1.0 PURPOSE

To outline the procedure for image acquisition and processing of PET scans for ACRIN protocols that include PET and/or PET/CT scans.

2.0 SCOPE

This procedure applies to all PET and PET/CT patient scans performed for ACRIN protocols, unless otherwise mandated in a specific ACRIN protocol, in which case the protocol-specific procedure must be followed.

3.0 DEFINITIONS

None

4.0 RESPONSIBILITIES

4.1 The principal investigator at each specific site is responsible for ensuring that personnel are trained and familiar with this procedure.

4.1.1 The principal investigator may delegate responsibility for some or all components of this standard operating procedure (SOP) to an imaging specialist/co-investigator at the site working in close collaboration with the imaging core laboratory. Ultimately, the principal investigator is responsible for adherence to this SOP and/or to protocol-specific requirements.

4.2 The technologist performing the scan is responsible for ensuring that all technical details outlined in this SOP are followed and documented appropriately.

4.3 The research coordinator is responsible for communicating to the technologist any protocol-specific variations from normal clinical acquisition and processing parameters.

5.0 MATERIALS

5.1 Protocol-specific ACRIN PET Technical Assessment Form (SOP 922.01, “Patient preparation and FDG administration procedure for ACRIN FDG scans”, Attachment 8.1).

6.0 PROCEDURE

6.1 Instrumentation Readiness.

6.1.1 Patient scans must be conducted on scanners that have been qualified by the ACRIN PET Core Laboratory per the instructions posted on the ACRIN Web site at: www.acrin.org/corelabs/pet.

6.1.2 For serial scans of the same patient, every attempt should be made to use the same scanner, or the same scanner model. Where two or more
scanners of the same model are to be used interchangeably. The ACRIN PET Core Laboratory must qualify these devices as equivalent.

6.1.3 The PET scanner must be kept calibrated in accordance with the manufacturer's recommendations, and the date of the latest verification of its quantitative accuracy must be recorded on the PET Technical Assessment Form (SOP 922.01, Attachment 8.1).

6.1.4 PET scanners should routinely be assessed for quantitative integrity and stability by being tested using various imaging protocols on a standard phantom. For SUV measurements, this assessment should include a comparison against a dose calibrator to ensure accuracy; that is, a comparison of the absolute activity measured, versus the measured activity injected, should be performed. This comparison is particularly important after software or hardware upgrades. Hardware and software changes should be reported to the imaging core laboratory, which will determine whether requalification of the scanner is necessary.

6.1.5 A daily QC check must be performed at the beginning of each day of scanner use in accordance with manufacturer recommendations. If any of the QC results are outside of the manufacturer's guidelines, the study must be rescheduled and the problem rectified before scanning any patients.

6.1.5.1 Documentation that daily scanner QC was performed on the date of the PET study must be entered on the protocol-specific PET Technical Assessment Form (SOP 922.01, Attachment 8.1).

6.2 Patient preparation and FDG administration

6.2.1 Patient preparation and dose administration is to be performed in accordance with SOP 922.01, “Patient preparation and FDG administration procedure for ACRIN FDG scans”, and any protocol-specific directives.

6.3 Determination of uptake period

Note: The FDG uptake period must be as tightly controlled as possible, especially when serial studies of the same patient will be compared.

6.3.1 If the patient has had a previous scan, the uptake period of the prior scan should be matched as closely as possible, if it complied with the uptake period specified in the protocol.

6.3.1.1 If the uptake period of the prior scan deviated from the protocol, then the post-injection procedures from SOP 922.01, “Patient preparation and FDG administration procedure for ACRIN FDG scans” should be followed.

6.4 Patient positioning

6.4.1 Unless a urinary catheter is in place, the patient must be encouraged to empty his/her bladder immediately prior to the scan, and whether or not he/she does so must be noted on PET Technical Assessment Form (SOP 922.01, Attachment 8.1).
6.4.2 Patients undergoing a CT scan should empty their pockets and remove any clothing containing metal and any metallic jewelry from the body parts to be scanned, changing into a hospital gown if necessary.

6.4.3 Patients undergoing a CT scan should be asked about the presence of implanted electronic devices (e.g., pacemakers, neural stimulators, cochlear implants). Additionally, the preliminary topogram should be inspected for the presence of such devices. If such devices are present and are to be within the CT scanning field, institutional procedures should be followed to minimize the risk of CT-induced device malfunction.

6.4.4 Patients must be positioned carefully in the center of the field of view (FOV) to prevent truncation artifacts. Support devices under the back and/or legs are encouraged to enable the patient to comfortably maintain his/her position throughout the scan.

6.4.5 Whole-body PET acquisition should be performed with the patient in the supine position with arms above the head (unless otherwise specified in protocol). Patients unable to maintain arms above the head should be handled according to protocol, and may be ineligible to participate in some protocols.

6.4.5.1 Arm positioning in a particular patient should be consistent for baseline and follow-up scans.

6.4.6 Prior to starting the acquisition the patient must be coached in the breathing protocol if one is used.

6.5 Acquisition

6.5.1 All patient demographics must be accurately entered into the acquisition interface, particularly:

6.5.1.1 The patient’s measured height and weight

6.5.1.2 The net injected dose (or equivalent, i.e., full syringe activity and residual syringe activity)

6.5.1.3 The time that the dose was assayed

6.5.1.4 The time of injection

6.5.1.4.1 If the acquisition interface has only one place to enter a time related to the dose, then the time of dose assay must be entered, not the time of injection.

6.5.2 In general, manufacturer recommendations for scanning parameters must be followed unless protocol directs otherwise. Any deviations from protocol specifications must be approved by the study chair,

6.5.2.1 For PET/CT scanners, the acquisition parameters for the CT data used for attenuation correction can vary widely, and protocol-specific parameters must be followed. Whether or not oral or intravenous contrast agents were used must be recorded on the protocol-specific PET Technical Assessment Form (SOP 922.01, Attachment 8.1).
6.5.2.2 For serial scans of the same patient, it is critical for the target lesion or lesions to be imaged with the same delay time after injection of the tracer. Therefore, all subsequent acquisition sequences must be as close as possible to those used on the baseline scan, including identical CT technique or transmission scan technique (as applicable), emission scan duration per bed position, patient orientation, start position on the patient, and gantry travel direction.

6.5.3 Whole-body PET scans should extend from the external auditory meatus to the mid-thigh region, unless the protocol specifies otherwise.

6.5.4 The following acquisition parameters must be recorded on the PET Technical Assessment Form (SOP 922.01, Attachment 8.1):

6.5.4.1 The number of bed positions
6.5.4.2 Make and model of the scanner
6.5.4.3 Start and end times of emission scan
6.5.4.4 Type of transmission scan
6.5.4.5 Any additional parameters required on the protocol-specific PET Technical Assessment Form (SOP 922.01, Attachment 8.1).

6.5.5 The patient must be monitored periodically during the scan and coached to remain motionless, if necessary.

6.5.6 If CT is to be performed with intravenous contrast material administration, it generally should be conducted after the PET scan, with the patient in the same anatomic position as during the PET scan. Protocol-specific instructions regarding performance of contrast-enhanced CT as part of the PET/CT procedure must be followed.

6.6 Post-scan procedures

6.6.1 Remove patient’s IV catheter.

6.6.2 After the scan, the patient must be asked to void again and whether or not he/she does so must be noted on PET Technical Assessment Form (SOP 922.01, Attachment 8.1).

6.6.3 The patient must be counseled on the importance of continuing to drink fluids for several hours after the scan. This will increase urine flow rate, which will help to minimize the radiation dose to the bladder wall.

6.7 Image processing and quality check

6.7.1 Before releasing the patient, the technologist should review an initial reconstruction of the PET data to ensure that:

6.7.1.1 The proper body regions were included in the scan
6.7.1.2 There are no obvious motion artifacts or other problems
6.7.1.3 The administered activity, injection time, patient weight have been entered correctly, as reflected in the DICOM header.
6.7.1.4 If problems are noted, the protocol-specific procedure must be followed, which may include re-scanning the patient.

6.7.2 Images must be reconstructed with and without attenuation correction. The slice thickness and pixel size of the images must be recorded on the PET Technical Assessment Form (SOP 922.01, Attachment 8.1) and should comply with protocol specifications.

6.7.3 For serial scans of the same patient, image reconstruction techniques and parameters must be consistent across all scans, including filters and application of the attenuation map.

6.8 When images are fully processed with all manufacturer-available corrections (commonly including attenuation correction, scatter correction, decay correction, and randoms correction), the technologist should inform the physician that the images are ready for review.

6.9 The technologist must ensure that all questions on the protocol-specific PET Technical Assessment Form (SOP 922.01, Attachment 8.1) have been answered, then sign and date the form.

6.9.1 The site-specific procedure for transmitting the PET Technical Assessment Form (SOP 922.01, Attachment 8.1) or the data from the form to ACRIN must be followed.

6.9.2 If data from the form is sent to ACRIN via the Web interface, then the person entering the data must sign and date the Local Interpretation Form.

6.10 The completed forms must be handled according to the site-specific procedure, and a copy placed in the site’s regulatory binder.

6.11 Removal of Confidential Participant Information: The header record on DICOM formatted image data, which often contains information identifying the participant by name, MUST be scrubbed before the images are transferred.

ACCEPTANCE CRITERIA

None

7.0 REFERENCES

7.1 SOP 922.01, “Patient preparation and FDG administration procedure for ACRIN FDG scans”.


8.0 ATTACHMENTS

8.1 ACRIN PET Technical Assessment Form
### Exam Data

1. **Clinical trial time point**
   - Select the time points.

2. **Imaging Agent Name**
   - Select FDG.

3. **Was imaging exam completed?**
   - Select Yes.

   - If imaging not completed, provide reason:
     - Scheduling problem
     - Claustrophobia
     - Participant death
     - Equipment failure
     - Participant withdrew consent
     - Progressive disease
     - Participant refusal
     - Unknown

4. **Date of imaging**: (mm-dd-yyyy)

5. **Weight**: ____________ kg

6. **Height**: ____________ cm

### Patient Preparation

1. **Duration of fasting pre-imaging**
   - ____________ hours (up to time of injection)

2. **Blood glucose before injection of FDG**
   - ____________ mg/dl

3. **Was Foley catheter in place for study?**
   - Select Yes.

4. **Patient voided immediately pre-imaging?**
   - Select Yes.

5. **Patient voided immediately post-imaging?**
   - Select Yes.
# ACRIN 66--
# FDG - PET/CT
# PET/CT Local Technical Assessment Form

## Imaging Agent: FDG

*If this is a revised or corrected form, please check box.*

## Scanner

1. **Check to confirm scanner is the same scanner used for all previous protocol scans for this participant**
   - If 1st scan, check to confirm scanner will be used for future protocol scans for this participant

2. **Has the scanner used for this study been qualified by ACRIN?**
   - No, specify reason (complete Q3):
   - Yes, provide ACRIN Scanner ID# (skip to Q4):

3. **Scanner used for this exam:**
   - Manufacturer
   - Manufacturer model name/or number

4. **Date of last PET Scanner SUV validation:**
   - _mm-dd-yyyy_

## CT Image Acquisition or Transmission Scan

1. **Type of attenuation correction used?**
   - CT (complete Q2 thru 6)
   - Ge-68 Segmentation (complete Q7)
   - Cs-137 Segmentation

2. **Was oral contrast administered?**
   - No (skip to Q3)
   - Yes, if used specify type: Positive Negative

3. **Was IV contrast administered?**
   - No (skip to Q4)
   - Yes

4. **kVp**
   - ____________/Unknown

5. **mAs**
   - ____________/Unknown

6. **Slice Thickness of reconstructed images**
   - ____________/Unknown

7. **Length of Transmission Scan:**
   - ____________/Unknown
**Imaging Agent:** FDG

If this is a revised or corrected form, please ✓ box.  

<table>
<thead>
<tr>
<th>PET Emission Scan</th>
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<tbody>
<tr>
<td><strong>1. Acquisition mode</strong></td>
<td>o 2D</td>
<td>o 3D</td>
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<tr>
<td><strong>2. Number of bed positions scanned</strong></td>
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<tr>
<td>PET Emission Scan:</td>
<td><strong>Start Time</strong> (military time)</td>
<td><strong>Stop Time</strong> (military time)</td>
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<tr>
<td>3a.</td>
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<td>3b.</td>
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<td>Reconstructed Images:</td>
<td><strong>4. Pixel Size:</strong></td>
<td><strong>5. Thickness:</strong></td>
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**Adverse Events**

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<tbody>
<tr>
<td><strong>1. Any adverse events related to imaging to report for this timepoint?</strong></td>
<td>o No (initial and date form) o Yes (Submit AE form)</td>
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<tr>
<td><strong>2. Does this event meet the criteria of a serious adverse event?</strong></td>
<td>o No o Yes</td>
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Initials of person completing this form  

Date form completed (mm-dd-yyyy)