

1.0 PURPOSE

To outline the procedure for patient preparation and for ¹⁸F-Fluorodeoxyglucose (FDG) administration for FDG-PET performed for ACRIN protocols.

2.0 SCOPE

This procedure applies to all FDG-PET 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.
- 4.2 The technologist performing the FDG-PET 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 pre-screening patients for eligibility and suitability for study participation, and for ensuring that patients are informed what procedures to follow prior to their arrival for the scan.

5.0 MATERIALS

- 5.1 FDG procured in compliance with ACRIN SOP 920.01 in single-use or multi-dose vial
- 5.2 Syringe, 3 mL or 5 mL
- 5.3 Needle, 21 gauge or larger
- 5.4 IV catheter, 21 gauge or larger
- 5.5 PET syringe shield
- 5.6 Saline and syringe for flushing IV line

- 5.7 Dose calibrator
- 5.8 Blood glucose meter (if blood glucose measurement is performed by PET facility staff on site)
- 5.9 Scale for measurement of patient weight and height

- 5.10 Materials necessary for sterile administration of tracer (e.g., alcohol swab, gauze pad, transpore tape, gloves)
- 5.11 Oral, non-caloric gastrointestinal contrast agent (as appropriate)
- 5.12 Intravenous iodinated contrast agent (as appropriate)
- 5.13 Protocol-specific ACRIIN PET Technical Assessment Form (Attachment 9.1)

6.0 PROCEDURE

Note: The major goals of preparation are to minimize tracer uptake in normal tissues, such as the myocardium and skeletal muscle, while maintaining uptake in target tissues (neoplastic disease).

6.1 Procedures to be followed prior to the patient's arrival for FDG-PET study.

- 6.1.1 Patients must be instructed to avoid strenuous exercise for 24 h before the FDG-PET study to minimize uptake of the radiotracer in muscles.
- 6.1.2 It is recommended that patients be instructed to restrict carbohydrate consumption for 24 h before the study.
- 6.1.3 Patients must be instructed to fast and not to consume beverages, except for water, for at least 4 h before the administration of FDG to decrease physiologic glucose levels and to reduce serum insulin levels to near basal levels. In general, patients should not eat anything after midnight if a study is planned for the following morning. For FDG-PET studies performed in the afternoon, a light breakfast with minimal carbohydrate content is acceptable. However, patients should fast for at least 4 h after finishing that meal.
 - 6.1.3.1 Diabetic patients should be scanned early in the morning before the first meal, and doses of insulin and/or hypoglycemic medication should be titrated appropriately in consultation with the patient's referring physician.
 - 6.1.3.2 Before scheduling an FDG-PET study, diabetic patients should test their ability to maintain reasonable plasma glucose levels after fasting, while avoiding insulin close to the time that FDG would be administered.
- 6.1.4 Intravenous fluids containing dextrose or parenteral feedings also must be withheld for 4–6 h.
- 6.1.5 While fasting, patients should consume at least two to three 8-12-oz glasses of water to ensure adequate hydration.
- 6.1.6 When intravenous contrast material is to be used, patients must be screened for a history of adverse reactions to iodinated contrast agents, use of metformin for the treatment of diabetes mellitus, and renal disease.
 - 6.1.6.1 Intravenous contrast material must not be administered when the serum creatinine level is above 2.0 mg/dL. A lower cut-off threshold, in accordance with institutional procedures, is acceptable. The investigator may authorize administration of

contrast material to a patient with known chronic renal failure on dialysis, with serum creatinine in excess of 2.0 mg/dL.

6.1.6.2 If steroid premedication is given to a patient with a history of contrast reaction, this must be documented in the medical record and on the study-specific case report form (if applicable).

6.1.7 Patients also must be screened for a history of claustrophobia and for the ability to lie still for the duration of the acquisition (typically 20-60 minutes depending on the type of scanner).

6.2 Procedures to be followed upon patient's arrival for FDG-PET study.

6.2.1 Procedures for women of child-bearing potential:

6.2.1.1 Site-specific policies regarding pregnancy and breast feeding must be followed.

6.2.1.2 Protocol-specific eligibility criteria for pregnant and breast feeding women must be followed.

6.3 Procedures prior to radiotracer injection.

6.3.1 The procedure must be explained to the patient and any questions the patient has about the procedure must be answered.

6.3.2 Obtain patient information

6.3.2.1 Patient's height and weight must be measured (not verbally relayed by the patient) and recorded on the PET Technical Assessment Form (Attachment 9.1).

6.3.2.2 Duration of patient fasting must be recorded on the PET Technical Assessment Form (Attachment 9.1).

Note: Tumor uptake of FDG is reduced in hyperglycemic states. Most institutions reschedule the patient if the blood glucose level is greater than 150–200 mg/dL.

6.3.3 The blood glucose level must be checked before FDG administration to ensure it is below the protocol-specified limit. Patients whose serum glucose concentration exceeds the limit should be rescheduled, and adjustments to diet and medications made if necessary, so that the fasting blood glucose concentration can be brought down to the acceptable range at the time of FDG injection.

6.3.4 The blood glucose level must be recorded on the PET Technical Assessment Form (Attachment 9.1). If applicable, quality control of the blood glucose meter must be performed according to the manufacturer's or institution's procedure to ensure proper functioning.

6.3.5 Depending on the type of study performed and the area of clinical concern, a urinary (e.g., Foley) catheter may be required in some cases to ensure adequate visualization of pelvic structures. If the patient is to be catheterized for the imaging study, the bladder catheter should be placed before the FDG injection. In other instances (or in addition to Foley catheter placement), for specific imaging of the pelvis or kidney region, intravenous administration of a diuretic, such as furosemide, 20–40 mg, may be required. For this purpose, furosemide is injected at the same time

as FDG, to allow time for the drug to clear the FDG from the renal collecting system and for patients to void before being placed on the scanner. If there are no medical contraindications, patients requiring clearance of the urinary background activity should receive 250–500 mL of intravenous 0.9% or 0.45% saline solution (not dextrose-containing solutions) during the FDG uptake period to ensure adequate hydration.

6.4 Procedures for radiotracer injection.

- 6.4.1 Prior to injection of FDG, patients should be asked to urinate to minimize the possibility that they will need to move during the FDG uptake phase.
- 6.4.2 Injection methodology may vary and site should follow site-specific standard of care. However, the ACRIN PET Core Laboratory recommends that:
 - 6.4.2.1 A large-bore intravenous catheter (21 gauge or larger) be placed in an arm or hand vein contralateral to any known site of disease for injection of the FDG.
 - 6.4.2.2 The catheter be flushed post-injection of FDG with 0.9% saline solution.
- 6.4.3 Location of injection site must be recorded on the PET Technical Assessment Form (Attachment 9.1).
- 6.4.4 For FDG in multidose vials, aseptic procedures must be followed according to good pharmaceutical practices and standard of patient care. A sterilization syringe filter may also be used.
- 6.4.5 The source of the FDG must be recorded on the PET Technical Assessment Form (Attachment 9.1) and if FDG is synthesized on site, the additional questions about radiochemical purity and pyrogen test results must be answered.
- 6.4.6 A daily constancy check of the dose calibrator must be performed prior to dose assay. Additional periodic quality control procedures, including quarterly linearity tests and annual accuracy checks, also must be followed.
- 6.4.7 In order to ensure optimal imaging results, the level of activity at time of injection should be known with a high degree of accuracy.
 - 6.4.7.1 Verify that the clock used to record time of assay and injection is correct and is synchronized with the scanner's clock.
 - 6.4.7.2 Assay the syringe and record the result on the PET Technical Assessment Form (Attachment 9.1).
 - 6.4.7.2.1.1 Amount of activity at time of injection must be within the range specified in the protocol.
 - 6.4.7.2.1.2 Time of injection must be recorded on PET Technical Assessment Form (Attachment 9.1). This form may differ slightly from study to study.

6.4.7.3 If required by protocol-specific procedure, assay the empty syringe after FDG injection promptly and record the result on the PET Technical Assessment Form (Attachment 9.1) before disposal of syringe in shielded sharps container.

6.4.7.4 The degree of radiotracer infiltration at the injection site (or other injection-associated problem) should be estimated and recorded on the PET Technical Assessment Form (Attachment 9.1).

6.5 Post-injection procedures.

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

6.5.1 Post-injection, patients must be maintained sitting or supine at quiet rest to avoid muscular uptake for a period of 50-70 minutes prior to scanning (unless otherwise specified in the protocol) and the patient must be instructed to minimize speaking for at least 30 minutes. For brain imaging, the patient must be in a quiet and dimly lit room for FDG administration and the subsequent uptake period.

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

6.5.3 In serial scans of the same patient, all subsequent image acquisitions should commence at the same time after injection of FDG as for the initial scan (within the limits set forth in the protocol).

6.5.4 The room should be kept warm to avoid shivering and other temperature effects that may increase muscular or brown adipose tissue uptake.

6.5.5 For either a CT scan done for attenuation correction/anatomic localization (AC/AL) or a diagnostic CT scan of the abdomen or pelvis, an intraluminal gastrointestinal contrast agent may be administered to provide adequate visualization of the gastrointestinal tract unless it is medically contraindicated or unnecessary for the clinical indication.

6.5.6 If possible, patients should drink 8-12 oz of water after injection and before scanning.

7.0 ACCEPTANCE CRITERIA

None.

8.0 REFERENCES

8.1 SOP 920.01, "Ensuring USP Compliance of [F-18]-Fluorodeoxyglucose used in ACRIN studies".

8.2 Shankar LK, Hoffman JM, Bacharach S, Graham MM, Karp J, Lammertsma A, Larson S, Mankoff DA, Siegel BA, Van den Abeele A, Yap J, Sullivan D. Consensus recommendations for the use of ¹⁸F-FDG PET as an indicator of therapeutic response in patients in National Cancer Institute trials. J Nucl Med 2006; 47:1059-1066.

9.0 ATTACHMENTS

9.1 ACRIN PET Technical Assessment Form (Example)



PET TECHNICAL ASSESSMENT FORM

Revision

Place Label Here

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

c. Minutes duration of transmission scan per bed position? [18]

minutes

15. Transmission scan processing used: [19]

- CT
- Segmentation
- Segmentation and emission subtraction
- Other, specify: _____ [20]

PET EMISSION SCAN

16. Minutes duration of emission scan per bed position: [21]

minutes

17. Emission start time: [22]
(military format)

18. Emission stop time: [23]

19. Number of bed positions scanned: [24]

20. Emission acquisition mode: [25]

- 2D
- 3D

PART III: SCANNER / F-18-FDG PROCUREMENT

21. Date of last PET scanner calibration: [25]

- - 20 (mm-dd-yyyy)

22. Daily scanner QC run on date of study? [26]

- No
- Yes

23. F-18-FDG Source: [27]

- Synthesized (complete 23a-c, skip 23d)
- Purchased (go to 23d)

a. Method: _____ [28]

b. Pyrogen test result: [29]

- Passed
- Failed
- Not done

c. Radiochemical purity test result: [30]

. %

d. Purchased: Name of licensed pharmacy providing F-18-FDG: [31]

Comments: [32] [33]

Signature of person responsible for data
(Radiologist or Technologist)

- - 20
Date form completed (mm-dd-yyyy)

ACRIN PET Technical Assessment Form

TA

PET TECHNICAL ASSESSMENT FORM

Place Label Here

Institution _____ Institution No. _____
 Participant initials _____ Case No. _____

If this is a revised or corrected form, check here

Instructions: The TA Form is to be completed, by the Radiologist or Technologist, for each protocol-specified PET scan. All images are to be transmitted to ACRIN as detailed in the study protocol. For check box questions, check only one response unless the form instructions indicate otherwise. All dates must be reported as month-day-year. All time fields must be reported in military format (i.e., 2:45pm = 1445 hours).

PART I: EXAM DATA

1. **Protocol time point:** [1]
 - Pre-Intervention... visit 1
 - Post-Intervention... visit 2
 - Month 6... visit 3
 - Month 9... visit 4
 - Month 12... visit 5
 - Month 18... visit 6
 - Month 24... visit 7

2. **Was PET imaging completed?** [2]
 - No (answer Q2a, then sign and date form)
 - Yes (go to Q3)

a. **Indicate primary reason:** [3]

 - Scheduling problem
 - Equipment failure
 - Patient refusal
 - Medical reason
 - Injection site complications
 - Claustrophobia
 - Insurance
 - Do not have required equipment
 - Other, specify: [4]

 - Unknown

3. **Date of imaging:** [5]

- - 20 (mm-dd-yyyy)

4. **Duration of patient fasting pre-PET imaging:** [6]

Hours (up to time of FDG injection)

5. **Blood glucose at start of PET imaging:**
 (record value measured before FDG injection)
 . mg/dl [7]

6. **Patient weight:** . kg [8]
 (as measured on day of scan)

7. **Patient height:** cm [9]

8. **Dose assay:** - mCi [10]

9. **Time of dose assay:** [11]
 (military format)

10. **Time of injection:** [12]
 (military format)

11. **Location of injection site:** [13]
 - Right antecubital
 - Right wrist
 - Left antecubital
 - Left wrist
 - Right foot
 - Left foot
 - Other, specify: _____ [13]
 - Unknown

12. **Radiotracer infiltration at injection site noted?** [14]
 - None
 - Minor (estimated less than 20% of dose)
 - Severe (estimated more than 20% of dose)

PART II: IMAGE ACQUISITION

TRANSMISSION SCAN

14. **Type of transmission scan:** [15]
 - CT (complete 14a - 14b, skip 14c)
 - Interleaved (go to 14c)
 - Non-Interleaved, PET emission first (go to 14c)
 - Non-Interleaved, transmission first (go to 14c)

- a. **Was oral contrast used?** [16]
 - No
 - Yes, positive contrast agent
 - Yes, negative contrast agent

- b. **Was IV contrast used?** [17]
 - No
 - Yes