conditions.

2. How many people will take part in this study?

Up to 200 people will take part in this study.

3. What will happen if I take part in this study?

After you have reviewed and signed this form with a study member, you will have your investigational PET/CT study performed. The CT scan performed will be used to improve the clarity of the PET scan and for anatomic correlation of the PET images. The CT scan involves radiation exposure and uses special x-ray equipment to take pictures of internal organs, bones, and other tissue.

You will be receiving a radiopharmaceutical injection, typically placed in the inside upper forearm. You may be asked to drink fluid to accelerate your urine production. This fluid may contain an oral contrast agent in case visualization of the GI tract is needed. For the imaging portion of the study, you will be asked to simply lie on the table of the PET/CT system for no longer than two hours total, but the exact length and any breaks in imaging will depend on your specific case. A study team member will explain the details of the PET/CT imaging process to you prior to beginning.

By agreeing to participate in this study, you agree to release your medical records for up to 10 years after your participation in this study in order to allow study personnel to track the current outcome and/or related procedures in the future. You can change your consent to participate at any time by contacting the Principal Investigator (contact information is provided at the end of this form).

4. How long will I be in the study?

Prior to any study activities you will review this form with a member of the study team. You will be given time review the form on your own and ask questions. This process is estimated to take no longer than 60 minutes. The research imaging is expected to be no longer than 2 hours. Your total time involved should be no more than 3 hours; however, your records may be reviewed for up to 10 years.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

We do not foresee any adverse (negative) events from participating in this study. Risks associated with the investigational PET are considered very unlikely and are the same type of physical events that could occur in any normal PET scan. These would include pinching of skin, minor falls or bumps. Normal risks of a nuclear medicine scan from injection of a radiopharmaceutical include allergic reactions, swelling, infections, intravenous injuries, bruising, pain, and discomfort. Clinical guidelines for the PET will be followed according to OSU hospital policy.

The CT scan performed will be used to improve the clarity of the PET scan and for anatomic correlation of the PET images. The CT scan involves radiation exposure and uses special

x-ray equipment to take pictures of internal organs, bones, and other tissue. Long term exposure to radiation may slightly increase one's risk for cancer. The exposure risk is cumulative over a lifetime, and the total should be kept as low as possible. The exact long-term risks from radiation are not known. To give you an idea about how much radiation you will receive from PET/CT scans, we will make a comparison with an every-day situation. Everyone receives a small amount of unavoidable radiation each year. Some of this radiation comes from space and some from naturally-occurring radioactive forms of water and minerals. This research gives the participant's body at most the equivalent of about 5 extra years' worth of this natural radiation.

7. What benefits can I expect from being in the study?

There are no direct benefits to participating in this study. However, your participation in this study may help us learn better ways to improve picture quality.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. This information will be kept indefinitely as an electronic record on a secure server at the Wright Center of Innovation. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

10. What are the costs of taking part in this study?

There are no additional costs associated with participating in this study. The research PET/CT pictures taken will be billed to the study research account.

11. Will I be paid for taking part in this study?

You will be paid $50 for your participation in this study. This payment will be presented at the time of your visit in the form of a gift card upon completion of the entire investigational PET/CT scan.

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

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

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

If you choose to participate in the study, you may leave the study at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subject research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
- Records about any study drug you received;
- Records about the study device; and

II. Who may use and give out information about you?

- Researchers and study staff.
- Those who oversee the study will have access to your information, including:
  Members and staff of the Ohio State University's Institutional Review Boards, including the Western Institutional Review Board
  The Office for Responsible Research Practices
  University data safety monitoring committees
  The Ohio State University Research Foundation
- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
  The Food and Drug Administration
  The Office for Human Research Protections
  The National Institutes of Health
  The Ohio Department of Job and Family Services

III. Who might get this information?

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules. All information related to this study, however, will be de-identified in order to best protect your privacy.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact**:**

Michael V. Knopp, MD, PhD, 614-293-9998, The Ohio State University, 396 West 12th Avenue, 4th Floor, Columbus, OH 43210.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact:

HIPAA Privacy Manager, 614-293-4477, The Ohio State University Medical Center, 600 Ackerman Road, Suite E2140, Columbus, OH 43202.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact**:**

Michael V. Knopp, MD, PhD, 614-293-9998, The Ohio State University, 396 West 12th Avenue, 4th Floor, Columbus, OH 43210.

16. What will happen in the case of incidental findings on the research imaging?

Although the scan(s) (imaging) you will have in this study is/are being taken for research purposes only, it is possible that doctors may notice something that could be important to your health. Any incidental findings in the acquired pictures will be compared to prior pictures that were taken as part of your healthcare at The Ohio State University. If these incidental findings were not previously reported on standard of care imaging, we will contact you to explain what was noticed. If you so desire, we will also communicate with your personal physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs. Please indicate below how you wish to be contacted in the event of incidental findings on the research imaging:

Printed name of subject	Preferred method of contact
Printed name of personal physician	Preferred method of contact

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time