ACRIN 6668

PET Pre and Post – Treatment Assessment for Locally Advanced NSCLC

Case Report Form Set

American College of Radiology Imaging Network
PET Imaging Pre and Post Treatment
Locally Advanced NSCLC
Forms Index

ACRIN Study 6668

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Please enter all data through ACRIN website Data Center. All data should be entered within two weeks of the procedure. Any questions related to these forms should be directed to Data management. Please see Study Contact Personnel.

6668 Form Completion Guidelines

The following is a list of all Data Collection forms, reports, and images due for ACRIN 6668. It includes form descriptions and general guidelines for completion.

Data Collection Forms:

A0 – Registration/Eligibility Checklist (Appendix II/A0) - This form is completed prior to registration to determine and confirm study eligibility. It includes general demographic characteristics (including age, gender, and race), inclusion/exclusion criteria checks, and receipt of written informed consent. At the time of enrollment, the participant is to review, sign and date the consent. The information gathered on the eligibility checklist will be data-entered at the time of registration and after confirmation of participant eligibility and participant consent**.**

I1 – Initial Evaluation Form - This form is completed by the site RA at the time of the participant's entry onto the study. It includes study-specific information related to the general health history, staging, and diagnostic work-up of the enrolled participant. It must be submitted within one week of the registration date.

TA - PET Technical Assessment Form - This form is used to record Technical Assessment on each PET scan. It includes information on institutional PET acquisition and pre-processing data. This form is completed by the Radiologist or the technologist for each PET imaging time-point (Pre and Post-Treatment PET Scans).

IM - Local PET Qualitative and Semi-Quantitative Assessment Form - This form is used to document the PET/CT Local Interpretation. It is completed by the Nuclear Medicine radiologist for each PET imaging time-point (Pre and Post-Treatment PET Scans).

TF- Chemotherapy Summary Form - This form records chemotherapy agents and treatment time. This form is completed by the site RA after completion of all definitive chemotherapy. For participants enrolled into an RTOG protocol, send both the ACRIN and the RTOG TF forms.

T1- Radiotherapy Summary Form – This form summarizes radiotherapy treatment. For participants enrolled into an RTOG protocol, send both the ACRIN and the RTOG T1 forms.

F1 - Follow-up Form - This form is used by the site RA to document follow-up. It records participant vital status, disease assessment and selected toxicities. Any cancer therapy (i.e. radiation therapy, chemotherapy, surgery, etc) given after the post-treatment scan should also be recorded on this form.

PR- Protocol Deviation Form – This form is completed by the site RA to record a protocol deviation. Only one deviation is recorded on each form.

QZ - PET (Core) Semi-Quantitative Assessment Form - Assessment of pre-and post-treatment PET scan with respect to local-regional and distant disease recorded at the central review facility. This form will be completed at the PET core lab at ACRIN.

Q2 - PET (Core) Semi-Quantitative Assessment Form- 2 - Assessment of pre-and post-treatment PET scan with respect to local-regional and distant disease recorded at the central review facility. This form will be completed at the PET core lab at ACRIN. *(Q2 Form captures the measurements using the Hottest Pixel new soft ware.)*

O1- Upstaging Form – This form is completed for all participants, regardless of disease status change. Forms are completed by a treating physician before the start any of treatment.

AE – Adverse Event Form – This form is completed if and when an adverse event occurs.

SAE – Serious Adverse Event Form – This form is completed if and when a serious adverse event occurs.

DS- End of Study Form – This form is completed after all Protocol criteria and follow-up is complete. This form is also completed if there is a premature discontinuation, such as Withdraws, Death, Lost to Follow-up or Other.

Images, Reports, and Films:

C5 - Pre-treatment PET Images – Pre-treatment PET images. (These scans should be sent electronically to ACRIN; see Section 10 of protocol.)

C6 - Post-treatment PET Images – Post-treatment PET images. (These scans should be sent electronically to ACRIN; see Section 10 of protocol.)

C1 - Pre-treatment CT Images – Pre-treatment CT scan images. (The scan can be sent electronically to ACRIN via DICOM; film copies are also acceptable. See Section 10 of protocol.) Each sheet of film should be printed with no more than 15 image frames per sheet of 14 X 17 film. An ACRIN supplied label should be affixed to each sheet of film. The label includes the study case number, the acquiring institution number, and the subject's initials. For a supply of film labels, contact Anthony Levering (alevering@phila.acr.org)

C4 - Post-treatment CT Images – Post-treatment CT scan images. (The scan can be sent electronically to ACRIN via DICOM, but film copy is acceptable. See Section 10). Each sheet of film should be printed with no more than 15 image frames per sheet of 14 X 17 film. An ACRIN supplied label should be affixed to each sheet of film. The label includes the study case number, the acquiring institution number, and the subject's initials. For a supply of film labels, contact Anthony Levering (alevering@phila.acr.org).

DR - Pre- and Post-treatment PET Report – Pre- and post-treatment PET dictated reports. Participant identifiers must be blacked out. Cover them with an ACRIN study label.

C3- Pre- and Post-treatment CT Report – Dictated reports complementary to pre- and post-treatment CT images. Participant identifiers must be blacked out. Cover them with an ACRIN study label.

P1 - Pathology Report – This report is required only for participants who have consented to the pathology/tissue portion of the study. Pathology report (with participant name, MR#, DOB and other identifying information removed) along with slides/blocks, to be submitted to LDS Hospital (see Section 14). This will be hard copy, and the information will be identified only by study name (ACRIN 6668/RTOG0235) and study case number.

T3 - Radiation Therapy Large Field Simulation Films – Film copy is acceptable. An ACRIN supplied label should be affixed to each sheet of film. The label includes the study case number, the acquiring institution number, and the subject's initials. For a supply of film labels, contact Anthony Levering (alevering@phila.acr.org). If the patient is on an RTOG trial, submitting films once to RTOG is acceptable.

T8 - Radiation Therapy Small Field (Boost) Films – Film copy is acceptable. An ACRIN supplied label should be affixed to each sheet of film. The label includes the study case number, the acquiring institution number, and the subject's initials. For a supply of film labels contact Anthony Levering (alevering@phila.acr.org). If the patient is on an RTOG trial, submitting films once to RTOG is acceptable.

Forms Chart:

Data Items	Submitted from	Submitted to	Time of Submission
Eligibility Checklist (Appendix II/A0)	Clinical Site	ACR	At registration
Initial Evaluation Form (I1)	Clinical Site	ACR	Within 1 week of registration
PET Technical Assessment Form (TA)	Clinical Site	ACR	Within 1 week of PET imaging
Pre-Treatment PET Images (C5)	Clinical Site	ACR	Within 1 week of PET imaging
Pre-treatment CT Digital Image (C1)	Clinical Site	ACR	Within 1 week of CT imaging
Post-Treatment PET Images (C6)	Clinical Site	ACR	Within 1 week of PET imaging
PET Imaging Report (DR)	Clinical Site	ACR	Within 1 week of PET imaging
Post-treatment CT Digital Image (C4)	Clinical Site	ACR	Within 1 week of CT imaging
Pre-and post-Treatment CT Report (C3)	Clinical Site	ACR	Within 1 week of CT imaging
Chemotherapy Summary Form (TF)	Clinical Site	ACR	Within 1 week chemotherapy completion

Radiotherapy Summary Form (T1)	Clinical Site	ACR	Within 1 week radiotherapy completion
Large Field Simulation Films (T3)	Clinical Site	ACR	Within 1 week radiotherapy start
Small Field (Boost) Films (T8)	Clinical Site	ACR	Within 1 week boost radiotherapy initiation
Local PET Semi-Quantitative Assessment Form (IM)	Clinical Site	ACR	Within 2 weeks of PET imaging
PET (Core) Semi-Quantitative Assessment Form (QZ)	NA	NA	Core PET-NSCLC facility at ACRIN
PET (Core) Semi-Quantitative Assessment Form 2 (Q2) (new software measurement)	NA	NA	Core PET-NSCLC facility at ACRIN
Follow-up Assessment (**F1**)	Clinical Site	ACR	q3 month year 1 and 2; q6 months year 3
Pathology Submission Form (PC)	Clinical Site	LDS	Per section 14.0
Pathology Report (P1)	Clinical Site	LDS	Per section 14.0
Adverse Event Form (AE)	Clinical Site	ACR	Per section 16.0
Protocol Variation Form (PR)	Clinical Site/DM	ACR	As needed
Upstaging Form (O1)	Clinical Site	ACR	Per Form Instructions
DS End of Study Form	Clinical Site	ACR	Per Form Instructions

APPENDIX II: ELIGIBILITY CHECK & REGISTRATION QUESTIONS

ELIGIBILITY CHECK

(A response coded other than prompted renders a patient ineligible for enrollment)

ACRIN Institution # _____

ACRIN 6668

Case # _____

_____ (Y) 1. Is there pathologically proven non-small cell lung carcinoma?

_____ (N) 2. Does the patient have diffuse bronchoalveolar carcinoma?

_____ (Y) 3. Is the clinical stage IIB or III?

_____ (Y) 4. Is the Zubrod performance status 0 or 1?

_____ (N) 5. Has the patient had a head CT or MRI showing evidence of brain metastases?

_____ (Y) 6. Age ≥ 18?

_____ (Y) 7. Is the patient medically able to tolerate and be compliant with full body PET scans before and after treatment?

_____ (N) 8. Does the patient have poorly controlled diabetes, defined as fasting blood glucose > 200 mg/dl?

_____ (N) 9. Is definitive surgery planned as part of the patient's treatment?

_____ (N) 10. Has the patient had prior thoracic radiotherapy?

_____ (Y) 11. Is the patient going to be treated with definitive, concurrent chemoradiotherapy at an RTOG member institution?

_____ (N) 12. Is the treatment plan anticipated to include adjuvant chemotherapy that extends beyond 16 weeks after the completion of radiotherapy?

_____ (Y/N) 13. Has the patient had a prior cancer other than basal or squamous skin cancer or carcinoma in situ?

_____(Y) 13a. If yes, has the patient been disease free for at least 3 years?

_____(Y/NA) 14. Has a pregnancy test been done and shown to be negative within 7 days of registration?

_____ (Y/NA) 15. If of reproductive potential, has the patient agreed to use medically acceptable form of contraception throughout the study period and at least 3 months after the second (post-treatment) PET scan?

_____ (Y) 16. Has the patient signed an IRB-approved study specific consent form?

ACRIN Institution # ____

ACRIN 6668 **REGISTRATION QUESTIONS**

Case # _____

The following questions will be asked at Study Registration:

_____ 1. Name of institutional person registering this case

_____(Y) 2. Has the Eligibility Checklist (above) been completed?

_____(Y) 3. Is the patient eligible for this study?

____/_____/__ 4. Date the study-specific Consent Form was signed? (must be prior to study entry)
(mm / dd / yyyy)

_____ 5. Participant's Initials (Last, First) (L, F)

_____ 6. Verifying Physician (ACRIN M.D.)

_____ 7. Verifying Physician (RTOG M.D.)

_____ 8. RTOG institution number

____/___/_____ 9. Date of Birth
(mm / dd / yyyy)

_____ 10. Ethnic Category

1 Hispanic or Latino
2 Not Hispanic or Latino
9 Unknown

11. Race (check all that apply)

- ☐ American Indian or Alaskan Native
- ☐ Asian
- ☐ Black or African American (not Latino)
- ☐ Native Hawaiian or other Pacific Islander
- ☐ White
- ☐ Unknown

_____ 12. Gender

1 male
2 female

_____ 13. Participant's Country of Residence (if country of residence is other, complete Q14)

1 United States
2 Canada
3 Other
9 Unknown

_____ 14. Other country, specify (completed only if Q13 is coded **other**)

_____ 15. Zip Code

_____ 16. Participant's Insurance Status

1 Private insurance
2 Medicare
3 Medicare and Private insurance
4 Medicaid
5 Medicaid and Medicare
6 Military or Veteran Administration
7 Self-pay
8 No means of payment
9 Unknown/declined to answer
0 Other

_____ 17. Will any component of the participant's care be given at a military or VA facility?

1 No
2 Yes
9 Unknown

_____/___/_____ 18. (Calendar base date)
(mm / dd / yyyy)

_____/___/_____ 19. Registration Date
(mm / dd / yyyy)

_____ 20. Did the participant already have a PET scan (If yes, must be within 6 weeks prior to registration)?

1 no
2 yes

_____ 21. Is the participant going to be treated on another protocol (e.g. RTOG study)?

1 no
2 yes

_____ 21a. If yes, indicate which study.

_____ 22. Did the participant consent to tissue analysis for the primary translational endpoint of the study?

1 no
2 yes

_____ 23. Did the participant consent to tissue storage and analysis for future translational studies related to cancer?

1 no
2 yes

_____ 24. Did the participant consent to tissue storage and analysis for future translational studies related to non-cancer diseases?

1 no
2 yes

_____ 25. Did the participant consent to allowing to be contacted for future studies?

1 no
2 yes

_____ 26. Date of planned or completed PRE-treatment PET scan

Completed by _____ Date completed _____/_____/_____
(mm / dd / yyyy)

_____
Signature of person entering data onto the web

I1

ACRIN 6668
PET Imaging Pre and Post Treatment Locally Advanced NSCLC
Initial Evaluation Form

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

ACRIN Study 6668

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 (1 week) of study registration date. All forms must be signed and dated as indicated.

GENERAL HEALTH HISTORY

1. Date of Birth
(Include 4 digit year, e.g., 1910, etc.)

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

2. ____.__ kg Patient's weight (.454 x lbs)

2a. _____ Estimated % weight loss in last 3 months
(0% = no weight loss)

☐ Unknown

3. _____ **Performance Status** (Zubrod)

0	*Fully Active*
1	*Ambulatory, capable of light work*
2	*In bed less than 50% of the time, capable of self-care, but not of work activities*
3	*In bed greater than 50% of the time, capable of only limited self care*
4	*Bedridden*
99	*Unknown*

STAGING

4. Clinical Stage (select one)

- ○ IIB
- ○ IIIA
- ○ IIIB
- ○ Other, specify: _____

5. Location of Primary Tumor (check all that apply)

- ☐ RUL
- ☐ RLL
- ☐ R hilum/middle lobe
- ☐ LUL
- ☐ LLL

6. Date of initial diagnosis of Primary Tumor - (NSCLC)

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

7. Is this Patient a surgical candidate?

- ○ No
- ○ Yes
- ○ Unknown

PRIOR TREATMENT

8. Prior Surgery to the study site?

- ○ No
- ○ Yes (If yes, provide date in Q8a)
- ○ Unknown

8a. Date of Surgery _____-_____-_____

9. Prior Thoracic radiotherapy?

- ○ No
- ○ Yes (If yes, provide date in Q9a)
- ○ Unknown

9a. Date XRT completed _____-_____-_____
(mm-dd-yyyy)

10. Is patient currently enrolled in an RTOG (NSCLC) lung protocol?

- ○ No
- ○ Yes (If yes, provide RTOG Protocol # in Q10a)

10a. RTOG Protocol # _____

11. Prior systemic chemotherapy?
(chemotherapy within 12 months of study enrollment)

- ○ No
- ○ Yes (If yes, provide date completed in Q11a)

11a. _____-_____-_____ (mm-dd-yyyy)

DIAGNOSTIC WORKUP

12. Procedures performed for diagnostic workup.
(If code 1-4, date of diagnostic exam is required)

1	Normal
2	Abnormal, non-indicative of malignancy
3	Equivocal
4	Abnormal, indicative of malignancy
98	Not done
99	Unknown

		Dates: mm-dd-yyyy
____	History/Physical exam	_____-_____-_____
____	CT scan Chest/Abdomen (including liver and adrenal glands)	_____-_____-_____
____	Head CT scan	_____-_____-_____
____	Head MRI	_____-_____-_____
____	Whole Body Bone Scan	_____-_____-_____
____	Whole Body PET Scan	_____-_____-_____
____	EKG	_____-_____-_____
____	Other, specify: _____	_____-_____-_____
____	Other, specify: _____	_____-_____-_____

TA

ACRIN
PET Imaging Pre and Post Treatment
Locally Advanced NSCLC
PET Technical Assessment Form

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

ACRIN Study **6668**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: The TA form is to be completed by the Technologist at the RTOG site for each time point specified in the protocol, i.e., question 1 on the form. PET images are to be transmitted as defined in section 10 of the protocol. Please see attached instructions (page 4) for image transfer and data submission address. All time fields must be reported in military format, i.e., 1:00pm = 13:00 hrs. Code all questions unless otherwise specified.

PET TIME-POINT INFORMATION

1. Protocol Imaging time point
- o Baseline PET
- o Post-treatment PET
- o Other treatment timepoint, specify: _____

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

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

2b. If PET imaging not done, specify missed timepoint.
(i.e., baseline or post treatment PET)
_____

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

4. Date of PET image submission:
_____ - _____ - _____ (mm-dd-yyyy)

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

PET Data Acquisition and Pre-processing

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

6. Patient voided immediately pre-imaging?
- o No
- o Yes

7. Patient voided immediately post-imaging?
- o No
- o Yes

8. Duration of patient fasting pre-PET imaging
|__|__| **hours** (recorded up to the time of FDG injection)

9. Blood glucose at start of PET imaging
(record value measured before FDG injection)
|__|__|__|.|__| mg/dl

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

11. Patient height |__|__|__| **cm**
(measured on the day of scan)

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

13. Dose assay |__|__|.|__| **mCi**

14. Time of dose assay (military time) |__|__|__|__|

15. Time of injection (military time) |__|__|__|__|

16. Has the scanner used for this study been qualified by ACRIN?
- o No
- o Yes, provide date: _____ - _____(mm-dd-yyyy)

6668 / RTOG 0235
PET -NSCLC
FORM ---- REVISION NOTICE (#1)

Implementation Date: 05/05/05

Below is a detailed list of each form revision.

The web data collection modules will reflect these revisions on a <u>rolling</u> basis.

The revised forms will be posted to the ACRIN web site on (05/05/05) and a reminder will be sent. In most cases these revisions will not need IRB approval but this will be site specific. If your site requires IRB review/approval of the CRF revisions, and approval has not been obtained, continue to use the previous form versions until IRB approval is obtained.

Questions or comments should be directed to ACRIN Data Management staff.

<u>Changed Forms:</u> Forms Index, TA- Technical Assessment Form

<u>Forms -INDEX</u>

- The TA forms current version date now reads: 05/02/05, it was previously 01/07/05

<u>TA-PET Technical Assessment Form</u>

- The following has been <u>removed</u> from Question 1, i.e. the below **<u>BOLDED</u>** sections:

  Protocol Imaging time point
  o Baseline PET **(pretreatment within 4 weeks prior to registration)**
  o Post-treatment PET**(within 3-5 weeks post induction therapy and no later than 1-3 weeks pre-surgery)**
  o Other treatment timepoint, specify: _____

- Question 16 was changed to now read:

  Has the scanner used for <u>this study</u> been qualified by ACRIN?
  o No
  o Yes, provide date: _____-_____-_____(mm-dd-yyyy)

TA **Revision** ☐

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

17. Type of scanner used for this exam?

17a. Vendor _____

17b. Model name and/or number

_____

18. ☐☐ **Number of bed positions scanned**

19. Type of transmission scan used? (check one)

- o CT (complete 19a, 19b, and 19c)
- o Interleaved transmission (complete 19d)
- o Non-interleaved transmission (define below; complete 19d)
  - o PET emission first
  - o Transmission first

19a. KVP ☐☐☐

MAS ☐☐☐

Slice thickness (mm) ☐☐.☐☐

19b. Oral contrast used?

- o No
- o Yes (define below)
  - o "Positive" contrast agent
  - o "Negative" contrast agent

19c. IV contrast used?

- o No
- o Yes

19d. ☐☐ **Minutes duration of transmission scan per bed position**

20. Transmission scan processing used

- o Segmentation
- o CT
- o Segmentation and emission subtraction
- o Other, specify: _____

21. Emission scan

21a. ☐☐ **Minutes duration of emission scan per bed**

21b. ☐☐☐☐ start time (military time)

21c. ☐☐☐☐ finish time (military time)

22. Emission acquisition mode

- o 2D
- o 3D

23. Pixel size of reconstructed images ☐☐.☐☐ mm

24. Slice thickness of reconstructed images

☐☐.☐☐ mm

25. Date of last scanner calibration:

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

26. Daily scanner QC run on date of study? (check one)

- o No
- o Yes

TA **Revision** ☐

ACRIN Study **6668**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

F-18-FDG Procurement

27. F-18-FDG Source
- o Synthesized
- o Purchased

If synthesized*, complete Q28a-c, if F-18-FDG is purchased**, complete 29.

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

28a. Method: _____

28b. Pyrogen test result
- o Passed
- o Failed
- o Not done

28c. Radiochemical purity test result: |__|__|.|__|__| **%**
- o Not done

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

_____

COMMENTS: _____

_____

_____

_____

_____

_____ _____ - _____ - _____

Signature of person responsible for the data[1] Date form completed [3] (mm-dd-yyyy)

_____

Signature of person entering data onto the web[2]

Image transmission via internet:

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

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

3. **PET Data Submission Instructions**
   http://www.acrin.org/petcorelab.html

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

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

IM

ACRIN 6668
PET Imaging Pre and Post Treatment
Local PET Qualitative and Semi-Quantitative
Assessment Form

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

ACRIN Study **6668**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions

Complete a separate form for each PET imaging time-point, i.e. PRE and POST treatment scans(s). Forms are completed by a Nuclear Medicine radiologist. Submit form(s) via the ACRIN website: www.acrin.org and only fax or mail form revisions.

A circular region of interest (0.75 - 1.5 cm) in diameter, centered on the maximum-value pixel will be drawn, and the manufacturer's algorithm will be used to calculate the mean SUV within this region; this value will be reported as the SUV (Peak). If two or more regions of interest are analyzed, the one with the higher SUV (Peak) will be reported for the purpose of this protocol. In addition, the maximum SUV should be determined with the manufacturer's algorithm and reported for each region where SUV (Peak) is measured and reported.

For question 7, if the baseline uptake scale for a region was 3, 4, or 5 as recorded on the pre-treatment PET table, then complete **all columns** for that **same region** in the post-treatment PET table. However, if for any region the baseline uptake was 1 or 2 as recorded on the pretreatment table, then begin by completing the “Uptake scale” column for that same region for the post-treatment table. If the uptake scale is 3, 4, or 5 then complete all the remaining columns for that same region in the post-treatment table. Otherwise if the uptake scale is still 1 or 2, then skip to the next region in the post-treatment table.

On the post-treatment PET study, one or more new regions of increased FDG uptake are commonly seen within the irradiated field that are most likely due to post-radiation inflammatory changes (e.g. radiation pneumonitis). A typical approach to recording of such new lesions on this form is as follows: (1) Record location (usually this will be listed under "other site, specify"); (2) Grade uptake (usually this will be 2 or 3 - if 3 or greater, measure SUV (Peak) and SUV (max)); (3) Grade change in uptake (usually this will be 4 or 5); (4) Local-regional disease assessment (response) does not apply and should not be completed; (5) Grade metastatic disease (usually this will be 2 or 3); and (6) Proximity does not apply and should not be completed.

IM

ACRIN
PET Imaging Pre and Post Treatment
Local PET Qualitative and Semi-Quantitative
Assessment Form

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

ACRIN Study **6668**
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part I

1. Was PET imaging completed?
- o No *(provide reason in Q1a and Q1b, then sign and date form)*
- o Yes *(proceed to Q2)*

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

1b. If no, provide timepoint not imaged: _____

2. Time point of PET-imaging (check one)
- o Pre-treatment
  (proceed to Q3) Continue with form
- o Post-treatment
  (complete Q2a, b, and c) Continue with form

2a. Is the pre-treatment PET scan available for post-treatment PET interpretation?
- o No *(complete Q2b)*
- o Yes *(complete Q2b)*

2b. Is the post-treatment CT scan available for post-treatment PET interpretation?
- o No *(proceed to Q3)*
- o Yes *(complete Q2c)*

2c. How was the post-treatment PET scan interpreted with the post-treatment CT scan? (check one)
- o CT scan and PET images displayed separately on view boxes
- o Software fusion
- o Hybrid CT/PET fusion

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

4. Date of PET Interpretation _____-_____-_____ (mm-dd-yyyy)

5. Image quality (check one)

(PRE-TREATMENT)

- o **Adequate**
  (complete Q6, then proceed to Q7)
- o **Suboptimal**
  (complete Q5a, then proceed to Q6, and Q7)

(POST-TREATMENT)

- o **Adequate**
  (complete Q6, then proceed to Q7)
- o **Suboptimal**
  (complete Q5a, then proceed to Q6, and Q7)

- o **Inadequate** ***(Pre or Post Treatment)***
  (complete Q5a, Q6 then skip to the end of the form, sign and date)

5a.
- o Entire study not complete
- o Noisy images
- o Patient motion
- o Radiotracer infiltration
- o SUVs cannot be calculated : specify reason,
  _____
- o Other, specify _____

6. Reader ID: |___|___|___|___|___|___|___|

IM

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part II 7. Semi-Quantitative Assessment

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

Response * (compared to baseline)**
0 (CR) Complete response
1 (PR) Partial response
2 (ND) No response
3 (PD) Progressive disease

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

NOTE:
If there is progression at this site when compared to Pre-treatment PET indicate the location of progression using the relationship to the port field. If there is no progression use "not applicable".

	Pre-treatment (PET) *If uptake scale < 3, then SUV is not recorded.*			Post-treatment (PET) *SEE INSTRUCTIONS PAGE 1*						
	Uptake	SUV (peak)	SUV (max)	Uptake	SUV (peak)	SUV (max)	** Change in uptake scale	*** Local-regional disease assessment	Metastatic disease (1 Definitely no metastatic disease; 2 Probably no metastatic disease; 3 Indeterminate; 4 Probably metastatic disease; 5 Definitely metastatic disease)	**** Progression based on proximity of the site(s) to local-regional progression
Lung (gross tumor/hilar mass)		__ __.__	__ __.__		__ __.__	__ __.__				
Regional Lymph Nodes (grossly involved with tumor)		__ __.__	__ __.__		__ __.__	__ __.__				
Pleura (remote from primary tumor site)		__ __.__	__ __.__		__ __.__	__ __.__				
Contralateral Lung		__ __.__	__ __.__		__ __.__	__ __.__				
Lymph nodes *(distant: e.g., cervical, axillary, abdomen, pelvis)*		__ __.__	__ __.__		__ __.__	__ __.__				
Adrenals		__ __.__	__ __.__		__ __.__	__ __.__				
Liver		__ __.__	__ __.__		__ __.__	__ __.__				
Bone		__ __.__	__ __.__		__ __.__	__ __.__				
(a) Other site, specify				(a) Other site, specify						
(b) Other site, specify				(b) Other site, specify						
(c) Other site, specify				(c) Other site, specify						
	(a)	__ __.__	__ __.__	(a)	__ __.__	__ __.__				
	(b)	__ __.__	__ __.__	(b)	__ __.__	__ __.__				
	(c)	__ __.__	__ __.__	(c)	__ __.__	__ __.__				

IM

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Part III

8. Indicate any Lymphadenopathy seen with PET

(Complete Q8 then proceed to Q9. If a nodal site is not examined code '98'.)

Anatomic Site	*Confidence in presence of disease
Supraclavicular	☐
Ipsilateral hilar	☐
Contralateral hilar	☐
Ipsilateral upper mediastinal	☐
Contralateral upper mediastinal	☐
Ipsilateral lower mediastinal	☐
Contralateral lower mediastinal	☐
Other, specify: _____	☐

***Confidence Scale**
1 Definitely no metastasis
2 Probably no metastasis
3 Possibly no metastasis
4 Probably metastasis
5 Definitely metastasis
98 Not examined

9. Distant Metastases with PET findings

(Complete Q9 then proceed to Q10. If a distant site is not examined code '98'.)

Anatomic Site	*Confidence in presence of disease
Contralateral lung/pleura	☐
Ipsilateral distant lung/pleura *(remote from primary tumor)*	☐
Adrenal glands	☐
Distant lymph nodes *(cervical, axillary, abdomen, pelvis, other)*	☐
Bone metastases (any location)	☐
Other, specify: _____	☐

***Confidence Scale**
1 Definitely no metastasis
2 Probably no metastasis
3 Possibly no metastasis
4 Probably metastasis
5 Definitely metastasis
98 Not examined

PART IV

PET Assessment

10. What is your overall confidence in the Presence or Absence of Stage IV disease as seen with PET? (check one)

- o Definitely not present
- o Probably not present
- o Indeterminate
- o Probably present
- o Definitely present

COMMENTS: _____

_____

_____

_____

_____
Signature of Nuclear Medicine M.D.

Date form completed ____-____-_____ (mm-dd-yyyy)

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

M E M O R A N D U M

TO: ACRIN 6668 Principle Investigators and Research Associates

FROM: Sharlene Snowdon, AS, RT(R)(CT)(MR)
ACRIN Senior Research Associate

Laura Hill, BS
ACRIN Research Associate

DATE: October 12, 2006

RE: **ACRIN Study 6668(IMb Form) Revision-Effective 10/12/2006**

CC: Irene Mahon, RN, MPH
ACRIN, Project Manager

Suddhasatta Acharyya, PhD
Protocol Statistician
Center for Statistical Sciences, Brown University

Bradley Snyder, MS
Biostatistician, Protocol Manager
Center for Statistical Sciences, Brown University

Pamela Harvey, M Mgt
Director, ACRIN Data Management

Anthony Levering, RT (R) (CT) (MR),
ACRIN Imaging Research Coordinator

<u>As of today, the following changes have taken place to the ACRIN 6668 IM Form:</u>

The IM(b) form has undergone several revisions on the paper form. The Web Screen for Data Entry has been updated to reflect these changes.

ACRIN Data Management
1818 Market Street, Suite 16
Philadelphia, PA 19103

American College Of Radiology

Memo

To: ACRIN 6668 Research Associates and Principal Investigators

From: Data Management

CC: Sophia Sabina, MBA, RT(R)(T).....*Director, Data Management*
Suddhasatta Acharyya, Ph.D.....*Assistant Professor, Protocol Statistician*
Bradley Snyder, MS.....*Protocol Manager, Biostatistician*
Irene Mahon, RN, MPH.....*Project Manager*
Anthony Levering, RT (R)(CT)(MR).....*Senior Imaging Technologist*

Date: 10/20/2005

Re: ACRIN Study 6668 (IM Form) Revision – Effective (10/20/05)

As of today, the following (IM) form changes have taken place:

The IM form has undergone revision on paper ONLY. At this time do NOT enter IM forms via the ACRIN WEB SITE until further notice. You will be notified when WEB entry for the IM form can resume.

The NEW VERSION of the (IM) form: is denoted (IM**b**) on the bottom of the form next to the form version date.

Detailed below are the revisions and instructions to clarify specific questions and their completion requirements. The ACRIN 6668 link for forms will reflect updated forms on 10/20/05 and the implementation date of the version IM**b** is (10/20/05).

Please **discard and DO NOT USE OBSOLETE FORMS FOR DATA COLLECTION.**

ACRIN 6668 Forms Index: IM form was updated to version 09/20/05

PET Imaging Form (IMb Version 09/20/05)

- The form has been changed to a landscape format
- Page 3 (PART II) Question 7: now contains a SUV **(MAX)** column and these instructions were moved to page 1 of the form:

  A circular region of interest (0.75 - 1.5 cm) in diameter, centered on the maximum-value pixel will be drawn, and the manufacturer's algorithm will be used to calculate the mean SUV within this region; this value will be reported as the peak SUV. If two or more regions of interest are analyzed, the one with the higher peak SUV will be reported for the purpose of this protocol.

- Page 1 instructions have been added: (**Bolded sentence**) below

A circular region of interest (0.75 - 1.5 cm) in diameter, centered on the maximum-value pixel will be drawn, and the manufacturer's algorithm will be used to calculate the mean SUV within this region; this value will be reported as the peak SUV.

In addition, the Maximum SUV should be determined with the manufacturer's algorithm and reported for each region where SUV (Peak) is measured and reported.

If two or more regions of interest are analyzed, the one with the higher peak SUV will be reported for the purpose of this protocol.

- Page 3 (PART II) Question7: The pre-treatment header was changed form:

  Pre-treatment (PET)
  If uptake scale <3, then SUV peak is not recorded

  Now reads: (the word **PEAK** was removed)
  Pre-treatment (PET)
  If uptake scale <3, then SUV is not recorded

For participant cases in which the IM version (02/17/05) has already been completed and web entered, please complete the following steps:

- Have the Nuclear Medicine M.D. (Re-Review) the PET scan and calculate the NEW SUV MAX data items on page 3.
- Print a copy of the NEW form IM**b** version 09/20/05 from the ACRIN website
- Complete the NEW SUV MAX column only and not the sections of the IM version (02/17/05) that were previously completed and submitted via the website.
- Fax a copy of the IM**b** version (09/20/05) to ACRIN (215-717-0936). Please be sure to send ALL pages of the form even though all section will NOT be completed and label all pages. Complete the NEW SUV MAX columns on page 3 and sign and date the form.

These columns: **SUV** (max) ↓

___.___
___.___
___.___
___.___

- Keep both versions of the IM forms in the case file
- Start collecting data on the NEW IM form for ALL new cases.
- You will be notified when IM form WEB entry can continue

ALL OTHER 6668 FORMS CAN BE WEB ENTERED AS USUAL

TF

ACRIN 6668
PET Imaging Pre and Post Treatment Locally Advanced NSCLC Chemotherapy Summary Form

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

ACRIN Study **6668**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: Submit this form for ALL Patients enrolled, within 1 week after completion of all definitive chemotherapy. All dates are recorded mm-dd-yyyy. Submit via the ACRIN website. Agent(s) questions (2-6) *must* be completed, if chemotherapy was initiated.

1. Was chemotherapy completed according to prescribed plan? (check one)

- o No-Not Initiated *(explain in comments, sign and date form)*
- o No *(complete questions 2-6 as applicable)*
- o Yes *(complete questions 2-6 as applicable)*

Agent Code Table
1 Cisplatin
2 Carboplatin
3 Paclitaxel
4 Etoposide
5 Navelbine
6 Taxotere
7 Vinblastine
8 Other*(specify agent)
9 No other agent

*** Reason(s) for Modification, Delay, Interruption or Termination**
1 Treatment completed per plan
2 Disease progression, relapse during active treatment
3 Toxicity/side effects/complications
4 Death on study
5 Patient withdrawal or refusal after beginning treatment
6 Patient withdrawal or refusal prior to begining treatment
7 Alternative therapy, specify**
8 Other complicating disease, specify **
9 Other, specify **

	Start Date (mm-dd-yyyy)	Completion Date (mm-dd-yyyy)	*Modification, Delay or Interruption?	*Treatment Termination?	
2. Agent ☐ * _____ _____	___-___-___	___-___-___	a.) ☐☐	b.) ☐☐	a.) **Other, specify: _____ b.) **Other, specify: _____
3. Agent ☐ * _____ _____	___-___-___	___-___-___	a.) ☐☐	b.) ☐☐	a.) **Other, specify: _____ b.) **Other, specify: _____
4. Agent ☐ * _____ _____	___-___-___	___-___-___	a.) ☐☐	b.) ☐☐	a.) **Other, specify: _____ b.) **Other, specify: _____
5. Agent ☐ * _____ _____	___-___-___	___-___-___	a.) ☐☐	b.) ☐☐	a.) **Other, specify: _____ b.) **Other, specify: _____
6. Agent ☐ * _____ _____	___-___-___	___-___-___	a.) ☐☐	b.) ☐☐	a.) **Other, specify: _____ b.) **Other, specify: _____

COMMENTS: _____

_____

_____

_____

_____
Signature of person responsible for the data [1]

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

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

T1 ACRIN 6668
PET Imaging Pre and Post Treatment Locally Advanced NSCLC Radiotherapy Summary Form

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

INSTRUCTIONS: Form is submitted within one week of completion or termination of RT to ACRIN DMC via www.acrin.org . Submit this form for ALL Patients enrolled. If assigned radiation and none given, complete Q1, and Q5, sign, date and submit form. Dates are recorded mm/dd/yyyy unless otherwise specified.

1. Did radiotherapy commence?

o No (complete Q5, sign and date form)

o Yes (continue with form)

1a. ____-____-____ **Date of First Treatment** **1b.** ____-____-____ **Date of Last Treatment**

2. DOSE SUMMARY: Complete for all treatment fields or as specified within the protocol. Specify fractions and dose for each volume a-d, record totals in e.

Gross Tumor Site

	Fractions	Dose (Gy)
a. Initial Volume	☐☐	☐☐.☐☐
b. Reduced Volume #1	☐☐	☐☐.☐☐
c. Reduced Volume #2	☐☐	☐☐.☐☐
d. Reduced Volume #3	☐☐	☐☐.☐☐
e. Total to Gross Tumor	☐☐	☐☐.☐☐

Electively Irradiated Regional Nodes

3.			
*Nodal Site	☐	☐☐	☐☐.☐☐
*Nodal Site	☐	☐☐	☐☐.☐☐
*Nodal Site	☐	☐☐	☐☐.☐☐
*Nodal Site	☐	☐☐	☐☐.☐☐
*Nodal Site	☐	☐☐	☐☐.☐☐

***Nodal Sites**
Lung (Upper/Mid/Lobes)
1 Ipsilateral hilar
2 Subcarinal
3 Contralateral hilar
4 Inferior mediastinal including pleural ligament
5 Upper mediastinal/not grossly involved

Other Volume, specify _____ ☐☐ ☐☐.☐☐

4.

	****Critical Structures**	**Maximum Dose (Gy)**	**Other, Specify (Code 3)**
a.	☐	☐☐.☐☐	_____
b.	☐	☐☐.☐☐	_____
c.	☐	☐☐.☐☐	_____

****Critical Structures**
1 Spinal Cord
2 Esophagus
3 Other, specify

5. ☐ REASON RT DISCONTINUED PRIOR TO REQUIRED DOSE OR IF THE ASSIGNED OPTION NOT GIVEN

Must be completed for all patients assigned radiotherapy
0 (N/A) XRT dose administered within protocol specifications
1 Progression or relapse
2 Toxicity or treatment reaction
3 Death
4 Patient refused
8 Other reason, specify: _____

6. TREATMENT INTERRUPTIONS (RX breaks while under RT)
***Do not include days on which treatment ordinarily would not be given; weekends, holidays, etc.**

* ☐☐☐ Total # of treatment days RT interrupted for toxicity

* ☐☐☐ Total # of treatment days RT interrupted for other reasons. (Specify, in comments)

Comments: _____

_____

_____ Signature of person responsible for the data [1]

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

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

PC

ACRIN 6668
PET Imaging Pre and Post Treatment Locally Advanced NSCLC Pathology Submission Form

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: This form must be completed and mailed with the Pathology Specimens whenever slides or blocks are sent to University of California San Francisco.
At the time of submission, a copy of this form must also be faxed to ACRIN Data Management @ 215-717-0936.
Please reference protocol section 14.O for details and for a list of required materials.

TYPE	PROCEDURE DATE	SITE OF MATERIAL	NUMBER OF SPECIMENS			PATHOLOGY ACCESSION#
			H&E Stained Slides	Unstained Slides	Blocks	
	____-____-_____					
	____-____-_____					
	____-____-_____					
	____-____-_____					
	____-____-_____					
	____-____-_____					
	____-____-_____					
	____-____-_____					

----------TYPE----------
1 Pre-treatment Bx
2 Surgical treatment
3 Post-treatment Bx
4 Autopsy
9 Unknown

ACRIN Calendar form due date: _____ (PC)

REQUIRED ENCLOSURES:

_____ **Pathology Report(s)**

_____ **Blocks/Slides**

_____ **This Submission Form**

_____ **Patient consent**

Check all that apply and submit with patient study consent form.

Patient consents to:
☐ 1 Current research as specified in the protocol
☐ 2 Future research using Tissue Bank samples
☐ 3 Being contacted about future research

SEND TO:

Non-frozen specimens only
RTOG Biospecimen Resource
University of California
San Francisco
Campus Box 1800
1657 Scott Street, Room 223
San Francisco, CA 94143-1800

Submitted By: _____

Date Submitted: _____-_____-_____ (mm-dd-yy)

Telephone NO: (___) _____

SEND TO:

Frozen specimens only
RTOG Biospecimen Resource
University of California
San Francisco
1657 Scott Street, Room 223
San Francisco, CA 94115

Form Revision Notice

Study: ACRIN 6668

From: Stephanie Clabo, ACRIN Data Management Department

Date: July 23, 2008

RE: ACRIN 6668 - PET Imaging PRE and POST Treatment Locally Advanced NSCLS Pathology Submission Form (PC)

The following form revision was:

- **Posted to the ACRIN study website on:** July 24, 2008
- **Posted to the online web entry system:** N/A
- **Effective date revised form distributed:** July 24, 2008

Form ID: PC

Revision to Pathology Submission Address

Old Response: Send to LDS Hospital

New Response: Send to University of California San Francisco

Non- frozen specimens only
RTOG Biospecimen Resource
University of California
San Francisco
Campus Box 1800
1657 Scott Street, Room 223
San Francisco, CA 94143-1800

Frozen specimens only
RTOG Biospecimen Resource
University of California
San Francisco
1657 Scott Street, Room 223
San Francisco, CA 94115

Revised Form Version: 07-21-08

For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

F1 ACRIN 6668
PET Imaging Pre and Post Treatment Locally Advanced NSCLC Follow-up Form

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

INSTRUCTIONS: Submit this form at the appropriate followup interval and whenever there is a change in the patient's status. Follow-up visits should be 3 months x 2 years, then 6 months x at least 1 year (or until this study has been terminated). Participants who are on another RTOG or other cooperative group study will be followed according to the follow-up schema of their primary therapeutic study. Dates are mm/dd/yyyy unless otherwise specified.

1. _____-_____-_____ **Date of last clinical assessment**
mm dd yyyy

2. Patient's Vital Status *(check one)*
[If patient's vital status is reported as "dead", the date of death must be reported in question 3 and a primary cause of death in question 4.]

[If reporting status is "lost-to follow-up", record the last date of contact in question 3.]

[If reporting status is dead, "date of death unknown", record the last date of contact in question 3 and provide primary cause of death in question 4.]

- O Alive (proceed to Q5)
- O Dead (complete Q3 and Q4)
- O Lost to follow-up; unable to contact (complete Q3)
- O Dead, date of death unknown (complete Q3 and Q4)

3. _____-_____-_____ **Date of last contact or death**
mm dd yyyy

4. Primary cause of death *(check one)*

- O Due to NSCLC (whether local, regional, or distant)
- O Related to or probably related to a second primary tumor
- O Due to protocol treatment (explain in COMMENTS)
- O Related to or probably related to complications of other treatment
- O Due to other cause (describe cause of death)

  _____
- O Unknown

5. ☐ **Performance Status** (Zubrod)

☐ Unknown (If Zubrod is unknown, ☑ unknown)

Disease Progression

6. Are there any sites of progression not previously recorded? *(check one)*

- O NED/NEPD - No evidence of disease / progressive disease (skip to Q8 and continue with form)
- O First progression, not previously reported (complete Q7a and Q7b, then continue with form)
- O First progression previously reported; however, stable from last report no new sites of progression (skip to Q8, and continue with form)
- O First progression previously reported with new sites to report (complete Q7a and Q7b, then continue with form)

7a. Site(s) of progression

1 No
2 Yes
98 Not evaluated
99 Uncertain

7b. Progression Assessment Method

** Up to 3 assessments may be coded for each anatomic site.*

1 Physical Exam
2 Conventional Imaging (CT)
3 PET with/without CT/MRI
4 Pathologic
5 MRI
6 Ultrasound
7 Bone scan
8 Other method (specify in comments)

Use Codetable 7a Codes (1 and 2 require a date)		Date of Assessment	(*Use codetable 7b)
☐☐	INFIELD XRT Lung/Nodes	___-___-___	☐☐☐
☐☐	LUNG (DISTANT)	___-___-___	☐☐☐
☐☐	LYMPH NODES (distant)	___-___-___	☐☐☐
☐☐	PLEURAL (distant)	___-___-___	☐☐☐
☐☐	ADRENALS	___-___-___	☐☐☐
☐☐	LIVER	___-___-___	☐☐☐
☐☐	BONE	___-___-___	☐☐☐
☐☐	CNS (BRAIN)	___-___-___	☐☐☐
☐☐	OTHER, Specify_____	___-___-___	☐☐☐

8. Has a new primary cancer or MDS (Myelodysplastic Syndrome) been diagnosed that has not been previously reported? *(check one)*

- O No (skip to Q9, and continue with form)
- O Yes (complete Q8a, Q8b, and Q8c, then continue with form)
- O Unknown (skip to Q9, and continue with form)

8a. New Primary Site:

_____

8b. New Primary Histologic type:

_____

8c. Date of diagnosis _____-_____
mm yyyy

F1 If this is a revised or corrected form, please √ box. ☐

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

9. Did the participant receive any cancer therapy not previously reported? *(check one)*

O No (skip to Q10)
O Yes (check all boxes that apply ☑)
O Unknown (skip to Q10)

☐ Radiation Therapy
Date of first radiotherapy: _____-_____-_____
mm-dd-yyyy

☐ Surgery
Date of first surgery: _____-_____-_____
mm-dd-yyyy

☐ Cytotoxic Therapy
Date of first therapy: _____-_____-_____
mm-dd-yyyy

☐ Other therapy (specify):

_____

Date of first therapy: _____-_____-_____
mm-dd-yyyy

10. Are there any continuing or new reportable (Grade 3 or >) adverse events related to imaging? (PET,CT)

O No (sign and date form)
O Yes (complete Adverse Event Reporting Form {AE})
O Unknown (sign and date form)

Comments: _____

_____

_____

_____

_____

_____

_____
Signature of person responsible for the data

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

_____
Signature of person entering data onto the web

F1 Form

Please review the below guidelines for completing the Follow up (F1) form.

The Follow–up (F1) form is to be Web entered by the Site. This form is used to document follow-up and record participant vital status, disease assessment and selected toxicities. The F1 form is collected every 3 months for the first two years and then 6 months for at least 1 year or until this study has been terminated.

This form must be completed and web entered for all cases for vital status.

- Please record the date of last clinical assessment (question 1). The F1 form should only contain data from after the prior assessment date / F1 form to the current assessment date / F1 form (An assessment date can only be used once.)

- Please record vital status (question 2). This includes:

    1. Alive – Please proceed in completing the F1 form to document disease assessment.

    2. Dead – Please complete date of death and Primary cause of death on the F1 form. After completing the F1 form please complete an End of Study (DS) form. (See End of Study Completion Guidelines.) Please submit all Data Collection Forms that were due prior to the date of death.

    3. **Lost to Follow-up; unable to contact – Please complete date of last contact on F1 form.

** Please make every effort to obtain information before recording Lost to Follow-up. The primary endpoint is survival, and so collection of survival data is essential to the success of ACRIN 6668. **If you cannot locate a participant, please attempt to locate and utilize information from the referring physician, oncologist, family M.D, hospital(s), and/or hospice(s).**

**If one F1 form has been submitted and documented as Lost to Follow–up, please continue to follow the participant and submit Data Collection Forms as required. However, if two consecutive F1 forms have been submitted that are documented as Lost to Follow-up, then please complete the End of Study (DS) form. (See End of Study Completion Guidelines.)

Thank you for all your continued efforts to ensure quality data submission on the ACRIN 6668 study.

M E M O R A N D U M

TO: ACRIN 6668 Principal Investigators and Research Associates

FROM: ACRIN Data Management

DATE: November 19, 2007

RE: **ACRIN 6668 F1 Follow-up Form Revision-Effective 11/19/07**

CC: Irene Mahon, RN, MPH
ACRIN, Project Manager

Pamela Harvey, M Mgt
Director, ACRIN Data Management

Anthony Levering, RT (R) (CT) (MR),
ACRIN Senior Imaging Technologist

Suddhasatta Acharyya, PhD
Protocol Statistician
Center for Statistical Sciences, Brown University

Bradley Snyder, MS
Biostatistician, Protocol Manager
Center for Statistical Sciences, Brown University

As of today, the following changes have taken place to the ACRIN 6668 F1 Form:

The F1 Follow-up form has undergone several revisions. The Web Screen for Data Entry has been updated to reflect these changes.

The NEW VERSION of the F1 form is dated 8/17/07.

****Please discard and do not use any obsolete forms for data collection.**

Detailed below are the revisions and instructions to clarify specific questions and their completion requirements. The ACRIN 6668 protocol link for forms will reflect all current updates.

The following changes were made:

- **Q 6- 'No evidence of disease/progressive disease'** was added to the code table to clarify the abbreviation NED/NEPD.
- **Q7b-** '**MRI', 'Ultrasound', 'Bone Scan', and 'other method (specify in comments'** were added to current code table list of progression assessment methods. It was discovered during recent audits that these assessment methods are also being used.
- **Q 8- MDS** expanded to Myelodysplastic Syndrome to clarify the abbreviation.
- **Q9 –** Wording revised. **'Salvage' and 'Palliative'** were removed. **We want to capture **ALL** additional treatment that was not previously reported.**

The new F1 form is effective starting today, November 19, 2007. Please remember that is it very important to use only the newest version of the form to preserve all previously reported data. All old versions of the form may be discarded. We appreciate your cooperation.

For questions, please contact **Laura Hill** at ACRIN Headquarters at lhill@phila.acr.org or 215-717-2767. Thank you.

DS

ACRIN 6668

PET Imaging Pre and Post Treatment Locally Advanced NSCLC End of Study Form

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

ACRIN Study **6668**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. End of Study status: [1]

- O 1 Protocol specific criteria and follow-up complete (sign and date form)
- O 2 Premature discontinuation (complete Q1a and 1b)

1a. Date of premature discontinuation: _____-_____-_____ *(mm/dd/yyyy)* [2]

1b. Primary reason for premature discontinuation: *(check only one)* [3]
(include in comments below an explanation of premature discontinuation)

- O Participant explicitly withdraws from further study participation
- O Death
- O Lost to follow-up (unable to obtain contact with the participant during the prescribed protocol intervals)
- O Other

COMMENTS: _____

_____

_____ [8]

_____ [9]
Initials of person completing the data

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

DS Form

Please review the below guidelines for completing the DS (End of Study) Form.

The End of Study (DS) form is to be Web entered by the Site. The DS form is used to capture End of Study status. The purpose of this form will be to classify and document cases for which no more study data is expected, either due to premature discontinuation or completion of required study follow-up. This is a standard form across all ACRIN studies and every effort possible should be made to comply with these guidelines.

This form must be completed and web entered for all cases for the following reasons:

- Protocol specific criteria and follow-up complete. This will be recorded if the data collection calendar has been completed, and no more Study Forms or Follow–up is required.
- Premature discontinuation. This will be recorded for the following reasons:

  1. **Participant withdraws**: This will eliminate the need for your Institution to code withdraws on the Protocol Variation Form (PR) and will be captured on the End of Study Form. The case status will change to Open-Withdrawn and all forms will be suppressed after the withdrawal date or premature discontinuation date. Please record in the comments an explanation of the withdrawal.

  2. **Death:** Please complete for all discovered deaths. In addition, please complete the final F1 follow-up form in order to document the primary cause of death and the date of death. Patient status will change to Dead and all forms after the date of death will be suppressed. Please record in the comments a description of the death.

  3. **Lost to follow-up**: If unable to obtain contact with the participant and **2 consecutive F1 forms with vital status lost to follow-up have been submitted**, then the DS form can be completed as Lost to follow-up. Patient Status will change to Lost and all forms after the last F1 assessment will be suppressed. Please record in the comments an explanation of lost to follow-up.

  4. **Other**: Please specify in comments with a detailed description and contact ACRIN Data Management.

Thank you for all your continued efforts to ensure quality data submission on the ACRIN 6668 study.

PR

ACRIN 6668
PET Imaging Pre and Post Treatment Locally Advanced NSCLC Protocol Variation Form

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: In the instance a protocol requirement is not met, record the requested information below. Complete a separate form for **each case** and for **each event**. Retain the form in the case study file and enter via the ACRIN web site. ***Incomplete forms will be returned for resolution of blank data fields.***

1. Check The Protocol Event Being Reported: (report only one per form)

- ☐ Inclusion/exclusion criteria not met at time of registration/randomization **(complete 1a)**
- ☐ Imaging-related deviation **(complete 1b)**
- ☐ Study activity performed prior to participant signing study consent form
- ☐ PET interpretation guidelines not followed (Pre-treatment)
- ☐ PET interpretation guidelines not followed (Post-treatment)
- ☐ Participant following other treatment preference
- ☐ Treatment work-up not completed
- ☐ Consent for tissue not acquired
- ☐ IMRT done
- ☐ Not able to submit pathology to RTOG Biospecimen Resource, University of California
- ☐ Post-treatment PET scan done between 8 and 12 weeks after the completion of XRT
- ☐ Post-treatment PET scan done between 16 and 20 weeks after the completion of all radiotherapy/chemotherapy
- ☐ Post-treatment PET scan done on a different PET scanner from the pre-treatment PET (but still within the same ACRIN-qualified institution)
  - o Scanner type used was same manufacturer and model
  - o Scanner type used was different manufacturer and/or model
- ☐ Post-treatment PET scan done sooner than 8 weeks after XRT
- ☐ Post-treatment PET scan done later than 20 weeks after the completion of all radiotherapy/chemotherapy
- ☐ Post-treatment PET scan done at a non-ACRIN-qualified institution
- ☐ Post-treatment PET scan not done according to protocol specifications (e.g. incorrect dosage of FDG, incorrect scan times)
- ☐ Post-treatment PET scan done 12 to 20 weeks after XRT but less than 4 weeks after adjuvant chemotherapy
- ☐ Post-treatment CT scan done sooner than 8 weeks after XRT
- ☐ Post-treatment CT scan done between 8 and 12 weeks after completion of XRT
- ☐ Post-treatment CT scan done between 16 and 20 weeks after the completion of all radiotherapy/chemotherapy
- ☐ Post-treatment CT scan done later than 20 weeks after the completion of all radiotherapy/chemotherapy
- ☐ Post-treatment CT scan done 12 to 20 weeks after XRT but less than 4 weeks after adjuvant chemotherapy
- ☐ Required blood glucose test not performed prior to administration of FDG
- ☐ Other, specify: _____

1a. Inclusion/exclusion criteria not met:

- ☐ Participant is on (Phase I study)
- ☐ Prior thoracic radiotherapy
- ☐ Pregnant
- ☐ [RTOG] protocol criteria not met
- ☐ Small cell (CA) histology
- ☐ Prior malignancy
  [Other than basal/squamous skin cancer, carcinoma in situ, or other cancer from which the participant has been disease free for less than 3 years.]
- ☐ Participant went on to have surgery
- ☐ Other, specify: _____

PR

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1b. Imaging Deviation:

*Pre-Treatment**

- ☐ *PET Images (lost or unavailable)
- ☐ *CT Images (lost or unavailable)
- ☐ *CT scan(s) not per protocol

*Post-Treatment***

- ☐ **PET Images (lost or unavailable)
- ☐ **CT Images (lost or unavailable)
- ☐ **CT scan(s) not per protocol

- ☐ Large field simulation films (lost or unavailable)
- ☐ Small field boost films (lost or unavailable)
- ☐ Other, specify: _____

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

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

4. Describe the protocol deviation:

_____

_____

_____

_____

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

_____

_____

_____

_____

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

Person responsible for data (RA, study staff) **Date form completed**

_____

Investigator Signature

Form Revision Notice

Study: ACRIN 6668

From: ACRIN Data Management Department

Date: August 19, 2008

RE: ACRIN 6668 PET Imaging Pre and Post Treatment Locally Advanced NSCLC Protocol Variation Form (PR)

The following form revision was:

- **Posted to the ACRIN study website on:** August 18, 2008
- **Posted to the online web entry system:** August 19, 2008
- **Effective date revised form distributed:** August 19, 2008

Form ID: PR

Revision to question number one, response description Number 10

Describe:

Old Response: Not able to submit pathology to LDS Hospital

New Response: Not able to submit pathology to RTOG Biospecimen Resource, University of California

Revised Form Version: 08-18-2008

For questions, please contact your ACRIN Data Manager at ACRIN Headquarters.

O1 ACRIN 6668 PET Imaging Pre and Post Treatment Locally Advanced NSCLC Upstaging Form

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

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Instructions: Submit this form for ALL Patients enrolled, i.e. patient's with or without a disease status change. Forms are completed by a Physician and submitted via the ACRIN web site. Complete before the patient starts any anti-cancer therapy. All dates are recorded mm-dd-yyyy unless otherwise specified.

1. Was the disease status upstaged based on PET and confirmatory studies? (check one)
- o No, **(complete Q1a, then sign and date form)**
- o Yes, unconfirmed by additional imaging **(complete Q1a, then sign and date form)**
- o Yes, confirmed in retrospect on previous CT/MRI scan **(complete Q1a - Q5)**
- o Yes, confirmed on additional directed CT/MRI scan <region of interest> **(complete Q1a - Q5)**
- o Unknown/Uncertain **(complete Q1a, then sign and date form)**

1a. Provide stage (check one) **(based on PET + confirmatory studies)**
- o IIB
- o IIIA
- o IIIB
- o IV

1b. Specify organ(s) involved in upstaging: (check all that apply)
- ☐ Brain
- ☐ Liver
- ☐ Kidney
- ☐ Adrenal
- ☐ Bone
- ☐ Multiple organs involved
- ☐ Other, specify: _____
- ☐ Unknown

2. Was a directed CT scan done to confirm upstaging based on PET findings? (check one)
- o No, unconfirmed on previous exam and additional imaging not done **(proceed to Q3)**
- o No, confirmed in retrospect on previous CT scan **(proceed to Q2a)**
- o Yes **(indicate type(s) of CT scan done and date imaging performed in Q2a)**
- o Unknown **(proceed to Q3)**

2a. Indicate all areas of interest within CT scan:
- ☐ Brain
  Date of imaging _____-_____-_____
- ☐ Chest
  Date of imaging _____-_____-_____
- ☐ Abdomen/Pelvis
  Date of imaging _____-_____-_____
- ☐ Chest/Abdomen/Pelvis
  Date of imaging _____-_____-_____
- ☐ Other, specify _____
  Date of imaging _____-_____-_____

3. Was a directed MRI scan done to confirm upstaging based on PET findings? (check one)
- o No, unconfirmed on previous exam and additional imaging not done **(proceed to Q4)**
- o No, confirmed in retrospect on previous MRI scan **(proceed to Q3a)**
- o Yes **(indicate type(s) of MRI scan done and date imaging performed in Q3a)**
- o Unknown **(proceed to Q4)**

3a. Indicate all areas of interest within MRI scan
- ☐ Brain
  Date of imaging _____-_____-_____
- ☐ Chest
  Date of imaging _____-_____-_____
- ☐ Abdomen/Pelvis
  Date of imaging _____-_____-_____
- ☐ Chest/Abdomen/Pelvis
  Date of imaging _____-_____-_____
- ☐ Other, specify _____
  Date of imaging _____-_____-_____

4. Was a whole body bone scan done? (check one)
- o No **(proceed to Q5)**
- o Yes **(complete Q4a)**
- o Unknown **(proceed to Q5)**

4a. Indicate all areas of interest within Bone scan
- ☐ Brain
  Date of imaging _____-_____-_____
- ☐ Chest
  Date of imaging _____-_____-_____
- ☐ Abdomen/Pelvis
  Date of imaging _____-_____-_____
- ☐ Chest/Abdomen/Pelvis
  Date of imaging _____-_____-_____
- ☐ Other, specify _____
  Date of imaging _____-_____-_____

5. Was a biopsy performed based on confirmed PET findings seen on CT/MRI? (check one)
- o No **(sign and date form)**
- o Yes **(complete Q5a, and Q5b)**
- o Unknown **(sign and date form)**

5a. Provide date of definitive biopsy _____-_____-_____

5b. Histology (check one)
- o Squamous cell carcinoma
- o Adenocarcinoma
- o Large cell
- o Combined squamous and adenocarcinoma
- o Carcinoma NOS
- o Bronchoalveolar
- o Non small cell, NOS
- o Other, specify: _____

COMMENTS: _____

_____
Signature of person responsible for the data [1]

Date form completed ____-____-_____ (mm-dd-yyyy)

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

SF ACRIN 6668 Supplemental Payment Form

ACRIN Study 6668

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Instructions: Please complete the SF form for a supplemental reimbursement payment of $1,000 for cases in which you need to repeat a pre-treatment PET scan for an otherwise eligible ACRIN 6668 participant when 1) the initial pre-treatment PET scan was conducted on a non-qualified PET scanner; or 2) if the initial pre-treatment PET scan was conducted > 6 weeks prior to registration. The supplemental case payment is not intended to reimburse sites for uninsured participants (the case reimbursement rate calculation included a percentage of funding to cover expenses for uninsured participants). Please submit the completed SF form to ACRIN **via fax: 215-717-0936** , and file the supporting documentation of **denial of pre-certification** or **denial of payment** in the participant chart, for review upon audit, if necessary. You do not need to submit the supporting documentation to ACRIN. The key data forms identified in the 6668 Case Reimbursement Schedule remain a requirement for triggering the standard and supplemental payment.

1. Please check the scenario that applies:

☐ The participant's initial pre-treatment PET scan was conducted on a non-qualified PET scanner. The participant required a repeat pre-treatment scan on the ACRIN qualified scanner. The participant's insurance company would not reimburse the repeat scan. [1]

(Please file the insurance claim denial letter in the participant chart. Retention of the denial of payment is required and subject to audit. Do not submit supporting documentation to ACRIN).

☐ The participant's initial pre-treatment PET scan was conducted out of protocol window (> 6 weeks prior to registration). The participant required a repeat pre-treatment scan on the ACRIN qualified scanner. The participant's insurance company would not reimburse the repeat scan. [2]

(Please file the insurance claim denial letter in the participant chart. Retention of the denial of payment is required and subject to audit. Do not submit supporting documentation to ACRIN).

☐ The participant's initial pre-treatment PET scan was conducted out of protocol window (> 6 weeks prior to registration) **and** on a non-qualified PET scanner. The participant required a repeat pre-treatment scan on the ACRIN qualified scanner. The participant's insurance company would not reimburse the repeat scan. [3]

(Please file the insurance claim denial letter in the participant chart. Retention of the denial of payment is required and subject to audit. Do not submit supporting documentation to ACRIN).

Signature: _____ [4]

Date: _____ - _____ - _____ (mm-dd-yyyy) [5]

ACRIN

GENERAL COMMUNICATION MEMO/REPLY TO FORMS DUE REQUEST

INSTRUCTIONS: Use this memo
- To communicate the unavailability of a required calendar item.
- To inform us that a participant has expired and you are awaiting details.
- To communicate information about the case that cannot be reported on a form. **Note**: A narrative will not be accepted in lieu of a form.

Use a separate form for each case.

Be sure to properly identify the study, case, the form your explanation refers to, and the calendar due date.
A **case specific label** can be affixed within the section below for convenience and study / case identification.

From Institution # / Name: _____ Forms Due Request Date _____

ACRIN Protocol # _____ Case # _____ Participant Initials / ID _____

Data Item	Data Collection Calendar Due Date	Assessment / Imaging Date Recorded on Form by Institution	Comment / Explanation
☐ Initial evaluation form	_____	_____	_____
☐ Imaging Form (specify)	_____	_____	_____
☐ Biopsy Form	_____	_____	_____
☐ Follow-up Form	_____	_____	_____
☐ Image Reports	_____	_____	_____
☐ Image(s)	_____	_____	_____
Other (specify)			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

_____ Research Associate _____ Date 04 / 04