ACRIN 6678

Lung Cancer:
Evaluation of Treatment Response with PET

CRF Set
Part I. The following questions will be asked at Study Registration:

1. Name of Institutional person registering this case [1]
2. (Y) Has the Eligibility Checklist been completed? [2]
3. (Y) Is the Patient eligible for this study? [3]
4. Date the study-specific Consent Form was signed? (mm-dd-yyyy) (Must be prior to study entry) [4]
5. Patient’s Initials (last, first) (L, F) [5]
6. Verifying Physician (Site PI) [6]
7. Participant’s ID Number (optional: 999999 may be coded) [7]
8. Date of Birth [mm-dd-yyyy (must be = or > than 18 years)] [8]
9. Ethnicity [9]
   1 Hispanic or Latino
   2 Not Hispanic or Latino
   9 Unknown
    1 Male
    2 Female
11. Participant’s country of residence (if other, complete Q18) [12]
    1 United States
    2 Canada
    3 Other
    9 Unknown
13. Patient’s Insurance Status [14]
    0 Other
    1 Private Insurance
    2 Medicare
    3 Medicare and Private Insurance
    4 Medicaid
    5 Medicaid and Medicare
    6 Military or Veteran’s Administration
    7 Self Pay
    8 No means of payment
    9 Unknown/Decline to answer
14. Will any component of the patient’s care be given at a Military or VA facility? [15]
    1 No
    2 Yes
    9 Unknown
16. Calendar Base Date [ = date of registration] [16]
17. Date of registration [randomization] (mm-dd-yyyy) [17]
18. Other Country, specify (completed if Q12 is coded "other") [18]
   Race (check all that apply) □ =1 No, □ =2 Yes
19. American Indian or Alaskan Native [19]
20. Asian [20]
21. Black or African American [21]
22. Native Hawaiian or other Pacific Islander [22]
23. White [23]
24. Unknown [24]
25. Start date of planned chemotherapy treatment (mm-dd-yyyy) (Group A and B only. Enter 99’s for Group C) [25]

Part II: The following questions are to determine patient eligibility:
26. (Y) Does the participant have histologically or cytologically proven NSCLC? [26]
27. (Y) Does the participant have tumor stage IIIIB (with malignant pleural effusion), stage IV, or recurrent metastatic disease? [27]
28. (Y/NA) Has the participant had a CT or MR scan of the chest? [28]
   NOTE: If necessary to determine/confirm stage disease, an upper abdomen CT scan (including liver and adrenals) must be performed.
29. Please provide date of CT or MR [29]
30. (Y) Has the participant had a history and physical examination within 6 weeks prior to registration? [30]
31. Please provide date of physical examination. [31]
32. (Y/NA) Has the participant had a CT or MR scan of the brain within 4 weeks prior to registration if there is headache, mental or physical impairment, or other signs or symptoms suggesting brain metastases... (Group A and B only) [32]
33. Please provide date of CT or MR [33]
34. (Y) Does the participant have at least one measurable primary or other intrathoracic/supraclavicular lesion ≥ 2 cm according to Response Evaluation Criteria in Solid Tumors (RECIST)? [34]
35. (Y) Does the participant have a performance status of 0 to 2 on the Eastern Cooperative Oncology Group (ECOG) scale? [35]
36. Please provide Performance Status (ECOG): [36]
   0 Fully active, able to carry on all pre-disease performance without restriction
   1 Restricted in physically strenuous activity but ambulatory and able to carry out of a light or sedentary nature, e.g., light house work, office work
   2 Ambulatory and capable of all selfcare but unable to carry out work activities. Up and about more than 50% of waking hours
   3 Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
   4 Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
   5 Dead
37. Please provide date the Performance Status (ECOG) was assessed. [37]
38. (Y/NA) Is the participant scheduled to be treated with a platinum-based dual-agent chemotherapy regimen administered at 3 weeks intervals? (Group A and B only) [38]

39. (Y) Is the participant 18 years of age or older? [39]

40. (Y/NA) Does the participant agree to use medically appropriate contraception if sexually active; women of child bearing potential must not be pregnant or breast-feeding [40]

41. (Y/NA) Has a pregnancy test been done and shown to be negative? [41]

42. If yes, please provide date of pregnancy test. [42]

43. (Y) Is the participant able to give study specific informed consent? [43]

44. (Y) Is the participant able to tolerate PET imaging required by protocol, to be performed at an ACRIN-qualified facility? [44]

45. (Y) Which treatment arm is the participant being registered to? [60]
   O Group A
   O Group B
   O Group C

Exclusion Criteria:

46. (N) Does the participant have small cell carcinoma histology? [46]

47. (N) Does the participant have a pure bronchioloalveolar cell carcinoma histology? [47]

48. (N) Has the participant had prior thoracic radiotherapy, lung surgery or chemotherapy within 3 months prior to inclusion in the study? (Radiotherapy or surgery non-thoracic lesions allowed) [48]

49. (N) Does the participant have poorly controlled diabetes (defined as fasting glucose level >150 mg/dl) despite medications? (see Section 5.2.4 for details) [49]

50. (N) Has the participant had a prior malignancy other than basal cell or squamous cell carcinoma of the skin, carcinoma in situ, or other cancer from which they have been disease free for less than (3) years? [50]

51. (N/NA) Is the participant planning to undergo chemoradiotherapy? (Exclusion for Group A and B only) [51]

52. (N) Does the participant show clinical or radiographic signs of post-obstructive pneumonia? [52]

53. (N/NA) Does the participant have symptomatic brain metastases? (Exclusion for Groups A and B only) [53]

54. (N/NA) Treatment planned with any targeted or biologic therapy other than bevacizumab or cetuximab? (Exclusion for Groups A and B only) [59]

55. (N) Is the participant, who is sexually active, unwilling and/or unable to use medically appropriate contraception, or women who are pregnant or breast-feeding? [55]

Completed by: [56]
(Research Associate, Investigator Designee, or Principal Investigator)

Signature of person entering data onto the web [57]

Date form completed - - - (mm-dd-yyyy) [58]
ACRIN 6678
FDG - PET/CT Tumor Response
Chemotherapy Assessment Form
Cycle 1

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

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

1. **Was Chemotherapy given for Cycle 1?**
   - [ ] No (Complete Q1a then sign and date form)
   - [ ] Yes

<table>
<thead>
<tr>
<th>Agent Code Table</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>End Date (mm/dd/yyyy)</th>
<th>Total Dose/Unit</th>
<th>Reason for Termination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Cisplatin</td>
<td></td>
<td></td>
<td></td>
<td>1 Cycle ended, per protocol</td>
</tr>
<tr>
<td>2 Carboplatin</td>
<td></td>
<td></td>
<td></td>
<td>2 Disease Progression</td>
</tr>
<tr>
<td>3 Docetaxel</td>
<td></td>
<td></td>
<td></td>
<td>3 Participant withdrew</td>
</tr>
<tr>
<td>4 Gemcitabine</td>
<td></td>
<td></td>
<td></td>
<td>4 Participant refused</td>
</tr>
<tr>
<td>5 Paclitaxel</td>
<td></td>
<td></td>
<td></td>
<td>5 Change in therapy</td>
</tr>
<tr>
<td>6 Vinorelbine</td>
<td></td>
<td></td>
<td></td>
<td>6 Low counts</td>
</tr>
<tr>
<td>7 Bevacizumab</td>
<td></td>
<td></td>
<td></td>
<td>88 Other* (specify reason)</td>
</tr>
<tr>
<td>8 Cetuximab</td>
<td></td>
<td></td>
<td></td>
<td>**</td>
</tr>
<tr>
<td>88 Other* (specify agent)</td>
<td></td>
<td></td>
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<td>**</td>
</tr>
</tbody>
</table>

2. **Weight first day this cycle:** [X] [ ]  kg
   - [ ] (Check if unknown)

3. **Serum creatinine at time of cycle:**
   - [X] [ ] mg/dL
   - [ ] (Check if unknown)

---

**1a. Primary reason chemotherapy not performed**
- [ ] 1 Participant withdrew
- [ ] 2 Participant refused
- [ ] 3 Change in therapy
- [ ] 4 Low counts
- [ ] 5 Death
- [ ] 6 Referred for supportive care / hospice
- [ ] 88 Other, specify _[X]_

**Signature of Person Responsible for Data**

**Signature of Person entering data onto the Web**

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ACRIN Study 6678
PLACE LABEL HERE

Institution_________________ Institution No. ____________
Participant Initials_________ Case No. ________________

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

1. Was Chemotherapy given for Cycle 2? [1]
   - O No (Complete Q1a then sign and date form)
   - O Yes

---

### Agent Code Table

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<th>Agent Code</th>
<th>Start Date (mm/dd/yyyy)</th>
<th>End Date (mm/dd/yyyy)</th>
<th>Total Dose/Unit</th>
<th>Reason for Termination</th>
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<tr>
<td>88</td>
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</tr>
</tbody>
</table>

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2. Weight first day this cycle:
   - kg [36]

   (Check if unknown) [37]

3. Serum creatinine at time of cycle:
   - mg/dL [38]

   (Check if unknown) [39]

---

Signature of Person Responsible for Data [40]

Date form completed (mm-dd-yyyy) [41]

Signature of Person entering data onto the Web [42]
1. Was Chemotherapy given for Cycle 3?  
   - No (Complete Q1a then sign and date form)
   - Yes

### Agent Code Table

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<th>Agent Code</th>
<th>Start Date (mm/dd/yyyy)</th>
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<td>2 Disease Progression</td>
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<tr>
<td>3 Docetaxel</td>
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<td></td>
<td></td>
<td>3 Participant withdrew</td>
</tr>
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<td>4 Gemcitabine</td>
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<td>6 Low counts</td>
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<tr>
<td>7 Bevacizumab</td>
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<td>88 Other* (specify reason)</td>
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<tr>
<td>8 Cetuximab</td>
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</tr>
<tr>
<td>88 Other* (specify agent)</td>
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</tr>
</tbody>
</table>

1a. Primary reason chemotherapy not performed
   - 1 Participant withdrew
   - 2 Participant refused
   - 3 Change in therapy
   - 4 Low counts
   - 5 Death
   - 6 Referred for supportive care / hospice
   - 88 Other, specify ____________________________

   Signature of Person Responsible for Data

   Signature of Person entering data onto the Web

2. Weight first day this cycle: Kg
   - (Check if unknown)

3. Serum creatinine at time of cycle: mg/dL
   - (Check if unknown)
ACRIN 6678
FDG - PET/CT Tumor Response
Chemotherapy Assessment Form
Cycle 4

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

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

1. Was Chemotherapy given for Cycle 4? [1]  
   O No (Complete Q1a then sign and date form)  
   O Yes

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<tr>
<th>Agent Code Table</th>
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<td></td>
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</tr>
<tr>
<td>88 Other*</td>
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</tbody>
</table>

Agent Code [2]  
  O mg  
  O other [7]  
Reason Code [8]  
** ___________ [9]  

Agent Code [10]  
  O mg  
  O other [15]  
Reason Code [16]  
** ___________ [17]  

Agent Code [18]  
  O mg  
  O other [23]  
Reason Code [24]  
** ___________ [25]  

Agent Code [26]  
* ___________ [27] ___________ [28] ___________ [29]  
  O mg  
  O other [31]  
Reason Code [32]  
** ___________ [33]  

1a. Primary reason chemotherapy not performed [34]  
   O 1 Participant withdrew  
   O 2 Participant refused  
   O 3 Change in therapy  
   O 4 Low counts  
   O 5 Death  
   O 6 Referred for supportive care / hospice  
   O 88 Other, specify ____________________________ [35]  

Signature of Person Responsible for Data [40]

Signature of Person entering data onto the Web [42]

2. Weight first day this cycle: [36]  
   kg [36]  
   (Check if unknown) [37]

3. Serum creatinine at time of cycle: [38]  
   mg/dL [38]  
   (Check if unknown) [39]

Date form completed (mm-dd-yyyy) [41]

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FDG - PET/CT Tumor Response
Chemotherapy Assessment Form
Cycle 5

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

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

1. Was Chemotherapy given for Cycle 5? [1]
   - O No (Complete Q1a then sign and date form)
   - O Yes

2. Weight first day this cycle: [36]
   - [ ] (Check if unknown) [37]

3. Serum creatinine at time of cycle: [38]
   - [ ] (Check if unknown) [39]

1a. Primary reason chemotherapy not performed [34]
   - O 1 Participant withdrew
   - O 2 Participant refused
   - O 3 Change in therapy
   - O 4 Low counts
   - O 5 Death
   - O 6 Referred for supportive care / hospice
   - O 88 Other, specify [35]

---

Signature of Person Responsible for Data [40]

Signature of Person entering data onto the Web [42]
ACRIN 6678
FDG - PET/CT Tumor Response
Chemotherapy Assessment Form
Cycle 6

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

INSTRUCTIONS: Submit this form for all enrolled participants after completion of the protocol specific chemotherapy cycle referred to in Q1.

1. Was Chemotherapy given for Cycle 6? [1]
   O No (Complete Q1a then sign and date form)
   O Yes

   1a. Primary reason chemotherapy not performed [34]
      O 1 Participant withdrew
      O 2 Participant refused
      O 3 Change in therapy
      O 4 Low counts
      O 5 Death
      O 6 Referred for supportive care / hospice
      O 88 Other, specify ________________________________

   Signature of Person Responsible for Data [40]

2. Weight first day this cycle: [36] kg [36]
   □ (Check if unknown) [37]

3. Serum creatinine at time of cycle:
   [ ] [ ] [ ] mg/dL [38]
   □ (Check if unknown) [39]

   Signature of Person entering data onto the Web [42]

   Date form completed (mm-dd-yyyy) [41]
ACRIN 6678
FDG - PET/CT Tumor Response
End of Study Form

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

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 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 in comments)
   - Other (specify reason in comments)

3. Date of death _____-_____ - _____ (mm/dd/yyyy) [4]
   3a. Cause of death [5]
   - Disease progression
   - Other ________________________________ (specify cause of death) [6]

COMMENTS: __________________________________________

Signature of person responsible for the data __________________________ [8]         Date form completed (mm-dd-yyyy) __________ [10]

Signature of person entering data onto the web ________________________ [9]
INSTRUCTIONS: The Research Staff will complete this form following contact with the participant’s treating physician. Please submit this form within 2 weeks of the three month evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of follow-up for purposes of this form. This is the date on which the participant’s treating physician was contacted for information pertaining to disease progression and vital status. For question 5, please refer to Appendix VII (section 3.2) which summarizes the categories of response status.

1. Timepoint for this follow-up [1]
   - 3 month follow-up

   1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation [2]
       _______:_____:______ (mm-dd-yyyy)

2. Was the follow-up evaluation completed? [3]
   - 1 No (complete Q2a, sign and date form)
   - 2 Yes (skip to Q3)

2a. Reason not completed: (check all that apply)
   - ☐ = 1 Not Marked, ☑ = 2 Marked
   - ☐ Scheduling problem [4]
   - ☐ Patient refusal [5]
   - ☐ Medical reason (define reason in comments) [6]
   - ☐ Withdrew consent (submit the end of study form (DS)) [7]
   - ☐ Other [8] specify ____________________________ [9]

3. Date of last contact between the treating physician and the participant [10]
   _______:_____:______ (mm-dd-yyyy)

4. Participant’s vital status at the time of this follow-up [11]
   - 1 Alive
   - 2 Dead (submit the end of study form (DS))
   - 99 Unknown

5. Response status at this assessment (see Instructions) [12]
   - 1 Complete response (CR)
   - 2 Partial response (PR)
   - 3 Stable disease (SD)
   - 4 Progressive disease (PD)
   - 99 Unknown

5a. Date the response status was determined [13]
    _______:_____:______ (mm-dd-yyyy)

6. Did the participant develop a first progression [14]
   - 1 No
   - 2 Yes (submit the progression form (PF))
   - 99 Unknown

7. Did the participant receive any Radiation Therapy not previously reported? [15]
   - 1 No
   - 2 Yes (specify location and provide date)
   - 99 Unknown

   7a. Anatomic location of Radiation Therapy:
       ________________________________________________ [16]

   7b. Date of Radiation Therapy: [17]
       _______:_____:______ (mm-dd-yyyy)

8. Did the participant have surgery not previously reported? [18]
   - 1 No
   - 2 Yes (specify location and provide date)
   - 99 Unknown

8a. Anatomic location of surgery:
    ________________________________________________ [19]

8b. Date of surgery: [20]
    _______:_____:______ (mm-dd-yyyy)

9. Did the participant have any non-protocol chemotherapy not previously reported [21]
   - 1 No
   - 2 Yes (specify and provide date)
   - 99 Unknown

9a. Type of non-protocol chemotherapy:
    ________________________________________________ [22]

9b. Date of non-protocol chemotherapy: [23]
    _______:_____:______ (mm-dd-yyyy)

10. Did the participant receive any other non-protocol treatment not previously reported [24]
    - 1 No
    - 2 Yes (specify and provide date)
    - 99 Unknown

10a. Type of treatment:
    ________________________________________________ [25]

10b. Date of non-protocol treatment: [26]
    _______:_____:______ (mm-dd-yyyy)
ACRIN 6678
FDG - PET/CT Tumor Response
3 Month Follow-up (F/U) Form

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

ACRIN Study 6678

PLACE LABEL HERE

Institution__________ Institution No.__________
Participant Initials__________ Case No.__________

3 MONTH FOLLOW-UP

Comments: ____________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

_____________________________________________________

[28]

Signature of Person responsible for the data

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

Signature of Person entering data onto the web
**ACRIN Study 6678**

**PLACE LABEL HERE**

Institution ________ Institution No. ________
Participant Initials ________ Case No. ________

6 MONTH FOLLOW-UP

**INSTRUCTIONS:** The Research Staff will complete this form following contact with the participant’s treating physician. Please submit this form within 2 weeks of the six month evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of follow-up for purposes of this form. This is the date on which the participant’s treating physician was contacted for information pertaining to disease progression and vital status. For question 5, please refer to Appendix VII (section 3.2) which summarizes the categories of response status.

1. **Timepoint for this follow-up** [1]
   - o 6 month follow-up

   **1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation** [2]
   
   _______._____._______. (mm-dd-yyyy)

2. **Was the follow-up evaluation completed?** [3]
   - o 1 No (complete Q2a, sign and date form)
   - o 2 Yes (skip to Q3)

2a. **Reason not completed: (check all that apply)**
   - □=1 Not Marked, [ ]= 2 Marked
   - [ ] Scheduling problem [4]
   - [ ] Patient refusal [5]
   - [ ] Medical reason (define reason in comments) [6]
   - [ ] Withdrew consent (submit the end of study form (DS)) [7]
   - [ ] Other, [8] specify ______________________ [9]

3. **Date of last contact between the treating physician and the participant** [10]
   
   _______._____._______. (mm-dd-yyyy)

4. **Participant’s vital status at the time of this follow-up** [11]
   - o 1 Alive
   - o 2 Dead (submit the end of study form (DS))
   - o 99 Unknown

5. **Response status at this assessment** (see Instructions) [12]
   - o 1 Complete response (CR)
   - o 2 Partial response (PR)
   - o 3 Stable disease (SD)
   - o 4 Progressive disease (PD)
   - o 99 Unknown

5a. **Date the response status was determined** [13]
   
   _______._____._______. (mm-dd-yyyy)

6. **Did the participant develop a first progression not previously reported** [14]
   - o 1 No
   - o 2 Yes (submit the progression form (PF))
   - o 99 Unknown

7. **Did the participant receive any Radiation Therapy not previously reported?** [15]
   - o 1 No
   - o 2 Yes (specify location and provide date)
   - o 99 Unknown

7a. **Anatomic location of Radiation Therapy:**

   ______________________ [16]

7b. **Date of Radiation Therapy:** [17]

   _______._____._______. (mm-dd-yyyy)

8. **Did the participant have surgery not previously reported?** [18]
   - o 1 No
   - o 2 Yes (specify location and provide date)
   - o 99 Unknown

8a. **Anatomic location of surgery:**

   ______________________ [19]

8b. **Date of surgery:** [20]

   _______._____._______. (mm-dd-yyyy)

9. **Did the participant have any non-protocol chemotherapy not previously reported** [21]
   - o 1 No
   - o 2 Yes (specify and provide date)
   - o 99 Unknown

9a. **Type of non-protocol chemotherapy:**

   ______________________ [22]

9b. **Date of non-protocol chemotherapy:** [23]

   _______._____._______. (mm-dd-yyyy)

10. **Did the participant receive any other non-protocol treatment not previously reported** [24]
    - o 1 No
    - o 2 Yes (specify and provide date)
    - o 99 Unknown

10a. **Type of treatment:**

    ______________________ [25]

10b. **Date of non-protocol treatment:** [26]

    _______._____._______. (mm-dd-yyyy)
ACRIN 6678
FDG - PET/CT Tumor Response
6 Month Follow-up (F/U) Form

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

ACRIN Study 6678

PLACE LABEL HERE

Institution_____________  Institution No. ___________
Participant Initials_________  Case No. ___________

6 MONTH FOLLOW-UP

Comments: ____________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

[27]

Signature of Person responsible for the data [28]  Date form completed (mm-dd-yyyy) [30]

Signature of Person entering data onto the web [29]
INSTRUCTIONS: The Research Staff will complete this form following contact with the participant’s treating physician. Please submit this form within 2 weeks of the nine month evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of follow-up for purposes of this form. This is the date on which the participant’s treating physician was contacted for information pertaining to disease progression and vital status. For question 5, please refer to Appendix VII (section 3.2) which summarizes the categories of response status.

1. Timepoint for this follow-up [1]
   - 9 month follow-up

   1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation [2]
       ____-____-_______ (mm-dd-yyyy)

2. Was the follow-up evaluation completed? [3]
   - 1 No (complete Q2a, sign and date form)
   - 2 Yes (skip to Q3)

   2a. Reason not completed: (check all that apply)
       - Scheduling problem [4]
       - Patient refusal [5]
       - Medical reason (define reason in comments) [6]
       - Withdrew consent (submit the end of study form (DS)) [7]
       - Other [8] specify ____-____-_______ (mm-dd-yyyy)

3. Date of last contact between the treating physician and the participant [10]
   ____-____-_______ (mm-dd-yyyy)

4. Participant’s vital status at the time of this follow-up [11]
   - 1 Alive
   - 2 Dead (submit the end of study form (DS))
   - 99 Unknown

5. Response status at this assessment (see Instructions) [12]
   - 1 Complete response (CR)
   - 2 Partial response (PR)
   - 3 Stable disease (SD)
   - 4 Progressive disease (PD)
   - 99 Unknown

5a. Date the response status was determined [13]
    ____-____-_______ (mm-dd-yyyy)

6. Did the participant develop a first progression not previously reported [14]
   - 1 No
   - 2 Yes (submit the progression form (PF))
   - 99 Unknown

7. Did the participant receive any Radiation Therapy not previously reported? [15]
   - 1 No
   - 2 Yes (specify location and provide date)
   - 99 Unknown

   7a. Anatomic location of Radiation Therapy:
       ____-____-_______ (mm-dd-yyyy)

   7b. Date of Radiation Therapy: [16]
       ____-____-_______ (mm-dd-yyyy)

8. Did the participant have surgery not previously reported? [18]
   - 1 No
   - 2 Yes (specify location and provide date)
   - 99 Unknown

   8a. Anatomic location of surgery:
       ____-____-_______ (mm-dd-yyyy)

   8b. Date of surgery: [19]
       ____-____-_______ (mm-dd-yyyy)

9. Did the participant have any non-protocol chemotherapy not previously reported [21]
   - 1 No
   - 2 Yes (specify and provide date)
   - 99 Unknown

   9a. Type of non-protocol chemotherapy:
       ____-____-_______ (mm-dd-yyyy)

10. Did the participant receive any other non-protocol treatment not previously reported [24]
    - 1 No
    - 2 Yes (specify and provide date)
    - 99 Unknown

   10a. Type of treatment:
        ____-____-_______ (mm-dd-yyyy)

   10b. Date of non-protocol treatment: [26]
        ____-____-_______ (mm-dd-yyyy)
ACRIN Study 6678

PLACE LABEL HERE

Institution _______________  Institution No. ____________
Participant Initials ___________  Case No. ____________

9 MONTH FOLLOW-UP

Comments: ________________________________

______________________________[27]

Signature of Person responsible for the data
[28]

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

Signature of Person entering data onto the web
[29]
INSTRUCTIONS: The Research Staff will complete this form following contact with the participant’s treating physician. Please submit this form within 2 weeks of the one year evaluation, following cycle two of chemotherapy. Question 1a, is considered the date of follow-up for purposes of this form. This is the date on which the participant’s treating physician was contacted for information pertaining to disease progression and vital status. For question 5, please refer to Appendix VII (section 3.2) which summarizes the categories of response status.

1. **Timepoint for this follow-up**[1]
   - o 1 year follow-up

1a. Date the site RA/PI contacted the treating physician for this follow-up evaluation[2]
   - _____-_____-______ (mm-dd-yyyy)

2. **Was the follow-up evaluation completed?**[3]
   - o 1 No (complete Q2a, sign and date form)
   - o 2 Yes (skip to Q3)

2a. Reason not completed: (check all that apply)
   - □=1 Not Marked, □= 2 Marked
   - o Scheduling problem [4]
   - o Patient refusal [5]
   - o Medical reason (define reason in comments) [6]
   - o Withdrew consent (submit the end of study form (DS) ) [7]
   - o Other [8] specify ______________________ [9]

3. **Date of last contact between the treating physician and the participant**[10]
   - _____-_____-______ (mm-dd-yyyy)

4. **Participant’s vital status at the time of this follow-up**[11]
   - o 1 Alive
   - o 2 Dead (submit the end of study form (DS) )
   - o 99 Unknown

5. **Response status at this assessment** (see Instructions)[12]
   - o 1 Complete response (CR)
   - o 2 Partial response (PR)
   - o 3 Stable disease (SD)
   - o 4 Progressive disease (PD)
   - o 99 Unknown

5a. Date the response status was determined[13]
   - _____-_____-______ (mm-dd-yyyy)

6. **Did the participant develop a first progression not previously reported**[14]
   - o 1 No
   - o 2 Yes (submit the progression form (PF) )
   - o 99 Unknown

7. **Did the participant receive any Radiation Therapy not previously reported?**[15]
   - o 1 No
   - o 2 Yes (specify location and provide date)
   - o 99 Unknown

7a. Anatomic location of Radiation Therapy:
   - ______________________ [16]

7b. Date of Radiation Therapy:
   - _____-_____-______ (mm-dd-yyyy)

8. **Did the participant have surgery not previously reported?**[18]
   - o 1 No
   - o 2 Yes (specify location and provide date)
   - o 99 Unknown

8a. Anatomic location of surgery:
   - ______________________ [19]

8b. Date of surgery:
   - _____-_____-______ (mm-dd-yyyy)

9. **Did the participant have any non-protocol chemotherapy not previously reported?**[21]
   - o 1 No
   - o 2 Yes (specify and provide date)
   - o 99 Unknown

9a. Type of non-protocol chemotherapy:
   - ______________________ [22]

9b. Date of non-protocol chemotherapy:
   - _____-_____-______ (mm-dd-yyyy)

10. **Did the participant receive any other non-protocol treatment not previously reported**[24]
    - o 1 No
    - o 2 Yes (specify and provide date)
    - o 99 Unknown

10a. Type of treatment:
    - ______________________ [25]

10b. Date of non-protocol treatment:
    - _____-_____-______ (mm-dd-yyyy)
If this is a revised or corrected form, please ✓ box.

Institution ___________________ Institution No. ______
Participant Initials ___________ Case No. ___________

1 YEAR FOLLOW-UP

Comments: ____________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

[27]

Signature of Person responsible for the data [28] Signature of Person entering data onto the web [29]

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

"Copyright 2007"
Instructions: Complete this form at the time of patient’s entry on study. Submit the I1 via the Acrin web site within one week of study registration date. All forms must be signed and dated as indicated.

STAGING

1. Date of initial diagnosis of NSCLC
   
   __________-________-________ (mm-dd-yyyy) [1]

2. Clinical Stage (select only one) [2]
   o IIIB (not recurrent)
   o IV (not recurrent)
   o Recurrent
   o IIA (not recurrent)

PRIOR TREATMENT

3. Prior Surgery to the study site? [3]
   (within 3 months prior to study enrollment)
   o No
   o Yes (if yes, provide date in Q3a)
   o Unknown

3a. Date of Surgery __________-________-________ (mm-dd-yyyy) [4]

   (within 3 months prior to study enrollment)
   o No
   o Yes (if yes, provide date in Q4a)
   o Unknown

4a. Date XRT completed __________-________-________ (mm-dd-yyyy) [6]

   (within 3 months prior to study enrollment)
   o No
   o Yes (if yes, provide date in Q5a)
   o Unknown

5a. Date last systemic chemotherapy administered
   __________-________-________ (mm-dd-yyyy) [8]

   o No
   o Yes (If yes, provide dates in Q6a/Q6b and dose in Q6c)
   o Unknown

6a. Start date of Brain XRT __________-________-________ [15]
   (mm-dd-yyyy)

6b. End date of Brain XRT __________-________-________ [16]
   (mm-dd-yyyy)

6c. Total Dose _______ _______ . ____ (Gy) [17]

DIAGNOSTIC WORK-UP

7. Blood glucose level [9]
   (performed within 4 weeks prior to registration)
   _______. ____ mg/dl

COMMENTS:

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________ [10]

__________________________________________________________________________ [11]

Signature of person responsible for the data

__________________________________________________________________________ [12]

Date form completed __________-________-________

Signature of person entering data onto the web
ACRIN Study 6678

PLACE LABEL HERE

Institution ____________________  Institution No. __________
Participant Initials ____________  Case No. _____________

Instructions: Please record the requested information for the target lesions per Appendix VI of the 6678 protocol.

1. Date of Central PET Interpretation _____-_____-______ (mm-dd-yyyy)
2. Reader ID ____________________

3. Table 1: Record the date and the overall quality of each image

<table>
<thead>
<tr>
<th>Timepoint 1</th>
<th>Timepoint 2</th>
<th>Timepoint 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of PET Imaging</td>
<td><em><strong><strong>-</strong></strong></em>-______</td>
<td><em><strong><strong>-</strong></strong></em>-______</td>
</tr>
<tr>
<td>Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)</td>
<td>O No</td>
<td>O No</td>
</tr>
<tr>
<td>Is the overall quality of the PET/CT acceptable (if suboptimal, check all reasons that apply below)</td>
<td>O Adequate</td>
<td>O Adequate</td>
</tr>
<tr>
<td>O Suboptimal</td>
<td>O Suboptimal</td>
<td>O Suboptimal</td>
</tr>
<tr>
<td>Reason images cannot be interpreted or image quality suboptimal (check all that apply)</td>
<td>O Injection time unknown</td>
<td>O Injection time unknown</td>
</tr>
<tr>
<td>O Scan start time unknown</td>
<td>O Scan start time unknown</td>
<td>O Scan start time unknown</td>
</tr>
<tr>
<td>O Injected dose unknown</td>
<td>O Injected dose unknown</td>
<td>O Injected dose unknown</td>
</tr>
<tr>
<td>O Scanner not or incorrectly calibrated</td>
<td>O Scanner not or incorrectly calibrated</td>
<td>O Scanner not or incorrectly calibrated</td>
</tr>
<tr>
<td>O Related to patient preparation (blood glucose &gt;150 mg/dL)</td>
<td>O Related to patient preparation (blood glucose &gt;150 mg/dL)</td>
<td>O Related to patient preparation (blood glucose &gt;150 mg/dL)</td>
</tr>
<tr>
<td>O Uptake time &lt; 45 mins</td>
<td>O Uptake time &lt; 45 mins</td>
<td>O Uptake time &lt; 45 mins</td>
</tr>
<tr>
<td>O Uptake time &gt;80 mins</td>
<td>O Uptake time &gt;80 mins</td>
<td>O Uptake time &gt;80 mins</td>
</tr>
<tr>
<td>O Uptake time for the baseline and a follow-up scan varies by &gt; 15 minutes</td>
<td>O Uptake time for the baseline and a follow-up scan varies by &gt; 15 minutes</td>
<td>O Uptake time for the baseline and a follow-up scan varies by &gt; 15 minutes</td>
</tr>
<tr>
<td>O Beam hardening artifacts on CT</td>
<td>O Beam hardening artifacts on CT</td>
<td>O Beam hardening artifacts on CT</td>
</tr>
<tr>
<td>O Patient movement</td>
<td>O Patient movement</td>
<td>O Patient movement</td>
</tr>
<tr>
<td>O Misregistration of PET and CT involving the target lesion</td>
<td>O Misregistration of PET and CT involving the target lesion</td>
<td>O Misregistration of PET and CT involving the target lesion</td>
</tr>
<tr>
<td>O Difference in liver SUV from baseline to follow-up scans &gt; 1.0</td>
<td>O Difference in liver SUV from baseline to follow-up scans &gt; 1.0</td>
<td>O Difference in liver SUV from baseline to follow-up scans &gt; 1.0</td>
</tr>
<tr>
<td>O Liver SUV &lt;1.5 or &gt; 4.0</td>
<td>O Liver SUV &lt;1.5 or &gt; 4.0</td>
<td>O Liver SUV &lt;1.5 or &gt; 4.0</td>
</tr>
<tr>
<td>O Uptake time &gt;45 mins and &lt; 50 mins</td>
<td>O Uptake time &gt;45 mins and &lt; 50 mins</td>
<td>O Uptake time &gt;45 mins and &lt; 50 mins</td>
</tr>
<tr>
<td>O Uptake time &gt;70 mins and &lt;= 80 mins</td>
<td>O Uptake time &gt;70 mins and &lt;= 80 mins</td>
<td>O Uptake time &gt;70 mins and &lt;= 80 mins</td>
</tr>
<tr>
<td>O Uptake time for the baseline and follow-up scan varies by &gt;10 mins, but less than 15 mins</td>
<td>O Uptake time for the baseline and follow-up scan varies by &gt;10 mins, but less than 15 mins</td>
<td>O Uptake time for the baseline and follow-up scan varies by &gt;10 mins, but less than 15 mins</td>
</tr>
<tr>
<td>O Other, specify_____________</td>
<td>O Other, specify_____________</td>
<td>O Other, specify_____________</td>
</tr>
</tbody>
</table>

Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)

O Injection time unknown
O Scan start time unknown
O Injected dose unknown
O Patient body weight unknown
O Scanner not or incorrectly calibrated
O Related to patient preparation (blood glucose >150 mg/dL)
O Uptake time < 45 mins
O Uptake time >80 mins
O Uptake time for the baseline and a follow-up scan varies by > 15 minutes
O Beam hardening artifacts on CT
O Patient movement
O Misregistration of PET and CT involving the target lesion
O Difference in liver SUV from baseline to follow-up scans > 1.0
O Liver SUV <1.5 or > 4.0
O Uptake time >45 mins and < 50 mins
O Uptake time >70 mins and <= 80 mins
O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins
O Other, specify_____________
4. Table 2: Record the following for each image. For 'unknown' code 999.

<table>
<thead>
<tr>
<th>Tumor Location</th>
<th>Timepoint 1</th>
<th>Timepoint 2</th>
<th>Timepoint 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tumor Location</td>
<td>Table Position</td>
<td>Tumor Size</td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Tumor Location**

1. Right upper lobe
2. Right middle lobe
3. Right lower lobe
4. Left upper lobe/ lingula
5. Left lower lobe
6. Right Mediastinal lymph node
7. Right hilar lymph node
8. Left Mediastinal lymph node
9. Left hilar lymph node
10. Subcarinal lymph node
11. Supraclavicular / scalene nodes
12. Pleura
13. Liver
14. Adrenals
15. Bone
16. Brain
17. Skin
18. Spleen
19. Other, specify

**Change in Uptake Scale**

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

*Copyright 2009*
5. Compared to baseline PET, has there been an increase in OR decrease in the total number of tumor lesion(s)?
   - O increase
   - O 2 stable
   - O 3 decrease

6. Compared to baseline PET, has there been an overall increase in OR decrease in the FDG uptake within the tumor lesion(s)?
   - O 1 increase
   - O 2 stable
   - O 3 decrease

7. Compared to baseline PET, has there been an increase OR decrease in the size of tumor lesion(s)?
   - O 1 increase
   - O 2 stable
   - O 3 decrease

8. Overall post treatment metabolic response: (metabolic response criteria defined below: indicate the overall metabolic response as prompted comparing to baseline)
   - O 1 Complete Metabolic Response (CMR): Complete resolution of all metabolically active tumor lesions, and no interval development of new lesions.
   - O 2 Partial metabolic Response (PMR): One or both of the following must occur: (indicate response)
     - Target lesions: 20% or greater decrease in maximum SUV from baseline. No unequivocal metabolic progression of other tumor lesions and no unequivocal new lesions.
     - Other lesions: decrease in total number of non-target lesions, without complete resolution of metabolically active disease, or unequivocal decrease in degree of FDG activity within > 50% of the lesions. No unequivocal new lesions.
   - O 3 Metabolically Stable: Does not qualify for CMR, PMR or Metabolic Progression.
   - O 4 Metabolic Progression: One or more of the following must occur: (indicate response)
     - Unequivocal development of one or more new metabolically active lesion(s).
     - Target lesions: 20% or greater increase in maximum SUV from baseline.
     - Other tumor lesions: unequivocal increase in FDG activity within other tumor lesions on PET.
     - Unequivocal increase in size of index or other tumor lesions on PET.

COMMENTS: ____________________________________________________________

__________________________________________________________

Initials of person entering data

Date form completed (mm-dd-yyyy)
Instructions: Please record the requested information for the target lesions per Appendix VI of the 6678 protocol.

1. Date of Central PET Interpretation _____-_____-____ (mm-dd-yyyy)  
2. Reader ID

3. Table 1: Record the date and the overall quality of each image

<table>
<thead>
<tr>
<th>Date of PET Imaging</th>
<th>Timepoint 1</th>
<th>Timepoint 2</th>
<th>Timepoint 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em><strong><strong>-</strong></strong></em>-_____</td>
<td><em><strong><strong>-</strong></strong></em>-_____</td>
<td><em><strong><strong>-</strong></strong></em>-_____</td>
</tr>
</tbody>
</table>

- Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)
  - O No
  - O Yes

- Is the overall quality of the PET/CT acceptable (if suboptimal, check all reasons that apply below)
  - O Adequate
  - O Suboptimal

- Reason images cannot be interpreted or image quality suboptimal (check all that apply)
  - O Injection time unknown
  - O Scan start time unknown
  - O Injected dose unknown
  - O Patient body weight unknown
  - O Scanner not or incorrectly calibrated
  - O Related to patient preparation (blood glucose >150 mg/dL)
  - O Uptake time < 45 mins
  - O Uptake time >80 mins
  - O Uptake time for the baseline and a follow-up scan varies by > 15 minutes
  - O Beam hardening artifacts on CT
  - O Patient movement
  - O Misregistration of PET and CT involving the target lesion
  - O Difference in liver SUV from baseline to follow-up scans > 1.0
  - O Liver SUV <1.5 or > 4.0
  - O Uptake time >=45 mins and < 50 mins
  - O Uptake time >70 mins and <= 80 mins
  - O Other, specify

- O Injection time unknown
- O Scan start time unknown
- O Injected dose unknown
- O Patient body weight unknown
- O Scanner not or incorrectly calibrated
- O Related to patient preparation (blood glucose >150 mg/dL)
- O Uptake time < 45 mins
- O Uptake time >80 mins
- O Uptake time for the baseline and a follow-up scan varies by > 15 minutes
- O Beam hardening artifacts on CT
- O Patient movement
- O Misregistration of PET and CT involving the target lesion
- O Difference in liver SUV from baseline to follow-up scans > 1.0
- O Liver SUV <1.5 or > 4.0
- O Uptake time >=45 mins and < 50 mins
- O Uptake time >70 mins and <= 80 mins
- O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins
- O Other, specify
### Table 2: Record the following for each image. For Group B, visit B1 and B2 scans must be read before visit B3 scan is read. For unknown code 999.

<table>
<thead>
<tr>
<th>Tumor Location</th>
<th>Timepoint 1</th>
<th>Timepoint 2</th>
<th>Timepoint 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tumor Location</td>
<td>Table Position</td>
<td>Tumor Size</td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Tumor Location**
1. Right upper lobe
2. Right middle lobe
3. Right lower lobe
4. Left upper lobe/lingula
5. Left lower lobe
6. Right Mediastinal lymph node
7. Right hilar lymph node
8. Left Mediastinal lymph node
9. Left hilar lymph node
10. Subcarinal lymph node
11. Supraclavicular / scalene nodes
12. Pleura
13. Liver
14. Adrenals
15. Bone
16. Brain
17. Skin
18. Spleen
88. Other, specify

**Change in Uptake Scale**
(compared to 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

"Copyright 2009"
Timepoint 2: Complete questions 5-8

5. Compared to baseline PET, has there been an increase in OR decrease in the total number of tumor lesion(s)?
   - O increase
   - O 2 stable
   - O 3 decrease

6. Compared to baseline PET, has there been an overall increase in OR decrease in the FDG uptake within the tumor lesion(s)?
   - O 1 increase
   - O 2 stable
   - O 3 decrease

7. Compared to baseline PET, has there been an increase OR decrease in the size of tumor lesion(s)?
   - O 1 increase
   - O 2 stable
   - O 3 decrease

8. Overall post treatment metabolic response: (metabolic response criteria defined below: indicate the overall metabolic response as prompted comparing to baseline)
   - O 1 Complete Metabolic Response (CMR): Complete resolution of all metabolically active tumor lesions, and no interval development of new lesions.
   - O 2 Partial metabolic Response (PMR): One or both of the following must occur: (indicate response)
     - ☐ Target lesions: 20% or greater decrease in maximum SUV from baseline. No unequivocal metabolic progression of other tumor lesions and no unequivocal new lesions.
     - ☐ Other lesions: decrease in total number of non-target lesions, without complete resolution of metabolically active disease, or unequivocal decrease in degree of FDG activity within > 50% of the lesions. No unequivocal new lesions.
   - O 3 Metabolically Stable: Does not qualify for CMR, PMR or Metabolic Progression.
   - O 4 Metabolic Progression: One or more of the following must occur: (indicate response)
     - ☐ Unequivocal development of one or more new metabolically active lesion(s).
     - ☐ Target lesions: 20% or greater increase in maximum SUV from baseline.
     - ☐ Other tumor lesions: unequivocal increase in FDG activity within other tumor lesions on PET.
     - ☐ Unequivocal increase in size of index or other tumor lesions on PET.
Timepoint 3: Complete questions 9-12

9. Compared to baseline PET, has there been an increase in OR decrease in the total number of tumor lesion(s)?
   - O increase
   - O 2 stable
   - O 3 decrease

10. Compared to baseline PET, has there been an overall increase in OR decrease in the FDG uptake within the tumor lesion(s)?
    - O 1 increase
    - O 2 stable
    - O 3 decrease

11. Compared to baseline PET, has there been an increase OR decrease in the size of tumor lesion(s)?
    - O 1 increase
    - O 2 stable
    - O 3 decrease

12. Overall post treatment metabolic response: (metabolic response criteria defined below: indicate the overall metabolic response as prompted comparing to baseline)
    - O 1 Complete Metabolic Response (CMR): Complete resolution of all metabolically active tumor lesions, and no interval development of new lesions.
    - O 2 Partial metabolic Response (PMR): One or both of the following must occur: (indicate response)
      - Target lesions: 20% or greater decrease in maximum SUV from baseline. No unequivocal metabolic progression of other tumor lesions and no unequivocal new lesions.
      - Other lesions: decrease in total number of non-target lesions, without complete resolution of metabolically active disease, or unequivocal decrease in degree of FDG activity within > 50% of the lesions. No unequivocal new lesions.
    - O 3 Metabolically Stable: Does not qualify for CMR, PMR or Metabolic Progression.
    - O 4 Metabolic Progression: One or more of the following must occur: (indicate response)
      - Unequivocal development of one or more new metabolically active lesion(s).
      - Target lesions: 20% or greater increase in maximum SUV from baseline.
      - Other tumor lesions: unequivocal increase in FDG activity within other tumor lesions on PET.
      - Unequivocal increase in size of index or other tumor lesions on PET.

COMMENTS:

__________________________________________________________________________________

__________________________________________________________________________________

__________________________________________________________________________________

Initials of person entering data

Date form completed (mm-dd-yyyy)
Please record the requested information for the target lesions per Appendix VI of the 6678 protocol.

1. Date of Central PET Interpretation _____-_____-____ (mm-dd-yyyy)

2. Reader ID [ ]

3. Table 1: Record the date and the overall quality of each image

<table>
<thead>
<tr>
<th>Date of PET Imaging</th>
<th>Timepoint 1</th>
<th>Timepoint 2</th>
<th>Timepoint 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em><strong><strong>-</strong></strong></em></td>
<td><em><strong><strong>-</strong></strong></em></td>
<td><em><strong><strong>-</strong></strong></em></td>
</tr>
</tbody>
</table>

Was the PET/CT Central Interpretation completed?
(if no, check all reasons that apply below)

- O No
- O Yes

Is the overall quality of the PET/CT acceptable
(if suboptimal, check all reasons that apply below)

- O Adequate
- O Suboptimal

Reason images cannot be interpreted or image quality suboptimal (check all that apply)

- O Injection time unknown
- O Scan start time unknown
- O Injected dose unknown
- O Patient body weight unknown
- O Scanner not or incorrectly calibrated
- O Related to patient preparation (blood glucose >150 mg/dL)
- O Uptake time < 45 mins
- O Uptake time >80 mins
- O Uptake time for the baseline and a follow-up scan varies by > 15 minutes
- O Beam hardening artifacts on CT
- O Patient movement
- O Misregistration of PET and CT involving the target lesion
- O Difference in liver SUV from baseline to follow-up scans > 1.0
- O Liver SUV <1.5 or > 4.0
- O Uptake time >=45 mins and < 50 mins
- O Uptake time >70 mins and <= 80 mins
- O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins
- O Other, specify__

- O Injection time unknown
- O Scan start time unknown
- O Injected dose unknown
- O Patient body weight unknown
- O Scanner not or incorrectly calibrated
- O Related to patient preparation (blood glucose >150 mg/dL)
- O Uptake time < 45 mins
- O Uptake time >80 mins
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- O Beam hardening artifacts on CT
- O Patient movement
- O Misregistration of PET and CT involving the target lesion
- O Difference in liver SUV from baseline to follow-up scans > 1.0
- O Liver SUV <1.5 or > 4.0
- O Uptake time >=45 mins and < 50 mins
- O Uptake time >70 mins and <= 80 mins
- O Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins
- O Other, specify__
4. Table 2: Record the following for each image. For 'unknown' code 999.

<table>
<thead>
<tr>
<th>Tumor Location</th>
<th>Timepoint 1</th>
<th>Timepoint 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tumor Size</td>
<td>SUV (max)</td>
</tr>
<tr>
<td>Liver</td>
<td>Table Position</td>
<td>SUV (peak)</td>
</tr>
<tr>
<td>Target Lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 3</td>
<td></td>
<td></td>
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<tr>
<td>Additional Lesion 4</td>
<td></td>
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</tr>
<tr>
<td>Additional Lesion 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Lesion 6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Tumor Location**

1. Right upper lobe
2. Right middle lobe
3. Right lower lobe
4. Left upper lobe/lingula
5. Left lower lobe
6. Right Mediastinal lymph node
7. Right hilar lymph node
8. Left Mediastinal lymph node
9. Left hilar lymph node
10. Subcarinal lymph node
11. Supraclavicular / scalene nodes
12. Pleura
13. Liver
14. Adrenals
15. Bone
16. Brain
17. Skin
18. Spleen
19. Other, specify

**Change in Uptake Scale**

(Compared to 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

**COMMENTS:**

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Initials of person entering data

Date form completed (mm-dd-yyyy)

Version 1.0  6678  IC  08-13-09  2 of 2
1. **Protocol Time point of PET/CT Imaging** *(check only one)*:
   - O Post-treatment after Cycle 1 *(Group A and Group B)*
   - O Post-treatment after Cycle 2 *(Group B only)*

2. **Was the quality of the PET/CT images adequate for interpretation?**
   - O No *(complete Q2a and 3, then sign and date form)*
   - O Yes

   2a. Reason image not interpreted:
      - O Entire study not complete
      - O Noisy Images
      - O Patient motion
      - O SUV's cannot be calculated; specify reason:
        _____________________________________________
      - O Other, specify _______________________________

3. **Date of PET exam** __________-________-________ *(mm/dd/yyyy)*

4. **Date of PET interpretation** __________-________-________ *(mm/dd/yyyy)*

5. **Reader ID** __________

6. **Is the pre-treatment PET scan available for post-treatment PET/CT interpretation?**
   - O No
   - O Yes

7. **Is the pre-treatment CT scan available for post-treatment PET/CT interpretation?**
   - O No
   - O Yes

8. **How was the post-treatment PET scan interpreted with the post-treatment CT scan?**
   - O Software fusion
   - O Hybrid CT/PET fusion

Instructions:
### ACRIN 6678
#### PET/CT Imaging Post-treatment
Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form

**ACRIN Study 6678**

**PLACE LABEL HERE**

<table>
<thead>
<tr>
<th>Institution</th>
<th>Institution No.</th>
<th>Case No.</th>
</tr>
</thead>
</table>

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

**Uptake Scale**
- 0: Not imaged; cannot evaluate
- 1: Definitely not tumor
- 2: Probably not tumor
- 3: Indeterminate
- 4: Probably tumor
- 5: Definitely tumor

**Change in Uptake Scale**
- 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

**Local Regional Response**
- 0: Complete Response
- 1: Partial Response
- 2: No Response
- 3: Progressive Disease

**Progression based on proximity of the site(s) to local regional assessment**

**Metastatic Disease**
- 0: Not Applicable
- 1: Definitely no metastatic disease
- 2: Probably no metastatic disease
- 3: Indeterminate
- 4: Probably Metastatic disease
- 5: Definitely metastatic disease

**Proximity**
- 1: Not applicable
- 2: In-field
- 3: Marginal
- 4: Remote

---

**Uptake Scale**

<table>
<thead>
<tr>
<th>Target Lesion</th>
<th>Uptake Scale</th>
<th>Change in Uptake Scale</th>
<th>Local Regional Assessment</th>
<th>Metastatic Disease</th>
<th>Progression based on proximity of the site(s) to local regional assessment</th>
<th>SUV (max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td>T2</td>
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<td>T3</td>
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<tr>
<td>T10</td>
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<td></td>
</tr>
</tbody>
</table>

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"Copyright 2009"
### Compared to Baseline Only

<table>
<thead>
<tr>
<th>Non-Target Lesion</th>
<th>Uptake Scale</th>
<th>Change in Uptake Scale</th>
<th>Local Regional Assessment</th>
<th>Metastatic Disease</th>
<th>Progression based on proximity of the site(s) to local regional assessment</th>
<th>SUV (max)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor Number</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(number should correspond to pre-treatment tumor)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S2</td>
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<tr>
<td>S3</td>
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<tr>
<td>S4</td>
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</tr>
<tr>
<td>S5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Post Treatment

<table>
<thead>
<tr>
<th>Uptake Scale</th>
<th>Change in Uptake Scale (compared to baseline)</th>
<th>Local Regional Response (compared to baseline)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Not imaged; cannot evaluate</td>
<td>0 No Uptake</td>
<td>0 (CR) Complete Response</td>
</tr>
<tr>
<td>1 Definitely not tumor</td>
<td>1 Marked decrease in uptake</td>
<td>1 (PR) Partial Response</td>
</tr>
<tr>
<td>2 Probably not tumor</td>
<td>2 Slight decrease in uptake</td>
<td>2 (ND) No Response</td>
</tr>
<tr>
<td>3 Indeterminate</td>
<td>3 No change in uptake</td>
<td>3 (PD) Progressive Disease</td>
</tr>
<tr>
<td>4 Probably tumor</td>
<td>4 Slight increase in uptake</td>
<td></td>
</tr>
<tr>
<td>5 Definitely tumor</td>
<td>5 Marked increase in uptake</td>
<td></td>
</tr>
</tbody>
</table>

### Proximity

<table>
<thead>
<tr>
<th>Proximity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Not applicable</td>
</tr>
<tr>
<td>2 In-field</td>
</tr>
<tr>
<td>3 Marginal</td>
</tr>
<tr>
<td>4 Remote</td>
</tr>
</tbody>
</table>

**Notes:**
- **Uptake Scale**
- **Change in Uptake Scale**
- **Metastatic Disease**
- **Local Regional Response**
- **Proximity**
11. Indicate any Lymphadenopathy

<table>
<thead>
<tr>
<th>Anatomic Site</th>
<th>Confidence in presence of disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supraclavicular</td>
<td></td>
</tr>
<tr>
<td>Ipsilateral hilar</td>
<td></td>
</tr>
<tr>
<td>Contralateral hilar</td>
<td></td>
</tr>
<tr>
<td>Ipsilateral upper mediastinal</td>
<td></td>
</tr>
<tr>
<td>Contralateral upper mediastinal</td>
<td></td>
</tr>
<tr>
<td>Ipsilateral lower mediastinal</td>
<td></td>
</tr>
<tr>
<td>Contralateral lower mediastinal</td>
<td></td>
</tr>
<tr>
<td>Other, Specify</td>
<td></td>
</tr>
</tbody>
</table>

12. Indicate any distant Metastasis with PET findings

<table>
<thead>
<tr>
<th>Anatomic Site</th>
<th>Confidence in presence of disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supraclavicular</td>
<td></td>
</tr>
<tr>
<td>Ipsilateral hilar</td>
<td></td>
</tr>
<tr>
<td>Contralateral hilar</td>
<td></td>
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<tr>
<td>Ipsilateral upper mediastinal</td>
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<tr>
<td>Contralateral upper mediastinal</td>
<td></td>
</tr>
<tr>
<td>Ipsilateral lower mediastinal</td>
<td></td>
</tr>
<tr>
<td>Contralateral lower mediastinal</td>
<td></td>
</tr>
<tr>
<td>Other, Specify</td>
<td></td>
</tr>
</tbody>
</table>

Confidence Scale
1. Definitely no metastasis
2. Probably no metastasis
3. Possibly no metastasis
4. Probably metastasis
5. Definitely metastasis
PET Assessment

13. What is your overall confidence in the Presence or Absence of Stage IV disease as seen with PET?
   - Definitely not present
   - Probably not Present
   - Indeterminate
   - Probably present
   - Definitely Present

Comments: __________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Signature of Nuclear medicine MD ___________________________ Date form completed __________

Signature of person entering data onto the web __________________________
1. Protocol Time point of PET/CT Imaging (check only one):
   - Pre-treatment (Within 2 weeks after registration visit: Group A only)
   - Pre-treatment (Within 1 weeks prior to 1st Chemotherapy Cycle: Group A and Group B)

2. Was the quality of the PET/CT images adequate for interpretation?
   - No (complete Q2a and 3, then sign and date form)
   - Yes

   2a. Reason image not interpreted:
       - Entire study not complete
       - Noisy Images
       - Patient motion
       - SUV’s cannot be calculated; specify reason:
         
       - Other, specify ________________________________

3. Date of PET exam ______-______-______ (mm/dd/yyyy)

4. Date of PET interpretation ______-______-______ (mm/dd/yyyy)

5. Reader ID [ ]
### Target Lesion

<table>
<thead>
<tr>
<th>Tumor Location</th>
<th>Tumor Size in Diameter (cm)</th>
<th>Uptake Scale</th>
<th>SUV (max)</th>
<th>Primary Tumor</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td></td>
<td></td>
<td></td>
<td>O No</td>
</tr>
<tr>
<td></td>
<td></td>
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<td>O Yes</td>
</tr>
<tr>
<td>T2</td>
<td></td>
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<tr>
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<td></td>
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<td>T3</td>
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<td>T4</td>
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</tr>
<tr>
<td>T10</td>
<td></td>
<td></td>
<td></td>
<td>O No</td>
</tr>
</tbody>
</table>

### Tumor Location

- Right upper lobe
- Right middle lobe
- Right lower lobe
- Left upper lobe
- Left middle lobe
- Right Mediastinal lymph node
- Right hilar lymph node
- Left Mediastinal lymph node
- Left hilar lymph node
- Subcarinal lymph node

### Uptake Scale

- 0: Not imaged; cannot evaluate
- 1: Definitely not tumor
- 2: Probably not tumor
- 3: Indeterminate
- 4: Probably tumor
- 5: Definitely tumor
### Tumor Location

1. Right upper lobe
2. Right middle lobe
3. Right lower lobe
4. Left upper lobe
5. Left middle lobe
6. Right Mediastinal lymph node
7. Right hilar lymph node
8. Left Mediastinal lymph node
9. Left hilar lymph node
10. Subcarinal lymph node

### Uptake Scale

0. Not imaged; cannot evaluate
1. Definitely not tumor
2. Probably not tumor
3. Indeterminate
4. Probably tumor
5. Definitely tumor

<table>
<thead>
<tr>
<th>Non-Target Lesion</th>
<th>Tumor Location</th>
<th>Tumor Size in Diameter (cm)</th>
<th>Uptake Scale</th>
<th>SUV (max)</th>
<th>Primary Tumor</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>O No</td>
</tr>
<tr>
<td>S2</td>
<td></td>
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<td>S3</td>
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<td>S4</td>
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<tr>
<td>S5</td>
<td></td>
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<td></td>
<td></td>
<td>O No</td>
</tr>
</tbody>
</table>
ACRIN 6678
PET/CT Imaging Pre-treatment
Core (Lab) PET Qualitative and
Semi-Qualitative Assessment Form

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

ACRIN Study 6678

Comments:

Signature of Nuclear medicine MD

Signature of person entering data onto the web
Instructions: Please record the requested information for the target lesions per Appendix VI of the 6678 protocol.

1. Date of Central PET Interpretation _____-_____-_____ (mm-dd-yyyy) [1]
2. Reader ID [2]

3. Table 1: Record the date and the overall quality of each image

<table>
<thead>
<tr>
<th>Date of PET Imaging</th>
<th>Timepoint 1</th>
<th>Timepoint 2</th>
<th>Timepoint 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of PET Imaging</td>
<td>- - - - - -</td>
<td>- - - - - -</td>
<td>- - - - - -</td>
</tr>
<tr>
<td>Was the PET/CT Central Interpretation completed? (if no, check all reasons that apply below)</td>
<td>O No</td>
<td>O No</td>
<td>O No</td>
</tr>
<tr>
<td>Is the overall quality of the PET/CT acceptable (if suboptimal, check all reasons that apply below)</td>
<td>O Adequate</td>
<td>O Adequate</td>
<td>O Adequate</td>
</tr>
</tbody>
</table>

- Injection time unknown [12]
- Scan start time unknown [13]
- Injected dose unknown [14]
- Patient body weight unknown [15]
- Scanner not or incorrectly calibrated [16]
- Related to patient preparation (blood glucose > 150 mg/dL) [17]
- Uptake time < 45 mins [18]
- Uptake time > 80 mins [19]
- Uptake time for the baseline and a follow-up scan varies by > 15 minutes [20]
- Beam hardening artifacts on CT [21]
- Patient movement [22]
- Misregistration of PET and CT involving the target lesion [23]
- Difference in liver SUV from baseline to follow-up scans > 1.0 [24]
- Liver SUV < 1.5 or > 4.0 [25]
- Uptake time >= 45 mins and < 50 mins [26]
- Uptake time >= 70 mins and <= 80 mins [27]
- Other, [28] specify_________________________ [29]

- Injection time unknown [31]
- Scan start time unknown [32]
- Injected dose unknown [33]
- Patient body weight unknown [34]
- Scanner not or incorrectly calibrated [35]
- Related to patient preparation (blood glucose > 150 mg/dL) [36]
- Uptake time < 45 mins [37]
- Uptake time > 80 mins [38]
- Uptake time for the baseline and a follow-up scan varies by > 15 minutes [39]
- Beam hardening artifacts on CT [40]
- Patient movement [41]
- Misregistration of PET and CT involving the target lesion [42]
- Difference in liver SUV from baseline to follow-up scans > 1.0 [43]
- Liver SUV < 1.5 or > 4.0 [44]
- Uptake time >= 45 mins and < 50 mins [45]
- Uptake time >= 70 mins and <= 80 mins [46]
- Uptake time for the baseline and follow-up scan varies by > 10 mins, but less than 15 mins [47]
- Other, [48] specify_________________________ [49]

- Injection time unknown [50]
- Scan start time unknown [51]
- Injected dose unknown [52]
- Patient body weight unknown [53]
- Scanner not or incorrectly calibrated [54]
- Related to patient preparation (blood glucose > 150 mg/dL) [55]
- Uptake time < 45 mins [56]
- Uptake time > 80 mins [57]
- Uptake time for the baseline and a follow-up scan varies by > 15 minutes [58]
- Beam hardening artifacts on CT [59]
- Patient movement [60]
- Misregistration of PET and CT involving the target lesion [61]
- Difference in liver SUV from baseline to follow-up scans > 1.0 [62]
- Liver SUV < 1.5 or > 4.0 [63]
- Uptake time >= 45 mins and < 50 mins [64]
- Uptake time >= 70 mins and <= 80 mins [65]
- Uptake time for the baseline and follow-up scan varies by > 10 mins, but less than 15 mins [66]
- Other, [67] specify_________________________ [68]
4. Table 2: Record the following for each image. For 'unknown' code 999.

<table>
<thead>
<tr>
<th>Tumor Location</th>
<th>Table Position</th>
<th>Tumor Size</th>
<th>SUV (max)</th>
<th>SUV (peak)</th>
<th>SUV (Avg)</th>
<th>Table Position</th>
<th>Tumor Size</th>
<th>Change in Uptake</th>
<th>SUV (max)</th>
<th>SUV (peak)</th>
<th>SUV (Avg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Lesion</td>
<td>[72]</td>
<td>[73]</td>
<td>[74]</td>
<td>[75]</td>
<td>[76]</td>
<td>[77]</td>
<td>[78]</td>
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<td>[80]</td>
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<td>[92]</td>
<td>[93]</td>
<td>[94]</td>
<td>[95]</td>
<td>[96]</td>
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<tr>
<td>Additional Lesion 1</td>
<td>[102]</td>
<td>[103]</td>
<td>[104]</td>
<td>[105]</td>
<td>[106]</td>
<td>[107]</td>
<td>[108]</td>
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<tr>
<td>Additional Lesion 2</td>
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<td>[118]</td>
<td>[119]</td>
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<td>[121]</td>
<td>[122]</td>
<td>[123]</td>
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<td>[125]</td>
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<tr>
<td>Additional Lesion 3</td>
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<td>[136]</td>
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<tr>
<td>Additional Lesion 4</td>
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<td>[149]</td>
<td>[150]</td>
<td>[151]</td>
<td>[152]</td>
<td>[153]</td>
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<tr>
<td>Additional Lesion 5</td>
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<td>[163]</td>
<td>[164]</td>
<td>[165]</td>
<td>[166]</td>
<td>[167]</td>
<td>[168]</td>
<td>[169]</td>
<td>[170]</td>
<td>[171]</td>
<td></td>
</tr>
</tbody>
</table>

**Tumor Location**
1. Right upper lobe 12. Pleura
2. Right middle lobe 13. Liver
4. Left upper lobe/ lingula 15. Bone
5. Left lower lobe 16. Brain
6. Right Mediastinal lymph node 17. Skin
7. Right hilar lymph node 18. Spleen
8. Left Mediastinal lymph node 88. Other, specify
9. Left hilar lymph node
10. Subcarinal lymph node
11. Supraclavicular / scalene nodes

**Change in Uptake Scale**
(Co compared to 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

**COMMENTS:**

Initials of person entering data

"Copyright 2012"
ACRIN 6678
FDG - PET/CT Tumor Response
Off Study Criteria

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

Instructions: Participants who meet any of the following criteria, per protocol section 8.5, will go off-study and be replaced with other eligible participants. Participants going off study will not undergo any additional FDG/PET scans or CT scans for tumor volumetric imaging, nor will the study follow-up visits continue. An End of Study Form (DS) should also be submitted for these participants.

1. Was the participant removed from the study for any of the following reasons as specified in section 8.5 of the protocol? [1]
   - No (Sign and date form)
   - Yes (Complete Q1a; complete an End of Study Form (DS))

1a. Select from the following off study criteria (check all that apply) □=1 Not Marked, ✓= 2 Marked
   1. The baseline SUV of the tumor (measured at the first PET/CT study) is less than 4.0. [2]
   2. There are significant protocol variations or image artifacts, as described on the Checklist for PET/CT Image Quality (Appendix VI), which result in an unrepeatable and inadequate PET/CT exam. [3]
   3. Participant receives less than 2 cycles of first-line chemotherapy due to drug toxicity. [4]
   4. Participant undergoes the baseline pre-chemotherapy FDG-PET/CT scan(s) after the initiation of chemotherapy. [5]
   5. Participant undergoes the post-chemotherapy cycle 1 FDG-PET/CT scan after initiation of chemotherapy cycle 2. [6]
   6. Participant refuses the FDG-PET/CT scan(s) at the study imaging visits and/or refuses study follow-up visits. [7]

__________________________________________ [8]  ________________________________ [10]
Signature of person responsible for the data  Date form completed (mm-dd-yyyy)

__________________________________________ [9]
Signature of person entering data onto the web

"Copyright 2007"
ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A1 - Pre-Chemotherapy
(Within 14 days of Registration)

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

INSTRUCTIONS: This form is to be completed by the Radiologist for the FDG-PET/CT performed at this timepoint.

1. Time point of PET/CT [1]
   - Pre-chemotherapy (Group A within 14 days after registration)

2. Was the FDG PET/CT interpretation completed? [2]
   - No (Complete Q2a, then sign and date form)
   - Yes (Skip to Q3)

2a. Reason images cannot be interpreted: (check all that apply) □=1 Not Marked, □= 2 Marked

   Related to SUV calculation
   - injection time unknown [3]
   - scan start time unknown [4]
   - injected dose unknown [5]
   - scanner not or incorrectly calibrated [7]

   Related to patient preparation (Blood glucose levels > 150 mg/dL) [8]

   Related to the uptake time (time between injection and start of scan)
   - Uptake time < 45 minutes [9]
   - Uptake time > 80 minutes [10]
   - Uptake time for the baseline and a follow-up scan varies by > 15 minutes [11]

   Related to beam hardening artifacts on CT [12]
   - (Beam hardening artifacts are overlying all possible target lesions in the chest)

   Patient movement [13]
   - Misregistration of PET and CT involving the whole target lesion (i.e. target lesion as defined on CT does not match target lesion as defined on PET) and no other target lesion available [14]

3. Date of FDG PET/CT exam ______-______-_______ (mm-dd-yyyy) [15]

4. Date of FDG PET/CT interpretation ______-______-_______ (mm-dd-yyyy) [16]

5. Reader ID _______ _______ _______ _______ _______ _______ [17]
6. Is the overall quality of the FDG PET/CT acceptable? □ Adequate (skip to Q7) □ Suboptimal (provide reason in Q6a, then sign and date form)

6a. Reason suboptimal (check all that apply) □=1 Not Marked, □=2 Marked
   □ Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL)
   □ Difference in liver SUV from the baseline to the follow-up scan > 1.0
   □ Liver SUV < 1.5 or > 4.0
   □ Related to uptake time (time between injection and start of scan)
     □ Uptake time >=45 minutes and < 50 minutes
     □ Uptake time > 70 and <= 80 minutes
     □ Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes
     □ Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region)
     □ Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices)

7. Record MAX SUV measurement of target lesion
   (refer to Appendix VI section 6 for details; if max SUV is less than 4.0, complete the (O1) Off Study Form)

8. Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)

9. Location of Target Lesion in the Chest (choose only one)
   □ Right upper lobe
   □ Right middle lobe
   □ Right lower lobe
   □ Left upper lobe / lingula
   □ Left lower lobe
   □ Right mediastinal lymph node
   □ Right hilar lymph node
   □ Left mediastinal lymph node
   □ Left hilar lymph node
   □ Subcarinal lymph node
   □ Supraclavicular/scalene nodes
VISIT: A1

10. Are there any metastatic lesions to report? [30]
   - No
   - Yes (complete Q10a)


- Hilar nodes
- Mediastinal nodes
- Supraclavicular/scalene nodes
- Ipsilateral lung
- Contralateral lung
- Pleura
- Liver
- Adrenals
- Bone
- Bone marrow
- Brain
- Skin

COMMENTS:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Radiologist responsible for data [45] Date form completed (mm-dd-yyyy) [46]

Person entering data onto the web [47]
ACRIN 6678
FDG - PET/CT Tumor Response
Progression Form

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

INSTRUCTIONS: Submit this form when signs of progression occur. Please specify the site of progression by placing an X in the box next to the anatomical part. Report all signs of progression. For each site, record the method of evaluation and date of evaluation in the subsequent columns. Dates are recorded as mm-dd-yyyy. If more than one method of evaluation is used, provide the most definitive method of evaluation used to determine progression. Repeat for all sites of progression.

Progressive Disease Documentation

METHOD OF EVALUATION (most definitive)
1 Pathology 5 Ultrasound
2 CT Scan 6 Bone Scan
3 MRI Scan 7 Physical Exam
4 PET Scan 88 Other (specify in comments)

(check all that apply)

<table>
<thead>
<tr>
<th>SITE OF PROGRESSION</th>
<th>METHOD OF EVALUATION</th>
<th>DATE OF EVALUATION (mm-dd-yyyy)</th>
</tr>
</thead>
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<tr>
<td>Right upper lobe [1]</td>
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<td></td>
</tr>
<tr>
<td>Right middle lobe [4]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right lower lobe [7]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left upper lobe / lingula [10]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left lower lobe [13]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right mediastinal lymph node [16]</td>
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<td></td>
</tr>
<tr>
<td>Right hilar lymph node [19]</td>
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<tr>
<td>Left mediastinal lymph node [22]</td>
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<td></td>
</tr>
<tr>
<td>Left hilar lymph node [25]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subcarinal lymph node [28]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supraclavicular/scalene nodes [31]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pleura [34]</td>
<td></td>
<td></td>
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<tr>
<td>Liver [37]</td>
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<tr>
<td>Adrenals [40]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone [43]</td>
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</tr>
<tr>
<td>Bone marrow[46]</td>
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</tr>
<tr>
<td>Brain [49]</td>
<td></td>
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<tr>
<td>Skin [52]</td>
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<td></td>
</tr>
<tr>
<td>Other, [55] specify</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

COMMENTS:

[59]

Signature of Person responsible for the data [60] Date form completed (mm-dd-yyyy) [62]

Signature of Person entering data onto the web [61]
1. Time point of PET/CT [1]
   o Visit A1/C1 (Groups A & C within 14 days of registration)

2. Was the FDG PET/CT interpretation completed? [2]
   o No (Complete Q2a, then sign and date form)
   o Yes (Skip to Q3)

2a. Reason images cannot be interpreted: (check all that apply) □=1 Not Marked, ✓= 2 Marked
   Related to SUV calculation
   □ injection time unknown [3]
   □ scan start time unknown [4]
   □ injected dose unknown [5]
   □ scanner not or incorrectly calibrated [7]
   □ Related to patient preparation (Blood glucose levels > 150 mg/dL) [8]
   Related to the uptake time (time between injection and start of scan)
   □ Uptake time < 45 minutes [9]
   □ Uptake time > 80 minutes [10]
   □ Uptake time for the baseline and a follow-up scan varies by > 15 minutes [11]
   □ Related to beam hardening artifacts on CT [12]
     (Beam hardening artifacts are overlying all possible target lesions in the chest)
   □ Patient movement [13]
   □ Misregistration of PET and CT involving the whole target lesion (i.e. target lesion as defined on CT does not match target lesion as defined on PET) and no other target lesion available [14]
   Other
   □ Other: [48] specify ___________________________ [49]

3. Date of FDG PET/CT exam ______-____-______ (mm-dd-yyyy) [15]

4. Date of FDG PET/CT interpretation ______-____-______ (mm-dd-yyyy) [16]

5. Reader ID ________________ [17]
6. Is the overall quality of the FDG PET/CT acceptable [18]
   - Adequate (skip to Q7)
   - Suboptimal (provide reason in Q6a, then sign and date form)

6a. Reason suboptimal (check all that apply) □=1 Not Marked, [2]=2 Marked
   - Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) [19]
   - Difference in liver SUV from the baseline to the follow-up scan > 1.0 [20]
   - Liver SUV < 1.5 or > 4.0 [21]
   - Related to uptake time (time between injection and start of scan)
     - Uptake time >=45 minutes and < 50 minutes [22]
     - Uptake time > 70 and <= 80 minutes [23]
     - Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes [24]
     - Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) [25]
     - Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) [26]
   - Other □ Other, [50] specify ____________________________ [51]

7. Record MAX SUV measurement of target lesion
   (refer to Appendix VI section 6 for details; if max SUV is less than 4.0, complete the (O1) Off Study Form)
   - ____________________ [27]

8. Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)
   - ____________________ [28]

9. Location of Target Lesion in the Chest (choose only one) [29]
   - Right upper lobe
   - Right middle lobe
   - Right lower lobe
   - Left upper lobe / lingula
   - Left lower lobe
   - Right mediastinal lymph node
   - Right hilar lymph node
   - Left mediastinal lymph node
   - Left hilar lymph node
   - Subcarinal lymph node
   - Supraclavicular/scalene nodes
10. Are there any metastatic lesions to report? □=1 Not Marked, □=2 Marked
   o No
   o Yes (complete Q10a)

10a. Indicate anatomic location *(check all that apply)*

- □ Hilar nodes
- □ Mediastinal nodes
- □ Supraclavicular/scalene nodes
- □ Ipsilateral lung
- □ Contralateral lung
- □ Pleura
- □ Liver
- □ Adrenals
- □ Bone
- □ Bone marrow
- □ Brain
- □ Skin
- □ Other, specify ____________________________

COMMENTS: ____________________________________________________________
_______________________________________________________________________
_______________________________________________________________________

Radiologist responsible for data ____________________________ Date form completed (mm-dd-yyyy) __________

Person entering data onto the web ____________________________
VISIT: A2/C2 AND B1

1. Time point of PET/CT [1]
   o Visit A2/C2 and B1 (Groups A and B within 1-7 days before the start of Chemotherapy Cycle 1; Group C pre-treatment)

2. Was the FDG PET/CT interpretation completed? [2]
   o No (Complete Q2a, then sign and date form)
   o Yes (Skip to Q3)

2a. Reason images cannot be interpreted: (check all that apply) □=1 Not Marked, □= 2 Marked

Related to SUV calculation
   □ injection time unknown [3]
   □ scan start time unknown [4]
   □ injected dose unknown [5]
   □ scanner not or incorrectly calibrated [7]
   □ Related to patient preparation (Blood glucose levels > 150 mg/dL) [8]

Related to the uptake time (time between injection and start of scan)
   □ Uptake time < 45 minutes [9]
   □ Uptake time > 80 minutes [10]
   □ Uptake time for the baseline and a follow-up scan varies by > 15 minutes [11]
   □ Related to beam hardening artifacts on CT [12]
   (Beam hardening artifacts are overlying all possible target lesions in the chest)
   □ Patient movement [13]
   □ Misregistration of PET and CT involving the whole target lesion (i.e. target lesion as defined on CT does not match target lesion as defined on PET) and no other target lesion available [14]

Other
   □ Other: [48] specify ____________________________________________ [49]

3. Date of FDG PET/CT exam ______-______-______ (mm-dd-yyyy) [15]

4. Date of FDG PET/CT interpretation ______-______-______ (mm-dd-yyyy) [16]

5. Reader ID ____________ [17]
VISIT: A2/C2 AND B1

6. Is the overall quality of the FDG PET/CT acceptable \[18\]
   o Adequate (skip to Q7)
   o Suboptimal (provide reason in Q6a, then sign and date form)

6a. Reason suboptimal (check all that apply) □ = 1 Not Marked, □ = 2 Marked
   □ Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) \[19\]
   Related to the whole body distribution of FDG
   □ Difference in liver SUV from the baseline to the follow-up scan > 1.0 \[20\]
   □ Liver SUV < 1.5 or > 4.0 \[21\]
   Related to uptake time (time between injection and start of scan)
   □ Uptake time >=45 minutes and < 50 minutes \[22\]
   □ Uptake time > 70 and <= 80 minutes \[23\]
   □ Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes \[24\]
   □ Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) \[25\]
   □ Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) \[26\]
   Other □ Other, \[50\] specify _______________________________ \[51\]

7. Record MAX SUV measurement of target lesion
   (refer to Appendix VI section 6 for details; if max SUV is less than 4.0, complete the (O1) Off Study Form)
   __________ \[27\]

8. Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)
   __________ \[28\]

9. Location of Target Lesion in the Chest (choose only one) \[29\]
   o Right upper lobe
   o Right middle lobe
   o Right lower lobe
   o Left upper lobe / lingula
   o Left lower lobe
   o Right mediastinal lymph node
   o Right hilar lymph node
   o Left mediastinal lymph node
   o Left hilar lymph node
   o Subcarinal lymph node
   o Supraclavicular/scalene nodes
VISIT: A2/C2 AND B1

10. Are there any metastatic lesions to report?
    
    o No (Skip to Q11)
    o Yes (Complete Q10a)

10a. Indicate anatomic location (check all that apply) □ = 1 Not Marked, ✓ = 2 Marked

- Hilar nodes [31]
- Mediastinal nodes [32]
- Supraclavicular/scalene nodes [33]
- Ipsilateral lung [34]
- Contralateral lung [35]
- Pleura [36]
- Liver [37]
- Adrenals [38]
- Bone [39]
- Bone marrow [40]
- Brain [41]
- Skin [42]
- Other, specify _____________________________ [53]

COMMENTS: ____________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

__________________________ [45] _______________________________ [46]
Radiologist responsible for data Date form completed (mm-dd-yyyy)

__________________________ [47]
Person entering data onto the web
ACRIN Study 6678
PLACE LABEL HERE

INSTRUCTIONS: This form is to be completed by the Radiologist for the FDG-PET/CT performed at this timepoint.

1. Time point of PET/CT
   - Post-chemotherapy Cycle 1 (Group A and B within 3 days before Cycle 2)

2. Was the FDG PET/CT interpretation completed?
   - No (Complete Q2a, then sign and date form)
   - Yes (Skip to Q3)

2a. Reason images cannot be interpreted: (check all that apply) □=1 Not Marked, ☑=2 Marked
   - Related to SUV calculation
     - injection time unknown
     - scan start time unknown
     - injected dose unknown
     - patient body weight unknown
     - scanner not or incorrectly calibrated
   - Related to patient preparation (Blood glucose levels > 150 mg/dL)
   - Related to uptake time
     - Uptake time < 45 minutes
     - Uptake time > 80 minutes
     - Uptake time for the baseline and a follow-up scan varies by > 15 minutes
   - Related to beam hardening artifacts on CT
     - Beam hardening artifacts are overlying all possible target lesions in the chest
   - Patient movement
   - Misregistration of PET and CT involving the whole target lesion (i.e. target lesion as defined on CT does not match target lesion as defined on PET) and no other target lesion available
   - Other

3. Date of FDG PET/CT exam ______-____-____ (mm-dd-yyyy)
4. Date of FDG PET/CT interpretation ______-____-____ (mm-dd-yyyy)
5. Reader ID ______ ______ ______ ______ ______ ______ ______ [17]
6. **Is the overall quality of the FDG PET/CT acceptable** [18]
   - Adequate (skip to Q7)
   - Suboptimal (provide reason in Q6a, then sign and date form)

6a. **Reason suboptimal** (check all that apply) □ = 1 Not Marked, □ = 2 Marked
   - Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) [19]
   - **Related to the whole body distribution of FDG**
     - Difference in liver SUV from the baseline to the follow-up scan > 1.0 [20]
     - Liver SUV < 1.5 or > 4.0 [21]
   - **Related to uptake time** (time between injection and start of scan)
     - Uptake time >=45 minutes and < 50 minutes [22]
     - Uptake time > 70 and <= 80 minutes [23]
     - Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes [24]
     - Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) [25]
     - Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) [26]
   - **Other**
     - Other, [50] specify ________________________________ [51]

7. **Record MAX SUV measurement of target lesion**
   (must be same target lesion recorded on Pre-chemotherapy PET/CT local interpretation form)
   __________ ☐ __________ [27]

8. **Record the mean SUV measurement in normal liver tissue** (refer to Appendix VI section 5)
   __________ ☐ __________ [28]
9. Are there any new metastatic lesions not previously reported? [30]
   - Yes (complete Q10a)

9a. Indicate anatomic location (check all that apply) □=1 Not Marked, ☑=2 Marked

   - Hilar nodes [31]
   - Mediastinal nodes [32]
   - Supraclavicular/scalene nodes [33]
   - Ipsilateral lung [34]
   - Contralateral lung [35]
   - Pleura [36]
   - Liver [37]
   - Adrenals [38]
   - Bone [39]
   - Bone marrow [40]
   - Brain [41]
   - Skin [42]
   - Other: [52] specify ____________________________ [53]

COMMENTS:______________________________________________ [44]

________________________________________________________ [44]

________________________________________________________ [44]

Radiologist responsible for data ___________________________ [45]

Date form completed (mm-dd-yyyy) __________________________ [46]

Person entering data onto the web ___________________________ [47]
VISIT: B3

1. Time point of PET/CT [1]
   - Post-chemotherapy Cycle 2 (Group B within 3 days before Cycle 3)

2. Was the FDG PET/CT interpretation completed? [2]
   - No (Complete Q2a, then sign and date form)
   - Yes (Skip to Q3)

2a. Reason images cannot be interpreted: (check all that apply) [3]
   - Related to SUV calculation
     - injection time unknown [3]
     - scan start time unknown [4]
     - injected dose unknown [5]
     - scanner not or incorrectly calibrated [7]
   - Related to patient preparation (Blood glucose levels > 150 mg/dL) [8]
   - Related to the uptake time (time between injection and start of scan)
     - Uptake time < 45 minutes [9]
     - Uptake time > 80 minutes [10]
     - Uptake time for the baseline and a follow-up scan varies by > 15 minutes [11]
     - Related to beam hardening artifacts on CT [12]
       (Beam hardening artifacts are overlying all possible target lesions in the chest)
     - Patient movement [13]
     - Misregistration of PET and CT involving the whole target lesion (i.e. target lesion as defined on CT does not match target lesion as defined on PET) and no other target lesion available [14]
   - Other
     - Other: __________________________________________________________ [48]

3. Date of FDG PET/CT exam ______-____-____ (mm-dd-yyyy) [15]

4. Date of FDG PET/CT interpretation ______-____-____ (mm-dd-yyyy) [16]

5. Reader ID ____________ [17]
6. Is the overall quality of the FDG PET/CT acceptable? [18]
   - Adequate (skip to Q7)
   - Suboptimal (provide reason in Q6a, then sign and date form)

6a. Reason suboptimal (check all that apply) □ = 1 Not Marked, □ = 2 Marked
   - Related to patient preparation (participant fasted for less than 4 hours, but blood glucose levels < 150 mg/dL) [19]
   - Difference in liver SUV from the baseline to the follow-up scan > 1.0 [20]
   - Liver SUV < 1.5 or > 4.0 [21]
   - Uptake time (time between injection and start of scan)
     - Uptake time >=45 minutes and < 50 minutes [22]
     - Uptake time > 70 and <= 80 minutes [23]
     - Uptake time for the baseline and a follow-up scan varies by >10 minutes, but less than 15 minutes [24]
   - Related to beam hardening artifacts on CT (beam hardening artifacts in the chest region) [25]
   - Participant movement (misregistration of PET and CT in the area of the target lesion by more than 3 axial slices) [26]
   - Other
     - Other, specify _____________________________________________________________________________ [51]

7. Record MAX SUV measurement of target lesion
   (must be same target lesion recorded on Pre-chemotherapy PET/CT local interpretation form)
   ___________ · ___________ [27]

8. Record the mean SUV measurement in normal liver tissue (refer to Appendix VI section 5)
   ___________ · ___________ [28]
9. Are there any new metastatic lesions not previously reported?  
   o No  
   o Yes (complete Q10a)  

9a. Indicate anatomic location (check all that apply)  
   □ Hilar nodes  
   □ Mediastinal nodes  
   □ Supraclavicular/scalene nodes  
   □ Ipsilateral lung  
   □ Contra-lateral lung  
   □ Pleura  
   □ Liver  
   □ Adrenals  
   □ Bone  
   □ Bone marrow  
   □ Brain  
   □ Skin  
   □ Other: [52] specify

COMMENTS:__________________________________________

__________________________________________  

__________________________________________  

Radiologist responsible for data [45]  
Date form completed (mm-dd-yyyy) [46]  

Person entering data onto the web [47]
Instructions: This form is to be completed by the Radiologist or Technologist, for the protocol-specified PET scan performed at this timepoint. All images are to be transmitted to ACRIN as detailed in the study protocol. All times must be reported in military format (i.e., 2:45pm = 1445 hours).

Part I: Exam Data

1. Protocol time point [1]
   - Visit A1/C1 (Groups A & C within 14 days of registration)

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

2a. *If No, provide reason: [3]
   - Scheduling problem
   - Equipment failure
   - Participant refusal
   - Medical reason
   - Injection site complications
   - Claustrophobia
   - Blood glucose level (per protocol specifications)
   - Participant withdrew consent
   - Progressive disease
   - Participant death
   - Other, specify: ____________________________ [4]

3. Date of PET imaging: [5]
   - _____ - _____ - ____________(mm-dd-yyyy)

4. Duration of participant fasting pre-PET imaging: [6]
   - ______ hours (up to time of FDG injection; if unknown record 99)

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

6. Participant weight (measured on day of scan) [8]
   - ______ kg

7. Participant height ______ cm [9]
   (measured on the day of scan)

8. Full activity in syringe before injection ______ mCi [51]
   8a. Residual activity in syringe after injection ______ mCi [52]


10. Time of injection (military time) ______ [12]

11. Location of injection site [13]
    - Right antecubital
    - Right wrist
    - Left antecubital
    - Left wrist
    - Right foot
    - Left foot
    - Other, specify: ____________________________ [14]

12. Any radiotracer infiltration at injection site noted? [15]
    - None
    - Minor (estimated to be less than 20% of dose)
    - Severe (estimated to be more than 20% of dose)

13. Participant voided immediately pre-imaging? [16]
    - No
    - Yes
    - Unknown

    - No
    - Yes
    - Unknown

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Part II: Image Acquisition

Transmission Scan

15. Type of transmission scan (check one) [18]
   o CT (complete Q16 thru 19, then skip to Q21)
   o Interleaved (go to Q20)
   o Non-interleaved, PET emission first (go to Q20)
   o Non-interleaved, transmission first (go to Q20)

16. CT transmission scan:
   16a. Was Oral contrast used? [19]
       o No
       o Yes, define below [20]
       o Positive contrast
       o Negative contrast
   16b. Was IV contrast used? [21]
       o No
       o Yes

17. kVp [22]

18. mAs [23]

19. Slice Thickness . mm [24]

20. Minutes duration of transmission scan per bed position? . minutes [25]

21. Transmission scan processing used:
   o Segmentation [26]
   o CT
   o Segmentation and emission subtraction
   o Other, specify:

PET Emission Scan

22. Emission start time: . [28]
   (military format)

23. Emission stop time: . [29]
   (military format)

24. Number of bed positions scanned [30]

25. Emission acquisition mode [31]
   o 2D
   o 3D

26. Pixel Size of Reconstruction image . mm [32]

27. Thickness of Reconstructed images . mm [33]

Part III: Scanner / F-18-FDG Procurement

28. PET or PET/CT Scanner used for this exam:
   Vendor
   Model name and/or number

29. Date of last PET scanner calibration:
   _____ - _____ - ____________ (mm-dd-yyyy) [36]

30. Daily scanner QC run on date of study? (check one) [37]
   o No
   o Yes

31. Has the scanner used for this study been qualified by ACRIN? [49]
   o No
   o Yes, provide date:

   _____ - _____ (mm-yyyy) [50]
32. F-18-FDG Source
   - Synthesized (If synthesized, complete Q32a, b, and c)
   - Purchased (If purchased, complete Q33)

32a. Method: ________________________________

32b. Pyrogen test result
   - Passed
   - Failed
   - Not done

32c. Radiochemical purity test result: ________ %

33. Purchased: name of licensed pharmacy providing F-18-FDG:
   ______________________________________

34. Are there any adverse events related to imaging to report for this timepoint?
   - No (Sign and date form)
   - Yes (Complete Q34a and submit adverse event reporting form (AE))

34a. Does this event meet the criteria of a serious adverse event?
   - No
   - Yes

COMMENTS: __________________________________________________________

___________________________________________________________

___________________________________________________________

___________________________________________________________

__________________________ [46]
Signature of person responsible for the data

__________________________ - ____________ - ____________ [47]
Date form completed (mm-dd-yyyy)

__________________________ [48]
Signature of person entering data onto the web
ACRIN Study 6678
PLACE LABEL HERE
Institution ______________ Institution No. __________
Participant Initials __________ Case No. __________

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

Instructions: This form is to be completed, by the Radiologist or Technologist, for the protocol-specified PET scan performed at this timepoint. All images are to be transmitted to ACRIN as detailed in the study protocol. All times must be reported in military format (i.e., 2:45 pm = 1445 hours).

Part I: Exam Data

1. Protocol time point [1]
   o Visit A2/C2 and B1 (Groups A and B within 1-7 days before the start of Chemotherapy Cycle 1; Group C pre-treatment)

2. Was PET imaging completed? [2]
   o No* (complete Q2a, then sign and date form)
   o Yes (proceed to Q3 and continue with form)

2a. *If No, provide reason: [3]
   o Scheduling problem
   o Equipment failure
   o Participant refusal
   o Medical reason
   o Injection site complications
   o Claustrophobia
   o Blood glucose level (per protocol specifications)
   o Participant withdrew consent
   o Progressive disease
   o Participant death
   o Other, specify:
      __________________________________________ [4]
   o Unknown

3. Date of PET imaging: [5]
   _____ - _____ - _________(mm-dd-yyyy)

4. Duration of participant fasting pre-PET imaging: [6]
   ______ hours (up to time of FDG injection; if unknown record 99)

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

6. Participant weight (measured on day of scan) [8]
   ________ kg

VISIT: A2/C2 AND B1

7. Participant height ______ cm [9]
   (measured on the day of scan)

8. Full activity in syringe before injection
   ______ mCi [51]

8a. Residual activity in syringe after injection
   ______ mCi [52]


10. Time of injection (military time) ________ [12]

11. Location of injection site [13]
    o Right antecubital
    o Right wrist
    o Left antecubital
    o Left wrist
    o Right foot
    o Left foot
    o Other, specify:
       __________________________________________ [14]
    o Unknown

12. Any radiotracer infiltration at injection site noted? [15]
    o None
    o Minor (estimated to be less than 20% of dose)
    o Severe (estimated to be more than 20% of dose)

13. Participant voided immediately pre-imaging? [16]
    o No
    o Yes
    o Unknown

    o No
    o Yes
    o Unknown

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Part II: Image Acquisition

Transmission Scan

15. Type of transmission scan (check one) [18]
   - CT (complete Q16 thru 19, then skip to Q21)
   - Interleaved (go to Q20)
   - Non-interleaved, PET emission first (go to Q20)
   - Non-interleaved, transmission first (go to Q20)

16. CT transmission scan:
   16a. Was Oral contrast used? [19]
       - No
       - Yes, define below [20]
       - Positive contrast
       - Negative contrast
   16b. Was IV contrast used? [21]
       - No
       - Yes

17. kVp [22]
18. mAs [23]
19. Slice Thickness [24]
20. Minutes duration of transmission scan per bed position? [25]
21. Transmission scan processing used:
    - Segmentation
    - CT
    - Segmentation and emission subtraction
    - Other, specify:

PET Emission Scan

22. Emission start time: [28]
    (military format)
23. Emission stop time: [29]
    (military format)
24. Number of bed positions scanned [30]
25. Emission acquisition mode [31]
    - 2D
    - 3D
26. Pixel Size of Reconstruction image [32]
27. Thickness of Reconstructed images [33]

Part III: Scanner / F-18-FDG Procurement

28. PET or PET/CT Scanner used for this exam:
    Vendor [34]
    Model name and/or number [35]
29. Date of last PET scanner calibration:
    _____ - _____ - ____________ (mm-dd-yyyy) [36]
30. Daily scanner QC run on date of study? (check one) [37]
    - No
    - Yes
31. Has the scanner used for this study been qualified by ACRIN? [49]
    - No
    - Yes, provide date:
32. F-18-FDG Source [38]
   - Synthesized (If synthesized, complete Q32a, b, and c)
   - Purchased (If purchased, complete Q33)


32b. Pyrogen test result [40]
   - Passed
   - Failed
   - Not done

32c. Radiochemical purity test result: [41]
   %

33. Purchased: name of licensed pharmacy providing F-18-FDG:
   ___________________________________________________ [42]

34. Are there any adverse events related to imaging to report for this timepoint? [43]
   - No (Sign and date form)
   - Yes (Complete Q34a and submit adverse event reporting form (AE))

34a. Does this event meet the criteria of a serious adverse event? [44]
   - No
   - Yes

COMMENTS: _______________________________________
__________________________________________________
__________________________________________________
__________________________________________________ [45]

Signature of person responsible for the data
__________________________________________________ [46]

Date form completed (mm-dd-yyyy)
__________________________________________________ [47]

Signature of person entering data onto the web
__________________________________________________ [48]
**ACRIN Study 6678**  
**PET/CT Local Technical Assessment Form**  
Visit A3 and B2 - Post-Chemotherapy Cycle 1  
(Within 3 days before Cycle 2)

*Instructions:* This form is to be completed, by the Radiologist or Technologist, for the protocol-specified PET scan performed at this timepoint. All images are to be transmitted to ACRIN as detailed in the study protocol. All times must be reported in military format (i.e., 2:45pm = 1445 hours).

### Part I: Exam Data

1. **Protocol time point**  
   - Post-chemotherapy Cycle 1  
   (Group A and B, within 3 days before Cycle 2)

2. **Was PET imaging completed?**  
   - No* (complete Q2a, then sign and date form)  
   - Yes (proceed to Q3 and continue with form)

   2a. *If No, provide reason:*
   - Scheduling problem  
   - Equipment failure  
   - Participant refusal  
   - Medical reason  
   - Injection site complications  
   - Blood glucose level (per protocol specifications)  
   - Participant withdrew consent  
   - Progressive disease  
   - Participant death  
   - Other, specify:

3. **Date of PET imaging:**  
   
   _____ - _____ - ____________(mm-dd-yyyy)

4. **Duration of participant fasting pre-PET imaging:**  
   
   [ ] hours (up to time of FDG injection; if unknown record 99)

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

### VISIT: A3 and B2

6. **Participant weight** (measured on day of scan)  
   [ ] kg

7. **Participant height** (measured on the day of scan)  
   [ ] cm

8. **Dose assay** [ ] mCi

9. **Time of dose assay (military time)** [ ]

10. **Time of injection (military time)** [ ]

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

   [ ]

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)

13. **Participant voided immediately pre-imaging?**  
    - No  
    - Yes  
    - Unknown

14. **Participant voided immediately post-imaging?**  
    - No  
    - Yes  
    - Unknown

---

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Part II: Image Acquisition

Transmission Scan

15. Type of transmission scan (check one) [18]
   - CT (complete Q16 thru 19, then skip to Q21)
   - Interleaved (go to Q20)
   - Non-interleaved, PET emission first (go to Q20)
   - Non-interleaved, transmission first (go to Q20)

16. CT transmission scan:
   
   16a. Was Oral contrast used? [19]
       - No
       - Yes, define below [20]
       - Positive contrast
       - Negative contrast

   16b. Was IV contrast used? [21]
       - No
       - Yes

17. kVp

18. mAs

19. Slice Thickness . mm [24]

20. Minutes duration of transmission scan per bed position? minutes [25]

21. Transmission scan processing used:
   - Segmentation [26]
   - CT
   - Segmentation and emission subtraction
   - Other, specify:

Part III: Scanner / F-18-FDG Procurement

28. PET or PET/CT Scanner used for this exam:

   Vendor ____________________________ [34]

   Model name and/or number ________________ [35]

29. Date of last PET scanner calibration:
   _____ - _____ - ____________ (mm-dd-yyyy) [36]

30. Daily scanner QC run on date of study? (check one) [37]
   - No
   - Yes

31. Has the scanner used for this study been qualified by ACRIN? [49]
   - No
   - Yes, provide date:

   _____ - _____ (mm-yyyy) [50]
VISIT: A3 and B2

32. F-18-FDG Source
   - Synthesized (If synthesized, complete Q32a, b, and c)
   - Purchased (If purchased, complete Q33)


32b. Pyrogen test result
   - Passed
   - Failed
   - Not done

32c. Radiochemical purity test result: [41]
   [ ] [ ] [ ] [ ] %

33. Purchased: name of licensed pharmacy providing F-18-FDG:
   __________________________________________________________ [42]

34. Are there any adverse events related to imaging to report for this timepoint? [43]
   - No (Sign and date form)
   - Yes (Complete Q34a and submit adverse event reporting form (AE))

34a. Does this event meet the criteria of a serious adverse event? [44]
   - No
   - Yes

COMMENTS:
__________________________________________________________
__________________________________________________________
__________________________________________________________
__________________________________________________________

Signature of person responsible for the data [46] Date form completed ______ - ______ - _______ [47]

Signature of person entering data onto the web [48]
**Part I: Exam Data**

1. **Protocol time point** [1]
   - Post-chemotherapy Cycle 2 (Group B, within 3 days before Cycle 3)

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

2a. *If No, provide reason: [3]
   - Scheduling problem
   - Equipment failure
   - Participant refusal
   - Medical reason
   - Injection site complications
   - Claustrophobia
   - Blood glucose level (per protocol specifications)
   - Participant withdrew consent
   - Progressive disease
   - Participant death
   - Other, specify:

2. **Date of PET imaging:** [5]

   _____ - _____ - ____________ (mm-dd-yyyy)

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

   ______ hours (up to time of FDG injection; if unknown record 99)

5. **Blood glucose at start of PET imaging** [7]

   (record value measured before FDG injection)

   ______ ______ mg/dl

**VISIT: B3**

6. **Participant weight** (measured on day of scan) [8]

   ______ ______ kg

7. **Participant height** [9]

   (measured on the day of scan)

   ______ ______ cm

8. **Dose assay** [10]

   ______ ______ mCi


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

11. **Location of injection site** [13]

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

12. **Any radiotracer infiltration at injection site noted?** [15]

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

13. **Participant voided immediately pre-imaging?** [16]

   - No
   - Yes
   - Unknown

14. **Participant voided immediately post-imaging?** [17]

   - No
   - Yes
   - Unknown

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Part II: Image Acquisition

Transmission Scan

15. Type of transmission scan (check one) [18]
   o CT (complete Q16 thru 19, then skip to Q21)
   o Interleaved (go to Q20)
   o Non-interleaved, PET emission first (go to Q20)
   o Non-interleaved, transmission first (go to Q20)

16. CT transmission scan:
   16a. Was Oral contrast used? [19]
       o No
       o Yes, define below [20]
           o Positive contrast
           o Negative contrast
   16b. Was IV contrast used? [21]
       o No
       o Yes

17. kVp [22]
18. mAs [23]
19. Slice Thickness . mm [24]

20. Minutes duration of transmission scan per bed position? minutes [25]

21. Transmission scan processing used:
   o Segmentation [26]
   o CT
   o Segmentation and emission subtraction
   o Other, specify:

PET Emission Scan

22. Emission start time: [28]
   (military format)
23. Emission stop time: [29]
   (military format)

24. Number of bed positions scanned [30]

25. Emission acquisition mode [31]
   o 2D
   o 3D

26. Pixel Size of Reconstruction image . mm [32]
27. Thickness of Reconstructed images . mm [33]

Part III: Scanner / F-18-FDG Procurement

28. PET or PET/CT Scanner used for this exam:
   Vendor
   Model name and/or number [34]

29. Date of last PET scanner calibration:
   _____ - _____ - ____________ (mm-dd-yyyy) [36]

30. Daily scanner QC run on date of study? (check one) [37]
   o No
   o Yes

31. Has the scanner used for this study been qualified by ACRIN? [49]
   o No
   o Yes, provide date:

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ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical Assessment Form
Visit B3 - Post-Chemotherapy Cycle 2
(Within 3 days before Cycle 3)

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

ACRIN Study 6678
PLACE LABEL HERE

Institution ___________________ Institution No. __________
Participant Initials ___________ Case No. __________

VISIT: B3

32. F-18-FDG Source
   O Synthesized (If synthesized, complete Q32a, b, and c)
   O Purchased (If purchased, complete Q33)

32a. Method: _____________________________ [38]

32b. Pyrogen test result [40]
   O Passed
   O Failed
   O Not done

32c. Radiochemical purity test result: [41]
   _______ %

33. Purchased: name of licensed pharmacy providing F-18-FDG:
   ____________________________________________ [42]

34. Are there any adverse events related to imaging to report for this timepoint? [43]
   O No (Sign and date form)
   O Yes (Complete Q34a and submit adverse event reporting form (AE))

34a. Does this event meet the criteria of a serious adverse event? [44]
   O No
   O Yes

COMMENTS: ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________ [45]

Signature of person responsible for the data [46]  Date form completed - (mm-dd-yyyy) [47]
Signature of person entering data onto the web [48]
# ACRIN Study 6678

**ACRIN 6678**

FDG - PET/CT Tumor Response
PET/CT Local Technical Assessment Form

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

## Part I: Exam Data

### 1. Protocol time point

- o Pre-treatment *(within 2 weeks after registration visit: Group A only)*
- o Pre-treatment *(Within 1 week prior to 1stChemotherapy Cycle: Group A and Group B)*
- o Post-treatment *(Post Chemotherapy Cycle 1, Group A and Group B)*
- o Post-treatment *(Post Chemotherapy Cycle 2, Group B only)*

### 2. Was PET imaging completed? [2]

- o No* (If no, complete 2a, then sign and date form)
- o Yes (go to Q3)

2a. *If No, provide reason:* [3]

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

### 3. Date of Imaging: [5]

____ - ____ - _________ (mm-dd-yyyy)

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

______ hours (up to time of FDG injection)

### 5. Blood glucose at start of PET imaging [7]

(record value measured before FDG injection)

______ mg/dl

---

### 6. Patient weight *(measured on day of scan)* [8]

______ kg

### 7. Patient height ______ cm [9]

*(measured on the day of scan)*

### 8. Dose assay ______ mCi [10]


### 10. Time of injection *(military time)* [12]

### 11. Location of injection site [13]

- o Right antecubital
- o Right wrist
- o Left antecubital
- o Left wrist
- o Right foot
- o Left foot
- o Other, specify:

### 12. Any radiotracer infiltration at injection site noted? [15]

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

### 13. Patient voided immediately pre-imaging? [16]

- o No
- o Yes
- o Unknown


- o No
- o Yes
- o Unknown

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ACRIN 6678
FDG - PET/CT Tumor Response
PET Technical Assessment Form

Part II: Image Acquisition

Transmission Scan

15. Type of transmission scan (check one) [18]
   - CT
   - Interleaved (go to Q20)
   - Non-interleaved, PET emission first (go to Q20)
   - Non-interleaved, transmission first (go to Q20)

16. CT transmission scan:
   16a. Was Oral contrast used? [19]
       - No
       - Yes, define below [20]
         - Positive contrast
         - Negative contrast
   16b. Was IV contrast used? [21]
       - No
       - Yes

17. KVP [22]

18. MAS [23]

19. Slice Thickness [24]

20. Minutes duration of transmission scan per bed position? [25] minutes

21. Transmission scan processing used:
   - Segmentation
   - CT
   - Segmentation and emission subtraction
   - Other, specify:

PET Emission Scan

22. Emission start time: [28] (military format)

23. Emission stop time: [29] (military format)

24. Number of bed positions scanned [30]

25. Emission acquisition mode [31]
   - 2D
   - 3D

26. Pixel Size of Reconstruction image [32] mm

Part III: Scanner / F-18-FDG Procurement

27. Thickness of Reconstructed images [33] mm

28. PET or PET/CT Scanner used for this exam:
   - Vendor ____________________________ [34]
   - Model name and/or number __________________ [35]

29. Date of last scanner calibration:
   _____ - _____ - _____________ (mm-dd-yyyy) [36]

30. Daily scanner QC run on date of study? (check one) [37]
   - No
   - Yes
31. F-18-FDG Source
   O Synthesized (If synthesized, complete Q31a, b, and c)
   O Purchased (If purchased, complete Q32)


31b. Pyrogen test result [40]
   O Passed
   O Failed
   O Not done

31c. Radiochemical purity test result: [41]

32. Purchased: name of licensed pharmacy providing F-18-FDG:
   ______________________________________________________ [42]

COMMENTS: ____________________________________________

_______________________________________________________

_______________________________________________________

_______________________________________________________

_______________________________________________________

_______________________________________________________ [43]

Signature of person responsible for the data¹ [44]  Date form completed ¹ (mm-dd-yyyy) [45]

Signature of person entering data onto the web² [46]