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
## Form Version

<table>
<thead>
<tr>
<th>Visit 1: Baseline FDG-PET/CT</th>
<th>Version Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>TA PET/CT Technical Assessment Form</td>
<td>v5.0 01-03-13</td>
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<tr>
<td>EX FDG &amp; FMISO-PET/CT Administration Treatment Exposure Form</td>
<td>v3.0 11-12-12</td>
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<tr>
<td>TD FDG-PET/CT Imaging-Related Drug History</td>
<td>v1.0 11-08-11</td>
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<tr>
<td>EX FDG &amp; FMISO-PET/CT Administration Treatment Exposure Form</td>
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<table>
<thead>
<tr>
<th>End of Study</th>
<th>Version Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>DS End of Study Form</td>
<td>v1.0 02-20-12</td>
</tr>
</tbody>
</table>

<table>
<thead>
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<th>Version Date</th>
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</tr>
<tr>
<td>PR Protocol Variation Form</td>
<td>v2.0 10-26-12</td>
</tr>
</tbody>
</table>
### Exam Data

1. **Clinical trial time point**
   - Baseline
   - During treatment

2. **Imaging Agent Name**
   - FDG
   - FMISO

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

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

4. **Date of imaging:** (mm-dd-yyyy)

5. **Weight**
   - kg

6. **Height**
   - cm

### Patient Preparation

1. **Duration of fasting pre-imaging:**
   - [ ] hours (up to time of injection)

2. **Blood glucose before injection of FDG**
   - mg/dl

3. **Was Foley catheter in place for study?**
   - Yes (skip to next section)

4. **Patient voided immediately pre-imaging?**
   - Yes
   - No
   - Unknown

5. **Patient voided immediately post-imaging?**
   - Yes
   - No
   - Unknown

---

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## Scanner

2. **Has the scanner used for this study been qualified by ACRIN?**
   - [ ] No
   - Yes, provide ACRIN Scanner ID#:

3. **Scanner used for this exam:**
   3a. Manufacturer

4. **Date of last PET Scanner SUV validation:**
   ___ - ___ - ______ (mm-dd-yyyy)

5. **Daily scanner QC run on date of study?**
   - [ ] No
   - Yes

6. **Was flat palette insert used?**
   - [ ] No
   - Yes

7. **Was the patient positioned in treatment planning position?**
   - [ ] No
   - Yes

8. **Scan extent?**
   - [ ] Skullbase to thighs
   - [ ] Apices through upper abdomen
   - [ ] Other, specify

## Transmission Scan

1. **Transmission scan type**
   - [ ] Low Dose CT

2. **kVp**
   - [ ] Unknown

3. **mAs**
   - [ ] Unknown

4. **Slice Thickness of reconstructed images**
   - [ ] Unknown

5. **Length of Transmission Scan:**
   - [ ] Unknown
   - Seconds

---

Imaging Agent: FDG / FMISO

If this is a revised or corrected form, please check the box.
**PET Emission Scan**

1. Acquisition mode: [ ] 2D  [ ] 3D

2. Number of bed positions scanned: [ ]

**PET Emission Scan:**

Start Time (military time)  Stop Time (military time)

3a. [ ] : [ ]

3b. [ ] : [ ]

**Reconstructed Images:**

4. Pixel Size: [ ] . [ ] mm

5. Thickness: [ ] . [ ] mm

**Adverse Events**

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

   - [ ] No (initial and date form)
   - [ ] Yes (Submit AE form)

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

   - [ ] No
   - [ ] Yes

______________________________  ________________________
Initials of person completing this form  Date form completed (mm-dd-yyyy)
### Imaging Agent: FDG / FMISO

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

<table>
<thead>
<tr>
<th>Exam Data</th>
</tr>
</thead>
</table>
| 1. **Planned time point:**
  - Baseline
  - During treatment
| 3. **Was imaging agent administered?**
  - No (Initial & date form)
  - Yes
| 4. **Administration date:**
  - _____-_______-_______ (mm-dd-yyyy)

<table>
<thead>
<tr>
<th>Imaging Agent Procurement</th>
</tr>
</thead>
</table>
| 5. **Identification number (Lot #):**

<table>
<thead>
<tr>
<th>Source of agent:</th>
</tr>
</thead>
</table>
| 6. **Prepared in-house (provide method by which agent is synthesized, complete Q6a)**
| 6a. **Method:**
| 6b. **Supplier:**

<table>
<thead>
<tr>
<th>Administration Information</th>
</tr>
</thead>
</table>
| 7. **Route of administration:**
  - IV
| 8. **Activity in full syringe before injection:**
  - mCi
| 8a. **Time of assay of full syringe before injection:**
  - (military time)
| 9. **Time of injection:**
  - (military time)
| 10. **Residual activity in syringe after injection:**
  - mCi
| 10a. **Time of assay of residual activity after injection:**
  - (military time)
| 11. **Net activity administered (Dosage Amount):**
  - mCi
| 11a. **Was the net activity administered decay corrected?**
  - No
  - Yes

<table>
<thead>
<tr>
<th>Site of injection:</th>
</tr>
</thead>
</table>
| 12. **Site of injection:**
  - Right antecubital
  - Right wrist
  - Right foot
  - Indwelling central catheter
  - Left antecubital
  - Left wrist
  - Left foot
  - Unknown
  - Other, specify

<table>
<thead>
<tr>
<th>Any infiltration at injection site noted?</th>
</tr>
</thead>
</table>
| 13. **Any infiltration at injection site noted?**
  - None
  - Minor (estimated to be less than 20% of dose)
  - Severe (estimated to be more than 20% of dose)

<table>
<thead>
<tr>
<th>Initials of person who completed form</th>
<th>Date form completed</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initials</strong></td>
<td><strong>Date (mm-dd-yyyy)</strong></td>
</tr>
</tbody>
</table>

"Copyright 2012"
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
   - Short-acting insulin [14] given, ______ ______ ______ ______ hours before FDG, given (check one) [16]
     - O Intravenously O Subcutaneously O Inhaled
   - 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 ______ ______ ______ ______ hours before FDG
     - 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]

Initials of Person(s) Completing this Form [43]
Date form completed (mm-dd-yyyy) [44]
Exam Data

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

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

   - No, imaging not completed (complete Q3a, then form as applicable)
   - Yes (proceed to Q4 and continue with form)

3a. "If imaging not completed, provide reason:" [5]
   - Scheduling problem
   - Equipment failure
   - Participant refusal
   - Medical reason
   - Injection site complications
   - Adverse event (complete AE form)
   - Participant death
   - FMISO not delivered
   - Unknown
   - Other, specify:

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

5. Weight

6. Height

Patient Preparation
(FDG-PET/CT only)

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

   (record value measured before injection)

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

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

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

"Copyright 2013"
### Implant Scan

1. **Transmission scan type**
   - Low Dose CT

2. **kVp**
   - [ ] Unknown
   - [ ] 90 [49]
   - [ ] 100 [48]
   - [ ] 120

3. **mAs**
   - [ ] Unknown
   - [ ] 100 [50]
   - [ ] 200 [51]

4. **Slice Thickness of reconstructed images**
   - [ ] Unknown
   - [ ] 1.5 mm [52]
   - [ ] 2.0 [53]

5. **Length of Transmission Scan**
   - [ ] Unknown
   - [ ] 230 Seconds [54]

### Scanner

2. **Has the scanner used for this study been qualified by ACRIN?**
   - [ ] No, specify reason (complete Q3):
   - [ ] Yes, provide ACRIN Scanner ID# (skip to Q4):

3. **Scanner used for this exam:**
   3a. **Manufacturer**
   - [ ]

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

5. **Daily scanner QC run on date of study?**
   - [ ] No
   - [ ] Yes

7. **Was the patient positioned in treatment planning position?**
   - [ ] No
   - [ ] Yes

8. **Scan extent?**
   - [ ] Skull base to thighs
   - [ ] Apices through upper abdomen
   - [ ] Other, specify

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Version 5.0 6697 TA 01-03-13 2 of 3
**Imaging Agent:** FDG / FMISO

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

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### PET Emission Scan

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acquisition mode</td>
<td>□ 2D □ 3D</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Number of bed positions scanned</td>
<td></td>
</tr>
</tbody>
</table>

#### PET Emission Scan:

- **Start Time** (military time)
- **Stop Time** (military time)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3a.</td>
<td></td>
</tr>
</tbody>
</table>

#### Reconstructed Images:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Pixel Size:</td>
<td>□.□□□□mm</td>
<td>5. Thickness:</td>
</tr>
</tbody>
</table>

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### Adverse Events

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Any adverse events related to imaging to report for this timepoint?</td>
<td>□ No (initial and date form) □ Yes (Submit AE form)</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Does this event meet the criteria of a serious adverse event?</td>
<td>□ No □ Yes</td>
</tr>
</tbody>
</table>

---

Initials of person completing this form

Date form completed (mm-dd-yyyy)
### Exam Data

1. Planned time point:
   - Baseline
   - During treatment

2. Was imaging agent administered?
   - No (Initial & date from)
   - Yes

3. Imaging agent name:
   - FDG
   - FMISO

4. Administration date:
   - _____ - _____ - ___________ (mm-dd-yyyy)

### Imaging Agent Procurement

5. Identification number (Lot #):

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

   6a. Method:

   6b. Supplier:

### Administration Information

7. Route of administration: IV

8. Activity in full syringe before injection:

   8a. Time of assay of full syringe before injection:

   9. Time of injection:

10. Residual activity in syringe after injection:

11. Net activity administered (Dosage Amount):

   11a. Was the net activity administered decay corrected?

   12. Site of injection:

   13. Any infiltration at injection site noted?

---

Initials of person who completed form Date form completed (mm-dd-yyyy)
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 \( \checkmark \) box.

1. **Timepoint (check one)** [1]
   - O 1 Baseline

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

<table>
<thead>
<tr>
<th>Time Point of Vital Sign Reading</th>
<th>Time Taken</th>
<th>Pulse</th>
<th>Blood Pressure</th>
<th>Respiration</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Military time</td>
<td></td>
<td>Systolic/Diastolic</td>
<td>Check one</td>
<td>°C</td>
</tr>
<tr>
<td>Prior to Injection</td>
<td>hh:mm</td>
<td>bpm</td>
<td>mmHg</td>
<td>O Labored/O Unlabored/O Unknown</td>
<td>°C</td>
</tr>
<tr>
<td>Completion of FMISO PET Imaging</td>
<td>hh:mm</td>
<td>bpm</td>
<td>mmHg</td>
<td>O Labored/O Unlabored/O Unknown</td>
<td>°C</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Time Taken</th>
<th>Pulse</th>
<th>Blood Pressure</th>
<th>Respiration</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Military time</td>
<td>hh:mm</td>
<td>bpm</td>
<td>mmHg</td>
<td>Check one</td>
</tr>
</tbody>
</table>

**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:

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

3. Date _____-_____-_______ (mm-dd-yyyy) [34]
   - O Unknown [35]

4. Time (Military Time) ____ : ____ hh:mm [36]
   - O Unknown [37]

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

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

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**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:

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

5. **Weight**
   - [kg][8]
   - [cm][10]
   - [Unknown][9]

6. **Height**
   - [cm][11]
   - [Unknown][11]

### Patient Preparation

(FDG-PET/CT only)

- o 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]

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

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

2a. **Time blood sample was obtained for glucose measurement** (military time) [17]

   - [Unknown][18]
### Scanner

2. **Has the scanner used for this study been qualified by ACRIN?**
   - No, specify reason (complete Q3):
   - Yes, provide ACRIN Scanner ID# (skip to Q4):

3. **Scanner used for this exam:**
   3a. Manufacturer
      - 
   3b. Manufacturer model name/or number
      -

4. **Date of last PET Scanner SUV validation:**
   - 

5. **Daily scanner QC run on date of study?**
   - No
   - Yes

6. **Was flat palette insert used?**
   - No
   - Yes

7. **Was the patient positioned in treatment planning position?**
   - No
   - Yes

8. **Scan extent?**
   - Skullbase to thighs
   - Apices through upper abdomen
   - Other, specify 

### Transmission Scan

1. **Transmission scan type**
   - Low Dose CT
2. **kVp**
   - Unknown
3. **mAs**
4. **Slice Thickness of reconstructed images**
   - Unknown
5. **Length of Transmission Scan**
   - Unknown
## PET Emission Scan

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Acquisition mode</td>
<td>o 2D</td>
<td>o 3D</td>
</tr>
<tr>
<td>2. Number of bed positions scanned</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### PET Emission Scan:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Time (military time)</td>
<td>Stop Time (military time)</td>
</tr>
<tr>
<td>3a.</td>
<td>3b.</td>
</tr>
</tbody>
</table>

### Reconstructed Images:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pixel Size:</td>
<td>Thickness:</td>
</tr>
</tbody>
</table>

## Adverse Events

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Any adverse events related to imaging to report for this timepoint?</td>
<td></td>
</tr>
<tr>
<td>o No (initial and date form)</td>
<td>o Yes (Submit AE form)</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Does this event meet the criteria of a serious adverse event?</td>
<td></td>
</tr>
<tr>
<td>o No</td>
<td>o Yes</td>
</tr>
</tbody>
</table>

---

Initials of person completing this form

Date form completed (mm-dd-yyyy)
## Exam Data

1. Planned time point:
   - Baseline
   - During treatment

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

3. Imaging agent name:
   - FDG
   - FMISO

4. Administration date:
   - (mm-dd-yyyy)

## Imaging Agent Procurement

5. Identification number (Lot #):

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

7a. Method:  

7b. Supplier:  

## Administration Information

8. Activity in full syringe before injection:
   - mCi

9. Time of assay of full syringe before injection:
   - (military time)

10. Time of injection:
    - (military time)

11. Residual activity in syringe after injection:
    - mCi

12. Site of injection:
    - Right antecubital
    - Left antecubital
    - Right wrist
    - Left wrist
    - Right foot
    - Left foot
    - Indwelling central catheter
    - Unknown
    - Other, specify

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

Initials of person who completed form

Date form completed (mm-dd-yyyy)
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Short-acting insulin [14] given, [15] hours before FDG, given (check one)</td>
<td></td>
</tr>
<tr>
<td>- Intermediate or long-acting insulin [16] given, [17] hours before FDG</td>
<td></td>
</tr>
<tr>
<td>- Insulin Pump [19] (check one)</td>
<td></td>
</tr>
<tr>
<td>- Other injectable agent(s), [22] specify, [23] given, [24] hours before FDG</td>
<td></td>
</tr>
<tr>
<td>3. Were any drugs administered as part of the PET imaging procedure?</td>
<td>[26] In addition to any listed in Q2a</td>
</tr>
<tr>
<td>O No, [27] Yes, check drug(s) used, [28] Unknown</td>
<td></td>
</tr>
<tr>
<td>- A benzodiazepine to decrease brown fat FDG uptake, [27] drug name</td>
<td></td>
</tr>
<tr>
<td>- A beta-blocker to decrease brown fat FDG uptake, [29] drug name</td>
<td></td>
</tr>
<tr>
<td>- A diuretic to decrease urinary tract activity, [31] drug name</td>
<td></td>
</tr>
<tr>
<td>- Sedation or anesthesia [33]</td>
<td></td>
</tr>
<tr>
<td>- Other drug(s), [34] drug name (s)</td>
<td></td>
</tr>
<tr>
<td>4. Is the participant currently being treated with corticosteroids?</td>
<td>[37] No, [38] Yes, [39] Unknown</td>
</tr>
<tr>
<td>Taking [38] hours before FDG</td>
<td></td>
</tr>
<tr>
<td>5. Has the participant received a bone marrow stimulating agent in the last 2 months?</td>
<td>[39] No, [40] Yes, provide; [41] Unknown, [42] Unknown</td>
</tr>
<tr>
<td>Agent Name:</td>
<td></td>
</tr>
<tr>
<td>Given approximately [41] days ago</td>
<td></td>
</tr>
</tbody>
</table>

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

Date form completed (mm-dd-yyyy) [44]
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)
     Cause of death [5]
     - O 1 Disease Progression
     - O 8 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]


3. Did the investigator review and sign off on the participant's disposition? [15]
   - O 1 No
   - O 2 Yes

Comments: [16]

--------------------------------------------------------------
Initials of person completing the form [17]
Date form completed (mm-dd-yyyy) [18]

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

Investigator's signature

"Copyright 2012"
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**

**AE Short Name** (online look-up)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Attribution</th>
<th>Expectedness</th>
<th>Serious AE?</th>
<th>Expedited Report Submitted</th>
<th>Action Taken</th>
<th>Outcome</th>
<th>Date of AE Onset and Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Unrelated</td>
<td>Expected</td>
<td>No</td>
<td>No</td>
<td>None</td>
<td>Recovered</td>
<td>Start date:</td>
</tr>
<tr>
<td>Moderate</td>
<td>Unlikely</td>
<td>Unexpected</td>
<td>Yes</td>
<td>No</td>
<td>Medication therapy</td>
<td>Improved</td>
<td>Resolution date:</td>
</tr>
<tr>
<td>Severe</td>
<td>Possible</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Procedure</td>
<td>Ongoing</td>
<td></td>
</tr>
<tr>
<td>Life threat-</td>
<td>Probable</td>
<td></td>
<td></td>
<td>No</td>
<td>Hospitalization</td>
<td>Death</td>
<td></td>
</tr>
<tr>
<td>or disabling</td>
<td>Definite</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Other</td>
<td>Unknown</td>
<td>[10]</td>
</tr>
</tbody>
</table>

**Comments:**

**Additional AEs to report?**

**Was the AE assessed, reviewed and signed by the investigator?**

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

**Investigator's signature**

"Copyright 2012"
1. Check the Protocol Event Being Reported: *(select only one)*

- O Inclusion/Exclusion criteria not met at time of registration/randomization
- O Imaging-related deviation
  - 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**

- 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**

- 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.
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