ACRIN 6678

Lung Cancer:
Evaluation of Treatment Response with PET

CRF Set

A0

ACRIN 6678
Registration/Eligibility Checklist
FDG-PET/CT Tumor Response
Patient Outcome - NSCLC

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: The eligibility checklist (A0) Part 2 must be completed prior to registration to determine and confirm study eligibility. At the time of enrollment, the participant is to review, sign and date the consent. The following questions will be asked at study registration. The date is submitted via the ACRIN website. Submit a paper form only in the event the website is down.

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

_____ **11.** Gender [11]
1 Male
2 Female

_____ **12.** Participant's country of residence (if other, complete Q18) [12]
1 United States
2 Canada
3 Other
9 Unknown

_____ **13.** Zip Code (5 digit code, US residents) [13]

_____ **14.** 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

_____ **15.** Will any component of the patient's care be given at a Military or VA facility? [15]
1 No
2 Yes
9 Unknown

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

___-___-___ **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 IIIB (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]

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

_____ **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? [49] (see Section 5.2.4 for details)

_____ **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)

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

Date form completed ____-____-_____ (mm-dd-yyyy) [58]

C1

ACRIN 6678

FDG - PET/CT Tumor Response Chemotherapy Assessment Form

Cycle 1

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

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 1? [1]

O No (Complete Q1a then sign and date form)
O Yes

CYCLE 1

Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	**Start Date** (mm/dd/yyyy)	**End Date** (mm/dd/yyyy)	**Total Dose/ Unit**	**Reason for Termination** 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
Agent Code ____ [2] *_____ [3]	_____-_____-_____ [4]	_____-_____-_____ [5]	_____ [6] O mg O other [7]	**Reason Code** ____ [8] **_____ [9]
Agent Code ____ [10] *_____ [11]	_____-_____-_____ [12]	_____-_____-_____ [13]	_____ [14] O mg O other [15]	**Reason Code** ____ [16] **_____ [17]
Agent Code ____ [18] *_____ [19]	_____-_____-_____ [20]	_____-_____-_____ [21]	_____ [22] O mg O other [23]	**Reason Code** ____ [24] **_____ [25]
Agent Code ____ [26] *_____ [27]	_____-_____-_____ [28]	_____-_____-_____ [29]	_____ [30] 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]

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]

_____ [40]
Signature of Person Responsible for Data

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

_____ [42]
Signature of Person entering data onto the Web

C2

ACRIN 6678

FDG - PET/CT Tumor Response Chemotherapy Assessment Form

Cycle 2

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

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.

CYCLE 2

1. Was Chemotherapy given for Cycle 2? [1]

O No (Complete Q1a then sign and date form)
O Yes

Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	**Start Date** (mm/dd/yyyy)	**End Date** (mm/dd/yyyy)	**Total Dose/ Unit**	**Reason for Termination** 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
Agent Code ____ [2] *_____ [3]	_____-_____-_____ [4]	_____-_____-_____ [5]	_____ [6] O mg O other [7]	**Reason Code** ____ [8] **_____ [9]
Agent Code ____ [10] *_____ [11]	_____-_____-_____ [12]	_____-_____-_____ [13]	_____ [14] O mg O other [15]	**Reason Code** ____ [16] **_____ [17]
Agent Code ____ [18] *_____ [19]	_____-_____-_____ [20]	_____-_____-_____ [21]	_____ [22] O mg O other [23]	**Reason Code** ____ [24] **_____ [25]
Agent Code ____ [26] *_____ [27]	_____-_____-_____ [28]	_____-_____-_____ [29]	_____ [30] 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]

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]

_____ [40]
Signature of Person Responsible for Data

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

_____ [42]
Signature of Person entering data onto the Web

C3

ACRIN 6678

FDG - PET/CT Tumor Response Chemotherapy Assessment Form

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.** _____

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

CYCLE 3

1. Was Chemotherapy given for Cycle 3? [1]

O No (Complete Q1a then sign and date form)
O Yes

Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	**Start Date** (mm/dd/yyyy)	**End Date** (mm/dd/yyyy)	**Total Dose/ Unit**	**Reason for Termination** 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
Agent Code ____ [2] *_____ [3]	_____-_____-_____ [4]	_____-_____-_____ [5]	_____ [6] O mg O other [7]	**Reason Code** ____ [8] **_____ [9]
Agent Code ____ [10] *_____ [11]	_____-_____-_____ [12]	_____-_____-_____ [13]	_____ [14] O mg O other [15]	**Reason Code** ____ [16] **_____ [17]
Agent Code ____ [18] *_____ [19]	_____-_____-_____ [20]	_____-_____-_____ [21]	_____ [22] O mg O other [23]	**Reason Code** ____ [24] **_____ [25]
Agent Code ____ [26] *_____ [27]	_____-_____-_____ [28]	_____-_____-_____ [29]	_____ [30] 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]

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]

_____ [40]
Signature of Person Responsible for Data

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

_____ [42]
Signature of Person entering data onto the Web

C4

ACRIN 6678

FDG - PET/CT Tumor Response Chemotherapy Assessment Form

Cycle 4

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

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.

CYCLE 4

1. Was Chemotherapy given for Cycle 4? [1]

O No (Complete Q1a then sign and date form)
O Yes

Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	**Start Date** (mm/dd/yyyy)	**End Date** (mm/dd/yyyy)	**Total Dose/ Unit**	**Reason for Termination** 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
Agent Code ____ [2] *_____ [3]	____-____-____ [4]	____-____-____ [5]	____ [6] O mg O other [7]	**Reason Code** ____ [8] **_____ [9]
Agent Code ____ [10] *_____ [11]	____-____-____ [12]	____-____-____ [13]	____ [14] O mg O other [15]	**Reason Code** ____ [16] **_____ [17]
Agent Code ____ [18] *_____ [19]	____-____-____ [20]	____-____-____ [21]	____ [22] O mg O other [23]	**Reason Code** ____ [24] **_____ [25]
Agent Code ____ [26] *_____ [27]	____-____-____ [28]	____-____-____ [29]	____ [30] 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]

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]

_____ [40]
Signature of Person Responsible for Data

_____ [42]
Signature of Person entering data onto the Web

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

C5

ACRIN 6678

FDG - PET/CT Tumor Response Chemotherapy Assessment Form

Cycle 5

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

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.

CYCLE 5

1. Was Chemotherapy given for Cycle 5? [1]

O No (Complete Q1a then sign and date form)
O Yes

Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	**Start Date** (mm/dd/yyyy)	**End Date** (mm/dd/yyyy)	**Total Dose/ Unit**	**Reason for Termination** 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
Agent Code ____ [2] *_____ [3]	_____-_____-_____ [4]	_____-_____-_____ [5]	_____ [6] O mg O other [7]	**Reason Code** ____ [8] **_____ [9]
Agent Code ____ [10] *_____ [11]	_____-_____-_____ [12]	_____-_____-_____ [13]	_____ [14] O mg O other [15]	**Reason Code** ____ [16] **_____ [17]
Agent Code ____ [18] *_____ [19]	_____-_____-_____ [20]	_____-_____-_____ [21]	_____ [22] O mg O other [23]	**Reason Code** ____ [24] **_____ [25]
Agent Code ____ [26] *_____ [27]	_____-_____-_____ [28]	_____-_____-_____ [29]	_____ [30] 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]

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]

_____ **[40]**
Signature of Person Responsible for Data

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

_____ **[42]**
Signature of Person entering data onto the Web

C6

ACRIN 6678

FDG - PET/CT Tumor Response Chemotherapy Assessment Form

Cycle 6

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

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.

CYCLE 6

1. Was Chemotherapy given for Cycle 6? [1]

O No (Complete Q1a then sign and date form)
O Yes

Agent Code Table 1 Cisplatin 2 Carboplatin 3 Docetaxel 4 Gemcitabine 5 Paclitaxel 6 Vinorelbine 7 Bevacizumab 8 Cetuximab 88 Other* (specify agent)	**Start Date** (mm/dd/yyyy)	**End Date** (mm/dd/yyyy)	**Total Dose/ Unit**	**Reason for Termination** 1 Cycle ended, per protocol 2 Disease Progression 3 Participant withdrew 4 Participant refused 5 Change in therapy 6 Low counts 88 Other** (specify reason)
Agent Code ____ [2] *_____ [3] _____	_____-_____-_____ [4]	_____-_____-_____ [5]	_____ [6] O mg O other [7]	**Reason Code** ____ [8] **_____ [9] _____
Agent Code ____ [10] *_____ [11] _____	_____-_____-_____ [12]	_____-_____-_____ [13]	_____ [14] O mg O other [15]	**Reason Code** ____ [16] **_____ [17] _____
Agent Code ____ [18] *_____ [19] _____	_____-_____-_____ [20]	_____-_____-_____ [21]	_____ [22] O mg O other [23]	**Reason Code** ____ [24] **_____ [25] _____
Agent Code ____ [26] *_____ [27] _____	_____-_____-_____ [28]	_____-_____-_____ [29]	_____ [30] 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]

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]

_____ [40]
Signature of Person Responsible for Data

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

_____ [42]
Signature of Person entering data onto the Web

DS

ACRIN 6678
FDG - PET/CT Tumor Response
End of Study Form

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

If this is a revised or corrected form, please √ 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]

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

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

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

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

3. Date of death _____-_____-_____ *(mm/dd/yyyy)* [4]

3a. Cause of death [5]

- O Disease progression
- O Other _____ *(specify cause of death)* [6]

COMMENTS: _____

_____

_____ [7]

_____ [8]
Signature of person responsible for the data

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

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

F1

ACRIN 6678
FDG - PET/CT Tumor Response
3 Month Follow-up (F/U) Form

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

3 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 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]
- o 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]
- 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 [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)*

F1

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: _____

_____

_____

_____

_____ [27]

_____ [28]
Signature of Person responsible for the data

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

_____ [29]
Signature of Person entering data onto the web

F2

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

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)*

F2

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]

_____ [28]
Signature of Person responsible for the data

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

_____ [29]
Signature of Person entering data onto the web

F3

ACRIN 6678
FDG - PET/CT Tumor Response
9 Month Follow-up (F/U) Form

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

9 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 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]
- o 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]
- 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)*

F3

ACRIN 6678
FDG - PET/CT Tumor Response
9 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.** _____

9 MONTH FOLLOW-UP

Comments: _____

_____

_____

_____

_____ [27]

_____ [28]
Signature of Person responsible for the data

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

_____ [29]
Signature of Person entering data onto the web

F4

ACRIN 6678
FDG - PET/CT Tumor Response
1 Year Follow-up (F/U) Form

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1 YEAR 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 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

- ☐ 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)*

F4

ACRIN 6678
FDG - PET/CT Tumor Response
1 Year 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.** _____

1 YEAR FOLLOW-UP

Comments: _____

_____

_____

_____

_____ [27]

_____ [28]
Signature of Person responsible for the data

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

_____ [29]
Signature of Person entering data onto the web

I1

ACRIN 6678

FDG-PET/CT Tumor Response Patient Outcome - NSCLC Initial Evaluation Form

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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 IIIA *(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]

4. Prior Thoracic radiotherapy? [5]
(within 3 months prior to study enrollment)
- o No
- o Yes (if yes, provide date in Q4a)
- o Unknown

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

5. Prior systemic chemotherapy? [7]
(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]

6. Prior whole brain radiotherapy? [14]
- 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 (mm-dd-yyyy)

_____ [13]
Signature of person entering data onto the web

IA

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group A

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

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

	Timepoint 1	**Timepoint 2**	**Timepoint 3**
Date of PET Imaging	_____-_____-_____	_____-_____-_____	_____-_____-_____
Was the PET/CT Central Interpretation completed? *(if no, check all reasons that apply below)*	O No O Yes	O No O Yes	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	O Adequate O Suboptimal	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 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 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__________

IA

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group A

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. Table 2: Record the following for each image. For 'unknown' code 999.

	Timepoint 1						Timepoint 2						Timepoint 3					
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver																		
Target Lesion																		
Additional Lesion 1																		
Additional Lesion 2																		
Additional Lesion 3																		
Additional Lesion 4																		
Additional Lesion 5																		
Additional Lesion 6																		

Tumor Location

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

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

IA

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group A

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

ACRIN Study 6678
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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)***

IB

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group B

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

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**

	Timepoint 1	**Timepoint 2**	**Timepoint 3**
Date of PET Imaging	_____-_____-_____	_____-_____-_____	_____-_____-_____
Was the PET/CT Central Interpretation completed? *(if no, check all reasons that apply below)*	O No O Yes	O No O Yes	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	O Adequate O Suboptimal	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 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 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__________

IB

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group B

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

ACRIN Study 6678
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. 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.

	Timepoint 1						Timepoint 2						Timepoint 3					
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver																		
Target Lesion																		
Additional Lesion 1																		
Additional Lesion 2																		
Additional Lesion 3																		
Additional Lesion 4																		
Additional Lesion 5																		
Additional Lesion 6																		

Tumor Location

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

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

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.

IB

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group B

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

ACRIN Study 6678
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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)***

IC

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group C

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

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

	Timepoint 1	**Timepoint 2**	**Timepoint 3**
Date of PET Imaging	_____-_____-_____	_____-_____-_____	_____-_____-_____
Was the PET/CT Central Interpretation completed? *(if no, check all reasons that apply below)*	O No O Yes	O No O Yes	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	O Adequate O Suboptimal	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 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 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__________

IC

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Group C

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

4. Table 2: Record the following for each image. For 'unknown' code 999.

	Timepoint 1						Timepoint 2					
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver												
Target Lesion												
Additional Lesion 1												
Additional Lesion 2												
Additional Lesion 3												
Additional Lesion 4												
Additional Lesion 5												
Additional Lesion 6												

Tumor Location

1	Right upper lobe	12	Pleura
2	Right middle lobe	13	Liver
3	Right lower lobe	14	Adrenals
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 (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)*

ID

ACRIN 6678

PET/CT Imaging Post-treatment Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions:

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 Hybird CT/PET fusion

ID

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

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

9.

Compared to Baseline Only						Post Treatment
Target Lesion Tumor Number (number should correspond to pre-treatment tumor)	**Uptake Scale**	**Change in Uptake Scale**	**Local Regional Assessment**	**Metastatic Disease**	**Progression based on proximity of the site(s) to local regional assessment**	**SUV (max)**
T1						
T2						
T3						
T4						
T5						
T6						
T7						
T8						
T9						
T10						

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
(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

Local Regional Response
(compared to baseline)

0 (CR) Complete Response
1 (PR) Partial Response
2 (ND) No Response
3 (PD) Progressive Disease

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

ID

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

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

10.

Compared to Baseline Only						Post Treatment
Non-Target Lesion Tumor Number (number should correspond to pre-treatment tumor)	**Uptake Scale**	**Change in Uptake Scale**	**Local Regional Assessment**	**Metastatic Disease**	**Progression based on proximity of the site(s) to local regional assessment**	**SUV (max)**
S1						
S2						
S3						
S4						
S5						

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 (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

Local Regional Response (compared to baseline)

0 (CR) Complete Response
1 (PR) Partial Response
2 (ND) No Response
3 (PD) Progressive Disease

Metastastic 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

ID

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

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

11. Indicate any Lymphadenopathy

Anatomic Site	Confidence in presence of disease
Supraclavicular	
Ipsilateral hilar	
Contralateral hilar	
Ipsilateral upper medialstinal	
Contralateral upper medialstinal	
Ipsilateral lower medialstinal	
Contralateral lower medialstinal	
Other, Specify _____ _____	

12. Indicate any distant Metastasis with PET findings

Anatomic Site	Confidence in presence of disease
Supraclavicular	
Ipsilateral hilar	
Contralateral hilar	
Ipsilateral upper medialstinal	
Contralateral upper medialstinal	
Ipsilateral lower medialstinal	
Contralateral lower medialstinal	
Other, Specify _____ _____	

Confidence Scale

1 Definetly no metastasis
2 Probably no metastasis
3 Possibly no metastasis
4 Probably metastasis
5 Definetly metastasis

ID

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

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PET Assessment

13. What is your overall confidence in the Prense or Absence of Stage IV disease as seen with PET?

- O Definitely not present
- O Probably not Present
- O Indeterminate
- O Probably present
- O Definitely Present

Comments: _____

_____

_____

_____

_____

_____
Signature of Nucelar medicine MD

_____-_____-_____
Date form completed

_____
Signature of person entering data onto the web

IM

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**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Please record the requested information for all target lesions. Refer to Appendix VII. Choose all measurable lesions up to a maximum of 5 lesions per organ and 10 lesions in total to follow as target lesions record any remaining measurable lesions and all non-measurable disease as non-target disease. **The same test procedures used for baseline disease assessment must be used for all required subsequent disease assessments.**

1. Protocol Time point of PET/CT Imaging *(check only one)***:**

- O Pre-treatment *(Within 2 weeks after registration visit: Group A only)*
- O 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?

- 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 |___|___|___|___|___|___|___|___|

IM

ACRIN 6678
PET/CT Imaging Pre-treatment Core (Lab) PET Qualalative and Semi-Qualitative Assessment 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.

Target Lesion	Tumor Location	Tumor Size in Diameter (cm)	Uptake Scale	SUV (max)	Primary Tumor
T1					O No O Yes
T2					O No O Yes
T3					O No O Yes
T4					O No O Yes
T5					O No O Yes
T6					O No O Yes
T7					O No O Yes
T8					O No O Yes
T9					O No O Yes
T10					O No O Yes

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

IM

ACRIN 6678
PET/CT Imaging Pre-treatment Core (Lab) PET Qualalative and Semi-Qualitative Assessment Form

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

7.

Non-Target Lesion	Tumor Location	Tumor Size in Diameter (cm)	Uptake Scale	SUV (max)	Primary Tumor
S1					O No O Yes
S2					O No O Yes
S3					O No O Yes
S4					O No O Yes
S5					O No O Yes

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

IM

ACRIN 6678
PET/CT Imaging Pre-treatment Core (Lab) PET Qualalative and Semi-Qualitative Assessment Form

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Comments: _____

_____

_____

_____

_____

_____
Signature of Nucelar medicine MD

_____-_____-_____
Date form completed

_____
Signature of person entering data onto the web

MC

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Merck

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

Merck ID: _____ [200]

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

	Timepoint 1	Timepoint 2	Timepoint 3
Date of PET Imaging	_____-_____-_____ [3]	_____-_____-_____ [4]	_____-_____-_____ [5]
Was the PET/CT Central Interpretation completed? *(if no, check all reasons that apply below)*	O No O Yes [6]	O No O Yes [7]	O No O Yes [8]
Is the overall quality of the PET/CT acceptable *(if suboptimal, check all reasons that apply below*	O Adequate O Suboptimal [9]	O Adequate O Suboptimal [10]	O Adequate O Suboptimal [11]
Reason images cannot be interpreted or image quality suboptimal *(check all that apply)*	☐ 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] ☐ Uptake time for the baseline and follow-up scan varies by >10 mins, but less than 15 mins [28] ☐ Other, [29] specify_____ [30]	☐ 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]

MC

ACRIN 6678
PET/CT Core (Lab) PET Qualitative and Semi-Qualitative Assessment Form Merck

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

4. Table 2: Record the following for each image. For 'unknown' code 999.

	Timepoint 1						Timepoint 2					
	Tumor Location	Table Position	Tumor Size	SUV (max)	SUV (peak)	SUV (Avg)	Table Position	Tumor Size	Change in Uptake	SUV (max)	SUV (peak)	SUV (Avg)
Liver						[69]						[70]
Target Lesion	[72]	[73]	[74]	[75]	[76]		[77]	[78]	[79]	[80]	[81]	
Additional Lesion 1	[87]	[88]	[89]	[90]	[91]		[92]	[93]	[94]	[95]	[96]	
Additional Lesion 2	[102]	[103]	[104]	[105]	[106]		[107]	[108]	[109]	[110]	[111]	
Additional Lesion 3	[117]	[118]	[119]	[120]	[121]		[122]	[123]	[124]	[125]	[126]	
Additional Lesion 4	[132]	[133]	[134]	[135]	[136]		[137]	[138]	[139]	[140]	[141]	
Additional Lesion 5	[147]	[148]	[149]	[150]	[151]		[152]	[153]	[154]	[155]	[156]	
Additional Lesion 6	[162]	[163]	[164]	[165]	[166]		[167]	[168]	[169]	[170]	[171]	

Tumor Location

1	Right upper lobe	12	Pleura
2	Right middle lobe	13	Liver
3	Right lower lobe	14	Adrenals
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 (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: _____

_____ [183]

_____ [184]
Initials of person entering data

_____-_____-_____ [185]
Date form completed *(mm-dd-yyyy)*

O1

ACRIN 6678

FDG - PET/CT Tumor Response
Off Study Criteria

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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]

O No (Sign and date form)
O 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

☐ The baseline SUV of the tumor (measured at the first PET/CT study) is less than 4.0. [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]

☐ Participant receives less than 2 cycles of first-line chemotherapy due to drug toxicity. [4]

☐ Participant undergoes the baseline pre-chemotherapy FDG-PET/CT scan(s) after the initiation of chemotherapy. [5]

☐ Participant undergoes the post-chemotherapy cycle 1 FDG-PET/CT scan after initiation of chemotherapy cycle 2. [6]

☐ Participant refuses the FDG-PET/CT scan(s) at the study imaging visits and/or refuses study follow-up visits. [7]

_____ [8]
Signature of person responsible for the data

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

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

P1

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

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 for the FDG-PET/CT performed at this timepoint.

VISIT: A1

1. Time point of PET/CT [1]

o Pre-chemotherapy (Group A within 14 days after 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]
- ☐ patient body weight unknown [6]
- ☐ 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]

P1

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. ☐

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A1

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 suboptiomal *(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]

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

P1

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. ☐

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A1

10. Are there any metastatic lesions to report? [30]

o No
o Yes (complete Q10a)

10a. Indicate anatomic location *(check all that apply)* ☐ =1 Not Marked, ☑ = 2 Marked

- ☐ Hilar nodes [31]
- ☐ Medialstinal 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]

COMMENTS: _____

_____

_____ [44]

_____ [45]
Radiologist responsible for data

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

_____ [47]
Person entering data onto the web

PF

ACRIN 6678
FDG - PET/CT Tumor Response Progression Form

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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) **SITE OF PROGRESSION** ☐ =1 Not Marked, ☑ = 2 Marked	**METHOD OF EVALUATION**	**DATE OF EVALUATION** *(mm-dd-yyyy)*
☐ Right upper lobe [1]	__ __ [2]	__ __ - __ __ - __ __ __ __ [3]
☐ Right middle lobe [4]	__ __ [5]	__ __ - __ __ - __ __ __ __ [6]
☐ Right lower lobe [7]	__ __ [8]	__ __ - __ __ - __ __ __ __ [9]
☐ Left upper lobe / lingula [10]	__ __ [11]	__ __ - __ __ - __ __ __ __ [12]
☐ Left lower lobe [13]	__ __ [14]	__ __ - __ __ - __ __ __ __ [15]
☐ Right mediastinal lymph node [16]	__ __ [17]	__ __ - __ __ - __ __ __ __ [18]
☐ Right hilar lymph node [19]	__ __ [20]	__ __ - __ __ - __ __ __ __ [21]
☐ Left mediastinal lymph node [22]	__ __ [23]	__ __ - __ __ - __ __ __ __ [24]
☐ Left hilar lymph node [25]	__ __ [26]	__ __ - __ __ - __ __ __ __ [27]
☐ Subcarinal lymph node [28]	__ __ [29]	__ __ - __ __ - __ __ __ __ [30]
☐ Supraclavicular/scalene nodes [31]	__ __ [32]	__ __ - __ __ - __ __ __ __ [33]
☐ Pleura [34]	__ __ [35]	__ __ - __ __ - __ __ __ __ [36]
☐ Liver [37]	__ __ [38]	__ __ - __ __ - __ __ __ __ [39]
☐ Adrenals [40]	__ __ [41]	__ __ - __ __ - __ __ __ __ [42]
☐ Bone [43]	__ __ [44]	__ __ - __ __ - __ __ __ __ [45]
☐ Bone marrow[46]	__ __ [47]	__ __ - __ __ - __ __ __ __ [48]
☐ Brain [49]	__ __ [50]	__ __ - __ __ - __ __ __ __ [51]
☐ Skin [52]	__ __ [53]	__ __ - __ __ - __ __ __ __ [54]
☐ Other, [55] specify _____ [56]	__ __ [57]	__ __ - __ __ - __ __ __ __ [58]

COMMENTS: _____

_____ [59]

_____ [60]
Signature of Person responsible for the data

_____-_____-_____ [62]
Date form completed *(mm-dd-yyyy)*

_____ [61]
Signature of Person entering data onto the web

R1

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A1 - Pre-Chemotherapy
and Visit C1 Pre-Treatment

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 for the FDG-PET/CT performed at this timepoint.

VISIT: A1/C1

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]
- ☐ patient body weight unknown [6]
- ☐ 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]

R1

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A1 - Pre-Chemotherapy
and Visit C1 Pre-Treatment

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A1/C1

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 suboptiomal *(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

R1

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A1 - Pre-Chemotherapy
and Visit C1 Pre-Treatment

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A1/C1

10. Are there any metastatic lesions to report? [30]

o No
o Yes (complete Q10a)

10a. Indicate anatomic location *(check all that apply)* ☐ =1 Not Marked, ☑ = 2 Marked

- ☐ Hilar nodes [31]
- ☐ Medialstinal 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]

_____ [45]
Radiologist responsible for data

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

_____ [47]
Person entering data onto the web

R2

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A2 and B1 - Pre-Chemotherapy and Visit C2 Pre-Treatment

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 for the FDG-PET/CT performed at this timepoint.

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]
- ☐ patient body weight unknown [6]
- ☐ 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]

R2

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A2 and B1 - Pre-Chemotherapy
and Visit C2 Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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 suboptiomal *(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

R2

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A2 and B1 - Pre-Chemotherapy
and Visit C2 Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A2/C2 AND B1

10. Are there any metastatic lesions to report? [30]
- 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]
- ☐ Medialstinal 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]

_____ [45]
Radiologist responsible for data

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

_____ [47]
Person entering data onto the web

R3

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A3 and B2 Post-Chemotherapy Cycle 1
(Within 3 days before Cycle 2)

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 for the FDG-PET/CT performed at this timepoint.

VISIT: A3 and B2

1. Time point of PET/CT [1]

o Post-chemotherapy Cycle 1 (Group A and B within 3 days before Cycle 2)

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]
☐ patient body weight unknown [6]
☐ 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]

R3

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A3 and B2 Post-Chemotherapy Cycle 1
(Within 3 days before Cycle 2)

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A3 and B2

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 suboptiomal *(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]

R3

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation Form
Visit A3 and B2 Post-Chemotherapy Cycle 1
(Within 3 days before Cycle 2)

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A3 and B2

9. Are there any new metastatic lesions not previously reported? [30]

o No
o Yes (complete Q10a)

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

☐ Hilar nodes [31]
☐ Medialstinal 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]

_____ [45]
Radiologist responsible for data

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

_____ [47]
Person entering data onto the web

R4

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

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 for the FDG-PET/CT performed at this timepoint.

VISIT: B3

1. Time point of PET/CT [1]

o Post-chemotherapy Cycle 2 (Group B within 3 days before Cycle 3)

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]
- ☐ patient body weight unknown [6]
- ☐ 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]

R4

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation 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

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 suboptiomal *(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]

R4

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Interpretation 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

9. Are there any new metastatic lesions not previously reported? [30]

o No
o Yes (complete Q10a)

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

☐ Hilar nodes [31]
☐ Medialstinal 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]

_____ [45]
Radiologist responsible for data

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

_____ [47]
Person entering data onto the web

T1

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical Assessment Form
Visit A1 - Pre-Chemotherapy and Visit C1 - Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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]
- o Visit A1/C1 (Groups A & C within 14 days of registration)

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: A1/C1

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]

9. Time of dose assay (military time) |_|_|_|_| [11]

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

14. Participant voided immediately post-imaging? [17]
- o No
- o Yes
- o Unknown

T1

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical Assessment Form
Visit A1 - Pre-Chemotherapy and Visit C1 - Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A1/C1

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: [26]
- o Segmentation
- o CT
- o Segmentation and emission subtraction
- o Other, specify:

_____ [27]

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 _____ [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]
- o No
- o Yes

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

_____ - _____ (mm-yyyy) [50]

T1

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical
Assessment Form
Visit A1 - Pre-Chemotherapy
and Visit C1 - Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A1/C1

32. F-18-FDG Source [38]

- o Synthesized (If synthesized, complete Q32a, b, and c)
- o Purchased (If purchased, complete Q33)

32a. Method: _____ [39]

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]

_____ [46]
Signature of person responsible for the data

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

_____ [48]
Signature of person entering data onto the web

T2

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical Assessment Form
Visit A2 and B1 - Pre-Chemotherapy and Visit C2 Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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]
- 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]

9. Time of dose assay (military time) |__|__|__|__| [11]

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

14. Participant voided immediately post-imaging? [17]
- o No
- o Yes
- o Unknown

T2

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical
Assessment Form
Visit A2 and B1 - Pre-Chemotherapy and Visit C2 Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A2/C2 AND B1

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: [26]
- o Segmentation
- o CT
- o Segmentation and emission subtraction
- o Other, specify:

_____ [27]

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 _____ [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]
- o No
- o Yes

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

T2

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical
Assessment Form
Visit A2 and B1 - Pre-Chemotherapy and Visit C2 Pre-Treatment

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A2/C2 AND B1

32. F-18-FDG Source [38]

- o Synthesized (If synthesized, complete Q32a, b, and c)
- o Purchased (If purchased, complete Q33)

32a. Method: _____ [39]

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]

_____ [46]
Signature of person responsible for the data

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

_____ [48]
Signature of person entering data onto the web

T3

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical Assessment Form
Visit A3 and B2 - Post-Chemotherapy Cycle 1 (Within 3 days before Cycle 2)

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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]
- o Post-chemotherapy Cycle 1 (Group A and B, within 3 days before Cycle 2)

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

VISIT: A3 and B2

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

|__|__|__|.|__| kg

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

8. Dose assay |__|__|.|__| **mCi** [10]

9. Time of dose assay (military time) |__|__|__|__| [11]

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

14. Participant voided immediately post-imaging? [17]
- o No
- o Yes
- o Unknown

T3

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical
Assessment Form
Visit A3 and B2 - Post-Chemotherapy Cycle 1
(Within 3 days before Cycle 2)

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A3 and B2

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: [26]
- o Segmentation
- o CT
- o Segmentation and emission subtraction
- o Other, specify:

_____ [27]

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 _____ [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]
- o No
- o Yes

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

_____ - _____ (mm-yyyy) [50]

T3

ACRIN 6678
FDG - PET/CT Tumor Response
PET/CT Local Technical
Assessment Form
Visit A3 and B2 - Post-Chemotherapy Cycle 1
(Within 3 days before Cycle 2)

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

ACRIN Study 6678

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

VISIT: A3 and B2

32. F-18-FDG Source [38]

- o Synthesized (If synthesized, complete Q32a, b, and c)
- o Purchased (If purchased, complete Q33)

32a. Method: _____ [39]

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]**

_____ **[46]**
Signature of person responsible for the data

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

_____ **[48]**
Signature of person entering data onto the web

T4

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.** _____

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]
- o Post-chemotherapy Cycle 2 (Group B, within 3 days before Cycle 3)

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

VISIT: B3

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

|__|__|__|.|__| kg

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

8. Dose assay |__|__|.|__| **mCi** [10]

9. Time of dose assay (military time) |__|__|__|__| [11]

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

14. Participant voided immediately post-imaging? [17]
- o No
- o Yes
- o Unknown

T4

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

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: [26]
- o Segmentation
- o CT
- o Segmentation and emission subtraction
- o Other, specify:

_____ [27]

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 _____ [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]
- o No
- o Yes

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

_____ - _____ (mm-yyyy) [50]

T4

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 [38]

- o Synthesized (If synthesized, complete Q32a, b, and c)
- o Purchased (If purchased, complete Q33)

32a. Method: _____ [39]

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]**

_____ **[46]**
Signature of person responsible for the data

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

_____ **[48]**
Signature of person entering data onto the web

TA

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

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 [1]
- o Pre-treatment *(within 2 weeks after registration visit: Group A only)*
- o Pre-treatment *(Within 1 week prior to 1st Chemotherapy 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:

_____ [4]

- o Unknown

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]

9. Time of dose assay (military time) |_|_|_|_| [11]

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

14. Patient voided immediately post-imaging? [17]
- o No
- o Yes
- o Unknown

TA

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

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

ACRIN Study **6678**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part II: Image Acquisition

Transmission Scan

15. Type of transmission scan *(check one)* [18]
- o CT
- 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 ___ . ___ [24]

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

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

_____ [27]

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]

Part III: Scanner / F-18-FDG Procurement

27. Thickness of Reconstructed images ___ . ___ **mm** [33]

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]
- o No
- o Yes

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PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

31. F-18-FDG Source [38]

- o Synthesized (If synthesized, complete Q31a, b, and c)
- o Purchased (If purchased, complete Q32)

31a. Method: _____ [39]

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]**

_____ **[44]**
Signature of person responsible for the data[1]

_____-_____-_____ **[45]**
Date form completed [3] (mm-dd-yyyy)

_____ **[46]**
Signature of person entering data onto the web[2]