High-resolution specimen PET-CT imaging for the intraoperative visualization of resection margins: an exploratory study

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VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	High-resolution specimen PET-CT imaging for the intraoperative visualization of resection margins: an exploratory study
Version Date:	07/30/2025
PI:	Michael Topf, MD, MSCI

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Imaging will be exploratory and be used intraoperatively. There have been no discovered risks associated with the device to be used in this study, and none are anticipated given the diagnostic and non-invasive, 'ex vivo' nature of device use. Of note, the surgical resection will proceed as per standard of care and will not be affected by the research protocol.

Potential Benefit: Imaging intra-operatively will ensure surgeons to identify at risk resection margins.
Time Commitment: There are no additional visits that will be asked of you to partake in this study.
Drug is FDA approved and **Exposure to Radiation** is minimal.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because your doctor is planning to have a Standard of Care surgical procedure to remove your cancer.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a

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research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:
We do not expect any side effects from the ^{18}F-FDG as this is used for Standard of Care procedures and is already FDA-approved and you would receive 20% or 1/5 of the normal dose as you would for any Standard of Care scan.

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There are no risks for you as the participant with this device as it is utilized as a specimen scanner and not as a full body scanner. Therefore, once your tumor or cancer specimen is removed per your planned Standard of Care surgery, our researchers will image without impacting or delaying the planned surgery.

Radiation Risks:
You are agreeing to participate in a research project that involves the use of imaging procedures that expose you to radiation. This section will discuss the risks associated with the imaging procedures that are for research only. Your doctors may order additional imaging procedures as part of your normal patient care that also expose you to radiation. Those normal imaging procedures are not included in the risk discussion below. Please discuss those procedures and radiation risks with your doctors.

As part of this research study, you may be asked to participate in a specialized procedure that uses a specialized Positron Emission Tomography-CT (PET-CT) unit to image tumor samples that have been removed from your body. You will be injected with a radioactive substance that will be absorbed in the tumor(s) prior to removal. This procedure will expose you to radiation. The amount of radiation that you could receive from this procedure is approximately 10%, or about one tenth of the amount allowed annually for persons who are exposed to radiation as part of their work. Additionally, to protect your bladder from the effects of the injected radioactive substance, you should drink plenty of fluids and empty your bladder every two hours for at least the first six hours after you have completed the procedure. If you are unable to drink fluids after surgery, you will be on maintenance IV fluids after surgery per standard of care which will help you empty your bladder.

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Other Risks:
One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job; however, our research team will prevent this by coding or de-identifying your samples.

Only the limited study staff will know the code. The name that belongs to your code will be kept in a locked file or in a computer with a password. Only Dr. Michael Topf and his delegated team members will have access to your name.

Good effects that might result from this study:
The goal of cancer surgery is always to remove as much of or all of the tumor as possible. The Aura 10 scanner will scan the removed tissues for clear edges/negative margins. This means that the tumor has not grown beyond the surgical border. It is important the surgeon knows this while a patient is still in the operating room, so if need be, borders can be extended until no more tumor is found. Having clear edges or negative margins has important implications for patients, such as: potential for decrease in adjuvant therapy, decreased cost, improved quality of life, and most importantly improved overall survival.

Research Study Procedures to be followed:

	Screening (≤ 30 days Surgery)	Day of Surgery (Day 0)
Informed Consent	X	
Medical History	X	
Vital Signs	X	X
Height and Weight	X	
Performance Status	X	X
Glucose Status		X
Pregnancy Test (if applicable)	X	
^{18}F-FDG Tracer Injection		X
Tumor Imaging		X
Adverse Events		X
Concomitant Medications	X	X

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Payments for your time spent taking part in this study or expenses:
You will not receive any compensation for taking part in this study.

Costs to you if you take part in this study:
You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact the Research Coordinator, or the Principal Investigator, Dr. Michael Topf, at 615-936-9372.

If you cannot reach the research staff, please page the study doctor by calling 615-322-5000 and ask the operator to page him.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at 615-322-2918 or toll free at (866) 224-8273.

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Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Confidentiality:
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de identified information might be re identified.

Privacy:
Tissue Storage for Future Research
Research using human specimens is an important way to try to understand human disease. You have been given this information because the investigators will save your specimens for future research if they are available from your standard of care and as a standard procedure for the Head and Neck Biorepository. There are several things we would like you to be informed.

Your specimens and any data collected as part of this study will be stored in the Head and Neck Tissue Repository (IRB# 030062) at Vanderbilt University Medical Center (VUMC). Samples will be labeled with a study ID code number that does not personally identify you. The key linking the study ID code with your personal information will not be shared with researchers. Your samples may be sent outside of VUMC for research and analysis. Your de-identified data will be shared with the Sponsor/Collaborator, XEOS.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you. At any time, you may ask to have your sample destroyed. You should contact Dr. Michael Topf at 615-936-9372 or the research coordinator to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

Identifiers will be removed from identifiable private information and/or identifiable specimens, and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

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Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers, insurance providers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____