

YALE UNIVERSITY PET INVESTIGATORS GUIDE

Addendum

Yale PET Center Forms, Guidelines and Instructions

Yale University PET Center Protocol Initiation Form
Yale University PET Center Subject Information Form
Guidelines for PET Center Research Subjects on Scan Days
PET Center Guidelines for Research Assistants
Radiation Safety Training Scheduling Procedures
Yale University PET Center Subject Discharge Instructions
Yale University PET Data Repository Request for Healthy Control PET Data

Note: The forms and guidelines listed above are found on the following pages of this document and on <https://medicine.yale.edu/pet/informationforinvestigators/>

Yale University PET Center Protocol Initiation Form

PI: _____

Email: _____

Phone: _____

Protocol Title: _____

Protocol Short Name (generated in PET Center): _____

HIC#: _____ IACUC#: _____

RA: _____ Phone: _____

Email: _____

Other

Personnel: _____ Email: _____

_____ Email: _____

Scheduler: _____ Phone: _____

Email: _____

Will medical / nursing / vet staff be provided by PI? If yes, please provide:

Name: _____

Phone _____ Email: _____

Number of subjects projected to be scanned: _____

Expected scanning start date: _____ Expected scanning end date: _____

Scanner to be used:

HRRT (Hi Resolution Brain Scanner)

HR+ (Brain or Whole Body)

mCT (Brain or Whole Body with Hi Resolution CT)

Focus-220 (Animal Scanner for Primate or Rodents)

mCT or HR+ (No Preference)

HRRT or HR+ (No Preference)

Any Human Scanner will suffice

PET Center decides

Tracer Name: _____

Yale University PET Center Protocol Initiation Form

Tracer Source:

Made by Yale PET Center

Purchased/delivered by outside source Source: _____

Contact Name: _____ Phone Number: _____

Dose delivery time window:

Metabolites Arterial line PK Samples

Pharmacologic Compound (i.e. cold non-radioactive drug), if applicable:

Number of scans per subject and any time/day restriction, if required, examples:

- 2 scans, 7 days apart, with both injections before 12 PM
- 2 injections on one day with break of at least 90 min between scans

COA and contact info for person responsible for billing [name, email and phone]:

COA Expiration Date: _____

Split Charges between 2 accounts

Second PTAE0 number: _____ Expires: _____

Billing Notes:

PET Center issuing subject payments? Yes No

COA for subject payments: _____ Expires: _____

These items must be on file at the PET Center before scan scheduling is allowed to begin:

- Y-NHH Radiation Safety Committee approval letter (human studies) and, if applicable, FDA 2915 Form for human studies with > 31 subjects)
- Yale University RSC approval letter
- Electronic copy of approved protocol
- Electronic copy of approved consents (human studies)
- HIC (IRB) Approval Letter

Funding Agency: _____

Funding Mechanism: _____

Yale University PET Center Subject Information Form

(Pg. 1)

Protocol Code: _____ HIC#: _____

PI: _____

PI Immediate Contact Phone Number¹: _____

PET Scan Date: _____ Subject Arrival Time: _____
Subject Injection Time: _____

Subject Legal Last Name (print): _____

Subject Legal First Name (print): _____

MRI TR#: _____ Scanset Number: _____

DOB: _____ Ethnicity²: _____

Subject Age at PET Scan Date _____ Known Allergies _____

Gender: Male ___ Female ___ Subject Study ID: _____

Primary Dx: _____ Secondary Dx [if any]: _____

Height: _____ meters Weight: _____ kg

Covering MD (If applicable; if not, please put N/A) _____

Subject Contact Phone Number: _____

Research Staff Accompanying Subject: _____

Please include pertinent medical labs or history and progress notes

PET Center to consent with Yale form on day of PET scan? Y___ N___

Vegetarian Lunch: Y___ N___

Subject Travel Arrangements: _____



Yale University PET Center Subject Information Form

(Pg. 2)

IMPORTANT: For the last scan of the day, a research staff member must be present a minimum of 15 minutes before the scheduled end of scan until the subject leaves the PET Center.

Subject may be required to be at the PET Center for a few hours longer than the planned scanning session, should there be delays due to issues with radiotracer production, arterial line insertion, or PET scanning equipment.

Send to PET.scheduling@yale.edu or fax to 203.785.2170, along with a valid, signed consent, a minimum of **3 business days before the scan is scheduled** or you risk cancellation.

¹Will only be used if absolutely necessary while subject is on-site at the PET Center.

²American Indian or Alaskan, Asian, Black (Not of Hispanic Origin), Hispanic or Latino, White (Not of Hispanic Origin), Native Hawaiian or Other Pacific Islander, Other / Unknown

Guidelines for PET Center Research Subjects on Scan Days

Please Advise Subject To:

- Not wear clothing with hoods as this interferes with setup.
- Remove jewelry and body piercings prior to scan day.
- Refrain from wearing tight fitting clothing (short sleeves are best). Warm, comfortable and loose fitting clothing is advised.
- Carry only the minimum amount of cash they will need (e.g. transportation costs).
- For PET scans that will require arterial lines, please reiterate to the subject that they are to abstain from physical exercise 24-48 hrs after scan day.
 - Advise the subject to drink at least 2-3 glasses of water the night prior to and after their PET scan.
- If a urine sample is required on scan day, please instruct the subject that they will need to provide urine first thing upon their arrival.
 - All females of child-bearing potential will need to provide a urine sample for a pregnancy test.
- If an ECG(s) will be performed, please instruct the subject to refrain from wearing lotions as this may interfere with adhering the cardiac leads.
- A DVD player is available for entertainment during down time. Please inform subjects that they may bring any DVD's, books, etc. for use during down time.
 - The PET Center is not, however, personally responsible for any lost items.

Please inform subjects that there is a possibility that scan days could lengthen, should any equipment failure occur

IMPORTANT:

***If your subject is running behind schedule, please contact the PET Center Nursing Staff at: (203) 491-8438.**

***We will notify you of any cancellations or major delays. Please provide us with a contact number for status updates.**

PET Center Guidelines for Research Assistants

- All study specific medications that will need to be administered (or will potentially need to be administered) to a subject should be given to a Research Nurse to keep locked up in the medication box until time of administration (examples include cold non-radioactive drugs, and/or antidotes such as valium).
- For pharmacologic studies (those using cold non-radioactive drug in addition to radiotracer), RAs must also provide subject medical records on day of scan (including laboratory and EKG results).
- Any study medication planned for administration under the protocol, or medication given to a subject for symptoms such as a headache, sore wrist, anxiety, etc., must be ordered by a medically responsible PI or Medical Director and administered by a nurse or physician.
- It is important to be familiar with the telephone paging system in the event that you are in a room with a subject who is in distress. Each PET Center room has a phone and a blue card taped above the phone with paging instructions and room numbers.
- Please be sure to tell your subjects, *not* to void when they arrive at the PET Center waiting room. It is very important that we get a urine specimen prior to arterial lines and IV's.
- Please use the clipboard in room 206 to sign in and out and leave a cell phone # in the event we need to contact you.
- Research Assistants who need Radiation Safety Training must contact June Tamkin-Price (june.tamkin-price@yale.edu) to schedule a training session.

Radiation Safety Training Scheduling Procedures

- Supervisor (or designee) will send an email to June Tamkin-Price (june.tamkin-price@yale.edu) identifying staff who will require PET-specific Radiation Safety Training. Staff member requiring training will also be cc'd on email.

Email will include:

Protocol short name/ HIC number

Staff member's name/ title/ departmental affiliation/ facility/ direct supervisor

Staff member's responsibilities (relative to the PET Center)

Training completion "due-by" date

- The trainer and trainee will be encouraged to communicate meeting times and location directly to each other, cc'ing the Supervisor (or designee).
- Additionally, cancellations and rescheduling must also be made directly between the trainer and the trainee, cc'ing the Supervisor (or designee).
- Dosimeters issued are required to be kept onsite at the PET Center, in a previously designated area. When possible, please let us know when the dosimeter badge is no longer needed so that it can be discontinued.
- A digital copy of training records will be kept on the Yale University PET Center website at Radiation Safety / PET-specific Radiation Safety Training / staff training
- This procedure will enable timely staff training and allow access to the PET Center



Subject ID: _____

Date: _____

Discharge Instructions

This form provides you with post scan instructions. Please do not hesitate to call one of the physicians listed below for any questions. Please take this form with you in case you need further care.

Nuclear medicine discharge instructions:

1. You received a nuclear medicine injection today and there is a very slight possibility that you could activate a radiation device. Please remember that you were given a blue, "security and law enforcement notification card," to present in the event it is needed.
2. You had an intravenous catheter(s) inserted into your R/L forearm vein; R/L hand vein; other_____. You may remove the band aid from the site in the morning. Please be advised that a small amount of bruising is normal. However, if you experience any swelling, redness or pain at the site, you should notify one of the physicians listed below.
3. You had blood drawn for today's study. Please drink plenty of fluids to help restore blood volume and prevent lightheadedness. Extra fluid aides in removing the radioisotope as well. Therefore please empty your bladder as frequently as possible.
4. You did/did not have a study medication. If you received medication, it is listed here: _____. Please notify the physicians listed below if you notice any of the symptoms listed on your consent form, such as: nausea, vomiting, lightheadedness, fainting, racing heart, headache, etc.

Arterial line discharge instructions: You had your R/L artery accessed, therefore please follow these instructions:

1. No bending affected arm or wrist for 4hr.
2. Refrain from strenuous exercise, reaching, or lifting heavy objects (no more than 5 lbs,) for 48 hours.
3. Refrain from repetitive movements in the affected wrist for 48 hr.
4. Keep elastic wrap in place until bedtime and then remove. Check site, and call the MD's listed below if there are any issues such as, pain, bleeding, swelling, numbness, tingling, and change in color or temperature.
5. Keep transparent, (clear) dressing clean and dry for 48hr, (wrap in plastic bag for showering or hold arm outside of shower.)
6. You may remove the transparent dressing in 48hr, but do not submerge wrist in water (no dishwashing, bathtub nor swimming,) for another 24hours.

IMPORTANT

If you experience any unusual bleeding or swelling at the site of the arterial line, you should:

- **Immediately apply continuous pressure at the site with your fingertips and a clean towel and/or go directly to an urgent center or emergency room and bring these instructions with you.**
- **Call: Dr. David Matuskey at 203-370-1403 (pager) or Dr. Ming-Kai Chen 203-766-4241 (pager)**
You will need to punch in your tel. number with area code followed by the, "#," sign.

Signature of research subject: _____

Signature of PET Center nurse or MD: _____

Please Note: Discharge instructions must be reviewed with subject, and subject must verbalize understanding prior to signing.
 A Signed copy to must be placed in subject folder.



**YALE UNIVERSITY PET CENTER DATA REPOSITORY
REQUEST FOR HEALTHY CONTROL PET DATA**



Date: _____

Investigator Name: _____

Department/ Academic Appointment: _____

Phone Number: _____ **Email Address:** _____

Purpose of Data Request/Research Objective:

Specify How Data will be Utilized: (e.g. Poster, Abstract, Publication, Grant application, etc)

Healthy Control PET Data Requested:(please provide/circle the following information needed)

Radiotracer Name(s): _____

Tracer Administration Information: (e.g., radiation dose, specific activity, purity)

Scanning Parameters: (time of injection, length of scan (min), date(s) when scan(s) were performed)

Arterial Line Blood Data: (e.g. metabolite correction plasma curve, whole blood total radioactivity curve, plasma free fraction, etc.)

Please Circle Data Needed:
Type of injection (infusion; bolus)
Scanner (HR+, HRRT, PET/CT, m/CT, MR)
Type of Image Data (raw PET data, DICOM reconstructed images, parametric images, calculated regional values)
Demographics (age, gender, race, height, weight, education level) _____

Neuropsychiatric Measures: (e.g., CogState, Barrett's impulsivity measures, Neo Inventory)

Other Considerations:



**YALE UNIVERSITY PET CENTER DATA REPOSITORY
REQUEST FOR HEALTHY CONTROL PET DATA**



I agree that the information I have requested will only be used for the research purpose stated in this Request Form and its accompanying documentation. I agree that I will use only the information necessary for the research purpose described. I will protect the confidentiality and security of this information while it is in my possession.

_____ **Date:** _____

Signature of Investigator Requesting PET Data
