GOG 0233/ACRIN 6671

Preoperative FDG-PET/CT Lymph Node Evaluation

Case Report Form Set for Endometrial Cancer

American College of Radiology Imaging Network
Forms Index
For Endometrial Cancer

GOG 0233/ACRIN 6671
Preoperative FDG - PET/CT
Lymph Node Evaluation

Form Version		Version Date
Visit 1: PET/CT Scan		
TA	PET Technical Assessment Form	02-25-09
TD	FDG-PET Imaging Related Drug History Form	11-05-09
E1	PET/CT Lymph Node Evaluation: Endometrial Cancer	06-14-10
C2	PET/CT Rt Obturator Lymph Nodes page 2	03-28-08
C3	PET/CT Lt Obturator Lymph Nodes page 3	03-28-08
C4	PET/CT Rt External Iliac Lymph Nodes page 4	03-28-08
C5	PET/CT Lt External Iliac Lymph Nodes page 5	03-28-08
C6	PET/CT Rt Common Iliac Lymph Nodes page 6	11-20-08
C7	PET/CT Lt Common Iliac Lymph Nodes page 7	11-20-08
C8	PET/CT Rt Para Caval and Aorto Caval LN page 8	03-28-08
C9	PET/CT Lt Para- Aortic Lymph Nodes page 9	03-28-08
CA	PET/CT Other Pelvic and Abdominal LN page 10	03-28-08
CB	PET/CT Thoracic Lymph Nodes page 11	03-28-08
CD	PET/CT Organ Involvement page 12	12-30-09
I1	PET/CT Rt Inguinal Lymph Nodes	01-12-10
I2	PET/CT Lt Inguinal Lymph Nodes	01-12-10
Image Review Prior to Surgery		
IM	Image Review Form	11-23-09
Follow-up Form		
F1	Follow-up Form	03-11-10
Visit 6: 6 months after PET/CT Scan		
CG	PET/CT 6 Month Institutional Reader Form	01-31-08
CH	PET/CT 6 Month Thoracic LN Form	03-28-08
CI	PET/CT 6 Month Organ Involvement Form	12-30-09
CJ	CT 6 Month Institutional Reader Form	02-05-08
CK	CT 6 Month Thoracic LN Form	03-27-08
CL	CT 6 Month Organ Involvement Form	12-30-09
End of Study		
DS	End of Study Form	02-06-08
Additional Forms		
PR	Protocol Deviation Form	08-01-07

Enter the data through the Data Center on the ACRIN website. All data should be entered within two weeks of the procedure. Any questions related to these forms should be directed to the ACRIN 6671 Data Manager.

Visit 1
PET/CT Scan

TA ACRIN 6671 PET Technical Assessment Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

If this is a revised or corrected form, indicate by checking box. ☐

Instructions: The TA form is to be completed by the technologist for each time point specified in the protocol, i.e., question 1 on the form. PET images are to be transmitted as defined in Appendix VII and X of the protocol. Please see attached instructions (page 4) for image transfer and data submission address. All dates must be reported as mm-dd-yyyy. All time fields must be reported in military format, i.e., 1:00pm = 13:00 hrs. Code all questions unless otherwise specified.

PET TIME-POINT INFORMATION

1. Protocol Imaging time point [1]

O Pre-op PET/CT abdomen, pelvis and chest
O Other imaging time point, specify:

_____ [2]

2. Was PET Imaging Completed? [3]

O No* (complete 2a, then sign and date form)
O Yes (proceed to Q3 and continue with form)

2a. *If No, provide reason: [4]

O Scheduling problem
O Equipment failure
O Patient refusal
O Medical reason
O Injection site complications
O Claustrophobia
O Other, specify:

_____ [5]

O Unknown

3. Date of PET Imaging: _____-_____-_____ [6]
(mm-dd-yyyy)

4. Date of PET Scan Image submission:

_____-_____-_____ (mm-dd-yyyy) [7]

5. Location of injection site: [8]

O Right antecubital
O Right wrist
O Left antecubital
O Left wrist
O Right foot
O Left foot
O Other, specify:

_____ [9]

O Unknown

PET Data Acquisition and Pre-processing

(Patient's weight /height are measured on the day of imaging, not verbally relayed by the patient)

6. Patient voided immediately pre-imaging? [10]

O No (complete Q6a)
O Yes

6a. Was Foley catheter placed? [11]

O No
O Yes

7. Patient voided immediately post-imaging? [12]

O No (complete Q7a)
O Yes

7a. Was Foley catheter in place for scan? [13]

O No
O Yes

8. Duration of patient fasting pre-PET imaging [14]

|_|_| **hours** (recorded up to the time of FDG injection)

9. Blood glucose at start of PET imaging [15]
(record value measured before FDG injection)

|_|_|_|.|_| mg/dl

10. Patient weight (measured on day of scan) [16]

|_|_|_|.|_| kg

11. Patient height |_|_|_| **cm** [17]
(measured on the day of scan)

12. Any radiotracer infiltration at injection site noted? [18]

O None
O Minor (estimated to be less than 20% of dose)
O Severe (estimated to be more than 20% of dose)

15. Time of injection (military time) |_|_|:|_|_| [21]

15a. Full activity in syringe before injection

|_|_|.|_| **mCi** [60]

15b. Time of assay of full syringe before injection

(military time) |_|_|:|_|_| [61]

15c. Residual activity in syringe after injection

|_|_|.|_| **mCi** [62]

15d. Time of assay of full syringe after injection

(military time) |_|_|:|_|_| [63]

15e. Administered activity (net injected dose)

|_|_|.|_| **mCi** [64]

16. Has a PET facility questionnaire been completed for this exam? [22]

O No
O Yes, provide date ____-____-____ *(mm-dd-yyyy)* [23]

17. Type of scanner used for this exam?

17a. Vendor _____ [24]

17b. Model name and/or number

_____ [25]

18. ☐☐ **Number of bed positions scanned** [26]

CT Information

19. Type of CT used for transmission Scan? [27]

O Diagnostic CT (complete Q19a-1)
O Low Dose CT (complete Q19a-2)
O Both (complete Q19a-1 and Q19a-2)

19a-1. Diagnostic CT

KVP ☐☐☐ [65]

mAs ☐☐☐ [66]

Slice thickness (mm) ☐.☐☐ [67]

Start time (military time) ☐☐:☐☐ [68]

End time (military time) ☐☐:☐☐ [69]

19a-2. Low Dose CT

KVP ☐☐☐ [70]

mAs ☐☐☐ [71]

Slice thickness (mm) ☐.☐☐ [72]

Start time (military time) ☐☐:☐☐ [73]

End time (military time) ☐☐:☐☐ [74]

19b. Oral contrast used? [31] [32]

O No
O Yes (define below)
  O "Positive" contrast agent
  O "Negative" contrast agent

19c. Name of Oral contrast used

_____ [33]

19d. Amount of Oral contrast ingested

☐☐☐☐ **ml** [34]

19e. Time Oral contrast ingested:

☐☐:☐☐ (military time) [35]

19f. IV contrast used? [36]

O No
O Yes

19g. Name of IV contrast used

_____ [37]

19h. Amount of IV contrast injected

☐☐☐ **ml** [38]

19i. Time IV contrast injected:

☐☐:☐☐ (military time) [39]

20. Emission scan

20a. ☐☐☐ **Minutes duration of emission scan per bed** [40]

20a-1. ☐☐ **Seconds duration of emission scan per bed** [75]

20b. ☐☐:☐☐ start time (military time) [41]

20c. ☐☐:☐☐ finish time (military time) [42]

21. Emission acquisition mode [43]

O 2D
O 3D

22. Pixel size of reconstructed images ☐.☐ mm [44]

23. Slice thickness of reconstructed images ☐.☐ mm [45]

24. Date of last scanner calibration:

____-____-____ (mm-dd-yyyy) [46]

25. Daily scanner QC run on date of study? (check one) [47]

O No
O Yes

25a. Has the scanner used for <u>this study</u> been qualified by ACRIN? [58]

O No
O Yes, provide date: ____-____-____ *(mm-dd-yyyy)* [59]

F-18-FDG Procurement

26. F-18-FDG Source [48]

O Synthesized
O Purchased

If synthesized*, complete Q27a-c, if F-18-FDG is purchased**, complete 28.

27. *If F-18-FDG is synthesized, provide the following:

27a. Method: _____ [49]

27b. Pyrogen test result [50]

O Passed
O Failed
O Not done

27c. Radiochemical purity test result: ___.___ **%** [51]

☐ Not done [52]

28. **If F-18-FDG is purchased, provide the name of the pharmacy licensed to provide F-18-FDG

_____ [53]

COMMENTS: _____

_____

_____ [54]

_____ [55]
Signature of person responsible for the data

____-____-____ [56]
Date form completed (mm-dd-yyyy)

_____ [57]
Signature of person entering data onto the web

Image transmission via internet:

1. **FTP Transfer**

   Digitally generated image files in DICOM v3.0 and scanned film diagnostic images can be transmitted to the ACRIN Image Management Center (IMC) via FTP directly to the image archive. For the PET imaging, processes are in place to collect the vendor specific image files. For further assistance in utilizing the electronic image submission option or for questions regarding image transfer, contact Rex Welsh (*rwelsh@phila.acr.org; 215-574-3215)* or Anthony Levering *(alevering@phila.acr.org; 215-574-3244).*

2. **Removal of Confidential Participant Information**

   If DICOM is being used, please note that the header record on DICOM formatted image data, which often contains information identifying the participant by name, MUST be scrubbed before the image is transferred. This involves replacing the Participant Name tag with the ACRIN Institution ID or number, replacing Participant ID stage with the ACRIN case number, and putting the study number into the Other Participant ID tag. This can be performed using a customized software program or using a program available from ACRIN. Contact Rex Welsh *(rwelsh@phila.acr.org)* or Anthony Levering *(alevering@phila.acr.org).*

3. **PET Data Submission Instructions**

   http://www.acrin.org/petcorelab.html

4. **CD Transfer**

   In the event that either DICOM capability or transfer of scrubbed image headers are not available, images may also be sent on a CD or other electronic medium for the ACRIN IMC to transfer to the image archive. Please contact ACRIN prior to sending the media to confirm compatibility, particularly before your first case *(rwelsh@phila.acr.org).*

5. **Plain Film Images**

   Plain film images for the PET scans are not acceptable for this study. Plain film images for submission of other images (CT scans, radiotherapy simulation films and port films) are acceptable.

TD

ACRIN 6671

FDG-PET Imaging-Related Drug History

ACRIN Study 6671 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. Clinical trial time point: [1] O Visit 1: PET/CT O 6 Month follow-up PET/CT

2. Is the participant a known diabetic? [2] O No O Yes, *complete Q2a*

2a. Were any drugs taken by the participant or administered to the participant on the day of PET study for control of blood glucose level? [3]

O No O Yes, check drug(s) used O Unknown

- ☐ A sulfonylurea, [4] drug name _____ [5] given ____ ____ [6] hours before FDG
- ☐ Metformin [7] given ____ ____ [8] hours before FDG
- ☐ Other oral agent (s) [9] drug name _____ [10] given ____ ____ [11] hours before FDG
  drug name _____ [12] given ____ ____ [13] hours before FDG
- ☐ Short-acting insulin [14] given, ____ ____ [15] hours before FDG, given (check one) [16] O Intravenously O Subcutaneously O Inhaled
  Record 99 if hours unknown
- ☐ Intermediate or long-acting insulin [17] given ____ ____ [18] hours before FDG
- ☐ Insulin Pump [19] *(check one)* [20] O On during FDG injection and uptake period
  O Off during FDG injection and uptake period, off ____ ____ [21] hours before FDG
- ☐ Other injectable agent [22] specify _____ [23] given ____ ____ [24] hours before FDG
  Record 99 if hours unknown
- ☐ Unknown [25]

3. Were any drugs administered as part of the PET imaging procedure? [26] *In addition to any listed in Q2a*

O No O Yes, check drug(s) used: O Unknown

- ☐ A benzodiazepine to decrease brown fat FDG uptake, [27] drug name _____ [28]
- ☐ A beta-blocker to decrease brown fat FDG uptake, [29] drug name _____ [30]
- ☐ A diuretic to decrease urinary tract activity, [31] drug name _____ [32]
- ☐ Sedation or anesthesia [33]
- ☐ Other drug(s), [34] drug name (s) _____ [35]
- ☐ Unknown [36]

4. Is the participant currently being treated with corticosteroids? [37] O No O Yes O Unknown

Taken ____ ____ [38] hours before FDG

5. Has the participant received a bone marrow stimulating agent in the last 2 months? [39] O No O Yes, *complete Q5a* O Unknown

5a. Agent Name: _____ [40]

Given approximately ____ ____ days ago [41]

☐ Unknown [42]

_____ [43]
Initials of Person(s) Completing this Form

__-__-__ [44]
Date form completed (mm-dd-yyyy)

E1

ACRIN 6671
PET/CT Lymph Node Evaluation: Endometrial Cancer
Institutional Reader Form

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

ACRIN Study 6671
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Institutional reader forms are to be completed by the nuclear physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional PET/CT reviewers, both PET and CT images are provided. The I1 and I2 form require completion by the PET/CT reviewer completing the E1 form.

1. Was PET/CT performed? [1]
- O No
- O Yes

1a. If no, provide reason: [2]
- O Scheduling problem
- O Equipment failure
- O Patient refusal
- O Medical reason
- O Injection site complications
- O Claustrophobia
- O Other, specify _____ [3]
- O Unknown

2. Date of PET/CT exam: ____-____-____ [4]
(mm-dd-yyyy)

3. Date of PET/CT Reading: ____-____-____ [5]
(mm-dd-yyyy)

4. Reader ID: |_|_|_|_|_|_|_| [6]

5. Image Quality: [7]
- O Adequate
- O Suboptimal (complete Q5a and/or Q5b)

5a. Reason study suboptimal (PET) [8]
- O Not enough of body imaged
- O Noisy images
- O Patient motion
- O FDG infiltration
- O SUVs cannot be calculated:
  specify reason: _____ [9]
- O Other _____ [10]

5b. Reason study suboptimal (CT) [11]
- O Not enough of body imaged
- O Noisy images
- O Patient motion
- O Metal artifact
- O Other _____ [12]

6. Primary Tumor Seen [13]
- O No
- O Yes
- O Indeterminate

7. Size of Primary Tumor (From Diagnostic CT)

AP ___ ___ ___ . ___ mm [14]

Transverse ___ ___ ___ . ___ mm [15]

Cephalocaudal ___ ___ ___ . ___ mm [16]

8. Primary Tumor Uptake Grade: [17]
- O Definitely Benign
- O Most likely benign
- O Probably benign
- O Probably malignant
- O Most likely malignant
- O Definitely malignant

9. Primary Tumor SUV

9a. SUV max: ___ ___ ___ . ___ [18]

9b. SUV peak: ___ ___ ___ . ___ [19]

10. Bladder Involvement [20]
- O No
- O Yes
- O Indeterminate

11. Rectum Involvement [21]
- O No
- O Yes
- O Indeterminate

12. Vaginal involvement [22]
- O No
- O Yes
- O Indeterminate

13. Cervical involvement [23]
- O No
- O Yes
- O Indeterminate

14. Pelvic sidewall involvement

14a. Right [24]
- O No
- O Yes
- O Indeterminate

14b. Left [25]
- O No
- O Yes
- O Indeterminate

15. Adnexal involvement

15a. Right [26]
- O No
- O Yes
- O Indeterminate

15b. Left [27]
- O No
- O Yes
- O Indeterminate

_____ [28]
Initials of person responsible for the data

_____ [29]
Initials of person(s) completing this form

_____-_____-_____ [30]
Date form completed *(mm-dd-yyyy)*

C2

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Pelvic Lymph Nodes
(Obturator Lymph Nodes)

A. RIGHT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. Number of Positive Lymph Nodes: _____ [17]

3. Number of Negative Lymph Nodes: _____ [18]

4. Is there a positive LN anterior/posterior to obturator nerve? [19]

O Anterior
O Posterior
O Both

C3

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Pelvic Lymph Nodes
(Obturator Lymph Nodes)

B. LEFT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. Number of Positive Lymph Nodes: _____ [17]

3. Number of Negative Lymph Nodes: _____ [18]

4. Is there a positive LN anterior/posterior to obturator nerve? [19]

O Anterior
O Posterior
O Both

C4

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study **6671**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Pelvic Lymph Nodes
(External Iliac Lymph Nodes)

A. RIGHT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. Number of Positive Lymph Nodes: _____ [17]

3. Number of Negative Lymph Nodes: _____ [18]

C5

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Pelvic Lymph Nodes
(External Iliac Lymph Nodes)

B. LEFT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. **Total number of LN's visible** _____ [1]
   (code 0 if no LN visible, proceed to next region)

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. **Number of Positive Lymph Nodes:** _____ [17]

3. **Number of Negative Lymph Nodes:** _____ [18]

C6

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Abdominal Lymph Nodes
(Common Iliac Lymph Nodes)

A. RIGHT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. Number of Positive Lymph Nodes: _____ [17]

3. Number of Negative Lymph Nodes: _____ [18]

4. Is there a positive LN medial/posterior to common iliac vessels? [20]
o No
o Yes (complete Q5)

5. Is positive LN medial/posterior to common iliac vessels the only positive LN in this region? [21]
o No
o Yes

C7

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Abdominal Lymph Nodes
(Common Iliac Lymph Nodes)

B. LEFT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. Number of Positive Lymph Nodes: _____ [17]

3. Number of Negative Lymph Nodes: _____ [18]

4. Is there a positive LN medial/posterior to common iliac vessels? [20]
o No
o Yes (complete Q5)

5. Is positive LN medial/posterior to common iliac vessels the only positive LN in this region? [21]
o No
o Yes

C8

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study **6671**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Abdominal Lymph Nodes (Right para caval and Aorto caval Lymph Nodes)

A. RIGHT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. Number of Positive Lymph Nodes: _____ [17]

3. Number of Negative Lymph Nodes: _____ [18]

4. Is there a positive retrocaval LN? [22]
o No
o Yes (complete Q5)

5. Is the retrocaval LN the only positive LN in this region? [23]
o No
o Yes

C9

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Abdominal Lymph Nodes
(Left Para-aortic Lymph Nodes)

B. LEFT

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

1. **Total number of LN's visible** _____ [1]
   (code 0 if no LN visible, proceed to next region)

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. **Number of Positive Lymph Nodes:** _____ [17]

3. **Number of Negative Lymph Nodes:** _____ [18]

CA

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Other Pelvic and Abdominal Lymph Node Regions (Choose one option for site location)

1 Internal Iliac - Right
2 Internal Iliac - Left
3 Presacral
4 Above IMA - Right para-aortic
5 Above IMA - Left para-aortic

Lymph nodes (or lesions within organs) are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes (or organs) are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged or there are lesions within the organs.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive LN's to report. If present, report one positive LN from each region mentioned above

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

Lymph Nodes	Site Use code table	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	[24]	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	[25]	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	[26]	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	[27]	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	[28]	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

CB

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13) are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Thoracic Lymph Nodes
(Choose one option for site location)

1 Supraclavicular - Right
2 Supraclavicular - Left
3 Mediastinum - Subcarina
4 Mediastinum - Other
88 Other

Lymph nodes (or lesions within organs) are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes (or organs) are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged or there are lesions within the organs.

1. Total number of LN's visible _____ [1]
(code 0 if no LN visible, proceed to next region)

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's

Lymph Nodes	Site Use code table	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	[24]	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	[25]	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	[26]	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	[27]	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	[28]	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

CD

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

ACRIN Study **6671**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: Institutional reader forms (pages 1 thru 13 are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Organ Involvement
(choose one option for site location)

1 Liver
2 Bone
3 Lung
4 Peritoneum
88 Other

Lymph nodes (or lesions within organs) are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes (or organs) are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged or there are lesions within the organs.

1. Total number of lesions visible _____ [1]

(code 0 if no lesion visible, sign and date form on page 13)

Yes (Complete chart below, then sign and date form page 13. Complete pages 12 and 13)

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive Lesion's to report

*** Report 5 Lesion's with the highest SUV max and SUV peak**

First report the Positive Lesion's
If less than 5 Positive Lesion's then report the benign Lesion's

Lesion	Site Use code table	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
Lesion # 1	[24]	___ • ___ [2]	[3]	___ • ___ [4]	___ • ___ [33]
Lesion # 2	[25]	___ • ___ [5]	[6]	___ • ___ [7]	___ • ___ [34]
Lesion # 3	[26]	___ • ___ [8]	[9]	___ • ___ [10]	___ • ___ [35]
Lesion # 4	[27]	___ • ___ [11]	[12]	___ • ___ [13]	___ • ___ [36]
Lesion # 5	[28]	___ • ___ [14]	[15]	___ • ___ [16]	___ • ___ [37]

CD

ACRIN 6671
PET/CT Lymph Node Evaluation
Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Comments: _____

_____

_____

_____

_____ [29]

_____ [30]
Signature of person responsible for the data

_____-_____-_____ [31]
Date Form Completed (mm-dd-yyyy)

_____ [32]
Signature of person entering data on web

I1

ACRIN 6671
PET/CT Lymph Node Evaluation:
Endometrial Cancer
Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Institutional reader forms are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional PET/CT reviewers, both PET and CT images are provided. Please continue to the I2 form.

Inguinal Lymph Nodes

A. RIGHT

1. **Total number of LNs visible** _____ [1]
   (code 0 if no LN visible, proceed to next region)

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive lymph nodes (LNs) to report. Report 5 lymph nodes with highest SUVmax/SUVpeak. Begin with the positive LNs, if less than 5 positive LNs, continue to report the benign LNs.

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. **Number of Positive Lymph Nodes:** _____ [17]

3. **Number of Negative Lymph Nodes:** _____ [18]

Note: The I1 and I2 forms are completed for endometrial cancer cases only and must be completed by the same institutional PET/CT reviewer with the corresponding Reader ID recorded on the E1 form (Q4) with sign off on the CD form.

I2

ACRIN 6671
PET/CT Lymph Node Evaluation:
Endometrial Cancer
Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Institutional reader forms are to be completed by the Nuclear Physician interpreting the exam. **This form must be completed while blinded to the results of other imaging examinations and clinical data.** The completed form is submitted via the ACRIN website. For institutional PET/CT reviewers, both PET and CT images are provided.

Inguinal Lymph Nodes

B. LEFT

1. **Total number of LNs visible** _____ [1]
   (code 0 if no LN visible, proceed to next region)

Lymph nodes are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged.

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive lymph nodes (LNs) to report. Report 5 lymph nodes with highest SUVmax/SUVpeak. Begin with the positive LNs, if less than 5 positive LNs, continue to report the benign LNs.

Lymph Nodes	CT Size (mm) (short axis)	PET/CT Uptake Use code from code table above	SUV_{max}	SUV_{peak}
LN #1	___ ___ ___ • ___ [2]	[3]	___ ___ ___ • ___ [4]	___ ___ ___ • ___ [33]
LN #2	___ ___ ___ • ___ [5]	[6]	___ ___ ___ • ___ [7]	___ ___ ___ • ___ [34]
LN #3	___ ___ ___ • ___ [8]	[9]	___ ___ ___ • ___ [10]	___ ___ ___ • ___ [35]
LN #4	___ ___ ___ • ___ [11]	[12]	___ ___ ___ • ___ [13]	___ ___ ___ • ___ [36]
LN #5	___ ___ ___ • ___ [14]	[15]	___ ___ ___ • ___ [16]	___ ___ ___ • ___ [37]

2. **Number of Positive Lymph Nodes:** _____ [17]

3. **Number of Negative Lymph Nodes:** _____ [18]

Note: The I1 and I2 forms are completed for endometrial cancer cases only and must be completed by the same institutional PET/CT reviewer with the corresponding Reader ID recorded on the E1 form (Q4) with sign off on the CD form.

Image Review Prior to Surgery

IM

ACRIN 6671
Image Review Prior to Surgery

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions: This form is completed following the image review. The image review involves the review of PET/CT images by radiologist and the gynecology oncologist prior to the planned lymphadenectomy to assure that all involved lymph nodes on imaging are considered during surgical planning and removed by surgeon.

1. Did the image review take place prior to surgery? [1]

O No
O Yes

1a. If no, provide reason: [2]

O Scheduling problem
O Equipment failure
O Lost images
O Participant death
O Participant withdrawal
O Other, specify: _____ [3]

2. Date of image review: ____-____-____ *(mm-dd-yyyy)* [4]

3. Initials of reviewing gynecology oncologist: _____ [5]

4. Reader ID of reviewing PET/CT radiologist: _____ [6]

5. Did the image review change the planned surgery? [7]

O No
O Yes

Comments: _____

_____

_____ [8]

_____ [9]
Initials of person(s) completing this form

_____-_____-_____ [10]
Date Form Completed (mm-dd-yyyy)

6671 – Follow Up Form

F1 ACRIN 6671 Follow-up Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Instructions: The F1 follow up form will be completed by the Site PI or designated research nurse at the GOG site. The completed form is submitted via the ACRIN website.

1. Was there evidence of disease outside of the pelvis or abdominal lymph nodes on PET/CT? [14]

O No (sign and date form)
O Yes (If yes, complete Q1a)

1a. Was the evidence of disease outside of the pelvis or abdominal region confirmed? [1]

O No (Perform 6 month PET/CT or CT follow-up per protocol) (sign and date form)
O Yes (Complete form)

2. Is there a confirmed positive Thoracic LN? [2]

O No
O Yes (If yes, choose option below)
O Supraclavicular-right
O Supraclavicular-left [3]
O Mediastinum-Subcarina
O Mediastinum-other
O Other

2a. What procedure was performed to diagnose positive Thoracic LN disease [4]

O Open biopsy
O Percutaneous biopsy
O Other, specify _____ [5]
O Unknown

3. Is there confirmed positive Organ involvement [6]

O No
O Yes (If yes, choose option below)
O Liver
O Bone
O Lung [7]
O Other

3a. What procedure was performed to diagnose positive Organ involvement disease [8]

O Open biopsy
O Percutaneous biopsy
O Other, specify _____ [9]
O Unknown

Comments: _____

_____

_____ [10]

_____ [11]
Signature of person responsible for the data

_____-_____-_____ [12]
Date Form Completed (mm-dd-yyyy)

_____ [13]
Signature of person entering data on web

6671 – Visit 6: 6 months after PET/CT Scan

CG

ACRIN 6671
PET/CT 6 Month
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

VISIT 6 MONTH

Instructions: Institutional reader forms (pages 1 thru 4) are to be completed by the Nuclear Physician interpreting the exam. The completed form is submitted via the ACRIN website . For institutional PET/CT reviewers, both PET and CT images are provided.

1. Timepoint for follow-up [1]
- O 6 month follow-up
- O Other, specify _____ [2]

2. Was a PET/CT performed? [3]
- O No (Complete Q2a, sign and date form)
- O Yes (Complete pages 1-4)

2a. If no, provide reason [4]
- O Scheduling problems
- O Equipment failure
- O Participant refusal
- O Medical reason
- O Injection site complications
- O Claustrophobia
- O Participant withdrew consent
- O Progressive disease
- O Participant death
- O Other, specify _____ [5]
- O Unknown

3. Date of PET/CT exam: _____ - _____ - _____ [6]
(mm-dd-yyyy)

4. Date of PET/CT reading _____ - _____ - _____ [7]
(mm-dd-yyyy)

5. Reader ID |_|_|_|_|_|_|_|_| [8]

Comments: _____

_____

_____ [9]

_____ [10]
Signature of person responsible for the data

_____-_____-_____ [11]
Date Form Completed (mm-dd-yyyy)

_____ [12]
Signature of person entering data on web

CH

ACRIN 6671 6 Month PET/CT Lymph Node Evaluation Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: Institutional reader forms (pages 1 thru 4) are to be completed by the Nuclear Physician interpreting the exam. The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Thoracic Lymph Nodes (Choose one option for site location)

1 Supraclavicular - Right
2 Supraclavicular - Left
3 Mediastinum - Subcarina
4 Mediastinum - Other
88 Other

1. Total number of LN's visible _____ [1]

(code 0 if no LN visible, proceed to next region)
(maximum of 5 positive LN's to report)

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive LN's to report

*** Report 5 LN's with the highest SUV max and SUV peak**

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's.

Lymph nodes (or lesions within organs) are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes (or organs) are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged or there are lesions within the organs.

Size Description Code table
(choose one option for size description in chart below)

1 Stable < 20% increase or < 30% reduction
2 Grown > 20% increase largest transverse diameter
3 Smaller > 30% in the largest transverse diameter
4 Resolved

Change in uptake scale (compared with baseline):

0 no uptake
1 marked decrease in uptake
2 slight decrease in uptake
3 no change in uptake
4 slight increase in uptake
5 marked increase in uptake

Lymph Node	Site	CT Size (mm) (short axis)	Size change Use code from code table above	PET/CT Uptake Use code from PET/CT Uptake table	SUV_{max}	SUV_{peak}	PET/CT Uptake Change Use change in uptake scale code table
LN #1	[24]	[2] ___ ___ ___ • ___	[43]	[3]	[4] ___ ___ ___ • ___	[33] ___ ___ ___ • ___	[38]
LN #2	[25]	[5] ___ ___ ___ • ___	[44]	[6]	[7] ___ ___ ___ • ___	[34] ___ ___ ___ • ___	[39]
LN #3	[26]	[8] ___ ___ ___ • ___	[45]	[9]	[10] ___ ___ ___ • ___	[35] ___ ___ ___ • ___	[40]
LN #4	[27]	[11] ___ ___ ___ • ___	[46]	[12]	[13] ___ ___ ___ • ___	[36] ___ ___ ___ • ___	[41]
LN #5	[28]	[14] ___ ___ ___ • ___	[47]	[15]	[16] ___ ___ ___ • ___	[37] ___ ___ ___ • ___	[42]

CI

ACRIN 6671 6 Month PET/CT Lymph Node Evaluation Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Instructions: Institutional reader forms (pages 1 thru 4) are to be completed by the Nuclear Physician interpreting the exam. The completed form is submitted via the ACRIN website. For institutional **PET/CT** reviewers, both **PET** and **CT** images are provided.

Organ Involvement (choose one option for site location)

1 Liver
2 Bone
3 Lung
4 Peritoneum
88 Other

1. Total number of lesions visible _____ [1]

(code 0 if no lesion visible, sign and date form on page 4)

Yes (include all positive lesions up to a maximum of 5. Complete pages 3 and 4)

PET/CT evidence of metastasis
PET/CT Uptake code table
(choose one option for PET/CT uptake)

1 Definitely Benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive Lesion's to report

*** Report 5 Lesion's with the highest SUV max and SUV peak**

First report the Positive Lesion's
If less than 5 Positive Lesion's then report the benign Lesion's

Lymph nodes (or lesions within organs) are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes (or organs) are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged or there are lesions within the organs.

Size Description Code table
(choose one option for size description in chart below)

1 Stable < 20% increase or < 30% reduction
2 Grown > 20% increase largest transverse diameter
3 Smaller > 30% in the largest transverse diameter
4 Resolved

Change in uptake scale
(compared with baseline):

0 no uptake
1 marked decrease in uptake
2 slight decrease in uptake
3 no change in uptake
4 slight increase in uptake
5 marked increase in uptake

Lesion	Site	CT Size (mm) (short axis)	Size change Use code from code table above	PET/CT Uptake Use code from PET/CT Uptake table	SUV_{max}	SUV_{peak}	PET/CT Uptake Change Use change in uptake scale code table
#1	[24]	[2] ___ ___ ___ • ___	[43]	[3]	[4] ___ ___ ___ • ___	[33] ___ ___ ___ • ___	[38]
#2	[25]	[5] ___ ___ ___ • ___	[44]	[6]	[7] ___ ___ ___ • ___	[34] ___ ___ ___ • ___	[39]
#3	[26]	[8] ___ ___ ___ • ___	[45]	[9]	[10] ___ ___ ___ • ___	[35] ___ ___ ___ • ___	[40]
#4	[27]	[11] ___ ___ ___ • ___	[46]	[12]	[13] ___ ___ ___ • ___	[36] ___ ___ ___ • ___	[41]
#5	[28]	[14] ___ ___ ___ • ___	[47]	[15]	[16] ___ ___ ___ • ___	[37] ___ ___ ___ • ___	[42]

CI

ACRIN 6671
6 Month PET/CT Lymph Node Evaluation Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Comments: _____

_____

_____

_____

_____ [29]

_____ [30]
Signature of person responsible for the data

_____-_____-_____ [31]
Date Form Completed (mm-dd-yyyy)

_____ [32]
Signature of person entering data on web

CJ

ACRIN 6671
CT 6 Month
Institutional Reader Form

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

VISIT 6 MONTH

Instructions: Institutional reader forms (pages 1 thru 4) are to be completed by the Local radiologist interpreting the exam. The completed form is submitted via the ACRIN website . For institutional PET/CT reviewers, both PET and CT images are provided.

1. Protocol imaging Timepoint [1]
- O 6 month follow-up
- O Other, specify _____ [2]

2. Was a CT performed? [3]
- O No (Complete Q2a, sign and date form)
- O Yes (Complete pages 1-4)

2a. If no, provide reason [4]
- O Scheduling problems
- O Equipment failure
- O Participant refusal
- O Medical reason
- O Injection site complications
- O Claustrophobia
- O Participant withdrew consent
- O Progressive disease
- O Participant death
- O Other, specify _____ [5]
- O Unknown

3. Date of CT exam: ____ - ____ - ____ [6]
(mm-dd-yyyy)

4. Date of CT reading ____ - ____ - ____ [7]
(mm-dd-yyyy)

5. Reader ID |_|_|_|_|_|_|_|_| [8]

6. Oral contrast used? [9]
- O No
- O Yes
  - O Positive contrast agent
  - O Negative contrast agent [10]

7. IV contrast used? [11]
- O No
- O Yes

7a. Amount of IV contrast injected? ____ ____ ____ ml [12]

Comments: _____

_____

_____ [13]

_____ [14]
Signature of person responsible for the data

____-____-____ [15]
Date Form Completed (mm-dd-yyyy)

_____ [16]
Signature of person entering data on web

CK

ACRIN 6671
6 Month CT Lymph Node Evaluation
Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Institutional reader forms (pages 1 thru 4) are to be completed by the Local radiologist interpreting the exam. The completed form is submitted via the ACRIN website. For institutional **CT** reviewers, **CT** images are provided.

Thoracic Lymph Nodes
(Choose one option for site location)

1 Supraclavicular - Right
2 Supraclavicular - Left
3 Mediastinum - Subcarina
4 Mediastinum - Other
88 Other

Lymph nodes (or lesions within organs) are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes (or organs) are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged or there are lesions within the organs.

1. Total number of LN's visible _____ [1]

(code 0 if no LN visible, proceed to next region)
(maximum of 5 positive LN's to report)

CT scale code

1 Definitely benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Size description code table

(choose one option for size description in chart below)

1 Stable < 20% increase or < 30% reduction
2 Grown > 20% increase largest transverse diameter
3 Smaller >30% in the largest transverse diameter
4 Resolved

Chart Instructions

Maximum of 5 positive LN's to report

First report the Positive LN's
If less than 5 Positive LN's then report the benign LN's.

Lymph Nodes	Site (Use code table)	CT Size (mm) (short axis)	Size (Use code table)	CT (Use above scale code)
LN #1	[24]	[2] ___ ___ ___ • ___	[29]	[34]
LN #2	[25]	[5] ___ ___ ___ • ___	[30]	[35]
LN #3	[26]	[8] ___ ___ ___ • ___	[31]	[36]
LN #4	[27]	[11] ___ ___ ___ • ___	[32]	[37]
LN #5	[28]	[14] ___ ___ ___ • ___	[33]	[38]

CL

ACRIN 6671
6 Month CT Lymph Node Evaluation
Institutional Reader Form

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

ACRIN Study 6671

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Institutional reader forms (pages 1 thru 4) are to be completed by the Local radiologist interpreting the exam. The completed form is submitted via the ACRIN website. For institutional **CT** reviewers, **CT** images are provided.

Organ Involvement
(choose one option for site location)

1 Liver
2 Bone
3 Lung
4 Peritoneum
88 Other

Lymph nodes (or lesions within organs) are considered malignant (positive) if there is abnormally increased FDG uptake (when accumulation of the tracer moderately to markedly increased relative to the uptake in comparable normal structures or surrounding tissues, with the exclusion of physiologic bowel and urinary activity) even if the lymph nodes (or organs) are normal in size. Lymph nodes are considered benign (negative) if there is no detectable FDG uptake, even if the lymph nodes are enlarged or there are lesions within the organs.

1. Total number of lesions visible _____ [1]

(code 0 if no lesion visible, sign and date form on page 4)

Yes (include all positive lesions up to a maximum of 5. Complete pages 3 and 4)

Size description code table

(choose one option for size description in chart below)

1 Stable < 20% increase or < 30% reduction
2 Grown > 20% increase largest transverse diameter
3 Smaller >30% in the largest transverse diameter
4 Resolved

CT scale code

1 Definitely benign
2 Most likely benign
3 Probably benign
4 Probably malignant
5 Most likely malignant
6 Definitely malignant

Chart Instructions

Maximum of 5 positive Lesion's to report

First report the Positive Lesion's
If less than 5 Positive Lesion's then report the benign Lesion's

Lesion	Site (Use code table)	CT Size (mm) (short axis)	Size (Use code table)	CT (Use above scale code)
Lesion #1	[24]	___ ___ ___ • ___ [2]	[29]	[34]
Lesion #2	[25]	___ ___ ___ • ___ [5]	[30]	[35]
Lesion #3	[26]	___ ___ ___ • ___ [8]	[31]	[36]
Lesion #4	[27]	___ ___ ___ • ___ [11]	[32]	[37]
Lesion #5	[28]	___ ___ ___ • ___ [14]	[33]	[38]

CL

ACRIN 6671
6 month CT Lymph Node Evaluation
Institutional Reader Form

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

ACRIN Study **6671**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Comments: _____

_____

_____

_____

_____ [39]

_____ [40]
Signature of person responsible for the data

_____-_____-_____ [41]
Date Form Completed (mm-dd-yyyy)

_____ [42]
Signature of person entering data on web

6671-End of Study

DS

ACRIN 6671
Pre-Operative FDG - PET/CT and Ferumoxtran - 10 MRI Lymph Node Evaluation
End of Study Form

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

ACRIN Study **6671**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: For each registered participant, please submit this form within two (2) weeks of study completion or premature discontinuation, including death.

1. End of Study status: [1]

- O 1 Protocol specific criteria and follow-up complete (sign and date form)
- O 2 Premature discontinuation (complete Q2 and Q2a)
- O 3 Participant death (skip to Q3 and Q3a)

2. Date of premature discontinuation: _____-_____-_____ *(mm/dd/yyyy)* [2]

2a. Primary reason for premature discontinuation: *(check only one)* [3]

- O Adverse events/side effect/complications (also specify on the Adverse Event form)
- O Participant explicitly withdraws from further study participation
- O Protocol violation
- O Did not meet baseline criteria
- O Lost to follow-up (unable to obtain contact with the participant during the prescribed protocol intervals)
- O Unsatisfactory therapeutic effect
- O Abnormal laboratory value(s)
- O Investigator decision (specify reason below)
- O Other (specify reason below)

Specify reason: _____ [4]

3. Date of death _____-_____-_____ *(mm/dd/yyyy)* [5]

3a. Cause of death [6]

- O Disease Progression
- O Other _____ *(specify cause of death)* [7]

COMMENTS: _____

_____

_____ [8]

_____ [9]
Signature of person responsible for the data

_____ - _____ - _____ [10]
Date form completed (mm-dd-yyyy)

_____ [11]
Signature of person entering data onto the web

6671-Additional Form(s)

PR

ACRIN 6671

PREOPERATIVE FDG-PET/CT AND FERUMOXTRAN – 1O MRI SCANS PROTOCOL DEVIATION FORM

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

ACRIN Study 6671 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: In the instance a protocol requirement is not met, record the requested information below. Complete a separate form for each case and for each deviation. Submit this form via the ACRIN web site; retain the form in the case study file.

1. Check the Protocol Event Being Reported: *(Select only one)* [1]

- ☐ Inclusion/exclusion criteria not met at time of registration/randomization
- ☐ Study activity performed prior to participant signing study consent form
- ☐ Imaging-related deviation *(complete Q1a)*
- ☐ PET/CT interpretation guidelines not followed
- ☐ PET/CT scan not performed according to protocol specific intervals
- ☐ Nuclear physician not blinded to the results of PET/CT
- ☐ MRI scan not performed according to protocol specific time
- ☐ MRI interpretation guidelines not followed
- ☐ Required pregnancy test not performed prior to scan
- ☐ Required blood glucose test not performed prior to administration of FDG
- ☐ Participant following other treatment preference
- ☐ Other, specify: _____ [2]

1a. Image Deviation: *(Select only one)*

i. PET Imaging Deviation *(select only one)* [3]

- ☐ PET scan performed at a non-ACRIN qualified institution
- ☐ PET scan performed on a non-ACRIN qualified scanner
- ☐ PET scan performed on a different scanner from the Baseline PET Imaging
- ☐ PET Images lost or unavailable
- ☐ PET Scan not per protocol
- ☐ Other, specify: _____ [4]

ii. CT Imaging Deviation *(select only one)* [5]

- ☐ CT scan performed at a non-ACRIN qualified institution
- ☐ CT scan performed on a non-ACRIN qualified scanner
- ☐ CT Images lost or unavailable
- ☐ CT Scan not per protocol
- ☐ Other, specify: _____ [6]

iii. MRI Imaging Deviation *(select only one)* [7]

- ☐ MRI scan performed at a non-ACRIN qualified institution
- ☐ MRI scan performed on a non-ACRIN qualified scanner
- ☐ MRI Images lost, series not obtained or images unavailable
- ☐ MRI Scan not per protocol
- ☐ Other, specify: _____ [8]

PR

ACRIN 6671

PREOPERATIVE FDG-PET/CT AND FERUMOXTRAN – 1O MRI SCANS PROTOCOL DEVIATION FORM

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

ACRIN Study 6671 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

2. Date the protocol deviation occurred: _____-_____-**20**_____ (mm-dd-yyyy) **[9]**

3. Date the protocol deviation was discovered: _____-_____-**20**_____ (mm-dd-yyyy) **[10]**

4. Describe the protocol deviation:

_____ [11]

_____ [12]

5. What was done to rectify the situation and/or prevent future occurrence:

_____ [13]

_____ [14]

6. Please provide the time point this Study Deviation applies to: *(select only one)* [15]

- ☐ **Visit 1**
- ☐ **Visit 2**
- ☐ **Visit 6** *(six month follow-up)*
- ☐ Other, specify: _____ [16]

_____ [17]
Person responsible for data (RA, study staff)

_____-_____-**20**_____ *(mm-dd-yyyy)*
Date Form Completed [18]

_____ [19]
Investigator Signature