



Human Study Policy

Yale PET Core

1. PURPOSE

The purpose of this document is to outline policies and procedures related to initiating, scheduling, and completing a human imaging study within the Yale PET Core. Please carefully review the document to ensure your study is executed as smoothly as possible.

Please note that a PET “study” refers to all services provided in support of one interaction. A PET study will typically include a PET Scan and Radiosynthesis. Some studies may include additional services such as A-line placement, Blood Sampling, Metabolite Analysis, etc.

If you have questions about what services will be included in your study, please contact PET Core staff.

Up-to-date forms, contact information, and policies can be found on our website: <https://medicine.yale.edu/biomedical-imaging-institute/core-facilities/pet-core/>. For any questions, contact: pet.scheduling@yale.edu

2. INITIATING A NEW PET STUDY OR PROTOCOL

2.1. Getting Started

- To get started, we recommend consulting with a PET Core faculty member to discuss your research ideas to determine the potential impact of PET imaging on your unique research project and the feasibility of collaboration.
- Next, draft a research protocol using the PET guidelines found below for required protocol and consent language and follow our recommendations to facilitate the PET Core, MRRC, HIC, and RSC protocol review/approval processes.
- Please notify the PET Core of all major protocol amendments. These updates are required to ensure proper upkeep of our internal documentation as well as accurate reporting to regulatory agencies (e.g. FDA) and Yale oversight committees (e.g. HIC, RIDC/RDRC, and YU RSC). If imaging procedures are impacted, an additional kick-off meeting may be required prior to amendment implementation.
- Ensure that investigators and research staff complete the required HIPAA and MRRC training before the protocol start date.

2.2. Protocol Initiation Form

Prior to initiating/scheduling a new PET protocol you are required to complete a Protocol Initiation Form and submit to: pet.scheduling@yale.edu

2.3. Kick-Off Meeting

After submitting your Protocol Initiation Form, the PET Core will contact you to schedule a protocol kick-off meeting. The purpose of this meeting is to confirm all PET procedures, including verification of key staff involved, level of medical coverage required, and scheduling requirements. The PI is responsible for providing a study overview during this meeting.

3. SCHEDULING

3.1. Scan Requests

All scheduling requests and questions must go through pet.scheduling@yale.edu. This includes every scan request and change request.

At the time of scheduling, all studies will incur a \$100 scheduling charge. If you are reassigned a scan slot that was cancelled by another PI, you will not incur the \$100 scheduling charge.

Please do not call or send emails to individual PET Core staff, as this will result in delayed receipt and processing of the request.

Assigned scan dates cannot be delegated to another PI. The PET Core will reassign canceled slots based upon the current pending scan requests. When you cancel a scan slot, you may offer replacement recommendations, if you are aware of another PI seeking a slot.

If a subject is identified after a slot is cancelled, please contact pet.scheduling@yale.edu to re-schedule.

3.2. PET Scan Dates

Scan dates are provided approximately 4-6 weeks in advance. If you are unable to use a scheduled PET scan date, contact pet.scheduling@yale.edu to cancel and request a new scan date. This should be done as soon as possible to avoid cancellation fees.

3.3. Scan Availability calendar

Scan availability can be found on our [monthly calendars](#). Contact Samantha Massaro (samantha.massaro@yale.edu) for access.

3.4. Funding

The funding source for your study will dictate the price. Please be sure to provide the appropriate COA at the time of scheduling. PET Core staff should be notified if there is a change in COA.

For questions related to billing or fee structure, contact petcore.eadmin@yale.edu.

4. TIMELINE

- Preliminary arrival and injection times will be provided 14 calendar days in advance. Please be aware these times are subject to change.
- Final arrival and injection times will be provided 7 calendar days in advance.
- For outside/purchased doses (e.g. [^{18}F]FDG), times are provided 30 days in advance.

Please note that times may change on the day of your study, due to unforeseen circumstances. We recommend that subject availability is confirmed for the full study day (~7am-5pm), to ensure studies may proceed in the event of delays. (see section 7.3 for more details on delayed studies)

5. SUBJECT INFORMATION

- Subject information must be provided to the PET Core no later than 3 business days prior to the scheduled scan.
- If subject information is not received by this deadline, a \$100 fee will be charged.
- Failure to provide subject information, or failure to respond to requests for information, may result in the study being canceled. In this situation, a late cancellation fee will be applied.

6. CHANGE REQUESTS

6.1. Radiotracer Change Requests

All radiotracer change requests must be received no later than 8 business days before the scheduled scan.

Changes received after this deadline, which are still able to be accommodated, will incur a tracer conversion fee of \$500.

For outside/purchased doses (e.g. [^{18}F]FDG), change requests must be received within 3 business days. Change requests that are received/implemented after this time will incur a tracer conversion fee of \$500.

6.2. Procedures Change Requests

Requests to add a procedure (e.g. add drug dosing, arterial line, medical coverage, or increase scan length) must be received no later than 4 business days before the scheduled scan, to ensure adequate staff coverage.

Changes received after this deadline that are still able to be accommodated will incur a procedure change fee of \$125.

6.3. Subject Change Requests

Subject changes must be made no later than 12PM 1 business day before the scheduled study.

If a change request is received after 12PM for scans occurring the next day, the PET Core may cancel your scan slot, and a late cancellation fee will be applied.

For studies that are scheduled on a Monday, changes will need to be made no later than 12PM Friday. This also applies to holidays; please consider official Yale holidays when planning your studies.

Participant changes cannot be completed on the day of the study.

Please note that late change requests require additional time/resources to confirm feasibility, adequate staff, and updated files. The PET Core aims to accommodate requests wherever possible.

7. CANCELLATION POLICY

7.1. Cancellations

The following fee structure will be used for cancelled studies:

- **No cancellation fee:** scans canceled ≥ 14 calendar days prior to the scheduled scan date. Please note that scans cancelled 14 calendar days prior to the scheduled study date will still incur a \$100 scheduling charge.
- **Early cancellation fee** (8% of the cost of the scheduled study): scans canceled between **13 and 8** calendar days prior to the scheduled scan date.
- **Late cancellation fee** (20% of the cost of the scheduled study): scans canceled **between 7 and 3** calendar days prior to the scheduled scan date.

- **A study canceled 2 business days or less prior to the scheduled scan date will incur 50% of the cost of the study.** *Please note that in certain situations, 3 calendar days may be less than 2 business days (i.e., holidays, recess, etc.); in this situation, the 2 business day cancellation charges are applicable.*
- **Day of study cancellation** studies cancelled on the same day as the scheduled study date may incur additional expenses related to products that were already produced prior to cancellation (e.g., radiosynthesis). Same day cancellations should be avoided.

7.2. Fee Waivers/Reductions

Cancellation charges may be waived or reduced under certain circumstances. Requests for a fee modification must be sent to pet.scheduling@yale.edu. Please include the study name, date, and cancellation reason. Requests will be approved at the discretion of the PET Core.

7.3. Delayed Scans

Due to chemistry, pharmacy, or other operational delays, the PET Core may need to adjust the injection time on the day of the study.

- If the delay is less than 2 hours and the subject declines the scan, a late cancellation fee will be charged.
- If the delay exceeds 2 hours, and the subject declines the scan, no cancellation fees will be charged.

Please ensure subjects are informed that delays are possible and they may be asked to remain at the PET Core longer than initially estimated.

7.4. Rescheduled Scans

In certain situations, the PET Core may need to reschedule your scan. In these instances, vulnerable or sensitive populations may supersede scans such as healthy controls. The PET Core will make every effort to avoid delayed or rescheduled studies.

8. PROCEDURES FOR DAY OF STUDY

8.1. Coordinator Coverage

All subjects must be accompanied to the PET Core imaging floor by a study coordinator.

The coordinator must stay onsite until the research subject has been injected with radiotracer.

Once scanning has begun, the coordinator may leave the area, however they need to be reachable in case of urgent issues. Coordinators are required to verify their contact

information is on file and return 15 minutes prior to the end of the PET scan, in order be onsite for subject discharge.

For certain vulnerable populations, a coordinator may be required to stay onsite throughout the scan day.

8.2. PET Core Access

All study personnel must leave with their subject at discharge. This is the end of the scan day and concludes access to the PET Core. Additional time/space is only permitted if required to comply with the protocol procedures and if approved in advance.

8.3. Physical Exam and/or EKG

If a recent physical exam or EKG is not available and cannot be obtained prior to the day of the study, please contact the PET Core to schedule these procedures. The cost for these additional procedures are \$250 for the physical exam and \$100 for the EKG.

8.4. Early Arrivals

Research subjects and non-PET Core research staff are not permitted to be on the imaging floor without PET Core medical personnel. If you arrive early, do not attempt to enter the imaging floor. You and your participant must wait to be checked-in by nursing staff or other medical personnel.

8.5. Late Arrivals

If your subject is running behind schedule, please contact the PET Core Nursing team at: (203) 491-8438

9. CONTACT INFORMATION

- To schedule or make changes to a scheduled study, contact: pet.scheduling@yale.edu. Please contact pet.scheduling@yale.edu for any other questions related to your study.
- For questions related to radiotracer usage, development, or validation, contact: marc.normandin@yale.edu, nabeel.nabulsi@yale.edu, henry.huang@yale.edu, jason.cai@yale.edu, or ming-qiang.zheng@yale.edu.
- For questions related PET IRB submissions, contact: shannan.henry@yale.edu.
- For questions related to clinical services, contact: david.matuskey@yale.edu, takuya.toyonaga@yale.edu, or maria.ceneri@yale.edu. On the day of scans, you can contact the nursing team at: (203) 491-8438