GOG 0233/ACRIN 6671

Preoperative FDG-PET/CT
Lymph Node Evaluation

Case Report Form Set for Endometrial Cancer
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</tr>
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<td>I2 PET/CT Lt Inguinal Lymph Nodes</td>
<td>01-12-10</td>
</tr>
</tbody>
</table>

**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
PET TIME-POINT INFORMATION

1. Protocol Imaging time point
   - **Pre-op PET/CT abdomen, pelvis and chest**
   - Other imaging time point, specify:

2. Was PET Imaging Completed?
   - **No** (complete 2a, then sign and date form)
   - **Yes** (proceed to Q3 and continue with form)

2a. "If No, provide reason:
   - Scheduling problem
   - Equipment failure
   - Patient refusal
   - Medical reason
   - Injection site complications
   - Claustrophobia
   - Other, specify:

3. Date of PET Imaging: ______-____-______ (mm-dd-yyyy)

4. Date of PET Scan Image submission:
   ______-____-______ (mm-dd-yyyy)

5. Location of injection site:
   - Right antecubital
   - Right wrist
   - Left antecubital
   - Left wrist
   - Right foot
   - Left foot
   - Other, specify:

   **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?
   - **No** (complete Q6a)
   - **Yes**

6a. Was Foley catheter placed?
   - **No**
   - **Yes**

7. Patient voided immediately post-imaging?
   - **No** (complete Q7a)
   - **Yes**

7a. Was Foley catheter in place for scan?
   - **No**
   - **Yes**

8. Duration of patient fasting pre-PET Imaging
   ______ hours (recorded up to the time of FDG injection)

9. Blood glucose at start of PET Imaging
   ______ mg/dl

10. Patient weight (measured on day of scan)
    ______ kg

11. Patient height ______ cm (measured on the day of scan)

12. Any radiotracer infiltration at injection site noted?
    - **None**
    - Minor (estimated to be less than 20% of dose)
    - Severe (estimated to be more than 20% of dose)

15. Time of injection (military time)
    ______ : ______

15a. Full activity in syringe before injection
    ______ mCi

15b. Time of assay of full syringe before injection
    (military time) ______ : ______

15c. Residual activity in syringe after injection
    ______ mCi

15d. Time of assay of full syringe after injection
    (military time) ______ : ______

15e. Administered activity (net injected dose)
    ______ mCi
16. Has a PET facility questionnaire been completed for this exam? [22]
   ○ No
   ○ 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]
   ○ Diagnostic CT (complete Q19a-1)
   ○ Low Dose CT (complete Q19a-2)
   ○ 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]
   ○ No
   ○ Yes (define below)
      ○ "Positive" contrast agent
      ○ "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]
   ○ No
   ○ 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]

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

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

21. Emission acquisition mode [43]
   ○ 2D
   ○ 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]
ACRIN 6671
PET Technical Assessment Form

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

ACRIN Study 6671
PLACE LABEL HERE

Institution ________________ Institution No. ____________
Participant Initials ____________ Case No. ________________

25. Daily scanner QC run on date of study? (check one) [47]
   - O No
   - O Yes

25a. Has the scanner used for this study 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


COMMENTS: ____________________________________________________________

________________________________________________________________________

________________________________________________________________________

Signature of person responsible for the data ____________________________ [55]
Date form completed (mm-dd-yyyy) _________________________________________ [56]

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

"Copyright 2009"
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](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.
ACRIN Study 6671

FDG-PET Imaging-Related Drug History

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

   □ Metformin [7] given ________ _______ [8] hours before FDG
   □ Short-acting insulin [14] given, ________ _______ [15] hours before FDG, given (check one)
       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]

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

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

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

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


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
       O No
       O Yes
       O Indeterminate

15. Adnexal involvement
    15a. Right [26] 15b. Left [27]
       O No
       O Yes
       O Indeterminate

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Initials of person responsible for the data [28]

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

Date form completed (mm-dd-yyyy) [30]
Institutional Reader Form

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

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

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV[^max]</th>
<th>SUV[^peak]</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>—— —— —— • ——</td>
<td>[2]</td>
<td>[3]</td>
<td>[4]</td>
</tr>
<tr>
<td>LN #2</td>
<td>—— —— —— • ——</td>
<td>[5]</td>
<td>[6]</td>
<td>[7]</td>
</tr>
<tr>
<td>LN #3</td>
<td>—— —— —— • ——</td>
<td>[8]</td>
<td>[9]</td>
<td>[10]</td>
</tr>
<tr>
<td>LN #4</td>
<td>—— —— —— • ——</td>
<td>[11]</td>
<td>[12]</td>
<td>[13]</td>
</tr>
<tr>
<td>LN #5</td>
<td>—— —— —— • ——</td>
<td>[14]</td>
<td>[15]</td>
<td>[16]</td>
</tr>
</tbody>
</table>

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]
   - Anterior
   - Posterior
   - Both

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 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.
**ACRIN Study 6671**

**PET/CT Lymph Node Evaluation Institutional Reader Form**

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

1. **Total number of LN's visible**

   (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

---

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV max</th>
<th>SUV peak</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LN #2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LN #3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LN #4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LN #5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. **Number of Positive Lymph Nodes:**

3. **Number of Negative Lymph Nodes:**

4. **Is there a positive LN anterior/posterior to obturator nerve?**

   [ ] Anterior
   [ ] Posterior
   [ ] Both

---

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

---

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# ACRIN Study 6671

**PET/CT Lymph Node Evaluation**

**Institutional Reader Form**

If this is a revised or corrected form, please check 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

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

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV(\text{max})</th>
<th>SUV(\text{peak})</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>__________________________</td>
<td>[2]</td>
<td>[3]</td>
<td>[4]</td>
</tr>
<tr>
<td>LN #2</td>
<td>__________________________</td>
<td>[5]</td>
<td>[6]</td>
<td>[7]</td>
</tr>
<tr>
<td>LN #3</td>
<td>__________________________</td>
<td>[8]</td>
<td>[9]</td>
<td>[10]</td>
</tr>
<tr>
<td>LN #4</td>
<td>__________________________</td>
<td>[11]</td>
<td>[12]</td>
<td>[13]</td>
</tr>
<tr>
<td>LN #5</td>
<td>__________________________</td>
<td>[14]</td>
<td>[15]</td>
<td>[16]</td>
</tr>
</tbody>
</table>

2. Number of Positive Lymph Nodes: [17]

3. Number of Negative Lymph Nodes: [18]

---

*Copyright 2008*
**Pelvic Lymph Nodes**  
(External Iliac Lymph Nodes)

**B. LEFT**

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

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV_{max}</th>
<th>SUV_{peak}</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #3</td>
<td>—— —— —— * ——</td>
<td>[16]</td>
<td>[17]</td>
<td>[18]</td>
</tr>
<tr>
<td>LN #4</td>
<td>—— —— —— * ——</td>
<td>[23]</td>
<td>[24]</td>
<td>[25]</td>
</tr>
<tr>
<td>LN #5</td>
<td>—— —— —— * ——</td>
<td>[30]</td>
<td>[31]</td>
<td>[32]</td>
</tr>
</tbody>
</table>

2. **Number of Positive Lymph Nodes:** [17]
3. **Number of Negative Lymph Nodes:** [18]
# Abdominal Lymph Nodes

## (Common Iliac Lymph Nodes)

### A. RIGHT

1. Total number of LN's visible: [ ]
   - 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

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake Use code from code table above</th>
<th>SUV\text{max}</th>
<th>SUV\text{peak}</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>—— —— —— * ——</td>
<td>[2]</td>
<td>[3]</td>
<td>[4]</td>
</tr>
<tr>
<td>LN #2</td>
<td>—— —— —— * ——</td>
<td>[5]</td>
<td>[6]</td>
<td>[7]</td>
</tr>
<tr>
<td>LN #3</td>
<td>—— —— —— * ——</td>
<td>[8]</td>
<td>[9]</td>
<td>[10]</td>
</tr>
<tr>
<td>LN #4</td>
<td>—— —— —— * ——</td>
<td>[11]</td>
<td>[12]</td>
<td>[13]</td>
</tr>
<tr>
<td>LN #5</td>
<td>—— —— —— * ——</td>
<td>[14]</td>
<td>[15]</td>
<td>[16]</td>
</tr>
</tbody>
</table>

2. Number of Positive Lymph Nodes: [ ]

3. Number of Negative Lymph Nodes: [ ]

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

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

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.
Abdominal Lymph Nodes
(Common Iliac Lymph Nodes)

B. LEFT

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

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV max</th>
<th>SUV peak</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LN #2</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>LN #3</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>LN #4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LN #5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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]
   - No
   - Yes (complete Q5)

5. Is positive LN medial/posterior to common iliac vessels the only positive LN in this region? [21]
   - No
   - Yes
Abdominal Lymph Nodes
(Right para caval and Aorto caval Lymph Nodes)

A. RIGHT

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

Lymph Nodes | CT Size (mm) (short axis) | PET/CT Uptake | SUV max | SUV peak
-----------------|--------------------------|--------------|---------|---------|
LN #1           | ________________________ | [2]          | [3]     | [4]     |
LN #2           | ________________________ | [5]          | [6]     | [7]     |
LN #3           | ________________________ | [8]          | [9]     | [10]    |
LN #4           | ________________________ | [11]         | [12]    | [13]    |
LN #5           | ________________________ | [14]         | [15]    | [16]    |

2. Number of Positive Lymph Nodes: [ ]
3. Number of Negative Lymph Nodes: [ ]

4. Is there a positive retrocaval LN? [ ]
   o No
   o Yes (complete Q5)
5. Is the retrocaval LN the only positive LN in this region? [ ]
   o No
   o Yes
Abdominal Lymph Nodes
(Left Para-aortic Lymph Nodes)

B. LEFT

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

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV\text{\textsubscript{max}}</th>
<th>SUV\text{\textsubscript{peak}}</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>— — — — • —</td>
<td>[2]</td>
<td>— — — • —</td>
<td>— — — • —</td>
</tr>
<tr>
<td>LN #2</td>
<td>— — — — • —</td>
<td>[5]</td>
<td>— — — • —</td>
<td>— — — • —</td>
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<tr>
<td>LN #3</td>
<td>— — — • —</td>
<td>[8]</td>
<td>— — — • —</td>
<td>— — — • —</td>
</tr>
<tr>
<td>LN #5</td>
<td>— — — • —</td>
<td>[14]</td>
<td>— — — • —</td>
<td>— — — • —</td>
</tr>
</tbody>
</table>

2. Number of Positive Lymph Nodes: ________ [17]
3. Number of Negative Lymph Nodes: ________ [18]

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 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.
**Institutional Reader Form**

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.

**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

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>Site</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV$_{\text{max}}$</th>
<th>SUV$_{\text{peak}}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td></td>
<td></td>
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<td>LN #2</td>
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<tr>
<td>LN #3</td>
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<tr>
<td>LN #4</td>
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<tr>
<td>LN #5</td>
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</tbody>
</table>

*Copyright 2008*
# ACRIN 6671
## PET/CT Lymph Node Evaluation
### Institutional Reader Form

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
5. Other

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 (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.

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>Site</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV&lt;sub&gt;max&lt;/sub&gt;</th>
<th>SUV&lt;sub&gt;peak&lt;/sub&gt;</th>
</tr>
</thead>
</table>

"Copyright 2008"
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.

**Organ Involvement**

*choose one option for site location*

- 1 Liver
- 2 Bone
- 3 Lung
- 4 Peritoneum
- 88 Other

**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

### 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

<table>
<thead>
<tr>
<th>Lesion</th>
<th>Site</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV&lt;sub&gt;max&lt;/sub&gt;</th>
<th>SUV&lt;sub&gt;peak&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion # 1</td>
<td></td>
<td>[24]</td>
<td>[2]</td>
<td>[3]</td>
<td>[4]</td>
</tr>
<tr>
<td>Lesion # 2</td>
<td></td>
<td>[25]</td>
<td>[5]</td>
<td>[6]</td>
<td>[7]</td>
</tr>
<tr>
<td>Lesion # 3</td>
<td></td>
<td>[26]</td>
<td>[8]</td>
<td>[9]</td>
<td>[10]</td>
</tr>
<tr>
<td>Lesion # 4</td>
<td></td>
<td>[27]</td>
<td>[11]</td>
<td>[12]</td>
<td>[13]</td>
</tr>
<tr>
<td>Lesion # 5</td>
<td></td>
<td>[28]</td>
<td>[14]</td>
<td>[15]</td>
<td>[16]</td>
</tr>
</tbody>
</table>
PET/CT Lymph Node Evaluation: Endometrial Cancer

Institutional Reader Form

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

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 (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

   - PET/CT evidence of metastasis
     - PET/CT Uptake code table
     - Use code from code table above

   - 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.

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm)</th>
<th>PET/CT Uptake</th>
<th>SUV_{\text{max}}</th>
<th>SUV_{\text{peak}}</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
</tr>
<tr>
<td>LN #2</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
</tr>
<tr>
<td>LN #3</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
</tr>
<tr>
<td>LN #4</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
</tr>
<tr>
<td>LN #5</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
<td>_____ _____ • _____</td>
</tr>
</tbody>
</table>

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.
### 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.

### Chart Instructions
Maximum of 5 positive lymph nodes (LN) 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.

### 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

### Inguinal Lymph Nodes

**B. LEFT**

1. **Total number of LNs visible**

   (code 0 if no LN visible, proceed to next region)

#### Lymph Nodes

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>CT Size (mm) (short axis)</th>
<th>PET/CT Uptake</th>
<th>SUV_{max}</th>
<th>SUV_{peak}</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>—— —— • • •</td>
<td>[2]</td>
<td>[3]</td>
<td>[4]</td>
</tr>
<tr>
<td>LN #2</td>
<td>—— —— • •</td>
<td>[5]</td>
<td>[6]</td>
<td>[7]</td>
</tr>
<tr>
<td>LN #3</td>
<td>—— —— • •</td>
<td>[8]</td>
<td>[9]</td>
<td>[10]</td>
</tr>
<tr>
<td>LN #4</td>
<td>—— —— • •</td>
<td>[11]</td>
<td>[12]</td>
<td>[13]</td>
</tr>
<tr>
<td>LN #5</td>
<td>—— —— • •</td>
<td>[14]</td>
<td>[15]</td>
<td>[16]</td>
</tr>
</tbody>
</table>

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
### 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.

<table>
<thead>
<tr>
<th>1. Did the image review take place prior to surgery? [1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>O No</td>
</tr>
<tr>
<td>O Yes</td>
</tr>
</tbody>
</table>

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]


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]

Initials of person(s) completing this form  Date Form Completed (mm-dd-yyyy)
6671 – Follow Up Form
1. Was there evidence of disease outside of the pelvis or abdominal lymph nodes on PET/CT? [14]
   - No (sign and date form)
   - Yes (If yes, complete Q1a)

1a. Was the evidence of disease outside of the pelvis or abdominal region confirmed? [1]
   - No (Perform 6 month PET/CT or CT follow-up per protocol) (sign and date form)
   - Yes (Complete form)

2. Is there a confirmed positive Thoracic LN? [2]
   - No
   - Yes (If yes, choose option below)
     - Supraclavicular-right
     - Supraclavicular-left [3]
     - Mediastinum-Subcarina
     - Mediastinum-other
     - Other

2a. What procedure was performed to diagnose positive Thoracic LN disease [4]
   - Open biopsy
   - Percutaneous biopsy
   - Other, specify ____________________________ [5]
   - Unknown

3. Is there confirmed positive Organ involvement [6]
   - No
   - Yes (If yes, choose option below)
     - Liver
     - Bone
     - Lung [7]
     - Other

3a. What procedure was performed to diagnose positive Organ involvement disease [8]
   - Open biopsy
   - Percutaneous biopsy
   - Other, specify ____________________________ [9]
   - Unknown

Comments: ____________________________ [10]

Signature of person responsible for the data [11]

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

Signature of person entering data on web [13]
6671 – Visit 6: 6 months after PET/CT Scan
**ACRIN 6671**  
**PET/CT 6 Month**  
**Institutional Reader Form**

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.

<table>
<thead>
<tr>
<th>1. Timepoint for follow-up</th>
<th>2. Was a PET/CT performed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>O 6 month follow-up</td>
<td>O No (Complete Q2a, sign and date form)</td>
</tr>
<tr>
<td>O Other, specify</td>
<td>O Yes (Complete pages 1-4)</td>
</tr>
</tbody>
</table>

2a. If no, provide reason:

- Scheduling problems
- Equipment failure
- Participant refusal
- Medical reason
- Injection site complications
- Claustrophobia
- Participant withdrew consent
- Progressive disease
- Participant death
- Other, specify
- Unknown

3. Date of PET/CT exam: __________ - _________ - _________ (mm-dd-yyyy)  

4. Date of PET/CT reading: __________ - _________ - _________ (mm-dd-yyyy)

5. Reader ID: ____________

6. Date of PET/CT exam: __________ - _________ - _________ (mm-dd-yyyy)

7. Date of PET/CT reading: __________ - _________ - _________

8. Reader ID: ____________

9. Comments: ____________________________________________

10. Signature of person responsible for the data

11. Date Form Completed (mm-dd-yyyy)

12. Signature of person entering data on web

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Thoracic Lymph Nodes
(Choose one option for site location)

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

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.

<table>
<thead>
<tr>
<th>Lymph Node</th>
<th>Site</th>
<th>CT Size (mm) (short axis)</th>
<th>Size change</th>
<th>PET/CT Uptake</th>
<th>SUV max</th>
<th>SUV peak</th>
<th>PET/CT Uptake Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>[24]</td>
<td>[2]</td>
<td>[43]</td>
<td>[3]</td>
<td>[4]</td>
<td>[33]</td>
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<td>[5]</td>
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<td>[6]</td>
<td>[7]</td>
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<td>LN #3</td>
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<td>LN #4</td>
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<td>LN #5</td>
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<td>Use code from code table above</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
Organ Involvement (choose one option for site location)

1. Liver
2. Bone
3. Lung
4. Peritoneum
8. 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.

**Organ Involvement**

**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

### 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

<table>
<thead>
<tr>
<th>Lesion</th>
<th>Site</th>
<th>CT Size (mm) (short axis)</th>
<th>Size change Use code from code table above</th>
<th>PET/CT Uptake Use code from PET/CT Uptake table</th>
<th>SUV&lt;sub&gt;max&lt;/sub&gt;</th>
<th>SUV&lt;sub&gt;peak&lt;/sub&gt;</th>
<th>PET/CT Uptake Change Use change in uptake scale code table</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>[24]</td>
<td>[2]</td>
<td>[43]</td>
<td>[3]</td>
<td>[4]</td>
<td>[33]</td>
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<td>#2</td>
<td>[25]</td>
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<td>[39]</td>
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<tr>
<td>#3</td>
<td>[26]</td>
<td>[8]</td>
<td>[45]</td>
<td>[9]</td>
<td>[10]</td>
<td>[35]</td>
<td>[40]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>#4</td>
<td>[27]</td>
<td>[11]</td>
<td>[46]</td>
<td>[12]</td>
<td>[13]</td>
<td>[36]</td>
<td>[41]</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>#5</td>
<td>[28]</td>
<td>[14]</td>
<td>[47]</td>
<td>[15]</td>
<td>[16]</td>
<td>[37]</td>
<td>[42]</td>
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</tr>
</tbody>
</table>
Comments:__________________________________________________________

________________________________________________________________________

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________________________________________________________________________

Signature of person responsible for the data

Date Form Completed (mm-dd-yyyy)

Signature of person entering data on web
# ACRIN Study 6671

**CT 6 Month Institutional Reader Form**

**Institution**

**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 PET/CT reviewers, both PET and CT images are provided.

---

<table>
<thead>
<tr>
<th>1. <strong>Protocol imaging Timepoint</strong> [1]</th>
<th>2. <strong>Was a CT performed?</strong> [3]</th>
</tr>
</thead>
<tbody>
<tr>
<td>O 6 month follow-up</td>
<td>O No (Complete Q2a, sign and date form)</td>
</tr>
<tr>
<td>O Other, specify ____________________</td>
<td>O Yes (Complete pages 1-4)</td>
</tr>
</tbody>
</table>

**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 ____________________
O Unknown

---

3. **Date of CT exam:** _______ - _______ - _______ [6]

4. **Date of CT reading:** _______ - _______ - _______ [7]

5. **Reader ID**

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:**

---

Signature of person responsible for the data

Date Form Completed (mm-dd-yyyy)

Signature of person entering data on web

---

*Copyright 2008*
# ACRIN Study 6671

## Institutional Reader Form

**ACRIN Study 6671**

**Institutional Reader Form**

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

**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

1. **Total number of LN's visible**
   (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

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

**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.

<table>
<thead>
<tr>
<th>Lymph Nodes</th>
<th>Site (Use code table)</th>
<th>CT Size (mm) (short axis)</th>
<th>Size (Use code table)</th>
<th>CT (Use above scale code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LN #1</td>
<td>[24]</td>
<td>__ ___ • __</td>
<td>[2]</td>
<td>[29]</td>
</tr>
<tr>
<td>LN #3</td>
<td>[26]</td>
<td>__ ___ • __</td>
<td>[8]</td>
<td>[31]</td>
</tr>
<tr>
<td>LN #4</td>
<td>[27]</td>
<td>__ ___ • __</td>
<td>[11]</td>
<td>[32]</td>
</tr>
<tr>
<td>LN #5</td>
<td>[28]</td>
<td>__ ___ • __</td>
<td>[14]</td>
<td>[33]</td>
</tr>
</tbody>
</table>
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.

### Organ Involvement (choose one option for site location)

1. Liver
2. Bone
3. Lung
4. Peritoneum
5. 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)

### 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 lesion's to report
- First report the positive lesion's
- If less than 5 positive lesion's then report the benign lesion's

<table>
<thead>
<tr>
<th>Lesion</th>
<th>Site (Use code table)</th>
<th>CT Size (mm) (short axis)</th>
<th>Size (Use code table)</th>
<th>CT (Use above scale code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion #1</td>
<td>[24]</td>
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<td>[37]</td>
</tr>
<tr>
<td>Lesion #5</td>
<td>[28]</td>
<td>[14]</td>
<td>[33]</td>
<td>[38]</td>
</tr>
</tbody>
</table>
6671-End of Study
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]
   - 1 Protocol specific criteria and follow-up complete (sign and date form)
   - 2 Premature discontinuation (complete Q2 and Q2a)
   - 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]
      - Adverse events/side effect/complications (also specify on the Adverse Event form)
      - Participant explicitly withdraws from further study participation
      - Protocol violation
      - Did not meet baseline criteria
      - Lost to follow-up (unable to obtain contact with the participant during the prescribed protocol intervals)
      - Unsatisfactory therapeutic effect
      - Abnormal laboratory value(s)
      - Investigator decision (specify reason below)
      - Other (specify reason below)
      
      Specify reason: ____________________________________________________________ [4]

3. Date of death _______-_____-______ (mm/dd/yyyy) [5]
   3a. Cause of death [6]
      - Disease Progression
      - Other ________________________________ (specify cause of death) [7]

COMMENTS: ________________________________________________________________

________________________________________________________________________

Signature of person responsible for the data _____________________________________ [9]

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

Signature of person entering data onto the web ________________________________ [11]
6671-Additional Form(s)
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)
   - 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]

   - 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]

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

Person responsible for data (RA, study staff)  Investigator Signature

[19]