ACRIN 6697 /
RTOG 1106

RANDOMIZED PHASE II TRIAL OF INDIVIDUALIZED ADAPTIVE RADIOTHERAPY USING DURING-TREATMENT FDG-PET/CT AND MODERN TECHNOLOGY IN LOCALLY ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

CRF Set

American College of Radiology Imaging Network

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TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

ACRIN Study 6697
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: FDG / FMISO

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

Exam Data

1. Clinical trial time point [1]
- o Baseline
- o During treatment

2. Imaging Agent Name [2]
- o FDG
- o FMISO

3. Was imaging exam completed? [4]
- o No, imaging not completed (complete Q3a, then form as applicable)
- o Yes (proceed to Q4 and continue with form)

3a. *If Imaging not completed, provide reason: [5]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Blood glucose level
- o Participant withdrew consent
- o Progressive disease
- o Imaging agent not administered
- o Adverse event (complete AE form)
- o Participant death
- o FMISO not delivered
- o Unknown
- o Other, specify: _____ [6]

4. Date of imaging: [7] (mm-dd-yyyy)
_____ - _____ - _____

5. Weight
___ . ___ kg [8]
☐ Unknown [9]

6. Height
___ cm [10]
☐ Unknown [11]

Patient Preparation (FDG-PET/CT only)

☐ Not Done [12]

1. Duration of fasting pre-imaging:
___ hours (up to time of injection) [13] ☐ Unknown [14]

2. Blood glucose before injection of FDG [15]
(record value measured before injection)
___ . ___ mg/dl ☐ Unknown [16]

2a. Time blood sample was obtained for glucose measurement (military time) [17]
___ : ___ ☐ Unknown [18]

3. Was Foley catheter in place for study? [19]
- o No (complete Q4-Q5)
- o Yes (skip to next section)

4. Patient voided immediately pre-imaging? [20]
- o No
- o Yes
- o Unknown

5. Patient voided immediately post-imaging? [21]
- o No
- o Yes
- o Unknown

TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

Imaging Agent: FDG / FMISO

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

ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Scanner

☐ Not Done[22]

2. Has the scanner used for <u>this study</u> been qualified by ACRIN?[24]

- o No, specify reason (complete Q3): _____[25]
- o Yes, provide ACRIN Scanner ID# (skip to Q4): _____[26]

3. Scanner used for this exam:

3a. Manufacturer

_____[27]

3b. Manufacturer model name/or number

_____[28]

4. Date of last PET Scanner SUV validation:[29]

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

5. Daily scanner QC run on date of study?[30]

o No o Yes

6. Was flat palette insert used?[86]

- o No
- o Yes

7. Was the patient positioned in treatment planning position?[87]

o No o Yes

8. Did the radiation oncology technologist assist with patient positioning?[88]

- o No
- o Yes

9. Scan extent?[89]

- o Skullbase to thighs
- o Apices through upper abdomen
- o Other, specify _____[90]

Transmission Scan

☐ Not Done[37]

1. Transmission scan type[38]

o Low Dose CT

2. kVp

|_|_|_|[48]

☐ Unknown[49]

3. mAs

|_|_|_|[50]

☐ Unknown[51]

4. Slice Thickness of reconstructed images

|_|.|_|_| mm[52]

☐ Unknown[53]

5. Length of Transmission Scan: |_|_|_| Seconds[54]

☐ Unknown[55]

TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

Imaging Agent: FDG / FMISO

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ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PET Emission Scan

☐ Not Done[56]

1. Acquisition mode[57] o 2D o 3D

2. Number of bed positions scanned ___[58]

PET Emission Scan:

Start Time (military time) **3a.** ___:___[60]

Stop Time (military time) **3b.** ___:___[61]

Reconstructed Images:

4. Pixel Size: ___.___ mm[62]

5. Thickness: ___.___ mm[63]

Adverse Events

1. Any adverse events related to imaging to report for this timepoint?[82]

o No (initial and date form) o Yes (Submit AE form)

2. Does this event meet the criteria of a serious adverse event?[83]

o No o Yes

_____[84]
Initials of person completing this form

_____-_____-_____[85]
Date form completed (mm-dd-yyyy)

EX

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in Locally Advanced NSCLC
Exposure Form

Imaging Agent: FDG / FMISO

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

ACRIN Study **6697**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Exam Data

1. Planned time point: [1]
- O Baseline
- O During treatment

2. Planned imaging agent name: [3]
- O FDG
- O FMISO

3. Was imaging agent administered? [2]
- O No (Initial & date form)
- O Yes

4. Administration date: [4]

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

Imaging Agent Procurement

5. Identification number (Lot #): [5] _____

6. Source of agent: [6]
- O Prepared in-house (provide method by which agent is synthesized, complete Q6a)
- O Obtained from outside supplier (complete Q6b)

6a. Method: [7] _____

6b. Supplier: [8] _____

Administration Information

7. Route of administration: [9]
- ● IV

8. Activity in full syringe before injection: ___.___ mCi [10]

8a. Time of assay of full syringe before injection: __:__ (military time) [11] ☐ Unknown [12]

9. Time of injection: __:__ (military time) [13] ☐ Unknown [14]

10. Residual activity in syringe after injection: ___.___ mCi [15] ☐ Unknown [16] (if unk, skip to Q12)

10a. Time of assay of residual activity after injection: __:__ (military time) [17] ☐ Unknown [18]

11. Net activity administered (Dosage Amount): ___.___ mCi [19]

11a. Was the net activity administered decay corrected? [25]
- O No
- O Yes

12. Site of injection: [20]
- O Right antecubital
- O Right wrist
- O Right foot
- O Indwelling central catheter
- O Left antecubital
- O Left wrist
- O Left foot
- O Unknown
- O Other, specify [21] _____

13. Any infiltration at injection site noted? [22]
- O None
- O Minor (estimated to be less than 20% of dose)
- O Severe (estimated to be more than 20% of dose)

_____ Initials of person who completed form [23]

_____ - _____ - _____ Date form completed (mm-dd-yyyy) [24]

TD

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in Locally Advanced NSCLC
FDG-PET Imaging-Related Drug History

ACRIN Study 6697 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. Clinical trial time point: [1] O Baseline O During treatment

2. Is the participant a known diabetic? [2] O No O Yes

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

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

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

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

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

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

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

Taken ____ ____ [38] hours before FDG

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

Agent Name: _____ [40]

Given approximately ____ ____ days ago [41]

☐ Unknown [42]

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

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

TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

ACRIN Study 6697
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: FDG / FMISO

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

Exam Data

1. Clinical trial time point [1]
- o Baseline
- o During treatment

2. Imaging Agent Name [2]
- o FDG
- o FMISO

3. Was imaging exam completed? [4]
- o No, imaging not completed (complete Q3a, then form as applicable)
- o Yes (proceed to Q4 and continue with form)

3a. *If Imaging not completed, provide reason: [5]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
- o Injection site complications
- o Claustrophobia
- o Blood glucose level
- o Participant withdrew consent
- o Progressive disease
- o Imaging agent not administered
- o Adverse event (complete AE form)
- o Participant death
- o FMISO not delivered
- o Unknown
- o Other, specify: _____ [6]

4. Date of imaging: [7] (mm-dd-yyyy)
_____ - _____ - _____

5. Weight
___ . ___ kg [8]
☐ Unknown [9]

6. Height
___ cm [10]
☐ Unknown [11]

Patient Preparation (FDG-PET/CT only)

☐ Not Done [12]

1. Duration of fasting pre-imaging:
___ hours (up to time of injection) [13] ☐ Unknown [14]

2. Blood glucose before injection of FDG [15]
(record value measured before injection)
___ . ___ mg/dl ☐ Unknown [16]

2a. Time blood sample was obtained for glucose measurement (military time) [17]
___ : ___ ☐ Unknown [18]

3. Was Foley catheter in place for study? [19]
- o No (complete Q4-Q5)
- o Yes (skip to next section)

4. Patient voided immediately pre-imaging? [20]
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TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

Imaging Agent: FDG / FMISO

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ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Scanner

☐ Not Done[22]

2. Has the scanner used for <u>this study</u> been qualified by ACRIN?[24]

- o No, specify reason (complete Q3): _____[25]
- o Yes, provide ACRIN Scanner ID# (skip to Q4): _____[26]

3. Scanner used for this exam:

3a. Manufacturer

_____[27]

3b. Manufacturer model name/or number

_____[28]

4. Date of last PET Scanner SUV validation:[29]

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

5. Daily scanner QC run on date of study?[30]

o No o Yes

6. Was flat palette insert used?[86]

- o No
- o Yes

7. Was the patient positioned in treatment planning position?[87]

o No o Yes

8. Did the radiation oncology technologist assist with patient positioning?[88]

- o No
- o Yes

9. Scan extent?[89]

- o Skullbase to thighs
- o Apices through upper abdomen
- o Other, specify _____[90]

Transmission Scan

☐ Not Done[37]

1. Transmission scan type[38]

o Low Dose CT

2. kVp

|_|_|_|[48]

☐ Unknown[49]

3. mAs

|_|_|_|[50]

☐ Unknown[51]

4. Slice Thickness of reconstructed images

|_|.|_|_| mm[52]

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5. Length of Transmission Scan: |_|_|_| Seconds[54]

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TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

Imaging Agent: FDG / FMISO

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

ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PET Emission Scan

☐ Not Done[56]

1. Acquisition mode[57] o 2D o 3D

2. Number of bed positions scanned ___[58]

PET Emission Scan:

Start Time (military time) **3a.** ___:___[60]

Stop Time (military time) **3b.** ___:___[61]

Reconstructed Images:

4. Pixel Size: ___.___ mm[62]

5. Thickness: ___.___ mm[63]

Adverse Events

1. Any adverse events related to imaging to report for this timepoint?[82]

o No (initial and date form) o Yes (Submit AE form)

2. Does this event meet the criteria of a serious adverse event?[83]

o No o Yes

_____[84]
Initials of person completing this form

_____-_____-_____[85]
Date form completed (mm-dd-yyyy)

EX

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in Locally Advanced NSCLC Exposure Form

Imaging Agent: FDG / FMISO

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

ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Exam Data

1. Planned time point:[1]
- O Baseline
- O During treatment

2. Was imaging agent administered?[2]
- O No (Initial & date form)
- O Yes

3. Imaging agent name:[3]
- O FDG
- O FMISO

4. Administration date:[4]

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

Imaging Agent Procurement

5. Identification number (Lot #):[5] _____

6. Source of agent:[6]
- O Prepared in-house (provide method by which agent is synthesized, complete Q6a)
- O Obtained from outside supplier (complete Q6b)

6a. Method:[7] _____

6b. Supplier:[8] _____

Administration Information

7. Route of administration:[9] ● IV

8. Activity in full syringe before injection: ___.___ mCi[10]

8a. Time of assay of full syringe before injection: __:__ (military time)[11] ☐ Unknown[12]

9. Time of injection: __:__ (military time)[13] ☐ Unknown[14]

10. Residual activity in syringe after injection: ___.___ mCi[15] ☐ Unknown[16] (if unk, skip to Q12)

10a. Time of assay of residual activity after injection: __:__ (military time)[17] ☐ Unknown[18]

11. Net activity administered (Dosage Amount): ___.___ mCi[19]

11a. Was the net activity administered decay corrected?[25]
- O No
- O Yes

12. Site of injection:[20]
- O Right antecubital
- O Right wrist
- O Right foot
- O Indwelling central catheter
- O Left antecubital
- O Left wrist
- O Left foot
- O Unknown
- O Other, specify[21] _____

13. Any infiltration at injection site noted?[22]
- O None
- O Minor (estimated to be less than 20% of dose)
- O Severe (estimated to be more than 20% of dose)

_____ Initials of person who completed form[23]

_____ - _____ - _____ Date form completed (mm-dd-yyyy)[24]

SA

RTOG 1106 / ACRIN 6697
Adaptive Therapy using FDG-PET/CT in Locally Advanced NSCLC
FMISO Safety Assessment Form

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

ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. Timepoint *(check one)* [1]

O 1 Baseline

Part I. Monitoring for Physiologic Effects of FMISO *Complete entire table for each FMISO imaging scan*

Time Point of Vital Sign Reading	Time Taken *Military time*	Pulse	Blood Pressure *Systolic/Diastolic*	Respirations *Check one*	Temperature
Prior to Injection	___ ___ : ___ ___ [2] *hh:mm* ☐ Unknown [3]	_____ bpm [4] ☐ Unknown [5]	_____ / _____ mmHg [6] [7] ☐ Unknown [8]	O Labored [9] O Unlabored O Unknown	_____ . ____ °C [10] ☐ Unknown [11]
Completion of FMISO PET Imaging	___ ___ : ___ ___ [12] *hh:mm* ☐ Unknown [13]	_____ bpm [14] ☐ Unknown [15]	_____ / _____ mmHg [16] [17] ☐ Unknown [18]	O Labored [19] O Unlabored O Unknown	_____ . ____ °C [20] ☐ Unknown [21]

1. Did the participant require any additional monitoring of vital signs? [22]

O 1 No
O 2 Yes

1a. If yes, provide the last reading of vital signs taken before the participant left the PET facility:

Time Taken *Military time*	Pulse	Blood Pressure *Systolic/Diastolic*	Respirations *Check one*	Temperature
___ ___ : ___ ___ [23] *hh:mm* ☐ Unknown [24]	_____ bpm [25] ☐ Unknown [26]	_____ / _____ mmHg [27] [28] ☐ Unknown [29]	O Labored [30] O Unlabored O Unknown	_____ . ____ °C [31] ☐ Unknown [32]

Part II. Adverse Events

Refer to Appendix VII of the protocol

1. Were any AE's reported *(as part of this Imaging visit)*? [33]

O 1 No
O 2 Yes *(Report on a AE Form)*

2. Was the patient contacted for AE assessment? [40]

O 1 No (*complete Q2a, sign and date form*)
O 2 Yes *(skip to Q3)*

2a. If no, please state reason: [41]

O Participant ill or hospitalized
O Participant deceased
O Incorrect contact information
O Telephone disconnected
O Participant unable to be contacted
O Other, specify: _____ [42]

Provide date and time of follow-up telephone call for AE assessment

3. Date _____-_____-_____ *(mm-dd-yyyy)* [34]
☐ Unknown [35]

4. Time *(Military Time)* ___ ___ : ___ ___ *hh:mm* [36]
☐ Unknown [37]

_____ [38]
Initials of person(s) completing this form

_____-_____-_____ [39]
Date form completed *(mm-dd-yyyy)*

TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

ACRIN Study 6697
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Imaging Agent: FDG / FMISO

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Exam Data

1. Clinical trial time point [1]
- o Baseline
- o During treatment

2. Imaging Agent Name [2]
- o FDG
- o FMISO

3. Was imaging exam completed? [4]
- o No, imaging not completed (complete Q3a, then form as applicable)
- o Yes (proceed to Q4 and continue with form)

3a. *If Imaging not completed, provide reason: [5]
- o Scheduling problem
- o Equipment failure
- o Participant refusal
- o Medical reason
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- o Progressive disease
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- o Participant death
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4. Date of imaging: [7] (mm-dd-yyyy)
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5. Weight
___ . ___ kg [8]
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2. Blood glucose before injection of FDG [15]
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2a. Time blood sample was obtained for glucose measurement (military time) [17]
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3. Was Foley catheter in place for study? [19]
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Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

Imaging Agent: FDG / FMISO

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PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Scanner

☐ Not Done[22]

2. Has the scanner used for <u>this study</u> been qualified by ACRIN?[24]

- o No, specify reason (complete Q3): _____[25]
- o Yes, provide ACRIN Scanner ID# (skip to Q4): _____[26]

3. Scanner used for this exam:

3a. Manufacturer

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5. Daily scanner QC run on date of study?[30]

o No o Yes

6. Was flat palette insert used?[86]

- o No
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7. Was the patient positioned in treatment planning position?[87]

o No o Yes

8. Did the radiation oncology technologist assist with patient positioning?[88]

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TA

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in
Locally Advanced NSCLC
Local Technical Assessment Form

Imaging Agent: FDG / FMISO

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

ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

PET Emission Scan

☐ Not Done[56]

1. Acquisition mode[57] o 2D o 3D

2. Number of bed positions scanned ___[58]

PET Emission Scan:

Start Time (military time) **3a.** ___:___[60]

Stop Time (military time) **3b.** ___:___[61]

Reconstructed Images:

4. Pixel Size: ___.___ mm[62]

5. Thickness: ___.___ mm[63]

Adverse Events

1. Any adverse events related to imaging to report for this timepoint?[82]

o No (initial and date form) o Yes (Submit AE form)

2. Does this event meet the criteria of a serious adverse event?[83]

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_____[84]
Initials of person completing this form

_____-_____-_____[85]
Date form completed (mm-dd-yyyy)

EX

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in Locally Advanced NSCLC Exposure Form

Imaging Agent: FDG / FMISO

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

ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

Exam Data

1. Planned time point:[1]
- O Baseline
- O During treatment

2. Was imaging agent administered?[2]
- O No (Initial & date form)
- O Yes

3. Imaging agent name:[3]
- O FDG
- O FMISO

4. Administration date:[4]

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5. Identification number (Lot #):[5] _____

6. Source of agent:[6]
- O Prepared in-house (provide method by which agent is synthesized, complete Q6a)
- O Obtained from outside supplier (complete Q6b)

6a. Method:[7] _____

6b. Supplier:[8] _____

Administration Information

7. Route of administration:[9] ● IV

8. Activity in full syringe before injection: ___.___ mCi[10]

8a. Time of assay of full syringe before injection: __:__ (military time)[11] ☐ Unknown[12]

9. Time of injection: __:__ (military time)[13] ☐ Unknown[14]

10. Residual activity in syringe after injection: ___.___ mCi[15] ☐ Unknown[16] (if unk, skip to Q12)

10a. Time of assay of residual activity after injection: __:__ (military time)[17] ☐ Unknown[18]

11. Net activity administered (Dosage Amount): ___.___ mCi[19]

11a. Was the net activity administered decay corrected?[25]
- O No
- O Yes

12. Site of injection:[20]
- O Right antecubital
- O Right wrist
- O Right foot
- O Indwelling central catheter
- O Left antecubital
- O Left wrist
- O Left foot
- O Unknown
- O Other, specify[21] _____

13. Any infiltration at injection site noted?[22]
- O None
- O Minor (estimated to be less than 20% of dose)
- O Severe (estimated to be more than 20% of dose)

_____ Initials of person who completed form[23]

_____ - _____ - _____ Date form completed (mm-dd-yyyy)[24]

TD

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in Locally Advanced NSCLC
FDG-PET Imaging-Related Drug History

ACRIN Study 6697 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. Clinical trial time point: [1] O Baseline O During treatment

2. Is the participant a known diabetic? [2] O No O Yes

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

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

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

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

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

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

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

Taken ____ ____ [38] hours before FDG

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

Agent Name: _____ [40]

Given approximately ____ ____ days ago [41]

☐ Unknown [42]

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

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

DS

RTOG 1106 / ACRIN 6697

Adaptive Therapy using FDG-PET/CT in Locally Advanced NSCLC

End of Study Disposition

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

ACRIN Study **6697**

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

1. Provide reason for study disposition by selecting *one* of the following: [1]

- O 1 Protocol defined follow-up completed
- O 2 Participant lost to follow-up
- O 3 Participant refused follow-up / withdrew
- O 4 Death *(specify date and cause below)*

  Date of death: _____[2]/_____[3]/_____[4] *(mm/dd/yyyy)*

  Cause of death [5]

  - O 1 Disease Progression
  - O 88 Other, specify _____[6]
- O 5 Adverse Event / Side Effects / Complications
- O 6 Protocol violation: *(check all that apply)*

  - ☐ Did not meet eligibility[7]
  - ☐ Technical problems[8]
  - ☐ Related to study visits[9]
  - ☐ Related to imaging[10]
  - ☐ Related to randomization[11]
  - ☐ Other[12] *(specify below)*
- O 7 Disease progression
- O 8 Study terminated by sponsor
- O 88 Other *(specify reason below)*

  Specify reason: _____[13]

2. Date of disposition: _____/_____/_____ *(mm/dd/yyyy)* [14]

3. Did the investigator review and sign off on the participant's disposition? [15]

- O 1 No
- O 2 Yes

Comments: _____[16]

_____[17]
Initials of person completing the form

_____/_____/_____[18]
Date form completed (mm-dd-yyyy)

To the best of my knowledge, the data collected for the participant are accurate and complete.

Investigator's signature _____

AE

ACRIN Adverse Event Form
ACRIN 6697
Adaptive Therapy using FMISO-PET/CT in Locally Advanced NSCLC

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

ACRIN Study 6697 Case #

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

All Adverse Events (AEs) and Serious Adverse Events (SAEs) as defined in the protocol require routine reporting via web entry of the AE CRF. Only one AE is captured per form. For further instructions in completing the form, please refer to the AE completion instructions. Please note that source documentation (ACRIN AE log, ACRIN AE CRF, printed AE web confirmation, or participant's chart) must have the investigator's signature. For AE reporting requirements, please refer to the AE reporting section of the protocol. Contact ACRIN's AE coordinator for any questions.

AE Description _____ [1, 2]

AE Short Name (online look-up) _____ [3]

Grade [4]	Attribution [5]	Expectedness [6]	Serious AE? [42]	Expedited Report Submitted [7]	Action Taken (mark ☒ all that apply)	Outcome [9]	Date of AE Onset and Resolution (mm-dd-yyyy); mark ☒ the box "ongoing" if the AE is ongoing at the time of report
O Mild O Moderate O Severe O Life threatening or disabling O Fatal	O Unrelated O Unlikely O Possible O Probable O Definite	O Expected O Unexpected	O No O Yes	O No O Yes	☐ None [43] ☐ Medication therapy [44] ☐ Procedure [45] ☐ Hospitalization [46] ☐ Other [47]	O Recovered O Improved O Ongoing O Death O Unknown	Start date: ____ - ____ - ____ [10] Resolution date: ____ - ____ - ____ [11] ☐ Ongoing [12]

Comments: _____ [37], [38]

Additional AEs to report? [39]
- O No
- O Yes (Please complete an additional AE form)

Was the AE assessed, reviewed and signed by the investigator? [40]
- O No
- O Yes

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

_____ [50]
Investigator's initials

Investigator's signature _____ *(for external use only)*

PR

RTOG 1106 / ACRIN 6697
PROTOCOL DEVIATION FORM

ACRIN Study 6697

PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

Instructions:

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

- O Inclusion/Exclusion criteria not met at time of registration/randomization
- O Imaging-related deviation [2]
  - O FDG-PET/CT (complete Q1a)
  - O FMISO PET/CT (complete Q1b)
- O Study activity performed prior to participant signing study consent form
- O PET/CT not performed
- O Patient weight not measured on day of scan
- O Case enrolled under expired IRB approval/FWA
- O Other, specify: _____ [3]

1a. FDG-PET/CT Imaging Deviation [4]

- O PET/CT scan performed on a non-ACRIN qualified scanner
- O PET/CT images lost or unavailable
- O Incomplete anatomic coverage
- O Patient not scanned on treatment planning flat table
- O Raw data deleted and unable to reconstruct images
- O Dose information not recorded
- O Blood glucose measurement >200 mg/dL
- O FDG-PET/CT not performed within 50-70 minutes post-injection

1b. FMISO-PET/CT Imaging Deviation [5]

- O PET/CT scan performed on a non-ACRIN qualified scanner
- O PET/CT images lost or unavailable
- O Incomplete anatomic coverage
- O Patient not scanned on treatment planning flat table
- O Raw data deleted and unable to reconstruct images
- O Dose information not recorded
- O FMISO dose >7 mCi
- O FMISO-PET/CT not performed within 110-130 minutes post-injection
- O Pre-FMISO vital signs not recorded or incomplete
- O Post-FMISO vital signs not recorded or incomplete
- O FMISO PET/CT performed within 24 hours of FDG-PET/CT
- O FMISO production unavailable for more than or about 72 hours.

PR

RTOG 1106 / ACRIN 6697
PROTOCOL DEVIATION FORM

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

ACRIN Study 6697
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

2. Date the protocol deviation occurred: _____ - _____ - **20**____ (mm-dd-yyyy) [6]

3. Date the protocol deviation was discovered: _____ - _____ - **20**____ (mm-dd-yyyy) [7]

4. Describe the protocol deviation:

_____ [8]

_____ [9]

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

_____ [10]

_____ [11]

6. At what time point did this study deviation occur: [12]

- O Baseline
- O During treatment

_____ [13]
Person responsible for data (RA, study staff)

_____ - _____ - **20**____ (mm-dd-yyyy) [14]
Date Form Completed

_____
Investigator Signature