<table>
<thead>
<tr>
<th>Form Version</th>
<th>Version Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration/Eligibility Baseline Visit</td>
<td></td>
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</tbody>
</table>
| A0 Registration/ Eligibility Checklist | 07/27/2009  
| I0 Initial Evaluation Form | 01/5/2009  
| TX Prior Therapies Form | 01/07/2010  
| TD FDG PET- Imaging Related Drug History | 11/25/2009  
| TA PET/CT Technical Assessment Form | 09/2/2009  
| PT PET/CT Local Reader Form | 04/02/2009  
| TS Tissue Slides Transmittal Form | 04/22/2010  
| Visit 1: 64Cu-ATSM Scan (within 14 days of baseline visit) |  
| V1 Visit 1 Evaluation Form | 04/28/2009  
| MH Baseline Abnormalities Form | 11/25/2009  
| CO Concomitant Medications Form | 11/24/2009  
| BR 64Cu-ATSM Batch Record Form | 10/27/2010  
| SA 64Cu-ATSM Safety Assessments | 12/29/2010  
| TA PET/CT Technical Assessment Form | 09/02/2009  
| PT PET/CT Local Reader Form | 04/02/2009  
| Visit 2: Initiation of Chemoradiotherapy (within 4 weeks of visit 1) |  
| V2 Visit 2 Evaluation Form | 05/10/2010  
| Visit 3: Completion of Treatment (within 4 weeks of completion of treatment) |  
| V3 Visit 3 Evaluation Form | 12/22/2008  
| CR Chemotherapy and Radiation Treatment Form | 04/16/2009  
| Visit 4: Follow-up FDG PET/CT (3 months after completion of treatment) |  
| V4 Visit 4 Evaluation Form | 02/23/2009  
| TD FDG PET- Imaging Related Drug History | 11/25/2009  
| TA PET/CT Technical Assessment Form | 09/02/2009  
| PT PET/CT Local Reader Form | 04/02/2009  
| Follow-up (quarterly after Visit 4 for a total of 2 years, semi-annually for 3rd year) |  
| F1 Follow up Form | 07/16/2010  
| Immunohistochemical Analysis |  
| IM Immunohistochemical Analysis Form | 07/27/2009  
| End of Study |  
| DS End of Study Form | 01/23/2009  
| Additional Forms |  
| PR Protocol Variation Form | 03/03/2009  
| PF Disease Progression Form | 02/09/2009  
| AE Adverse Event Form | 01/21/2010  
| MH Supplemental Baseline Abnormalities Form | 01/07/2010  
| CO Supplemental Concomitant Medications Form | 01/11/2010  

Please enter all data through ACRIN website Data Center. All data should be entered within 2 weeks of the visit. Any questions related to these forms should be directed to Data Manager.
The eligibility checklist (A0) Part II and Part III must be completed prior to registration to determine and confirm participant eligibility. If any of the questions are answered in a way different than the prompts provided at the start of each question, the participant is ineligible and should not be enrolled. If the participant is being enrolled, they are to review, sign and date the consent. The data is submitted via the ACRIN website.

**DEMOGRAPHICS**

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

1. Name of institutional person registering this case

2. Has the Eligibility Checklist been completed?  
   1. No  
   2. Yes

3. Is the participant eligible for this study?  
   1. No  
   2. Yes

4. Date the study-specific consent form was signed (mm-dd-yyyy)  (Must be prior to study entry)

5. Participant's Initials (last, first) (L, F)

6. Verifying physician (Site PI)

8. Date of birth (mm-dd-yyyy)

9. Ethnicity  
   1. Hispanic or Latino  
   2. Not Hispanic or Latino  
   3. Unknown

11. Gender  
   1. Male  
   2. Female

12. Participant's country of residence (if other, complete Q12a)  
   1. United States  
   2. Canada  
   3. Other

12a. Other country, specify (completed if Q12 is coded “other”)  

14. Participant’s insurance status

- Other
- Private Insurance
- Medicare
- Medicare and Private Insurance
- Medicaid
- Medicaid and Medicare
- Military or Veteran’s Administration
- Self Pay
- No means of payment
- Unknown/Decline to answer

15. Will any component of the participant’s care be given at a military or VA facility?

- No
- Yes
- Unknown

16. Calendar base date [Date of registration] (mm-dd-yyyy)

17. Date of registration (mm-dd-yyyy)

Race (check all that apply)

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- Unknown
**Part II**

25. Does the participant have histologically proven invasive cervical cancer (Stages IB2-IVA)?
   1. No
   2. Yes (complete Q25a and Q25b)

25a. Please indicate date diagnosis was reported to patient and/or PCP (mm-dd-yyyy)

25b. Please indicate participants FIGO stage:

   1. II 7. II A
   2. III 8. II B
   3. IA1 9. III A
   4. IA2 10. III B
   5. IB1 11. IVA
   6. IB2 12. IVB

26. Does the participant have Karnofsky performance status of > 70?
   1. No
   2. Yes (complete Q26a)

26a. Please indicate Karnofsky Performance Status Rating

   1. 100 6. 50
   2. 90 7. 40
   3. 80 8. 30
   4. 70 9. 20
   5. 60 10. 10

27. Does the participant meet one of the following criteria as determined by the baseline FDG PET/CT?
   a. PET or CT shows only pelvic nodal (or no nodal disease), and participant will undergo standardized concurrent pelvic radiation therapy and cisplatin chemotherapy

   and/or

   b. PET or CT shows para-aortic nodal metastasis and participant will undergo standardized concurrent pelvic radiation therapy and cisplatin chemotherapy as well as radiotherapy to para-aortic nodes

   1. No
   2. Yes

28. Did the participant have a FDG PET/CT scan performed within 4 weeks of enrollment on an ACRIN qualified scanner?
   1. No
   2. Yes (complete Q28a)

28a. Provide date of scan (mm-dd-yyyy)
29. Was the participants FDG PET/CT scan performed as part of the baseline visit? [36]
   1. No (continue to Q30)
   2. Yes (complete Q29a)

29a. If yes, was a pregnancy test performed within 7 days prior to the scan? [37]
   1. No
   2. Yes (complete Q29b)
   3. Participant is not of childbearing potential as defined by protocol
   4. Participant is not sexually active

29b. Provide date of pregnancy test ___-____-___ (mm-dd-yyyy) [38]

30. Is the participant an adult female 18 years of age or older? [39]
   1. No
   2. Yes

31. Is the patient of child-bearing potential? [40]
   1. No (complete Q31a, then continue to Q32)
   2. Yes (skip Q31a and continue to Q31b)

31a. If subject is not of child bearing potential please provide justification [41]
   1. Post menopausal, amenorrhic for at least 12 consecutive months
   2. Hysterectomy
   3. Tubal ligation at least 12 months ago
   88. Other

31b. Does the participant agree to use medically appropriate contraception if sexually active? [42]
   1. No
   2. Yes
   3. Not sexually active

32. Is the participant able to tolerate PET Imaging that is required by the protocol (i.e. lie flat for the duration of PET/CT scan)? [43]
   1. No
   2. Yes

33. Is the participant able to give study specific IRB approved informed consent including authorization for release of personal health information? [44]
   1. No
   2. Yes
Part III

34. Does the participant have Stage IVB disease with confirmed distant metastasis and/or supraclavicular metastasis shown on baseline whole body FDG-PET/CT? [45]
   1 No
   2 Yes

35. Does the participant have recurrent invasive carcinoma of the uterine cervix (regardless of previous treatment)? [46]
   1 No
   2 Yes

36. Does the participant have known metastases to lungs, supraclavicular lymph nodes or metastases to other organs outside of the pelvis or abdominal lymph nodes, at the time of the original clinical diagnosis? [47]
   1 No
   2 Yes

37. Has the participant had a prior pelvic or abdominal lymphadenectomy performed for any reason? [48]
   1 No
   2 Yes

38. Has the participant received prior pelvic radiation therapy for any reason? [49]
   1 No
   2 Yes

39. Is the participant pregnant or breast feeding? [50]
   1 No
   2 Yes

40. Does the participant have septicemia or severe infection? [51]
   1 No
   2 Yes

41. Does the participant have uncontrolled or poorly controlled diabetes? [52]
   1 No
   2 Yes

42. Does the participant have any circumstances that will not permit completion of the imaging studies or required clinical follow up? [53]
   1 No
   2 Yes
43. Has the participant had (or have) any other invasive malignancies (with the exception of non-melanoma skin cancer)?

   1. No (initial and date form)
   2. Yes (complete Q43a and Q43b)

43a. Have they had any evidence of the other cancer within the last 5 years?

   1. No
   2. Yes

43b. Does their previous cancer treatment contraindicate this protocol therapy?

   1. No
   2. Yes
**Part I. Cervical Biopsy**

Please complete the following questions pertaining to the cervical biopsy in which the diagnosis of cervical squamous cell carcinoma was determined.

1. **Date cervical biopsy performed**
   - 
   - (mm-dd-yyyy) [2]
2. **Date histopathology reported**
   - 
   - (mm-dd-yyyy) [3]
3. **Have cervical biopsy slides been sent to Washington University Pathology lab for hypoxic markers analysis?** [4]
   - O 1 No (provide reason in Q3a)
   - O 2 Yes (continue to Q3c)
   - 
   - 
   -
4a. **Reason slides not sent**
   - (Please mark all that apply □ = 1 not marked; ✓ = 2 marked)
   - □ Slides not available [5]
   - □ Slides lost [6]
   - □ Administrative reasons [7]
   - □ Slides will be sent on future date (please provide tentative date in Q3b) [8]
   - O Other [9] specify ______________________ [10]
   - O Unknown [11]
5. **Tentative date slides will be sent**
   - 
   - (mm-dd-yyyy) [12]
6. **Date slides sent**
   - 
   - (mm-dd-yyyy) [13]

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**Part II. Blood Specimen Collection**

Please complete the following questions pertaining to the whole blood sample consent and, if applicable, collection.

1. **Did the participant consent to blood sampling for future correlative studies?** [14]
   - O 1 No (continue to Part III)
   - O 2 Yes
2. **Were blood samples collected?** [15]
   - O 1 No (provide reason in Q2a)
   - O 2 Yes (continue to Q2b)
   - 
   - 
   -
4a. **Reason blood samples not collected**
   - (Please mark all that apply □ = 1 not marked; ✓ = 2 marked)
   - □ Patient withdrew blood sample consent [16]
   - □ Medical reasons [17]
   - □ Administrative reasons [18]
   - □ Time constraints [19]
   - O Other, [20] specify ______________________ [21]
   - O Unknown [22]
5. **Date blood samples collected**
   - 
   - (mm-dd-yyyy) [23]
6. **Have the blood samples been sent to Washington University?** [24]
   - O 1 No (continue to Q3a)
   - O 2 Yes (continue to Q3c)
   - 
   - 
   -
4a. **Reason(s) samples not sent**
   - (Please mark all that apply □ = 1 not marked; ✓ = 2 marked)
   - □ Sample Lost [25]
   - □ Sample Damaged [26]
   - □ Administrative reasons [27]
   - □ Sample will be sent on future date (please provide tentative date in Q3b) [28]
   - O Other, [29] specify ______________________ [30]
   - O Unknown [31]
5. **Tentative date samples will be sent**
   - 
   - (mm-dd-yyyy) [32]
6. **Date samples sent**
   - 
   - (mm-dd-yyyy) [33]
Part III. Baseline Visit Study Procedures

Complete the following questions regarding the visit procedures. Protocol defined procedures at the baseline visit are: collection of medical history, collection of concomitant medication, and physical exam. Details should be recorded in source.

1. Please check routine clinical follow-up assessed
   (Please mark all that apply □ = 1 not marked; ✓ = 2 marked)
   - Physical exam [34]
   - Laboratory test [35]
   - Medical history [36]
   - Concomitant medication [37]
   - CT [38]
   - PET [39]
   - FDG PET/CT [40]
   - Other imaging, specify [41]
   - Other, specify [42]

1a. If protocol defined Baseline visit procedures (medical history collection, concomitant medication collection, and/or physical examination) were not assessed, provide reason

   (Please mark all that apply □ = 1 not marked; ✓ = 2 marked)
   - Participant Refusal [45]
   - Time constraints [46]
   - Not clinically indicated per treating physician [47]
   - Other, specify [48]

   Unknown [50]

Comments: __________________________________________________________

__________________________________________________________ [51]

__________________________________________________________ [52]

Initials of person(s) completing this form

__________________________________________________________ [53]

Date Form Completed (mm-dd-yyyy)
1. Did the participant ever receive any type of cancer treatment (chemotherapy, hormonal therapy, surgery, vaccine, etc)?

- No, initial and date form
- Yes, complete table

<table>
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<tr>
<th>Therapy Type</th>
<th>Any Therapy?</th>
<th># Prior Chemo Regimens</th>
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</thead>
<tbody>
<tr>
<td>Anti-Retroviral Therapy</td>
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<td></td>
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<tr>
<td>Antisense</td>
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<td>Bone Marrow transplant</td>
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<td>Chemotherapy (NOS)</td>
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<td>Chemotherapy multiple agents systemic</td>
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<tr>
<td>Chemotherapy non-cytotoxic</td>
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<td>Chemotherapy single agent systemic</td>
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<td>Drug and/or immunotherapy</td>
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<td>Gene Transfer</td>
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<td>Hormonal therapy</td>
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<td>Image directed local therapy</td>
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<td>Oncolytic Virotherapy</td>
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<td>Radiation Therapy</td>
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<td>Surgery</td>
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<tr>
<td>Therapy (NOS)</td>
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<tr>
<td>Vaccine</td>
<td>O No</td>
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</tbody>
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Initials of person(s) completing this form

Date form completed (mm-dd-yyyy)
1. Clinical trial time point: [1] O Registration / eligibility Visit (baseline) O Visit 4 (3 months post TX)

2. Is the participant a known diabetic? [2] O No O Yes, complete Q2a

2a. 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

- Other oral agent(s) [12] drug name ___________________________ [13] given _______ _______ [14] hours before FDG
- Intermediate or long-acting insulin [18] given _______ _______ [19] hours before FDG
- Insulin Pump [20] (check one) O On during FDG injection and uptake period O Off during FDG injection and uptake period, off _______ _______ [21] hours before FDG
- Unknown [25] Record 99 if hours unknown

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] Record 99 if hours unknown

4. Is the participant currently being treated with corticosteroids? [37] O No O Yes, complete Q5a O Unknown

5. Has the participant received a bone marrow stimulating agent in the last 2 months? [39] O No O Yes, complete Q5a O Unknown

5a. Agent Name: ___________________________ [40]

Given approximately _______ _______ days ago [41]
- Unknown [42]
### Part I. FDG scan (Baseline Visit and Visit 3 only)

1. **Was blood glucose testing done?**
   - O 1 No (complete Q1a and Q2, then skip to Part III)
   - O 2 Yes (continue to Q2)

1a. If no, provide reason *(check all that apply)*
   - Imaging not completed
   - Participant refusal
   - Unknown
   - Other, specify:

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

3. **Blood glucose before injection of FDG**
   - [ ] [ ] [ ] mg/dL
   - Unknown

4. **Time blood sample was obtained for glucose measurement**
   (military time): [ ] [ ] [ ] [ ]

5. **18F-FDG Source**
   - O Purchase, provide:
     - Name of licensed pharmacy:
   - O Synthesized, provide:
     - Method:

6. **18F-FDG Source**
   - O Pyrogen test result
     - Passed
     - Failed
     - Not done
   - O Radiochemical purity test result:

### Part II. 64Cu-ATSM scan (Visit 1 only)

1. **64Cu-ATSM underwent quality control and passed?**
   - O 1 No
   - O 2 Yes

   *If 64Cu-ATSM fails any part of the quality control (or if quality control is not completed), the radiopharmaceutical should NOT be injected into the participant. Complete rest of form as instructed in Part III. Q1.*

### Part III. All Scans

1. **Was PET/CT imaging completed?**
   - O No, radiotracer not given and imaging not done (Q1a and Q2 required, then initial and date form)
   - O No, radiotracer given, imaging not started (Q1a-Q10 required, complete Q11 if applicable)
   - O No, radiotracer given, imaging not completed (Q1a-Q17 required, complete Q18-27 as applicable)
   - O Yes, radiotracer given and imaging completed (Q2-Q27 required)

1a. *If PET/CT Imaging not completed, provide reason *(check all that apply):*
   - 64Cu-ATSM did not pass QC
   - Scheduling problem
   - Equipment failure
   - Participant refusal
   - Medical reason
   - Injection site complications
   - Claustrophobia
   - Blood glucose level
   - Participant withdrew consent
   - Progressive disease
   - Participant death
   - Other, specify:

2. **Date of PET/CT imaging (appointment):**
   - [ ] [ ] [ ] (mm-dd-yyyy)
3. **Subject weight** (measured on day of scan) [36]
   - kg
   - Unknown [36]

4. **Subject height** (measured on day of scan) [80]
   - cm
   - Unknown [81]

5. **Full activity in syringe before injection**
   - mCi [37]
   - 5a. Time of assay of full syringe before injection
     - (military time) : [38]
     - Unknown [39]

6. **Time of injection** (military time)
   - : [40]
   - Unknown [41]

7. **Residual activity in syringe after injection**
   - mCi [42]
   - 7a. Time of assay of residual activity after injection
     - (military time) : [43]
     - Unknown [44]

8. **Net Administered activity** . mCi [45]

9. **Location of injection site** [46]
   - 1 Right antecubital
   - 2 Right wrist
   - 3 Left antecubital
   - 4 Left wrist
   - 5 Right foot
   - 6 Left foot
   - 88 Other, specify: [47]
   - 99 Unknown

10. **Any radiotracer infiltration at injection site noted?** [48]
    - 1 None
    - 2 Minor (estimated to be less than 20% of dose)
    - 3 Severe (estimated to be more than 20% of dose)

11. **Was Foley catheter in place for study?** [49]
    - 1 No (complete Q12-Q13)
    - 2 Yes (skip to Q14)

12. **Patient voided immediately pre-imaging?** [50]
    - 1 No
    - 2 Yes
    - 99 Unknown

13. **Patient voided immediately post-imaging?** [51]
    - 1 No
    - 2 Yes
    - 99 Unknown

**Scanner**

14. **Has the scanner used for this study been qualified by ACRIN?** [52]
    - 1 No, specify reason: (complete Q15)
    - 2 Yes, provide ACRIN Scanner ID# (skip to Q16)

15. **PET/CT Scanner used for this exam:**
    - Manufacturer [55]
    - Manufacturer model name/or number [56]

16. **Date of last PET/CT Scanner SUV calibration/validation:**
    - mm-dd-yyyy [57]

17. **Daily scanner QC run on date of study?** [58]
    - 1 No
    - 2 Yes
**Image Acquisition**

**Transmission Scan**

18. CT transmission scan:

18a. Was Oral contrast used? [59]
- 1 No (skip to Q18c)
- 2 Yes, specify type [60]
  - 1 Positive contrast
  - 2 Negative contrast

18b. Amount of Oral contrast ingested [61]

[_____] ml
- Unknown [62]

18c. Was IV contrast used? [63]
- 1 No (skip to Q19)
- 2 Yes

18d. Amount of IV contrast injected [64]

[_____] ml
- Unknown [65]

18e. Time IV contrast injection [66]

[_____] : [_____] (military time)
- Unknown [67]

**PET Emission Scan**

22. Emission acquisition mode [71]
- 1 2D
- 2 3D

23. Number of bed positions scanned [72]

24. Emission scan start time: (military time) [_____] : [_____] [73]

25. Emission scan stop time: (military time) [_____] : [_____] [74]

26. Pixel Size of Reconstructed images [_____] . [_____] mm [75]

27. Thickness of Reconstructed images [_____] . [_____] mm [76]

Comments: _______________________________________________________

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ACRIN 6682
64CU-ATSM in Cervical Cancer
PET/CT Local Reader Form

This PET/CT Reader corresponds to: [1]
1. Baseline FDG-PET/CT (complete Part I and Part II)
2. Visit 1 Cu-ATSM PET/CT (complete Part I and Part III)
3. Visit 4 FDG-PET/CT (complete Part I and Part II)

Part I. All Scans

1. Image quality [2]
   1. Uninterpretable (complete Q1a, then initial and date form)
   2. Adequate (continue to Q2)

   1a. Reason (check all that apply):
       □ Missing images [3]
       □ Noisy images [4]
       □ Patient motion [5]
       □ Artifact [6]
       □ Non-diagnostic [7]
       □ Other, [9] specify ____________________________ [10]

2. Date of Imaging _______ - _______ - _______ (mm-dd-yyyy) [11]

3. Date of PET/CT Interpretation _______ - _______ - _______ (mm-dd-yyyy) [12]

4. Reader ID _______ _______ _______ _______ _______ _______ _______ [13]

Instructions: This PT form is to be completed by the study Radiologist/Nuclear Medicine Physician for all scans. All dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN at www.acrin.org.
### Part II. FDG-PET/CT

<table>
<thead>
<tr>
<th>Site</th>
<th>Uptake Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Tumor</td>
<td>[14]</td>
</tr>
<tr>
<td>Pelvic Lymph Nodes</td>
<td>[15]</td>
</tr>
<tr>
<td>Common Iliac Lymph Nodes</td>
<td>[16]</td>
</tr>
<tr>
<td>Para-aortic Lymph Nodes</td>
<td>[17]</td>
</tr>
<tr>
<td>Mediastinal Lymph Nodes</td>
<td>[18]</td>
</tr>
<tr>
<td>Supraclavicular Lymph Nodes</td>
<td>[19]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[20]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[21]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[22]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[23]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[24]</td>
</tr>
</tbody>
</table>

### Part III. 64Cu-ATSM PET/CT

1. Was the primary tumor included in the field of view?
   - O 1 No (please complete Q1a)
   - O 2 Yes (initial and date form)

1a. Please provide reason (check all that apply):
   - ☐ Image not adequate (as described in part I Q1a)
   - ☐ Other [28] specify ____________________________

<table>
<thead>
<tr>
<th>Site</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Tumor</td>
<td></td>
</tr>
<tr>
<td>Pelvic Lymph Nodes</td>
<td></td>
</tr>
<tr>
<td>Common Iliac Lymph Nodes</td>
<td></td>
</tr>
<tr>
<td>Para-aortic Lymph Nodes</td>
<td></td>
</tr>
<tr>
<td>Mediastinal Lymph Nodes</td>
<td></td>
</tr>
<tr>
<td>Supraclavicular Lymph Nodes</td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
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<tr>
<td>Other, specify</td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
</tr>
</tbody>
</table>

Comments: __________________________________________________________
__________________________________________________________

Radiologist/Nuclear Medicine physician Responsible for this Data ___________________________ Date form completed ____________

Initials of Person(s) completing this form ___________________________
Part A. Completed and Web Entered by Site

1. Did the site request the tissue slides? [7]
   O No, complete Q1a
   O Yes, skip to Q2

1a. If no, provide reason then initial and date form [8]
   O Central pathology lab requesting slides directly
   O Other, specify ____________________________ [9]

2. Number of tissue sample slides sent: _____ _____ [1]

Before sending the slides, please check to confirm:

☐ ALL study participants’ personal identifying information (participant name, medical record number, SS#, etc.) on all of the material is marked out [2]

☐ Each slide is labeled with the study number, patient case number, and numbered per the pathology specimen process [3]

The pathology specimens and a copy of this form should be shipped to the central pathology laboratory at:

Denfeng Cao, MD PhD.
Director, Research Immunohistochemical Laboratory
Division of Anatomic and Molecular Pathology
Washington University in Saint Louis
660 South Euclid Ave
Campus Box 8118
Saint Louis, MO 63110

Re: ACRIN 6682 Pathology

3. Date slides sent to path lab: _____·____·_____ mm-dd-yyyy [4]

________________________________________________________________ [5]
Initials of person(s) from site completing this form

________________________________________________________________ [6]
Date form completed (mm-dd-yyyy)

Signature of person from site ________________________________ (for external use only)
INSTRUCTIONS: The V1 form is to be completed after the participant completes the Cu-ATSM scan by the study Research Associate. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org

1. Was Visit 1 - 64 Cu-ATSM PET/CT performed? [1]
   O 1 No (indicate reason in Q1a, then initial and date form. Complete DS form)
   O 2 Yes (continue to Q2)

1a. Reason visit 1 not done
   (Please mark all that apply [2] = 1 not marked; [3] = 2 marked)
   [ ] Scheduling problem
   [ ] Participant refusal
   [ ] Participant withdrew consent
   [ ] Participant death
   [ ] Unknown

2. Date of Visit 1: ______ - _______ - ______ (mm-dd-yyyy) [9]

Part I. 64Cu-ATSM PET/CT

1. Was a pregnancy test performed within 7 days of 64Cu-ATSM PET/CT? [10]
   O 1 No (skip to Q2, complete PR form)
   O 2 Yes (complete Q1a)
   O 3 Participant is not of childbearing potential as defined by protocol (skip to Q2)

1a. Please provide date of pregnancy test
   ______ - _______ - ______ (mm-dd-yyyy) [11]

2. Were any AE(s) associated with investigational radiotracer reported? [12]
   O 1 No
   O 2 Yes, please report AE(s) per protocol

Part II. Visit 1 Study Procedures

Complete the following questions regarding the visit procedures. Protocol defined procedures at visit 1 are: collection of concomitant medication. Details should be recorded in source.

1. Please check routine clinical follow-up assessed
   (Please mark all that apply [2] = 1 not marked; [3] = 2 marked)
   [ ] Physical exam [13]
   [ ] Laboratory test [14]
   [ ] Medical history [15]
   [ ] Concomitant medication [16]
   [ ] Other, [17] specify ____________________________ [18]

1a. If protocol defined Visit 1 procedures (concomitant medication collection) were not assessed, provide reason
   (Please mark all that apply [2] = 1 not marked; [3] = 2 marked)
   [ ] Participant Refusal [19]
   [ ] Time constraints [20]
   [ ] Not clinically indicated per treating physician [21]
   [ ] Other, [22] specify ____________________________ [23]
   [ ] Unknown [24]

Comments: _____________________________________________________

__________________________________________________________________________ [25]

__________________________________________________________________________ [25]

Initials of person(s) completing the form ____________________________ [26]

Date form completed (mm-dd-yyyy) ____________________________ [27]
### VISIT 1: BASELINE ABNORMALITIES

**NOTE**: Do not record any prior cancer treatment/therapies on this form. Record all on the Prior Therapies (TX) form.

Check "none" if there are no abnormalities to report.

- None

<table>
<thead>
<tr>
<th>Sequence #</th>
<th>Condition / Event</th>
<th>Online CTCAE/MedDRA Term</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<td>3</td>
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<tr>
<td>12</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

***Important: If there are additional records to report, list on Supplemental MH form.***
### Concomitant Medications

<table>
<thead>
<tr>
<th># of medication being reported</th>
<th>Medication (Generic Name only)</th>
<th>Start date (mm/dd/yyyy)</th>
<th>End date (mm/dd/yyyy)</th>
<th>Indication (reasons for use)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
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<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**None**  
Check "none" if there are no Concomitant Medications to report.

***List additional Concomitant Medications on Supplemental CO form.***
Part 1. Materials and Equipment

Table A. Materials and Equipment

<table>
<thead>
<tr>
<th>Item</th>
<th>Manufacturer</th>
<th>Lot Number</th>
<th>Expiration Date</th>
<th>Verified / Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>$^{64}$CuCl$_2$</td>
<td>MIR, Cyclotron Facility</td>
<td>[1]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ATSM lyophilized vial</td>
<td>PTI</td>
<td>[58]</td>
<td>[59]</td>
<td></td>
</tr>
<tr>
<td>Reconstitution solution</td>
<td>PTI</td>
<td>[61]</td>
<td>[62]</td>
<td></td>
</tr>
<tr>
<td>0.22 µm Sterile Filter Units</td>
<td></td>
<td>[10]</td>
<td>[11]</td>
<td>[64]</td>
</tr>
</tbody>
</table>

Part 2. Drug Preparation

2. Method of $^{64}$Cu-ATSM Preparation

☐ Version 2 PTI Kit Formulation Preferred Method Complete Table B, then skip to Part 3
☐ Version 1 PTI Kit Formulation Skip to Table C

Table B. Version 2 Method Per Appendix 1 of the Investigator’s Brochure

Drug Preparation

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Verified / Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Record the volume and reference the time ATSM added to $^{64}$CuCl$_2$</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Activity added ________ mCi [66]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Volume added ________ mL [67]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time __ : __ [68]</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Sterile filtration performed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time Completed __ : __ [70]</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Radioactivity assay in Product Vial: ________ mCi [72]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time of measurement __ : __ [73]</td>
<td></td>
</tr>
</tbody>
</table>

Table C. Version 1 Method Per Appendix 2 of the Investigator’s Brochure

Drug Preparation

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Verified / Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Record the volume and reference the time $^{64}$CuCl$_2$ added to ATSM kit.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Activity added ________ mCi [46]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Volume added ________ mL [47]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time __ : __ [15]</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Sterile filtration performed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time Completed __ : __ [17]</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Radioactivity assay in Product Vial: ________ mCi [56]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Time of measurement __ : __ [36]</td>
<td></td>
</tr>
</tbody>
</table>

Continue to next page
Part 3. Radiochemical Purity

3. Method of $^{64}$Cu-ATSM Radiochemical Purity Measurement

- Paper Chromatography Method **Preferred Method** Complete Table D, then skip to Part 4
- Oasis Cartridge Method Skip to Table E

Table D. Paper Chromatography Method  
Per Appendix 3 of the Investigator’s Brochure

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Verified / Initials</th>
</tr>
</thead>
</table>
| 1    | Time of spotting: ______ [76]  
Start time of chromatographic development: ____ : ____ [77]  
Finish time of chromatographic development: ____ : ____ [78]  
Solvent front distance: __________ cm [79] | | [80]  
| 2    | Time of radioactivity analysis: __________ [81]  
Check method of analysis:  
- Radiochromatographic scanner [82]  
- Sectional assay | | [83]  

Table E. Oasis Cartridge Method  
Per Appendix 4 of the Investigator’s Brochure

<table>
<thead>
<tr>
<th>Item</th>
<th>Manufacturer</th>
<th>Lot Number</th>
<th>Verified / Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oasis Cartridge</td>
<td>Waters Corporation</td>
<td>[8]</td>
<td>[9]</td>
</tr>
</tbody>
</table>

Radiochemical Purity Measurement

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Verified / Initials</th>
</tr>
</thead>
</table>
| 1    | Background dose calibrator reading: Activity ______ $\mu$Ci [48]  
Time ____ : ____ [20] | | [21]  
| 2    | Dose calibrator measurements of fractions  
a. Activity C1 ______ $\mu$Ci [49]  
b. Activity C2 ______ $\mu$Ci [50]  
c. Activity C3 ______ $\mu$Ci [51]  
Net Activity ______ : ____ [52]  
Net Activity ______ : ____ [53]  
Net Activity ______ : ____ [54]  
Net Activity ______ : ____ [55] | | [31]  
| 3    | Percentage purity of $^{64}$Cu-ATSM = C3/ (C1+C2+C3) x 100% Radiochemical purity____ : ____ % | | [33]  

Also record results in Question 8.

Part 4. Release Specifications for $^{64}$Cu-ATSM

Table F. Oasis Cartridge Method

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
<th>Procedure</th>
<th>Testing result</th>
<th>Verified / Initials</th>
</tr>
</thead>
</table>
| Radiochemical Purity  | $\geq$ 95%          | Chromogenic method or Gel clot method [38] | Pass or Fail [39] | [85]  
| Bacterial Endotoxin   | $\leq$ 175 EU/V (where V is the maximum total dose) | | | [84]  

$^{64}$Cu-ATSM prepared by: ________________________________ Date prepared: __-__-____ [41]  
QC performed by: ________________________________ Date performed: __-__-____ [43]  
Data reviewed by: ________________________________ Date reviewed: __-__-____ [86]  

"Copyright 2010"
Part I.

Provide the vital sign readings taken part of the 64Cu-ATSM scan. All elements in this table are required.

<table>
<thead>
<tr>
<th>Time Point of Reading</th>
<th>Prior to Injection</th>
<th>15 Minutes Post Injection</th>
<th>75 Minutes Post Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before patient goes into scanner</td>
<td>After completion of scan, before the patient leaves the PET facility</td>
<td></td>
</tr>
</tbody>
</table>

Part II.

1. Were there any significant changes in vital signs accompanied by signs or symptoms suggesting an adverse reaction? [19]
   - O 1 No (Initial and date form)
   - O 2 Yes (Provide vital signs in Q1a. Complete an AE form)

   1a. If yes, provide the last reading of vital signs in the table below (taken before the patient leaves the PET facility)

<table>
<thead>
<tr>
<th>Time Taken Military Time</th>
<th>Pulse</th>
<th>Blood Pressure Systolic / Diastolic</th>
<th>Respiration Check one</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>O Unlabored</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Part III. Follow up AE Assessment within 24 hours of Cu-ATSM injection

1. Were any AE’s reported? [29]
   - O 1 No
   - O 2 Yes (Report on a AE Form)

   Provide date and time of follow-up telephone call for AE assessment (if the participant is unable to be reached detail attempts in comments field)

   2. Date _____-_______-_______ (mm-dd-yyyy) [30] Unknown [31]

   3. Time (Military Time) __ __ : __ __ hh:mm [32] Unknown [33]

   Comments: ____________________________________________________________ [26]
   ____________________________________________________________ [28]

   Date form completed

   Initials of person(s) completing this form
ACRIN 6682

64 Cu-ATSM PET/CT in Cervical Cancer

PET/CT Technical Assessment Form

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

1. Study time point
   O 1 Baseline FDG-PET/CT (complete Part I and Part III)
   O 2 Visit 1 - 64Cu-ATSM (complete Part II and Part III)
   O 3 Visit 4 - post-treatment FDG-PET/CT (complete Part I and Part III)

Part I. FDG scan (Baseline Visit and Visit 3 only)

1. Was blood glucose testing done?
   O 1 No (complete Q1a and Q2, then skip to Part III)
   O 2 Yes (continue to Q2)

1a. If no, provide reason (check all that apply)
   □ Imaging not completed
   □ Participant refusal
   □ Unknown
   □ Other, specify:

2. Duration of participant fasting pre-PET/CT imaging:
   [ ] Hours
   (up to time of FDG injection; if unknown record 99)

3. Blood glucose before injection of FDG
   [ ] mg/dL
   □ Unknown

4. Time blood sample was obtained for glucose measurement
   (military time): [ ]

5. 18F-FDG Source
   O Purchase, provide:
   Name of licensed pharmacy:

   O Synthesized, provide:
   Method:

   Pyrogen test result
   O Passed
   O Failed
   O Not done

   Radiochemical purity test result:

Part II. 64Cu-ATSM scan (Visit 1 only)

1. 64Cu-ATSM underwent quality control and passed?
   O 1 No
   O 2 Yes

If 64Cu-ATSM fails any part of the quality control (or if quality control is not completed), the radiopharmaceutical should NOT be injected into the participant. Complete rest of form as instructed in Part III. Q1.

Part III. All Scans

1. Was PET/CT imaging completed?
   O No, radiotracer not given and imaging not done
   O No, radiotracer given, imaging not started
   O No, radiotracer given, imaging not completed
   O Yes, radiotracer given and imaging completed

1a. *If PET/CT Imaging not completed, provide reason (check all that apply):
   □ 64Cu-ATSM did not pass QC
   □ Scheduling problem
   □ Equipment failure
   □ Participant refusal
   □ Medical reason
   □ Injection site complications
   □ Claustrophobia
   □ Blood glucose level
   □ Participant withdrew consent
   □ Progressive disease
   □ Participant death
   □ Other, specify:

2. Date of PET/CT imaging (appointment):
   [ ] - [ ] - [ ] (mm-dd-yyyy)

"Copyright 2009"
3. **Subject weight** (measured on day of scan) [36]
   - [ ] _______ . _______ kg
   - [ ] Unknown [36]

4. **Subject height** (measured on day of scan) [80]
   - [ ] _______ cm
   - [ ] Unknown [81]

5. **Full activity in syringe before injection** [37]
   - [ ] _______ . _______ mCi

   5a. **Time of assay of full syringe before injection** (military time) [38]
   - [ ] _______ : _______ [38]
   - [ ] Unknown [39]

6. **Time of injection** (military time) [40]
   - [ ] _______ : _______ [40]
   - [ ] Unknown [41]

7. **Residual activity in syringe after injection** [42]
   - [ ] _______ . _______ mCi

   7a. **Time of assay of residual activity after injection** (military time) [43]
   - [ ] _______ : _______ [43]
   - [ ] Unknown [44]

8. **Net Administered activity** [45]
   - [ ] _______ . _______ mCi

9. **Location of injection site** [46]
   - [ ] 1 Right antecubital
   - [ ] 2 Right wrist
   - [ ] 3 Left antecubital
   - [ ] 4 Left wrist
   - [ ] 5 Right foot
   - [ ] 6 Left foot
   - [ ] 88 Other, specify: ____________________________ [47]
   - [ ] 99 Unknown

10. **Any radiotracer infiltration at injection site noted?** [48]
    - [ ] 1 None
    - [ ] 2 Minor (estimated to be less than 20% of dose)
    - [ ] 3 Severe (estimated to be more than 20% of dose)

11. **Was Foley catheter in place for study?** [49]
    - [ ] 1 No (complete Q12-Q13)
    - [ ] 2 Yes (skip to Q14)

12. **Patient voided immediately pre-imaging?** [50]
    - [ ] 1 No
    - [ ] 2 Yes
    - [ ] 99 Unknown

13. **Patient voided immediately post-imaging?** [51]
    - [ ] 1 No
    - [ ] 2 Yes
    - [ ] 99 Unknown

**Scanner**

14. **Has the scanner used for this study been qualified by ACRIN?** [52]
    - [ ] 1 No, specify reason: ____________________________ [53]
    - [ ] 2 Yes, provide ACRIN Scanner ID# (skip to Q16)

15. **PET/CT Scanner used for this exam:**
    - Manufacturer ____________________________ [55]
    - Manufacturer model name/or number ____________________________ [56]

16. **Date of last PET/CT Scanner SUV calibration/validation:**
    - [ ] _____ - _____ - _________(mm-dd-yyyy) [57]

17. **Daily scanner QC run on date of study?** [58]
    - [ ] 1 No
    - [ ] 2 Yes
Image Acquisition

Transmission Scan

18. CT transmission scan:

18a. Was Oral contrast used? [59]
   O 1 No (skip to Q18c)
   O 2 Yes, specify type [60]
      O 1 Positive contrast
      O 2 Negative contrast

18b. Amount of Oral contrast ingested [61]
   ml
   Unknown [62]

18c. Was IV contrast used? [63]
   O 1 No (skip to Q19)
   O 2 Yes

18d. Amount of IV contrast injected [64]
   ml
   Unknown [65]

18e. Time IV contrast injection [66]
   (military time)
   Unknown [67]

PET Emission Scan

22. Emission acquisition mode [71]
   O 1 2D
   O 2 3D

23. Number of bed positions scanned [72]

PET Emission Scan

24. Emission scan start time: (military time)

25. Emission scan stop time: (military time)

26. Pixel Size of Reconstructed images
   mm

27. Thickness of Reconstructed images
   mm

Comments: __________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Initials of person(s) completing this form

Date form completed (mm-dd-yyyy)
This PET/CT Reader corresponds to:

- 1 Baseline FDG-PET/CT (complete Part I and Part II)
- 2 Visit 1 Cu-ATSM PET/CT (complete Part I and Part III)
- 3 Visit 4 FDG-PET/CT (complete Part I and Part II)

### Part I. All Scans

1. **Image quality**
   - 1 Uninterpretable (complete Q1a, then initial and date form)
   - 2 Adequate (continue to Q2)

1a. Reason *(check all that apply)*:
   - Missing images
   - Noisy images
   - Patient motion
   - Artifact
   - Non-diagnostic
   - Other, specify ____________________________

2. **Date of Imaging** _______ - _______ - _______ *(mm-dd-yyyy)*

3. **Date of PET/CT Interpretation** _______ - _______ - _______ *(mm-dd-yyyy)*

4. **Reader ID** ____________

Instructions: This PT form is to be completed by the study Radiologist/Nuclear Medicine Physician for all scans. All dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN at www.acrin.org.
### Part II. FDG-PET/CT

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- **Site**: Primary Tumor, Pelvic Lymph Nodes, Common Iliac Lymph Nodes, Para-aortic Lymph Nodes, Mediastinal Lymph Nodes, Supraclavicular Lymph Nodes, Other, specify

#### Part III. $^{64}$Cu-ATSM PET/CT

1. **Was the primary tumor included in the field of view?**
   - O 1 No (please complete Q1a)
   - O 2 Yes (initial and date form)

1a. **Please provide reason (check all that apply):**
   - [ ] Image not adequate (as described in part I Q1a)
   - [ ] Other, specify

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

- **Other, specify**: Other, specify

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#### Comments:

________________________________________________________________________

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**Radiologist/Nuclear Medicine physician Responsible for this Data**

__________________________

**Date form completed**

_____________
**ACRIN 6682**

**64Cu-ATSM PET/CT in Cervical Cancer**

**Visit 2 Evaluation**

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

### INSTRUCTIONS:

The V2 form is to be completed by the study Research Associate regarding initiation of chemoradiotherapy. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org.

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

### VISIT 2

1. **Was Visit 2 performed?**
   - [ ] O 1 No (indicate reason in Q1a)
   - [ ] O 2 Yes (continue to Q2)

   **1a. Reason visit 2 not done**
   (Please mark all that apply [ ] = 1 not marked √ = 2 marked)
   - [ ] Non-Scheduling problems
   - [ ] Participant refusal
   - [ ] Participant withdrew consent
   - [ ] Participant death (please complete DS form)
   - [ ] Other, specify
   - [ ] Unknown

2. **Date of Visit 2:**
   - [ ] mm-dd-yyyy

---

### Part I. Chemoradiotherapy

1. **Was treatment initiated per protocol (within 4 weeks of 64Cu-ATSM PET/CT)?**
   - [ ] O 1 No (continue to Q1a)
   - [ ] O 2 Yes (continue to Q1b)

   **1a. Please provide reason**
   (Please mark all that apply [ ] = 1 not marked √ = 2 marked)
   - [ ] Adverse event/side effects/complications
   - [ ] Scheduling problems
   - [ ] Participant refusal
   - [ ] Progressive disease
   - [ ] Participant withdrew consent (complete DS form)
   - [ ] Participant death
   - [ ] Not done per treating physician discretion
   - [ ] Treatment delayed per treating physician
   - [ ] Treatment delayed per patient
   - [ ] Other medical reason, specify
   - [ ] Alternative therapy, specify
   - [ ] Other, specify
   - [ ] Unknown

2. **Please provide initiation date of treatment:**
   - [ ] mm-dd-yyyy
   - [ ] Treatment not initiated as of this visit

3. **Please check the type of treatment this initiation date corresponds to (check all that apply)**
   - [ ] Chemotherapy
   - [ ] Radiation
   - [ ] Other, specify

---

### Part II. Adverse Events

Please provide AE information in relation only to the Cu-ATSM scan.

1. **Were any AEs associated with investigational radiotracer reported (within 24 hours of scan)?**
   - [ ] O 1 No
   - [ ] O 2 Yes, please report AE(s) per protocol.

   **Comments:**

   ____________________________

---

**Initials of person(s) completing the form**

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

"Copyright 2010"
INSTRUCTIONS: The V3 form is to be completed 4 weeks after completion of chemoradiotherapy. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at www.acrin.org.

1. Was Visit 3 conducted? 
   O 1 No (indicate reason in Q1a)  
   O 2 Yes (continue to Q2)

1a. Reason visit 3 not done
(Please mark all that apply = 1 not marked; ✓ = 2 marked)
- Scheduling problem [2]
- Participant refusal [3]
- Participant withdrew consent [4]
- Participant death (please complete DS form) [5]
- Unknown [8]

2. Date of Visit 3: _____ - _____ - ______ (mm-dd-yyyy) [9]
   Should occur 4 weeks after completion of chemoradiotherapy

Part I. Visit 3 Study Procedures

Complete the following questions regarding the routine clinical follow-up conducted as part of this visit. Protocol defined clinical follow-up at this visit are: physical examination and clinical lab tests. Details of this clinical follow-up should be recorded in source.

1. Please check routine clinical follow-up assessed
(Please mark all that apply = 1 not marked; ✓ = 2 marked)
- Physical exam [10]
- Laboratory test [11]
- Medical history [12]
- Concomitant medication [13]
- Other, [14] specify [15]

1a. If protocol defined Visit 3 procedures (physical examination and/or laboratory tests) were not assessed, provide reason
(Please mark all that apply = 1 not marked; ✓ = 2 marked)
- Participant Refusal [16]
- Time constraints [17]
- Not clinically indicated per treating physician [18]
- Other, [19] specify [20]
- Unknown [21]

Comments: ____________________________________________________________ [22]

______________________________________________________________________ [22]

______________________________________________________________________ [23]

Initials of person(s) completing the form

____________________________________________________ [24]

Date form completed (mm-dd-yyyy)

"Copyright 2008"
### CHEMORADIOThERAPY FORM

**ACRIN Study 6682**

**PLACE LABEL HERE**

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<th>Participant Initials</th>
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**Instructions:** At the completion of chemotherapy and radiation, complete this form for all participants. All dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via the web at www.acrin.org

---

1. **Did the participant receive the protocol defined chemoradiotherapy?**
   - *i.e. definitive irradiation (both external beam radiation and intracavitary brachytherapy) and concurrent cisplatinum chemotherapy (6 weekly cycles).*
   - O 1 No (complete Q2 and Q3)
   - O 2 Yes (skip to Part I)

2. **Was Radiation Given?**
   - O 1 No (provide reason in Q2a, then continue to Q3)
   - O 2 Yes (continue to Q3, then provide details of radiation in Part I)

2a. **Primary Reason Radiation Not Given** (complete PR and DS form)
   - O 1 Adverse event/complications
   - O 2 Scheduling problems
   - O 3 Participant refusal
   - O 4 Participant withdrew consent
   - O 5 Not done per treating physicians discretion
   - O 88 Other, specify ____________________________
   - O 99 Unknown

3. **Was Concurrent Chemotherapy Given?**
   - O 1 No (please provide reason in Q3a)
   - O 2 Yes (provide details in Part II)

3a. **Primary Reason Concurrent Chemotherapy Not Given** (complete PR and DS form)
   - O 1 Adverse event/complications
   - O 2 Scheduling problems
   - O 3 Participant refusal
   - O 4 Participant withdrew consent
   - O 5 Not done per treating physicians discretion
   - O 88 Other, specify ____________________________
   - O 99 Unknown

---

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## CHEMORADIOThERAPY FORM

### Part I. Radiation

#### Part Ia. Brachytherapy

1. **Indicate type of brachytherapy** [8]
   - 1. LDR
   - 2. HDR
   - 3. Participant did not receive any brachytherapy (skip to part Ib)
   - 88. Other, specify ____________________________ [9]

2. **Start date** _______ - _______ - _______ (mm-dd-yyyy) [10]
   - Unknown [11]

3. **End date** _______ - _______ - _______ (mm-dd-yyyy) [12]
   - Unknown [13]

4. **Total dose to point A** _______ : _______ Gy [14]

5. **Status** [15]
   - 1. Completed as Planned
   - 2. Treatment not completed
   - 88. Other, specify ____________________________ [16]

#### Part Ib. External Radiation

1. **Indicate type of external radiation** [17]
   - 1. 3D Conformal
   - 2. IMRT
   - 3. 2D External Beam
   - 4. Participant did not receive any external radiation (if applicable skip to Part II, otherwise skip to Part III)
   - 88. Other, specify ____________________________ [18]

2. **Start date** _______ - _______ - _______ (mm-dd-yyyy) [19]
   - Unknown [20]

3. **End date** _______ - _______ - _______ (mm-dd-yyyy) [21]
   - Unknown [22]

4. **Total dose to Pelvis/Pelvic Nodes** _______ : _______ Gy [23]

5. **Total dose to Para-Aortic Nodes** _______ : _______ Gy [24]

6. **Status** [25]
   - 1. Completed as Planned
   - 2. Treatment not completed
   - 88. Other, specify ____________________________ [26]

### Part II. Concurrent Chemotherapy

1. **Type of Concurrent Chemotherapy** [27]
   - 1. Cisplatin
   - 2. Carboplatin
   - 88. Other, specify ____________________________ [28]

2. **Start date** _______ - _______ - _______ (mm-dd-yyyy) [29]
   - Unknown [30]

3. **End date** _______ - _______ - _______ (mm-dd-yyyy) [31]
   - Unknown [32]

4. **Number of Full Weekly Cycles** _______ [33]

5. **Number of Reduced Weekly Cycles** _______ [34]

### Part III. Additional Treatment

1. **Did the participant receive any additional treatment not recorded on this form?** [35]
   - 1. No (initial and date form)
   - 2. Yes (provide details in comments)
### VISIT 4

**INSTRUCTIONS:** This form is to be completed during visit 4, 3 months after completion of chemoradiotherapy, to collect the visit details as described in the protocol. Dates are recorded as mm-dd-yyyy. This form is submitted to ACRIN via web at [www.acrin.org](http://www.acrin.org).

1. **Was Visit 4 conducted?**
   - O 1 No (complete Q1a, then initial and date form)
   - O 2 Yes (continue to Q2)

   **1a. Reason visit 4 not done**
   (Please mark all that apply with an X)
   - Scheduling problem
   - Participant refusal
   - Participant withdrew consent
   - Participant death (please complete DS form)
   - Other, specify
   - Unknown

2. **Date of Visit 4:** _______ - _______ - _______ (mm-dd-yyyy)

### Part I. Disease Status

Provide the patients disease status as of this visit referencing the FDG PET/CT, additional imaging, and/or other clinical follow-up.

1. **Participants disease status at this visit**
   - O 1 No evidence of disease
   - O 2 Evidence of disease (complete PF form)
   - O 99 Unknown

### Part II. Blood Specimen Collection

Complete the following questions pertaining to the whole blood sample consent and, if applicable, collection of whole blood.

1. **Did the participant consent to blood sampling for future correlative studies?**
   - O 1 No (continue to Part III)
   - O 2 Yes

2. **Were blood samples collected?**
   - O 1 No (provide reason in Q2a, then skip to Part III)
   - O 2 Yes (continue to Q2b)

   **2a. Reason blood samples not collected**
   (Please mark all that apply with an X)
   - Patient withdrew blood sample consent
   - Medical reasons
   - Administrative reasons
   - Time constraints
   - Other, specify
   - Unknown

   **2b. Date blood samples collected:**
   _______ - _______ - _______ (mm-dd-yyyy)

3. **Have the blood samples been sent to Washington University?**
   - O 1 No (complete Q3a, then skip to Part III)
   - O 2 Yes (continue to Q3c)

   **3a. Reason(s) samples not sent**
   (Please mark all that apply with an X)
   - Samples lost
   - Sample damaged
   - Administrative reasons
   - Sample will be sent on future date (please provide tentative date in Q3b)
   - Other, specify
   - Unknown

   **3b. Tentative date samples will be sent:**
   _______ - _______ - _______ (mm-dd-yyyy)

   **3c. Date samples sent:**
   _______ - _______ - _______ (mm-dd-yyyy)
ACRIN 6682
64Cu-ATSM PET/CT in Cervical Cancer
Visit 4 Evaluation

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

Part III. Visit 4 Study Procedures

Complete the following questions regarding the routine clinical follow-up conducted as part of this visit. **Protocol defined clinical follow-up at this visit are: medical history, physical examination, and clinical lab tests. Details of this clinical follow-up should be recorded in source.**

1. Please check routine clinical follow-up assessed

(Please mark all that apply = 1 not marked; ✓ = 2 marked)

☐ Physical exam [31]
☐ Laboratory test [32]
☐ Medical history [33]
☐ Concomitant medication [34]
☐ CT [35]
☐ PET [36]
☐ FDG PET/CT [37]
☐ Other imaging, [38] specify [39]
☐ Other, [40] specify [41]

1a. If protocol defined Visit 4 procedures (medical history, physical examination, and clinical lab tests) were not assessed, provide reason

(Please mark all that apply = 1 not marked; ✓ = 2 marked)

☐ Participant Refusal [42]
☐ Time constraints [43]
☐ Not clinically indicated per treating physician [44]
☐ Other, [45] specify [46]
☐ Unknown [47]

Comments: ________________________________________________________________
________________________________________________________________________
________________________________________________________________________
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Initials of person(s) completing this form [49] Date Form Completed (mm-dd-yyyy) [50]
1. Clinical trial time point: [1] O Registration / eligibility Visit (baseline) O Visit 4 (3 months post TX)

2. Is the participant a known diabetic? [2] O No O Yes, complete Q2a
   2a. 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
   - Intermediate or long-acting insulin [17] given [18] 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] given [29] hours before FDG
   - A diuretic to decrease urinary tract activity, [31] drug name [32] given [33] hours before FDG
   - 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, complete Q5a O Unknown
   5a. Agent Name: [40] Given approximately [41] days ago [42] O Unknown
      Date form completed (mm-dd-yyyy) [44]
ACRIN 6682

64 Cu-ATSM PET/CT in Cervical Cancer

PET/CT Technical Assessment Form

Instructions:

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

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

Part I. FDG scan (Baseline Visit and Visit 3 only)

1. Was blood glucose testing done? [2]
   O 1 No (complete Q1a and Q2, then skip to Part III)
   O 2 Yes (continue to Q2)

1a. If no, provide reason (check all that apply)
   □ Imaging not completed [3]
   □ Participant refusal [4]
   □ Unknown [6]
   □ Other, specify: ____________________________ [7]

2. Duration of participant fasting pre-PET/CT imaging: [8]

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

3. Blood glucose before injection of FDG

   ______ mg/dL [9]
   □ Unknown [10]

4. Time blood sample was obtained for glucose measurement

   (military time) ______ : ______  [11]

5. 18F-FDG Source [82]
   O Purchase, provide:
   Name of licensed pharmacy:
   ___________________________________________ [83]

   O Synthesized, provide:
   Method:
   ___________________________________________ [84]

   Pyrogen test result [85]
   O Passed
   O Failed
   O Not done

   Radiochemical purity test result:

   ______ % [86]

Part II. 64Cu-ATSM scan (Visit 1 only)

1. 64Cu-ATSM underwent quality control and passed? [87]
   O 1 No
   O 2 Yes

If 64Cu-ATSM fails any part of the quality control (or if quality control is not completed), the radiopharmaceutical should NOT be injected into the participant. Complete rest of form as instructed in Part III. Q1.

Part III. All Scans

1. Was PET/CT imaging completed? [19]
   O No, radiotracer not given and imaging not done
     (Q1a and Q2 required, then initial and date form)
   O No, radiotracer given, imaging not started
     (Q1a-Q10 required, complete Q11 if applicable)
   O No, radiotracer given, imaging not completed
     (Q1a-Q17 required, complete Q18-27 as applicable)
   O Yes, radiotracer given and imaging completed
     (Q2-Q27 required)

1a. *If PET/CT Imaging not completed, provide reason (check all that apply):

   □ 64Cu-ATSM did not pass QC [20]
   □ Scheduling problem [21]
   □ Equipment failure [22]
   □ Participant refusal [23]
   □ Medical reason [24]
   □ Injection site complications [25]
   □ Claustrophobia [26]
   □ Blood glucose level [27]
   □ Participant withdrew consent [28]
   □ Progressive disease [29]
   □ Participant death [30]
   □ Other, specify: ____________________________ [31]

   Unknown [32]

2. Date of PET/CT imaging (appointment):

   ______ - ______ - ____________ (mm-dd-yyyy) [34]
   □ Participant missed imaging appointment [34]

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**ACRIN Study 6682**

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**3. Subject weight** (measured on day of scan) [36]

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<tr>
<td>Subject weight</td>
<td>[kg]</td>
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**4. Subject height** (measured on day of scan) [80]

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<tr>
<td>Subject height</td>
<td>[cm]</td>
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**5. Full activity in syringe before injection** [37]

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<tr>
<td>Full activity</td>
<td>[mCi]</td>
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**5a. Time of assay of full syringe before injection** (military time) [38]

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<tr>
<td>Time of assay</td>
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**6. Time of injection** (military time) [40]

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<td>Time of injection</td>
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**7. Residual activity in syringe after injection** [42]

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<tr>
<td>Residual activity</td>
<td>[mCi]</td>
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**7a. Time of assay of residual activity after injection** (military time) [43]

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<tr>
<td>Time of assay</td>
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**8. Net Administered activity** [45]

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<tr>
<td>Net activity</td>
<td>[mCi]</td>
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**9. Location of injection site** [46]

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<tr>
<td>Location of injection</td>
<td>[site]</td>
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**10. Any radiotracer infiltration at injection site noted?** [48]

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<tr>
<td>Infiltration</td>
<td>[type]</td>
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**11. Was Foley catheter in place for study?** [49]

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<tr>
<td>Foley catheter</td>
<td>[status]</td>
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**12. Patient voided immediately pre-imaging?** [50]

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<tr>
<td>Patient voided</td>
<td>[status]</td>
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**13. Patient voided immediately post-imaging?** [51]

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</thead>
<tbody>
<tr>
<td>Patient voided</td>
<td>[status]</td>
</tr>
</tbody>
</table>

**Scanner**

**14. Has the scanner used for this study been qualified by ACRIN?** [52]

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanner qualified</td>
<td>[status]</td>
</tr>
</tbody>
</table>

**15. PET/CT Scanner used for this exam:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>[name]</td>
</tr>
</tbody>
</table>

**16. Date of last PET/CT Scanner SUV calibration/validation:**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Calibration date</td>
<td>[mm-dd-yyyy]</td>
</tr>
</tbody>
</table>

**17. Daily scanner QC run on date of study?** [58]

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>QC run on study</td>
<td>[status]</td>
</tr>
</tbody>
</table>
Image Acquisition

Transmission Scan

18. CT transmission scan:

18a. Was Oral contrast used? [59]
   O 1 No (skip to Q18c)
   O 2 Yes, specify type [60]
      O 1 Positive contrast
      O 2 Negative contrast

18b. Amount of Oral contrast ingested [61]
   ml
   Unknown [62]

18c. Was IV contrast used? [63]
   O 1 No (skip to Q19)
   O 2 Yes

18d. Amount of IV contrast injected [64]
   ml
   Unknown [65]

18e. Time IV contrast injection [66]
   : (military time)
   Unknown [67]

PET Emission Scan

22. Emission acquisition mode [71]
   O 1 2D
   O 2 3D

23. Number of bed positions scanned [72]

PET Emission Scan

24. Emission scan start time: (military time) [73]

25. Emission scan stop time: (military time) [74]

26. Pixel Size of Reconstructed images mm [75]

27. Thickness of Reconstructed images mm [76]

Comments:

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

____________________________________________________________________

Initials of person(s) completing this form [78]

Date form completed (mm-dd-yyyy) [79]
This PET/CT Reader corresponds to:

- O 1 Baseline FDG-PET/CT (complete Part I and Part II)
- O 2 Visit 1 Cu-ATSM PET/CT (complete Part I and Part III)
- O 3 Visit 4 FDG-PET/CT (complete Part I and Part II)

Part I. All Scans

1. Image quality
   - O 1 Uninterpretable (complete Q1a, then initial and date form)
   - O 2 Adequate (continue to Q2)

   1a. Reason (check all that apply):
       - □ Missing images
       - □ Noisy images
       - □ Patient motion
       - □ Artifact
       - □ Non-diagnostic
       - □ Other, specify __________________________________________________________________ [10]

2. Date of Imaging ______-_______-_______ (mm-dd-yyyy) [11]

3. Date of PET/CT Interpretation ______-_______-_______ (mm-dd-yyyy) [12]

4. Reader ID __________ [13]
### Part II. FDG-PET/CT

<table>
<thead>
<tr>
<th>Site</th>
<th>Uptake Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Tumor</td>
<td>[14]</td>
</tr>
<tr>
<td>Pelvic Lymph Nodes</td>
<td>[15]</td>
</tr>
<tr>
<td>Common Iliac Lymph Nodes</td>
<td>[16]</td>
</tr>
<tr>
<td>Para-aortic Lymph Nodes</td>
<td>[17]</td>
</tr>
<tr>
<td>Mediastinal Lymph Nodes</td>
<td>[18]</td>
</tr>
<tr>
<td>Supraclavicular Lymph Nodes</td>
<td>[19]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[20]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[21]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[22]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[23]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[24]</td>
</tr>
</tbody>
</table>

### Part III. 64Cu-ATSM PET/CT

1. Was the primary tumor included in the field of view?  
   - O 1 No (please complete Q1a)  
   - O 2 Yes (initial and date form)

1a. Please provide reason (check all that apply):
   - Image not adequate (as described in part I Q1a)  
   - Other, specify ____________________________  

**Comments:**

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________  

Radiologist/Nuclear Medicine physician Responsible for this Data

_______  ____  _______  ________  [32]  

Date form completed

Initials of Person(s) completing this form

__________________________________________________________________________  

"Copyright 2009"
INSTRUCTIONS: This form is completed every 3 months for 2 years after Visit 4, then every 6 months for the 3rd year. All dates are recorded as mm-dd-yyyy. The completed form is submitted to ACRIN via the web, www.acrin.org. Please refer to the form completion instructions for further instructions.

1. Timepoint for this follow-up [1]
   - O 3 month follow-up
   - O 6 month follow-up
   - O 9 month follow-up
   - O 12 month follow-up
   - O 15 month follow-up
   - O 18 month follow-up
   - O 21 month follow-up
   - O 24 month follow-up
   - O 30 month follow-up
   - O 36 month follow-up

2. Participant's vital status at the time of this follow-up [2]
   - O 1 Alive
     - Date confirmed: _____-____-____ mm-dd-yyyy [3]
   - O 2 Dead
   - O 99 Unknown, check reason then initial and date form [4]
     - O Participant lost
     - O Other, specify ____________________________ [5]

3. Please indicate method vital status was obtained
   Check all that apply
   - Last visit with treating physician [6]
   - PET imaging [7]
   - Other imaging, specify _______________________ [8]
   - Other source, specify _________________________ [9]

4. Disease status at this assessment [12]
   - O 1 No evidence of disease (Skip to Q5)
   - O 2 Evidence of disease (Continue to Q4a)
   - O 99 Unknown (Skip to Q7)

4a. Did the participant develop a confirmed 1st progression and/or new distant metastatic disease since the last F1 was submitted? [13]
   Progression is defined as persistence, recurrence, and/or new lesion. Progression should only be reported when it is 1st established. Any future progression with the exception of 1st report of distant metastasis should not be reported.
   - O 1 No
   - O 2 Yes (Complete PF form)
   - O 99 Unknown

5. Date the disease status was determined [14]
   _____-____-____ mm-dd-yyyy

6. Please indicate method disease status was obtained
   Check all that apply
   - Last visit with treating physician [15]
   - PET imaging [16]
   - Other imaging, specify _______________________ [17]
   - Other source, specify _________________________ [18]

7. Did the participant receive any radiation therapy related to cervical cancer (not previously reported) [21]
   - O 1 No (Skip to Q8)
   - O 2 Yes (Continue to Q7a. If > 1 course, record details in comments)
   - O 99 Unknown (Skip to Q8)

7a. Anatomic location of radiation therapy
   ________________________________ [22]

7b. Start date of radiation therapy
   _____-____-____ mm-dd-yyyy [23]
   - Unknown [24]

7c. Stop date of radiation therapy
   _____-____-____ mm-dd-yyyy [25]
   - Unknown [26] or Ongoing [27]

8. Did the participant have any surgery related to cervical cancer (not previously reported) [28]
   - O 1 No (Skip to Q9)
   - O 2 Yes (Continue to Q8a. If > 1 surgery, record details in comments)
   - O 99 Unknown (Skip to Q9)

8a. Anatomic location of surgery
   ________________________________ [29]

8b. Date of surgery
   _____-____-____ mm-dd-yyyy [30]
   - Unknown [31]

9. Did the participant receive any chemotherapy related to cervical cancer (not previously reported) [32]
   - O 1 No (Initial and date form)
   - O 2 Yes (Continue to Q9a. If > 1 course, record details in comments)
   - O 99 Unknown (Initial and date form)

9a. Type of chemotherapy
   ________________________________ [33]

9b. Start date of chemotherapy
   _____-____-____ mm-dd-yyyy [34]
   - Unknown [35]

9c. Stop date of chemotherapy
   _____-____-____ mm-dd-yyyy [36]
   - Unknown [37] or Ongoing [38]

Comments: ________________________________ [39, 40]

Initials of person(s) completing the form
   ________________________________ [41]

Date form completed mm-dd-yyyy [42]
1. Number of slides received: ________________________________ [20]
   - [ ] No slides received, [30] reason:
   - ________________________________________________________ [31]

2. Was tissue analysis for tumor hypoxic markers completed? [1]
   - [ ] 1 No (Complete Q2a, then initial and date form)
   - [ ] 2 Yes (Complete Table below)

2a. Reason not completed [2]
   - [ ] 1 Slides never received from site
   - [ ] 2 Limited size of biopsy specimen
   - [ ] 3 Slides lost
   - [ ] 88 Other, specify ____________________________ [3]
   - [ ] 99 Unknown

3. Number of Slides Analyzed __________ [28]

<table>
<thead>
<tr>
<th>Hypoxic Marker</th>
<th>Percentage of Tumor Cells Staining Score</th>
<th>Staining Intensity Score</th>
<th>Composite Score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 = &lt;1% tumor cells</td>
<td>0 = no staining</td>
<td>= % tumor cells staining (Column 2) X staining intensity (Column 3)</td>
</tr>
<tr>
<td></td>
<td>1 = 1%–33% tumor cells</td>
<td>1 = weak staining</td>
<td>Range 0-6</td>
</tr>
<tr>
<td></td>
<td>2 = 34%–66% tumor cells</td>
<td>2 = moderate to strong staining</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 = &gt;66% tumor cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLUT-1</td>
<td>[7]</td>
<td>[8]</td>
<td>[9]</td>
</tr>
<tr>
<td>CA-IX</td>
<td>[10]</td>
<td>[11]</td>
<td>[12]</td>
</tr>
<tr>
<td>OPN</td>
<td>[13]</td>
<td>[14]</td>
<td>[15]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[17]</td>
<td>[18]</td>
<td>[19]</td>
</tr>
<tr>
<td>Other, specify</td>
<td>[21]</td>
<td>[22]</td>
<td>[23]</td>
</tr>
</tbody>
</table>

Comments: ____________________________________________________________ [24]

______________________________________________________________________
______________________________________________________________________

Initials of person(s) completing this form ____________________________ [25]

Date form completed ____________________________ [26]

Blinded Investigator signature

*Copyright 2010*
ACRIN 6682
End of Study Form
Cu-ATSM PET/CT in Cervical Cancer

1. Did the participant complete the trial? [1]
   O 1 No (continue to Q2)
   O 2 Yes (continue to Q4, then initial and date form)

2. Date of discontinuation: ______-_______-_______ (mm/dd/yyyy) [2]

   2a. Primary reason for premature discontinuation: (check only one) [3]
      O 1 Adverse events/side effect/complications (also specify on the Adverse Event form)
      O 2 Participant explicitly withdraws from further study participation
      O 3 Protocol violation
      O 4 Did not meet eligibility criteria
      O 5 Lost to follow-up (unable to obtain contact with the participant during the prescribed protocol intervals)
      O 6 Unsatisfactory therapeutic effect
      O 7 Abnormal laboratory value(s)
      O 8 Investigator decision (specify reason below)
      O 9 Participant death (complete Q3)
      O 10 Site regulatory violation (specify reason below)
      O 88 Other (specify reason below)
      Specify reason: __________________________________________________________ [4]

3. Date of death ______-_______-_______ (mm/dd/yyyy) [5]

   3a. Cause of death [6]
      O 1 Disease Progression
      O 88 Other ________________________________ (specify cause of death) [7]

4. Was the data assessed, reviewed, and approved by the investigator? [12]
   O 1 No
   O 2 Yes

COMMENTS: ____________________________

____________________________________

____________________________________

____________________________________

Initials of person(s) completing the form [9]

Date form completed ______-_______-_______ [10]

"Copyright 2009"
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 deviation. Submit this form via the ACRIN web site; retain the form in the case study file.

1. Check the Protocol Event Being Reported: *(select only one)*
   - O 1 Inclusion/exclusion criteria not met at time of registration
   - O 2 Imaging-related deviation (complete 1b)
   - O 3 Study activity performed prior to participant signing study consent form
   - O 4 Blood sample taken prior to participant signing biomarker consent form
   - O 5 Cervical biopsy slides not obtained/sent/analyzed per protocol
   - O 6 Blood sample not obtained/sent per protocol
   - O 7 Visit or follow-up procedures not performed per protocol (specify visit in Q6)
   - O 8 Baseline FDG-PET/CT not performed within 4 weeks of enrollment
   - O 9 Visit performed outside of protocol specified time frame (specify visit in Q6)
   - O 10 Chemoradiotherapy not per protocol
   - O 11 Case enrolled under expired IRB approval/FWA
   - O 88 Other, specify: ____________________________________________________________

1b. Image Deviation: *(select only one)*

I. Cu-ATSM
   - O 1 PET instrument not credentialed prior to performing scan
   - O 2 PET scan done at an non-ACRIN qualified institution
   - O 3 PET images lost/unavailable
   - O 4 Cu-ATSM preparation, apyrogenicity, and/or radiochemical purity not done per protocol *(NOTE: IND violation)*
   - O 5 Time between injection and start of scan is unknown
   - O 6 Time between Cu-ATSM injection and start of scan ≥ 40 or < 30 minutes
   - O 7 Injected dose <18 mCi or >25 mCi
   - O 8 Cu-ATSM PET/CT emission scan duration not 30 minutes
   - O 9 Body weight is incorrect or unknown
   - O 10 Misregistration of the tumor between PET and CT by more than 3 slices
   - O 11 CT acquisition parameters not per protocol
   - O 88 Other, specify: ____________________________________________________________

II. FDG
   - O 1 PET instrument not credentialed prior to performing scan
   - O 2 PET scan done at an non-ACRIN qualified institution
   - O 3 PET images lost/unavailable
   - O 4 Time between injection and start of scan is unknown
   - O 5 Blood glucose testing not done
   - O 6 Body weight is incorrect or unknown
   - O 7 Scan not performed according to ACRIN SOP
   - O 88 Other, specify: ____________________________________________________________

*Copyright 2009*
2. Date the protocol deviation occurred: _____ - _____ - 20[mm-dd-yyyy] [7]

3. Date the protocol deviation was discovered: _____ - _____ - 20[mm-dd-yyyy] [8]

4. Describe the protocol deviation:

   ________________________________________________ [9]

   ________________________________________________ [10]

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

   ________________________________________________ [11]

   ________________________________________________ [12]

6. Please provide the time point this Study Deviation applies to: [13]
   
   O 1 Study Enrollment Visit
   O 2 Visit 1 (14 days from baseline Visit 1)
   O 3 Visit 2 (within 4 weeks from baseline Visit 1)
   O 4 Visit 3 (4 weeks post completion of chemoradiotherapy)
   O 5 Visit 4 (3 months post completion of chemoradiotherapy)
   O 6 Follow-up Time Point, specify (check only one): [14]
       O 3 month follow up O 15 month follow up O 30 month follow up
       O 6 month follow up O 18 month follow up O 36 month follow up
       O 9 month follow up O 21 month follow up
       O 12 month follow up O 24 month follow up

   _____ - _____ - 20[mm-dd-yyyy] [15]

   Initials of person responsible for data (RA, study staff)

   Date Form Completed

   Investigator Signature

"Copyright 2009"
If this is a revised or corrected form, please √ box.

INSTRUCTIONS: This form should be completed to capture 1st progression of disease and/or any new distant metastatic disease. Please specify in each table whether each listed site has progression based upon persistent disease, progression based upon recurrence of disease, progression based upon a new lesion, no progression, or unknown if the site has not been evaluated for disease. If there is a 1st progression and/or a new distant metastatic disease at a site not listed, please enter the site into the appropriate table under ‘other, specify’. For each site with progression (persistent, recurrence, or new lesion) please provide the method of evaluation and the date the progression was documented. If more than one method of evaluation was used, please provide the most definitive method that determined the progression. The date documented should be recorded as the date the method of evaluation was performed. Dates are recorded as mm-dd-yyyy. This form is to be submitted to ACRIN via web at www.acrin.org.

1. Indicate disease status
   - O 1 1st report of any progression (complete table 1)
   - O 2 New distant metastatic disease not previously reported (complete table 2)
   - O 3 Both of the above (complete table 1 and 2)

Table 1. 1st Report of Any Progression

<table>
<thead>
<tr>
<th>Site</th>
<th>Status of Disease at Site</th>
<th>Method of Evaluation</th>
<th>Date Documented (mm-dd-yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pelvic Lymph Nodes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common Iliac Lymph Nodes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Para-aortic Lymph Nodes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supraclavicular Lymph Nodes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other pelvic organ, specify:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Table 2. New Distant Metastatic Disease Not Previously Reported

<table>
<thead>
<tr>
<th>Site</th>
<th>Status of Disease at Site</th>
<th>Method of Evaluation</th>
<th>Date Documented (mm-dd-yyyy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suprachiavicular Lymph Nodes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Non Pelvic/Non Abdominal Lymph Nodes specify</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other, specify</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### COMMENTS:

________________________________________________________________________

Initials of person(s) completing the form

Date form completed (mm-dd-yyyy)
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>
</table>
| Mild           | Unrelated   | Expected     | No          | No                          | None, Medication therapy | Recovered, Improved, Ongoing, Death, Unknown | Start date:  
| Moderate       | Unlikely    | Unexpected   | No          | Yes                         | Procedure, Hospitalization | Ongoing  |
| Severe         | Possible    |              | Yes         |                             | Other             |         |
| Life threatening or disabling | Definite |              |             |                             |                  |         |
| Fatal          |             |              |             |                             |                  |         |

Comments:  

Additional AEs to report?  

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

Date form completed (mm-dd-yyyy)  

Investigator's signature (for external use only)
### SUPPLEMENTAL BASELINE ABNORMALITIES

**NOTE:** Do not record any prior cancer treatment/therapies on this form. Record all on the Prior Therapies (TX) form. Check "none" if there are no abnormalities to report.

<table>
<thead>
<tr>
<th>Sequence #</th>
<th>Condition / Event</th>
<th>Online CTCAE/MedDRA Term</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1 = Mild</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 = Moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 = Severe</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4 = Life threatening or disabling</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>99 = Unknown</td>
</tr>
<tr>
<td>[2]</td>
<td></td>
<td></td>
<td>0 1 0 2 0 3 0 4 0 99</td>
</tr>
<tr>
<td>[3]</td>
<td></td>
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<td>[11]</td>
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<td>0 1 0 2 0 3 0 4 0 99</td>
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<tr>
<td>[12]</td>
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<td>0 1 0 2 0 3 0 4 0 99</td>
</tr>
<tr>
<td>[13]</td>
<td></td>
<td></td>
<td>0 1 0 2 0 3 0 4 0 99</td>
</tr>
</tbody>
</table>

***Important: If there are additional records to report, list on Supplemental MH form.***
**ACRIN Study 6682**

**64 Cu-ATSM in Cervical Cancer**

**Supplemental Concomitant Medications**

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

- **None**[13] Check "none" if there are no Concomitant Medications to report.

### SUPPLEMENTAL CONCOMITANT MEDICATIONS

<table>
<thead>
<tr>
<th>Medication (Generic Name only)</th>
<th>Start date (mm/dd/yyyy) [3] [4] [5]</th>
<th>End date (mm/dd/yyyy) [7] [8] [9]</th>
<th>Indication (reasons for use) [12]</th>
</tr>
</thead>
<tbody>
<tr>
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***List additional Concomitant Medications on subsequent Supplemental CO form.***