



Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

INCLUSION CRITERIA

- 25. Is the participant \geq 18 years of age? [28]
 1 No 2 Yes
- 26. Does the participant have histological confirmation of a first time diagnosed SCC head & neck? [29]
 1 No 2 Yes
- 27. Is unilateral or bilateral neck dissection planned for the patient's care? [30]
 1 No 2 Yes
- 28. Has the participant had CT or MR images taken within six (6) weeks prior to enrollment? [54]
 1 No 2 Yes
- 29. Does the participant have at least one neck that is clinically N0 as defined by clinical exam (physical exam with CT and/or MRI as the gold standard); Stages T2, T3, or T4. N0-N3, excluding N2c for bilateral disease based on criteria from American Joint Commission on cancer (AJCC)? [32]
 1 No 2 Yes

NOTE: Stages T2, T3 or T4 should be based on physical exam or CT or MRI with the largest size on any of these exams determining stage.

29a. Is the tumor a T1 SCC? [53]
 1 No 2 Yes

30. Is it considered a viable clinical option to perform neck dissection on the participant when primary cancers are at high risk for neck metastasis? [33]
 1 No 2 Yes

31. Does the participant have one of the following? [56]

- Oral cavity cancer [34]
- Oropharynx cancer, including base of tongue and tonsil [35]
- Larynx cancer [36]
- Supraglottic cancer [37]
- None of the above

31a. List any second primary: _____ [57]

32. Is the participant willing to provide a written informed consent? [38]
 1 No 2 Yes



Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

EXCLUSION CRITERIA

- 33. Is the patient pregnant and/or breast feeding? ^[39]
 1 No 2 Yes
- 34. Does the patient have sinonasal carcinoma? ^[40]
 1 No 2 Yes
- 35. Does the patient have tumors in the head and neck that are not SCC? ^[41]
 1 No 2 Yes
- 36. Does the patient have salivary gland malignancies? ^[42]
 1 No 2 Yes
- 37. Does the patient have thyroid cancer? ^[43]
 1 No 2 Yes
- 38. Does the patient have advanced skin cancer? ^[44]
 1 No 2 Yes
- 39. Does the patient have nasopharyngeal carcinoma? ^[45]
 1 No 2 Yes
- 40. Does the patient have poorly controlled diabetes (defined as fasting glucose level > 200 mg/dL) despite attempts to improve glucose control by fasting duration and adjustment of medications? ^[58]
 1 No 2 Yes
- 41. Is the patient not a candidate for surgery due to an underlying medical condition? ^[47]
 1 No 2 Yes
- 43. Is the patient's weight > than PET/CT table weight limit? ^[52]
 1 No 2 Yes

[25] A Waiver to override participant eligibility has been granted
 [26] Waiver granted by
 [27] Date Waiver Granted
 [31] CT or MR images taken within four (r) weeks prior to enrollment (obsolete)

Initials of Person(s) who determined eligibility ^[49]

_____-_____-_____
Date form completed (mm-dd-yyyy) ^[50]

Initials of Person(s) completing this form ^[51]



ACRIN 6685
FDG-PET/CT Staging of
Head and Neck Cancer
Blood Collection Form

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____
 Participant Initials _____ Case No. _____

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

- 1. Was blood collected day of PET/CT?** [1]
 No
 Yes (skip to Q3)

- 1a. Reason blood was not collected day of PET/CT?** [2]
 Collected during pre-op labs
 FDG administered prior to blood draw
 Other, specify _____ [3]
 Unknown

- 2. Was blood collected prior to surgery?** [4]
 No (complete Q2a then initial and date form)
 Yes (skip to Q3)

- 2a. Reason blood was not collected (check only one)** [5]
 Scheduling problem
 Patient refusal
 Medical contraindication
 Patient death
 Other, specify _____ [6]
 Unknown

3. Date blood collected _____ - _____ - _____ [7]

4. What time was blood collected? _____ : _____ [8]

5. What time was blood separated by centrifugation? _____ : _____ [9]

- 6. Was sera separated by centrifugation within 2 hours of blood draw?** [10]
 No
 Yes

- 7. What temperature was blood stored at?** Positive
 Negative [16]
 _____ °C [11]

Comments: _____

 _____ [12]

 Initials of person responsible for the data [13]

 Date form completed (mm-dd-yyyy) [14]

 Initials of person entering data onto the web [15]



ACRIN 6685
FDG-PET/CT Staging of
Head and Neck Cancer
Biopsy Form

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

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

1. **Was a biopsy of distant metastases performed?** [1]

- 1 No (complete Q1a then stop and sign form)
- 2 Yes (skip to Q2)

1a. **Reason biopsy not performed (check only one)** [2]

- 1 Scheduling problem
- 2 Patient refusal
- 3 Medical contraindication
- 4 Patient death
- 5 Not standard of care
- 88 Other, specify _____ [3]

2. **Procedure date** _____ - _____ - _____ (mm-dd-yyyy) [4]

3. **Type of procedure** [5]

- 1 FNA
- 2 Core needle biopsy
- 3 FNA and core needle biopsy
- 4 Surgical (wedge, excisional, etc . . .) biopsy
- 88 Other, specify _____ [6]
- 99 Unknown

4. **Image guided** [7]

- 1 No
- 2 Yes
- 88 Other, specify _____ [8]
- 99 Unknown

5. **Location of biopsy** [9]

- 1 Lung (complete **Q5a**)
- 2 Liver (complete **Q5b**)
- 3 Soft Tissue (complete **Q5c**)
- 4 Bone / bone marrow (complete **Q5d**)
- 5 Brain (skip to **Q6**)
- 6 Lymph node distant from primary site (complete **Q5e**)
- 88 Other, specify _____ [10]

Anatomic Locations

5a. **Lung** [11]

- 1 RUL
- 2 RML
- 3 RLL
- 4 LUL
- 5 LLL

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

5b. **Liver** ^[12]

- 1 Right lobe, anterior
- 2 Right lobe, posterior
- 3 Left lobe, medial
- 4 Left lobe, lateral
- 5 Caudate

5c. **Soft Tissue** ^[13]

- 1 Head and Neck
- 2 Upper extremity, right
- 3 Upper extremity, left
- 4 Chest wall
- 5 Abdominal wall
- 6 Pelvis
- 7 Lower extremity, right
- 8 Lower extremity, left

5d. **Bone / bone marrow** ^[14]

- | | |
|------------------------|---|
| 1 Skull | 12 Sternum |
| 2 C-spine | 13 T-spine |
| 3 Humerus, right | 14 L-spine |
| 4 Humerus, left | 15 Pelvis |
| 5 Radius / ulna, right | 16 Femur, right |
| 6 Radius / ulna, left | 17 Femur, left |
| 7 Hand, right | 18 Tibia / fibula, right |
| 8 Hand, left | 19 Tibia / fibula, left |
| 9 Ribs, right | 20 Foot, right |
| 10 Ribs, left | 21 Foot, left |
| 11 Scapula / clavicle | 88 Other, specify _____ ^[15] |

5e. **Lymph node distant from primary site** ^[16]

- | | |
|--------------------------|---|
| 1 Cervical | 7 Chest, mediastinal |
| 2 Hilar | 8 Abdomen |
| 3 Upper extremity, right | 9 Pelvis |
| 4 Upper extremity, left | 10 Lower extremity, right |
| 5 Supraclavicular | 11 Lower extremity, left |
| 6 Chest, axillary | 88 Other, specify _____ ^[17] |

6. **Histology** ^[18]

- 1 Negative
- 2 Positive
- 3 Indeterminate
- 4 Specimen inadequate
- 88 Other, specify _____ ^[19]

BX

Revision

ACRIN Study 6685

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

COMMENTS: _____

_____ [20]

Initials of person responsible for the data [21]

Date from completed ____-____-____ (mm-dd-yyyy) [22]

Initials of person entering data onto the web [23]



ACRIN 6685
FDG-PET/CT Staging of
Head and Neck Cancer
CT Interpretation Form

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

GENERAL IMAGING INFORMATION

1. Reader ID [1]
2. Date of CT scan ____-____-____ (mm-dd-yyyy) [2]
3. Was the CT scan obtained from a PET/CT? [3]
 - No (skip to Q4)
 - Yes (Complete Q3a)
- 3a. Was the CT read independent of the PET? [4]
 - No
 - Yes
4. Image quality [5]
 - Adequate
 - Suboptimal
 - Uninterpretable (complete Q4a then initial and date form)
- 4a. Reason uninterpretable [mark all that apply]
 - Motion [6]
 - Artifacts [7]
 - Contrast Media [8]
 - DICOM Header [9]
 - Lost Images [10]
 - Poor S/N [11]
 - Incomplete anatomic coverage [12]
 - Other, [13] specify: _____ [14]
5. Oral contrast used? [15]
 - No (Skip to Q6)
 - Yes (Skip to Q5a)
- 5a. Type of oral contrast used [16]
 - Positive contrast agent
 - Negative contrast agent
6. IV contrast used? [17]
 - No (Skip to Q7)
 - Yes (Skip to Q6a)
- 6a. Amount of IV contrast injected _____ mL [18]

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____
 Participant Initials _____ Case No. _____

7. Subject weight _____ kg [19]
 (measured on day of scan) Unknown [20]
8. Scan start time (military time) _____ : _____ [21]
9. Scan stop time (military time) _____ : _____ [22]
10. Primary Tumor (List up to 3 primary tumors)

	Location	Greatest Diameter (cm)
1	[23]	[24]
2	[25]	[26]
3	[27]	[28]

Code Table for Q10	
1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	17. Primary not seen
9. Hard Palate	88. Other (specify in comments)

10a. If alveolar ridge indicate location (mark all that apply)

- Anterior [29]
- Lateral [30]
- Superior [31]
- Inferior [32]

11. Primary Tumor Invasion (check all that apply)

- Muscle Invasion [33]
- Bone Invasion [34]
- Cartilage Invasion [35]
- Nerve Involvement [36]
- Fixed Vocal Cord [37]
- Superficial invasion [38]
- No invasion [39]

12. Lateralization of Tumor [40]

- Right
- Left
- Bilateral
- Midline



Institution _____ Institution No. _____
 Participant Initials _____ Case No. _____

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

13. Number of nodal basins identified _____ [41]

14. Number of suspected metastatic lymph nodes by nodal basins (indicate number for all locations)

	Left	Right	Extra-capsular spread?	Necrosis present?	No nodes seen
IA	[42]	[43]	<input type="checkbox"/> No <input type="checkbox"/> Yes [44]	<input type="checkbox"/> No <input type="checkbox"/> Yes [45]	<input type="checkbox"/> [46]
IB	[47]	[48]	<input type="checkbox"/> No <input type="checkbox"/> Yes [49]	<input type="checkbox"/> No <input type="checkbox"/> Yes [50]	<input type="checkbox"/> [51]
IIA	[52]	[53]	<input type="checkbox"/> No <input type="checkbox"/> Yes [54]	<input type="checkbox"/> No <input type="checkbox"/> Yes [55]	<input type="checkbox"/> [56]
IIB	[57]	[58]	<input type="checkbox"/> No <input type="checkbox"/> Yes [59]	<input type="checkbox"/> No <input type="checkbox"/> Yes [60]	<input type="checkbox"/> [61]
III	[62]	[63]	<input type="checkbox"/> No <input type="checkbox"/> Yes [64]	<input type="checkbox"/> No <input type="checkbox"/> Yes [65]	<input type="checkbox"/> [66]
IV	[67]	[68]	<input type="checkbox"/> No <input type="checkbox"/> Yes [69]	<input type="checkbox"/> No <input type="checkbox"/> Yes [70]	<input type="checkbox"/> [71]
V	[72]	[73]	<input type="checkbox"/> No <input type="checkbox"/> Yes [74]	<input type="checkbox"/> No <input type="checkbox"/> Yes [75]	<input type="checkbox"/> [76]
VI	[77]	[78]	<input type="checkbox"/> No <input type="checkbox"/> Yes [79]	<input type="checkbox"/> No <input type="checkbox"/> Yes [80]	<input type="checkbox"/> [81]
Total	[82]	[83]			

15. Other involved areas: _____ [84]

Comments: _____

 _____ [85]

 Initials of person completing the form [86]

____ - ____ - ____ [87]
 Date form completed (mm-dd-yyyy)

 Initials of person entering data onto the web [88]



End of Study Disposition

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

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

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

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

Cause of death [5]

- 1 Disease Progression
- 88 Other, specify _____ [6]
- 5 Adverse Event / Side Effects / Complications
- 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)
- 8 Study terminated by sponsor
- 88 Other (specify reason below)

DSe1=7 Disease progression

Specify reason: _____ [13]

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

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

- 1 No
- 2 Yes

Comments: _____ [16]

_____^[17]
 Initials of person completing the form

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

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

Investigator's signature _____



Institution _____ Institution No. _____
 Participant Initials _____ Case No. _____

Imaging Agent: FDG

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

Exam Data

1. **Planned time point:**_[1]
 Visit 2
2. **Was imaging agent administered?**_[2]
 No (Initial & date form) Yes
3. **Imaging agent name:**_[3]
 FDG
4. **Administration date:**_[4]
 _____ - _____ - _____ (mm-dd-yyyy)

Imaging Agent Procurement

5. **Identification number (Lot #):**_[5] _____
6. **Source of agent:**_[6] Prepared in-house (provide method by which agent is synthesized, complete Q6a)
 Obtained from outside supplier (complete Q6b)
- 6a. **Method:**_[7] _____
- 6b. **Supplier:**_[8] _____

Administration Information

7. **Route of administration:**_[9] IV
8. **Activity in full syringe before injection:** _____ . _____ mCi_[10]
- 8a. **Time of assay of full syringe before injection:** _____ : _____ (military time)_[11] Unknown_[12]
9. **Time of injection:** _____ : _____ (military time)_[13] Unknown_[14]
10. **Residual activity in syringe after injection:** _____ . _____ mCi_[15] Unknown_[16]
 (if unk, skip to Q12)
- 10a. **Time of assay of residual activity after injection:** _____ : _____ (military time)_[17] Unknown_[18]
11. **Net activity administered (Dosage Amount):** _____ . _____ mCi_[19]
12. **Site of injection:**_[20]
- | | |
|---|--|
| <input type="radio"/> Right antecubital | <input type="radio"/> Left antecubital |
| <input type="radio"/> Right wrist | <input type="radio"/> Left wrist |
| <input type="radio"/> Right foot | <input type="radio"/> Left foot |
| <input type="radio"/> Indwelling central catheter | <input type="radio"/> Unknown |
| | <input type="radio"/> Other, specify _[21] _____ |
13. **Any infiltration at injection site noted?**_[22]
- 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_[23]

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



**ACRIN 6685
Clinical Assessment
Follow-up Form**

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

ACRIN Study 6685

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

1. Timepoint for this follow-up? [1]

- 1= One year post-surgery
- 2= Two year post-surgery
- 88= Other, specify _____ [2]

2. Date the site RA/PI contacted the treating physician for this follow-up evaluation

____-____-____ (mm-dd-yyyy) [3]

3. Date of last contact between the treating physician and the participant/participant's family

____-____-____ (mm-dd-yyyy) [4]

Unknown [5]

4. Was follow-up information obtained? [6]

- No (Complete Q4a)
- Yes

4a. Reason not completed: [7]

- 1= The participant refused
- 2= Patient lost to follow-up
- 3= Unable to contact treating physician
- 4= Records not available
- 88= Other, specify _____ [8]

5. Source of follow-up data (check all that apply)

Medical record review [9]
____-____-____ (mm-dd-yyyy) [10]

Participant/proxy/family self-report [11]
____-____-____ (mm-dd-yyyy) [12]

Other, [13] specify _____ [14]
____-____-____ (mm-dd-yyyy) [15]

6. Participant's vital status at the time of this follow-up [16]

- 1= Alive
- 2= Dead (complete Q6a)
- 99= Unknown

6a. Date of death: ____-____-____ [17]
(mm-dd-yyyy) Unknown [18]

7. Most recent interim treatments:

	Start Date	Stop Date	
XrT	____-____-____ [19]	____-____-____ [20]	<input type="checkbox"/> Ongoing [21]
Chemotherapy	____-____-____ [22]	____-____-____ [23]	<input type="checkbox"/> Ongoing [24]
Surgery	____-____-____ [25]		
Other, specify [26]	____-____-____ [27]	____-____-____ [28]	<input type="checkbox"/> Ongoing [29]

8. Initial primary disease status at this assessment: [30]

- 1 Recurrent disease
- 2 Disease-free
- 3 Persistent disease
- 99 Unknown

8a. Date recurrence determined: ____-____-____ [31]
(mm-dd-yyyy)

8b. Method/modality used to determine recurrence (check all that apply)

- PET [32]
- CT [33]
- MR [34]
- Physical examination [35]
- Biopsy / pathology [36]
- US [37]
- Participant/proxy/family self-report [38]
- Other, [39] specify _____ [40]

8c. Location of recurrence (check all that apply)

- Local [41]
- Regional [42]
- Distant metastasis [43]

9. Neck assessment

Left	Right
<input type="radio"/> 1= Positive [44]	<input type="radio"/> Positive [45]
<input type="radio"/> 2= Negative	<input type="radio"/> Negative
<input type="radio"/> 3= Completely resected	<input type="radio"/> Completely resected
<input type="radio"/> 99= Unknown	<input type="radio"/> Unknown

F1**ACRIN 6685
Clinical Assessment
Follow-up Form**

ACRIN Study 6685

PLACE LABEL HEREInstitution _____ Institution No. _____
Participant Initials _____ Case No. _____If this is a revised or corrected form, please box. **10a. Site(s) of metastatic disease**

- 1 No
- 2 Yes
- 98 Not evaluated
- 99 Uncertain

10b. Assessment Method** Up to 3 assessments may be coded for each anatomic site.*

- 1 Physical Exam
- 2 Conventional Imaging (CT)
- 3 PET with/without CT/MRI
- 4 Pathologic
- 5 MRI
- 6 Ultrasound
- 7 Bone scan
- 8 Autopsy
- 9 Participant/proxy/family self-report
- 88 Other method (specify in comments)

Use Codetable 10a
Codes (1 and 2 require a date)

Date of Assessment (*Use codetable 10b)

<input type="text"/> [46] LUNG	___-___-___ [47]	<input type="text"/> [48] <input type="text"/> [49] <input type="text"/> [50]
<input type="text"/> [51] LYMPH NODES (distant)	___-___-___ [52]	<input type="text"/> [53] <input type="text"/> [54] <input type="text"/> [55]
<input type="text"/> [56] LIVER	___-___-___ [57]	<input type="text"/> [58] <input type="text"/> [59] <input type="text"/> [60]
<input type="text"/> [61] BONE	___-___-___ [62]	<input type="text"/> [63] <input type="text"/> [64] <input type="text"/> [65]
<input type="text"/> [66] CNS (BRAIN)	___-___-___ [67]	<input type="text"/> [68] <input type="text"/> [69] <input type="text"/> [70]
<input type="text"/> [71] OTHER, Specify _____ [72]	___-___-___ [73]	<input type="text"/> [74] <input type="text"/> [75] <input type="text"/> [76]

11. Was a new head and neck primary identified? [81]

- No
- Yes

CLINICAL EXAMINATION**11a. New primary tumor (List up to 3 primary tumors)**

	Location
1.	[82]
2.	[83]
3.	[84]

Code Table for Q11a

- | | |
|------------------------------------|---------------------------------|
| 1. Tongue (tip) | 10. Buccal Mucosa |
| 2. Tongue (lateral) | 11. Tonsil |
| 3. Tongue (base) | 12. Hypopharynx |
| 4. Floor of Mouth (anterior) | 13. Larynx (supraglottic) |
| 5. Floor of Mouth (lateral) | 14. Larynx (glottic) |
| 6. Alveolar Ridge | 15. Larynx (subglottic) |
| 7. Retromolar Trigone (maxillar) | 16. Larynx (transglottic) |
| 8. Retromolar Trigone (mandibular) | 88. Other (specify in comments) |
| 9. Hard Palate | |

11b. If alveolar ridge indicate location (mark all that apply)

- Anterior [85]
- Lateral [86]
- Superior [87]
- Inferior [88]

Comments: _____

_____ [77]

_____ [78]

Initials of person responsible for data

___-___-___ [79]

Date form completed (mm-dd-yyyy)

_____ [80]

Initials of person entering data onto the web



ACRIN 6685
FDG-PET/CT Staging of
Head and Neck Cancer
Initial Evaluation Form

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

GENERAL IMAGING INFORMATION

1. Was endoscopy performed ^[1]
 - No (skip to Q2)
 - Yes
 - 1a. Where was the endoscopy performed? ^[2]
 - Office (flexible)
 - OR (direct)
2. Is there evidence of vocal cord paralysis? ^[3]
 - No
 - Yes
3. Was a diagnostic MRI performed within 6 weeks of enrollment? ^[62]
 - No
 - Yes
4. Was a diagnostic CT performed within 6 weeks of enrollment? ^[63]
 - No (Skip to Q5)
 - Yes (Complete Q4a)
 - 4a. Was the CT obtained from a PET/CT? ^[6]
 - No
 - Yes
5. Subject weight _____ kg ^[7]
 - Unknown ^[8]
6. Subject height _____ cm ^[9]
 - Unknown ^[10]

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

CLINICAL EXAMINATION

7. Primary Tumor (List up to 3 primary tumors)

	Location	Histology SCC?
1.	[11]	<input type="checkbox"/> No <input type="checkbox"/> Yes ^[12]
2.	[13]	<input type="checkbox"/> No <input type="checkbox"/> Yes ^[14]
3.	[15]	<input type="checkbox"/> No <input type="checkbox"/> Yes ^[16]

Code Table for Q7	
1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	88. Other (specify in comments)
9. Hard Palate	

- 7a. If alveolar ridge indicate location (mark all that apply)

- Anterior ^[17]
- Lateral ^[18]
- Superior ^[19]
- Inferior ^[20]

8. Primary Tumor Invasion (check all that apply)

- Muscle Invasion ^[21]
- Bone Invasion ^[22]
- Cartilage Invasion ^[23]
- Nerve Involvement ^[24]
- Fixed Vocal Cord ^[25]
- Superficial invasion ^[26]
- No invasion ^[27]

9. Lateralization of Tumor ^[28]

- Right
- Left
- Bilateral
- Midline

10. Which side of the neck is N0? ^[29]

- Right
- Left
- Both sides
- Neither side

I1

ACRIN 6685
FDG-PET/CT Staging of Head and Neck Cancer
Initial Evaluation Form

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

11. Number of Suspected Metastatic Lymph Nodes by Nodal Basins, based on clinical exam
(indicate number for all locations)

	Left	Right	No nodes seen
IA	[30]	[31]	<input type="checkbox"/> [32]
IB	[33]	[34]	<input type="checkbox"/> [35]
IIA	[36]	[37]	<input type="checkbox"/> [38]
IIB	[39]	[40]	<input type="checkbox"/> [41]
III	[42]	[43]	<input type="checkbox"/> [44]
IV	[45]	[46]	<input type="checkbox"/> [47]
V	[48]	[49]	<input type="checkbox"/> [50]
VI	[51]	[52]	<input type="checkbox"/> [53]

12. Other involved areas: _____ [54]

Comments: _____

 _____ [58]

 Initials of person completing the form [59]

_____-_____-_____
 Date form completed (mm-dd-yyyy) [60]

 Initials of person entering data onto the web [61]

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ **Institution No.** _____
Participant Initials _____ **Case No.** _____

13. Clinical Stage:

T Stage	N Stage	M Stage
[55]	[56]	[57]

Code Table for Q13		
T Stage	N Stage	M Stage
1 T1	1 N0	5 N2c
2 T2	2 N1	6 N3
3 T3	3 N2a	7 NX
4 T4	4 N2b	
		1 M0
		2 M1
		3 MX



ACRIN 6685

FDG-PET/CT Staging of Head and Neck Cancer

PET/CT Local Interpretation Form

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

ACRIN Study 6685 PLACE LABEL HERE

Institution Institution No.

Participant Initials Case No.

GENERAL IMAGING INFORMATION

1. If the patient is female, was a urine pregnancy test performed?

- No (Skip to Q2)
Yes (Complete Q1a)
Not applicable (Skip to Q2)

1a. Was the test negative?

- No
Yes

2. Did the patient consent to blood collection?

- No (Skip to Q3)
Yes (Complete Q2a)

2a. Was blood collected?

- No (complete Q2b)
Yes (skip to Q3)

2b. If no, will blood be collected prior to surgery?

- No
Yes

3. Date of PET/CT scan: (mm-dd-yyyy)

4. Reader ID

5. Image quality

- Adequate
Suboptimal (complete Q5a, then continue with form)
Uninterpretable (complete Q5a, then initial and date form)

5a. Reason suboptimal or uninterpretable [mark all that apply]

- Motion
Artifacts
Contrast Media
DICOM Header
Lost Images
Poor S/N
Incomplete anatomic coverage
Other, specify:

6. Did the study include a dedicated head and neck acquisition?

- No
Yes

7. Primary Tumor (List up to 3 primary tumors)

Table with 5 columns: Location, Malignancy (Refer to code table), Max SUV, Greatest Diameter (cm). Rows 1, 2, 3.

Primary Tumor Code Table for Q7

- 1. Tongue (tip) 10. Buccal Mucosa
2. Tongue (lateral) 11. Tonsil
3. Tongue (base) 12. Hypopharynx
4. Floor of Mouth (anterior) 13. Larynx (supraglottic)
5. Floor of Mouth (lateral) 14. Larynx (glottic)
6. Alveolar Ridge 15. Larynx (subglottic)
7. Retromolar Trigone (maxillar) 16. Larynx (transglottic)
8. Retromolar Trigone (mandibular) 17. Primary not seen
9. Hard Palate 88. Other (specify in comments)

Malignancy Code Table for Q7

- 1. Definitely Benign 4. Probably Malignant
2. Probably Benign 5. Definitely Malignant
3. Indeterminate

7a. If alveolar ridge indicate location (mark all that apply)

- Anterior
Lateral
Superior
Inferior

8. Primary Tumor Invasion (check all that apply)

- Muscle Invasion
Bone Invasion
Cartilage Invasion
Nerve Involvement
Fixed Vocal Cord
Superficial invasion
No invasion

9. Lateralization of Tumor

- Right
Left
Bilateral
Midline



ACRIN 6685
PET/CT Local Interpretation Form

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

10. Location of Nodal Basins

Left

	Malignancy <i>(Refer to code table)</i>	Max SUV	Extra-capsular spread?	Necrosis present?
IA	[52]	[49]	[50] O No O Yes	[51] O No O Yes
IB	[58]	[55]	[56] O No O Yes	[57] O No O Yes
IIA	[64]	[61]	[62] O No O Yes	[63] O No O Yes
IIB	[70]	[67]	[68] O No O Yes	[69] O No O Yes
III	[76]	[73]	[74] O No O Yes	[75] O No O Yes
IV	[82]	[79]	[80] O No O Yes	[81] O No O Yes
V	[88]	[85]	[86] O No O Yes	[87] O No O Yes
VI	[94]	[91]	[92] O No O Yes	[93] O No O Yes

Malignancy Code Table for Q10

- | | |
|-----------------------|-------------------------|
| 1. Definitely Benign | 5. Definitely Malignant |
| 2. Probably Benign | 6. No nodes seen |
| 3. Indeterminate | 7. Not imaged |
| 4. Probably Malignant | |

11. Overall visual neck assessment

	Left	Right
Overall visual assessment	[164] O Positive O Negative	[165] O Positive O Negative

12. Are distant metastases present? [144]

- No (*Skip to Q13*)
 Yes (*Complete Q12a*)
 Indeterminate (*Skip to Q13*)

12a. Location of metastasis (check all that apply)

- Lung [145]
 Distant lymph nodes [146]
 Liver [147]
 Adrenals [148]
 Bone [149]
 Brain [150]
 Skin [151]
 Kidneys [152]
 Other, [153] specify: _____ [154]

13. Were non-head and neck primaries seen? [155]

- No
 Yes, specify _____ [156]

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Right

	Malignancy <i>(Refer to code table)</i>	Max SUV	Extra-capsular spread?	Necrosis present?
IA	[100]	[97]	[98] O No O Yes	[99] O No O Yes
IB	[106]	[103]	[104] O No O Yes	[105] O No O Yes
IIA	[112]	[109]	[110] O No O Yes	[111] O No O Yes
IIB	[118]	[115]	[116] O No O Yes	[117] O No O Yes
III	[124]	[121]	[122] O No O Yes	[123] O No O Yes
IV	[130]	[127]	[128] O No O Yes	[129] O No O Yes
V	[136]	[133]	[134] O No O Yes	[135] O No O Yes
VI	[142]	[139]	[140] O No O Yes	[141] O No O Yes

14. Clinical Stage based on PET/CT:

T Stage	N Stage	M Stage
[157]	[158]	[159]

Code Table for Q14

T Stage	N Stage	M Stage
1 T1	1 N0	5 N2c
2 T2	2 N1	6 N3
3 T3	3 N2a	7 NX
4 T4	4 N2b	
5 TX		
		1 M0
		2 M1
		3 MX

Comments: _____

 _____ [160]

 _____ [161]
 Initials of person responsible for data

 _____ [162]
 Date form completed

 _____ [163]
 Initials of person entering data onto the web

M4**ACRIN 6685****FDG-PET/CT Staging of
Head and Neck Cancer****MRI Interpretation Form**If this is a revised or corrected form, please box. **GENERAL IMAGING INFORMATION**

1. Reader ID [1]
2. Date of MRI scan ____ - ____ - ____ (mm-dd-yyyy) [2]
3. Image quality [3]
 Adequate
 Suboptimal
 Uninterpretable (complete Q3a then initial and date form)
- 3a. Reason uninterpretable [mark all that apply]
 Motion [4]
 Artifacts [5]
 Contrast Media [6]
 DICOM Header [7]
 Lost Images [8]
 Poor S/N [9]
 Incomplete anatomic coverage [10]
 Other, [11] specify _____ [12]
4. Was T-1 weighted pre-contrast imaging performed? [13]
 No
 Yes
- 4a. Was T-1 weighted post-contrast imaging performed? [14]
 No
 Yes
- 4b. Was T2 weighted imaging performed? [15]
 No
 Yes
- 4c. Was FLAIR imaging performed? [16]
 No
 Yes
- 4d. Was diffusion-weighted or diffusion tensor imaging performed? [17]
 No
 Yes
5. Subject weight _____ . _____ kg [18]
(measured on day of scan) Unknown [19]
6. Was contrast used? [20]
 No (Skip to Q12)
 Yes
7. Time of injection (military time) _____ : _____ [21]

ACRIN Study 6685
PLACE LABEL HERE
Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

8. Rate of injection _____ cc/sec [22]
9. Volume of contrast injection _____ . _____ cc [23]
10. Volume of saline injection _____ . _____ cc [24]
11. Brand of contrast agent injected (check only one) [25]
 Magnevist
 Omniscan
 ProHance
 OptiMark
 MultiHance
 Other, specify _____ [26]
12. Scan start time (military time) _____ : _____ [27]
13. Scan stop time (military time) _____ : _____ [28]
14. Primary Tumor (List up to 3 primary tumors)

	Location	Greatest Diameter (cm)
1	[29]	[30]
2	[31]	[32]
3	[33]	[34]

Code Table for Q14

1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	17. Primary not seen
9. Hard Palate	88. Other (specify in comments)

14a. If alveolar ridge indicate location (mark all that apply)

-
- Anterior [35]
-
-
- Lateral [36]
-
-
- Superior [37]
-
-
- Inferior [38]

15. Primary Tumor Invasion (check all that apply)

-
- Muscle Invasion [39]
-
-
- Bone Invasion [40]
-
-
- Cartilage Invasion [41]
-
-
- Nerve Involvement [42]
-
-
- Fixed Vocal Cord [43]
-
-
- Superficial invasion [44]
-
-
- No invasion [45]



**ACRIN 6685
FDG-PET/CT Staging of
Head and Neck Cancer
MRI Interpretation Form**

ACRIN Study **6685**
PLACE LABEL HERE

Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

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

16. Lateralization of Tumor [46]

- Right
- Left
- Bilateral
- Midline

17. Number of nodal basins identified _____ [47]

18. Number of suspected metastatic lymph nodes by nodal basins (indicate number for all locations)

	Left	Right	Extra-capsular spread?	Necrosis present?	No nodes seen
IA	[48]	[49]	[50] <input type="checkbox"/> No <input type="checkbox"/> Yes	[51] <input type="checkbox"/> No <input type="checkbox"/> Yes	[52] <input type="checkbox"/>
IB	[53]	[54]	[55] <input type="checkbox"/> No <input type="checkbox"/> Yes	[56] <input type="checkbox"/> No <input type="checkbox"/> Yes	[57] <input type="checkbox"/>
IIA	[58]	[59]	[60] <input type="checkbox"/> No <input type="checkbox"/> Yes	[61] <input type="checkbox"/> No <input type="checkbox"/> Yes	[62] <input type="checkbox"/>
IIB	[63]	[64]	[65] <input type="checkbox"/> No <input type="checkbox"/> Yes	[66] <input type="checkbox"/> No <input type="checkbox"/> Yes	[67] <input type="checkbox"/>
III	[68]	[69]	[70] <input type="checkbox"/> No <input type="checkbox"/> Yes	[71] <input type="checkbox"/> No <input type="checkbox"/> Yes	[72] <input type="checkbox"/>
IV	[73]	[74]	[75] <input type="checkbox"/> No <input type="checkbox"/> Yes	[76] <input type="checkbox"/> No <input type="checkbox"/> Yes	[77] <input type="checkbox"/>
V	[78]	[79]	[80] <input type="checkbox"/> No <input type="checkbox"/> Yes	[81] <input type="checkbox"/> No <input type="checkbox"/> Yes	[82] <input type="checkbox"/>
VI	[83]	[84]	[85] <input type="checkbox"/> No <input type="checkbox"/> Yes	[86] <input type="checkbox"/> No <input type="checkbox"/> Yes	[87] <input type="checkbox"/>
Total	[88]	[89]			

19. Other involved areas: _____ [90]

Comments: _____

_____ [91]

Initials of person completing the form [92]

____ - ____ - _____ [93]
Date form completed (mm-dd-yyyy)

Initials of person entering data onto the web [94]



ACRIN 6685
 Pathology Report Review Form

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ **Institution No.** _____

Participant Initials _____ **Case No.** _____

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

1. Pathology report available ^[1]

- No (if no initial and date form)
- Yes

2. Date of surgery _____ - _____ - _____ (mm-dd-yyyy) ^[2]

3. HPV testing ^[3]

- Positive
- Equivocal
- Negative
- Not done

4. P16 test results ^[4]

- Strongly diffusely positive
- Strongly focally positive
- Weakly focally positive
- Negative
- Not done

_____ ^[5]
 Initials of person(s) completing this form

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



**ACRIN 6685
Local Pathology Form**

**ACRIN Study 6685
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

- 1. Is pathology data available to complete this form?** ^[1]
 No (Provide reason in question 1a, then sign and date form.)
 Yes (Skip to question 2)

- 1a. If not, what is the reason that data is unavailable?** ^[2]
 Records not available from outside institution
 Specimen lost or unavailable for review
 Specimen inadequate
 Unknown
 Other, specify _____ ^[3]

2. Date specimen was obtained _____ ^[4]
 (mm-dd-yyyy)

3. Date of pathology review _____ ^[5]
 (mm-dd-yyyy)

4. How many primary tumors were identified? _____ ^[6]

5. Primary Tumor (List up to 3 primary tumors)

	Location	Greatest Diameter (cm)	Histology SCC?
1.	[7]	[8]	<input type="checkbox"/> No <input type="checkbox"/> Yes ^[9]
2.	[10]	[11]	<input type="checkbox"/> No <input type="checkbox"/> Yes ^[12]
3.	[13]	[14]	<input type="checkbox"/> No <input type="checkbox"/> Yes ^[15]

Primary Tumor Code Table for Q5	
1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	88. Other (specify in comments)
9. Hard Palate	

5a. If alveolar ridge, indicate location (mark all that apply)

- Anterior ^[16]
 Lateral ^[17]
 Superior ^[18]
 Inferior ^[19]

6. Primary Tumor Invasion (check all that apply)

- Muscle Invasion ^[20]
 Bone Invasion ^[21]
 Cartilage Invasion ^[22]
 Nerve Involvement ^[23]
 Fixed Vocal Cord ^[24]
 Superficial invasion ^[25]
 No invasion ^[26]

7. Were clear margins obtained? ^[27]

- No
 Yes

8. Histologic Grade (G) ^[28]

- GX Grade cannot be assessed
 G1 Well differentiated
 G2 Moderately differentiated
 G3 Poorly differentiated
 G4 Undifferentiated

9. HPV testing ^[153]

- Positive
 Equivocal
 Negative
 Not done

10. P16 test results ^[154]

- Strongly diffusely positive
 Strongly focally positive
 Weakly focally positive
 Negative
 Not done



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

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

DISSECTION INFORMATION

11. Location of Nodal Basins

Right Side

Level	Specimen Submitted	Number of positive lymph nodes	Number of lymph nodes identified	Max tumor deposit: cross-sectional diameter (mm)	Max tumor deposit: perpendicular diameter (mm)	Histology SCC?	Extra-capsular spread?	Necrosis present?
IA	<input type="checkbox"/> [158]	[29]	[30]	[31]	[32]	<input type="checkbox"/> No <input type="checkbox"/> Yes [33]	<input type="checkbox"/> No <input type="checkbox"/> Yes [34]	<input type="checkbox"/> No <input type="checkbox"/> Yes [35]
IB	<input type="checkbox"/> [159]	[36]	[37]	[38]	[39]	<input type="checkbox"/> No <input type="checkbox"/> Yes [40]	<input type="checkbox"/> No <input type="checkbox"/> Yes [41]	<input type="checkbox"/> No <input type="checkbox"/> Yes [42]
IIA	<input type="checkbox"/> [160]	[43]	[44]	[45]	[46]	<input type="checkbox"/> No <input type="checkbox"/> Yes [47]	<input type="checkbox"/> No <input type="checkbox"/> Yes [48]	<input type="checkbox"/> No <input type="checkbox"/> Yes [49]
IIB	<input type="checkbox"/> [161]	[50]	[51]	[52]	[53]	<input type="checkbox"/> No <input type="checkbox"/> Yes [54]	<input type="checkbox"/> No <input type="checkbox"/> Yes [55]	<input type="checkbox"/> No <input type="checkbox"/> Yes [56]
III	<input type="checkbox"/> [162]	[57]	[58]	[59]	[60]	<input type="checkbox"/> No <input type="checkbox"/> Yes [61]	<input type="checkbox"/> No <input type="checkbox"/> Yes [62]	<input type="checkbox"/> No <input type="checkbox"/> Yes [63]
IV	<input type="checkbox"/> [163]	[64]	[65]	[66]	[67]	<input type="checkbox"/> No <input type="checkbox"/> Yes [68]	<input type="checkbox"/> No <input type="checkbox"/> Yes [69]	<input type="checkbox"/> No <input type="checkbox"/> Yes [70]
V	<input type="checkbox"/> [164]	[71]	[72]	[73]	[74]	<input type="checkbox"/> No <input type="checkbox"/> Yes [75]	<input type="checkbox"/> No <input type="checkbox"/> Yes [76]	<input type="checkbox"/> No <input type="checkbox"/> Yes [77]
VI	<input type="checkbox"/> [165]	[78]	[79]	[80]	[81]	<input type="checkbox"/> No <input type="checkbox"/> Yes [82]	<input type="checkbox"/> No <input type="checkbox"/> Yes [83]	<input type="checkbox"/> No <input type="checkbox"/> Yes [84]
Total		[85]	[86]					

Left Side

Level	Specimen Submitted	Number of positive lymph nodes	Number of lymph nodes identified	Max tumor deposit: cross-sectional diameter (mm)	Max tumor deposit: perpendicular diameter (mm)	Histology SCC?	Extra-capsular spread?	Necrosis present?
IA	<input type="checkbox"/> [166]	[87]	[88]	[89]	[90]	<input type="checkbox"/> No <input type="checkbox"/> Yes [91]	<input type="checkbox"/> No <input type="checkbox"/> Yes [92]	<input type="checkbox"/> No <input type="checkbox"/> Yes [93]
IB	<input type="checkbox"/> [167]	[94]	[95]	[96]	[97]	<input type="checkbox"/> No <input type="checkbox"/> Yes [98]	<input type="checkbox"/> No <input type="checkbox"/> Yes [99]	<input type="checkbox"/> No <input type="checkbox"/> Yes [100]
IIA	<input type="checkbox"/> [168]	[101]	[102]	[103]	[104]	<input type="checkbox"/> No <input type="checkbox"/> Yes [105]	<input type="checkbox"/> No <input type="checkbox"/> Yes [106]	<input type="checkbox"/> No <input type="checkbox"/> Yes [107]
IIB	<input type="checkbox"/> [169]	[108]	[109]	[110]	[111]	<input type="checkbox"/> No <input type="checkbox"/> Yes [112]	<input type="checkbox"/> No <input type="checkbox"/> Yes [113]	<input type="checkbox"/> No <input type="checkbox"/> Yes [114]
III	<input type="checkbox"/> [170]	[115]	[116]	[117]	[118]	<input type="checkbox"/> No <input type="checkbox"/> Yes [119]	<input type="checkbox"/> No <input type="checkbox"/> Yes [120]	<input type="checkbox"/> No <input type="checkbox"/> Yes [121]
IV	<input type="checkbox"/> [171]	[122]	[123]	[124]	[125]	<input type="checkbox"/> No <input type="checkbox"/> Yes [126]	<input type="checkbox"/> No <input type="checkbox"/> Yes [127]	<input type="checkbox"/> No <input type="checkbox"/> Yes [128]
V	<input type="checkbox"/> [172]	[129]	[130]	[131]	[132]	<input type="checkbox"/> No <input type="checkbox"/> Yes [133]	<input type="checkbox"/> No <input type="checkbox"/> Yes [134]	<input type="checkbox"/> No <input type="checkbox"/> Yes [135]
VI	<input type="checkbox"/> [173]	[136]	[137]	[138]	[139]	<input type="checkbox"/> No <input type="checkbox"/> Yes [140]	<input type="checkbox"/> No <input type="checkbox"/> Yes [141]	<input type="checkbox"/> No <input type="checkbox"/> Yes [142]
Total		[143]	[144]					

12. Other involved areas: _____ [145]

13. Pathologic Stage:

T Stage	N Stage	M Stage
[146]	[147]	[148]

T Stage	N Stage	M Stage
1. T1	1. N0	1. M0
2. T2	2. N1	2. M1
3. T3	3. N2a	3. MX
4. T4	4. N2b	
	5. N2c	
	6. N3	
	7. NX	

Comments: _____

Initials of person responsible for data [150]

Date form completed (mm-dd-yyyy) [151]

Initials of person entering data onto the web [152]



PET/CT Central Interpretation Form

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

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

GENERAL IMAGING INFORMATION

1. Reader ID [1]
2. Date of PET/CT scan: ____-____-____ (mm-dd-yyyy) [14]

3. Image quality [2]
- Adequate
 - Adequate-Primary included in dedicated head and neck image
 - Suboptimal (complete Q3a, then continue with form)
 - Uninterpretable (complete Q3a, then initial and date form)

- 3a. Reason suboptimal or uninterpretable [mark all that apply]
- Motion [3]
 - Artifacts [4]
 - Contrast Media [5]
 - DICOM Header [6]
 - Lost Images [7]
 - Poor S/N [8]
 - Incomplete anatomic coverage [9]
 - Other, [10] specify: _____ [11]

4. Images being read [12]
- Whole body PET/CT
 - Dedicated head and neck scan

5. Primary Tumor (List up to 3 primary tumors)

	Location	Malignancy (Refer to code table)	Max SUV	Greatest Diameter (cm)
1	[20]	[24]	[22]	[23]
2	[25]	[29]	[27]	[28]
3	[30]	[34]	[32]	[33]

Primary Tumor Code Table for Q5	
1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	17. Primary not seen
9. Hard Palate	88. Other (specify in comments)

Malignancy Code Table for Q5	
1. Definitely Benign	4. Probably Malignant
2. Probably Benign	5. Definitely Malignant
3. Indeterminate	

5a. If alveolar ridge indicate location (mark all that apply)

- Anterior [35]
- Lateral [36]
- Superior [37]
- Inferior [38]

6. Primary Tumor Invasion (check all that apply)

- Muscle Invasion [39]
- Bone Invasion [40]
- Cartilage Invasion [41]
- Nerve Involvement [42]
- Fixed Vocal Cord [43]
- Superficial invasion [44]
- No invasion [45]

7. Lateralization of Tumor [46]

- Right
- Left
- Bilateral
- Midline



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

8. Location of Nodal Basins

Left

	Malignancy (Refer to code table)	Max SUV	Extra-capsular spread?	Necrosis present?
IA	[52]	[49]	[50] O No O Yes	[51] O No O Yes
IB	[58]	[55]	[56] O No O Yes	[57] O No O Yes
IIA	[64]	[61]	[62] O No O Yes	[63] O No O Yes
IIB	[70]	[67]	[68] O No O Yes	[69] O No O Yes
III	[76]	[73]	[74] O No O Yes	[75] O No O Yes
IV	[82]	[79]	[80] O No O Yes	[81] O No O Yes
V	[88]	[85]	[86] O No O Yes	[87] O No O Yes
VI	[94]	[91]	[92] O No O Yes	[93] O No O Yes
Other	[166]	[167]	[168] O No O Yes	[169] O No O Yes

Malignancy Code Table for Q8	
1. Definitely Benign	5. Definitely Malignant
2. Probably Benign	6. No nodes seen
3. Indeterminate	7. Not imaged
4. Probably Malignant	

9. Overall visual neck assessment

	Left	Right
Overall visual assessment	[164] O Positive O Negative	[165] O Positive O Negative

10. Are distant metastases present? [144]

- No (Skip to Q11)
- Yes (Complete Q10a)
- Indeterminate (Skip to Q11)

10a. Location of metastasis (check all that apply)

- Lung [145]
- Distant lymph nodes [146]
- Liver [147]
- Adrenals [148]
- Bone [149]
- Brain [150]
- Skin [151]
- Kidneys [152]
- Other, [153] specify: _____ [154]

11. Were non-head and neck primaries seen? [155]

- No
- Yes, specify _____ [156]

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Right

	Malignancy (Refer to code table)	Max SUV	Extra-capsular spread?	Necrosis present?
IA	[100]	[97]	[98] O No O Yes	[99] O No O Yes
IB	[106]	[103]	[104] O No O Yes	[105] O No O Yes
IIA	[112]	[109]	[110] O No O Yes	[111] O No O Yes
IIB	[118]	[115]	[116] O No O Yes	[117] O No O Yes
III	[124]	[121]	[122] O No O Yes	[123] O No O Yes
IV	[130]	[127]	[128] O No O Yes	[129] O No O Yes
V	[136]	[133]	[134] O No O Yes	[135] O No O Yes
VI	[142]	[139]	[140] O No O Yes	[141] O No O Yes
Other	[170]	[171]	[172] O No O Yes	[173] O No O Yes

12. Clinical Stage based on PET/CT:

T Stage	N Stage	M Stage
[157]	[158]	[159]

Code Table for Q12		
T Stage	N Stage	M Stage
1 T1	1 N0 5 N2c	1 M0
2 T2	2 N1 6 N3	2 M1
3 T3	3 N2a 7 NX	3 MX
4 T4	4 N2b	
5 TX		

Comments: _____

_____ [160,174, 175, 176]

_____ [161]
Initials of person responsible for data

_____-_____-_____- [162]
Date form completed

_____ [163]
Initials of person completing form



**ACRIN 6685
PROTOCOL DEVIATION FORM**

**ACRIN Study 6685
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

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)* ^[1]

- Inclusion/exclusion criteria not met at time of registration/randomization *(complete Q1a)*
- Imaging-related deviation *(complete 1b)*
- Study activity performed prior to participant signing study consent form
- Baseline QOL questionnaires not administered or completed
- PET/CT not performed
- PET/CT not done within 14 days of surgery
- Patient consented to blood collection but no sample taken
- PET/CT images not reviewed by surgeon prior to surgery
- Participant did not have surgery
- Case enrolled under expired IRB approval/FWA
- Incomplete neck dissection
- N0 neck(s) not dissected
- Pre-registration PET from PET/CT used in initial diagnosis
- Nodal dissections not separated by level for pathology analysis
- Blood specimen hemolyzed
- Sera not separated within 2 hours of collection
- Other, specify: _____ ^[2]

1a. Inclusion/exclusion deviation: *(select only one)* ^[3]

- CT/MR not done within 4 weeks of registration
- Neither side of neck is N0
- Participant does not have pathology-proven SCC head and neck cancer
- T1 stage at enrollment

1b. Imaging deviation: *(select only one)* ^[4]

- PET / CT interpretation guidelines not followed
- PET / CT scan performed on a non-ACRIN qualified scanner
- PET / CT scan performed at a non-ACRIN qualified institution
- PET / CT images lost or unavailable
- Blood glucose over acceptable limit at time of PET/CT scan
- PET / CT not performed within 50-70 minutes post-injection
- Head and neck not included in whole body images
- Incorrect imaging parameters



**ACRIN 6685
PROTOCOL DEVIATION FORM**

**ACRIN Study 6685
PLACE LABEL HERE**

Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

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

2. Date the protocol deviation occurred: _____ - _____ - **20**_____ (mm-dd-yyyy) [5]

3. Date the protocol deviation was discovered: _____ - _____ - **20**_____ (mm-dd-yyyy) [6]

4. Describe the protocol deviation:

_____ [7]
_____ [8]

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

_____ [9]
_____ [10]

Person responsible for data (RA, study staff) [11]

_____ - _____ - **20**_____ (mm-dd-yyyy) [12]
Date Form Completed

Investigator Signature



**ACRIN 6685
Central Pathology Review Form**

**ACRIN Study 6685
PLACE LABEL HERE**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

- 1. Is pathology data available to complete this form?** [1]
 No (*Provide reason in question 1a, then sign and date form.*)
 Yes (*Skip to question 2*)

- 1a. If not, what is the reason that data is unavailable?** [2]
 Records not available from outside institution
 Specimen lost or unavailable for review
 Specimen inadequate
 Unknown
 Other, specify _____ [3]

2. Date specimen was obtained _____ [4]
 (mm-dd-yyyy)

3. Date of pathology review _____ [5]
 (mm-dd-yyyy)

4. How many primary tumors were identified? _____ [6]

5. Primary Tumor (*List up to 3 primary tumors*)

	Location	Greatest Diameter (cm)	Histology SCC?
1.	[7]	[8]	<input type="checkbox"/> No <input type="checkbox"/> Yes [9]
2.	[10]	[11]	<input type="checkbox"/> No <input type="checkbox"/> Yes [12]
3.	[13]	[14]	<input type="checkbox"/> No <input type="checkbox"/> Yes [15]

Primary Tumor Code Table for Q5	
1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	88. Other (specify in comments)
9. Hard Palate	

- 5a. If alveolar ridge, indicate location** (*mark all that apply*)
- Anterior [16]
 Lateral [17]
 Superior [18]
 Inferior [19]

6. Primary Tumor Invasion (check all that apply)

- Muscle Invasion [20]
 Bone Invasion [21]
 Cartilage Invasion [22]
 Nerve Involvement [23]
 Fixed Vocal Cord [24]
 Superficial invasion [25]
 No invasion [26]

7. Were clear margins obtained? [27]
 No
 Yes

8. Histologic Grade (G) [28]
 GX Grade cannot be assessed
 G1 Well differentiated
 G2 Moderately differentiated
 G3 Poorly differentiated
 G4 Undifferentiated

9. HPV testing [153]
 Positive
 Equivocal
 Negative
 Not done

10. P16 test results [154]
 Strongly diffusely positive
 Strongly focally positive
 Weakly focally positive
 Negative
 Not done



Institution _____ Institution No. _____
Participant Initials _____ Case No. _____

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

DISSECTION INFORMATION

11. Location of Nodal Basins

Right Side

Level	Specimen Submitted	Number of positive lymph nodes	Number of lymph nodes identified	Max tumor deposit: cross-sectional diameter (mm)	Max tumor deposit: perpendicular diameter (mm)	Histology SCC?	Extra-capsular spread?	Necrosis present?
IA	<input type="checkbox"/> [158]	[29]	[30]	[31]	[32]	<input type="checkbox"/> No <input type="checkbox"/> Yes [33]	<input type="checkbox"/> No <input type="checkbox"/> Yes [34]	<input type="checkbox"/> No <input type="checkbox"/> Yes [35]
IB	<input type="checkbox"/> [159]	[36]	[37]	[38]	[39]	<input type="checkbox"/> No <input type="checkbox"/> Yes [40]	<input type="checkbox"/> No <input type="checkbox"/> Yes [41]	<input type="checkbox"/> No <input type="checkbox"/> Yes [42]
IIA	<input type="checkbox"/> [160]	[43]	[44]	[45]	[46]	<input type="checkbox"/> No <input type="checkbox"/> Yes [47]	<input type="checkbox"/> No <input type="checkbox"/> Yes [48]	<input type="checkbox"/> No <input type="checkbox"/> Yes [49]
IIB	<input type="checkbox"/> [161]	[50]	[51]	[52]	[53]	<input type="checkbox"/> No <input type="checkbox"/> Yes [54]	<input type="checkbox"/> No <input type="checkbox"/> Yes [55]	<input type="checkbox"/> No <input type="checkbox"/> Yes [56]
III	<input type="checkbox"/> [162]	[57]	[58]	[59]	[60]	<input type="checkbox"/> No <input type="checkbox"/> Yes [61]	<input type="checkbox"/> No <input type="checkbox"/> Yes [62]	<input type="checkbox"/> No <input type="checkbox"/> Yes [63]
IV	<input type="checkbox"/> [163]	[64]	[65]	[66]	[67]	<input type="checkbox"/> No <input type="checkbox"/> Yes [68]	<input type="checkbox"/> No <input type="checkbox"/> Yes [69]	<input type="checkbox"/> No <input type="checkbox"/> Yes [70]
V	<input type="checkbox"/> [164]	[71]	[72]	[73]	[74]	<input type="checkbox"/> No <input type="checkbox"/> Yes [75]	<input type="checkbox"/> No <input type="checkbox"/> Yes [76]	<input type="checkbox"/> No <input type="checkbox"/> Yes [77]
VI	<input type="checkbox"/> [165]	[78]	[79]	[80]	[81]	<input type="checkbox"/> No <input type="checkbox"/> Yes [82]	<input type="checkbox"/> No <input type="checkbox"/> Yes [83]	<input type="checkbox"/> No <input type="checkbox"/> Yes [84]
Total		[85]	[86]					

Left Side

Level	Specimen Submitted	Number of positive lymph nodes	Number of lymph nodes identified	Max tumor deposit: cross-sectional diameter (mm)	Max tumor deposit: perpendicular diameter (mm)	Histology SCC?	Extra-capsular spread?	Necrosis present?
IA	<input type="checkbox"/> [166]	[87]	[88]	[89]	[90]	<input type="checkbox"/> No <input type="checkbox"/> Yes [91]	<input type="checkbox"/> No <input type="checkbox"/> Yes [92]	<input type="checkbox"/> No <input type="checkbox"/> Yes [93]
IB	<input type="checkbox"/> [167]	[94]	[95]	[96]	[97]	<input type="checkbox"/> No <input type="checkbox"/> Yes [98]	<input type="checkbox"/> No <input type="checkbox"/> Yes [99]	<input type="checkbox"/> No <input type="checkbox"/> Yes [100]
IIA	<input type="checkbox"/> [168]	[101]	[102]	[103]	[104]	<input type="checkbox"/> No <input type="checkbox"/> Yes [105]	<input type="checkbox"/> No <input type="checkbox"/> Yes [106]	<input type="checkbox"/> No <input type="checkbox"/> Yes [107]
IIB	<input type="checkbox"/> [169]	[108]	[109]	[110]	[111]	<input type="checkbox"/> No <input type="checkbox"/> Yes [112]	<input type="checkbox"/> No <input type="checkbox"/> Yes [113]	<input type="checkbox"/> No <input type="checkbox"/> Yes [114]
III	<input type="checkbox"/> [170]	[115]	[116]	[117]	[118]	<input type="checkbox"/> No <input type="checkbox"/> Yes [119]	<input type="checkbox"/> No <input type="checkbox"/> Yes [120]	<input type="checkbox"/> No <input type="checkbox"/> Yes [121]
IV	<input type="checkbox"/> [171]	[122]	[123]	[124]	[125]	<input type="checkbox"/> No <input type="checkbox"/> Yes [126]	<input type="checkbox"/> No <input type="checkbox"/> Yes [127]	<input type="checkbox"/> No <input type="checkbox"/> Yes [128]
V	<input type="checkbox"/> [172]	[129]	[130]	[131]	[132]	<input type="checkbox"/> No <input type="checkbox"/> Yes [133]	<input type="checkbox"/> No <input type="checkbox"/> Yes [134]	<input type="checkbox"/> No <input type="checkbox"/> Yes [135]
VI	<input type="checkbox"/> [173]	[136]	[137]	[138]	[139]	<input type="checkbox"/> No <input type="checkbox"/> Yes [140]	<input type="checkbox"/> No <input type="checkbox"/> Yes [141]	<input type="checkbox"/> No <input type="checkbox"/> Yes [142]
Total		[143]	[144]					

12. Other involved areas: _____ [145]

13. Pathologic Stage:

T Stage	N Stage	M Stage
[146]	[147]	[148]

T Stage	N Stage	M Stage
1. T1	1. N0	1. M0
2. T2	2. N1	2. M1
3. T3	3. N2a	3. MX
4. T4	4. N2b	5. N2c
	6. N3	
	7. NX	

14. Agree with Local Pathology assessment? [174]

- No
- Yes

Comments: _____ [149]

Initials of person responsible for data [150]

Date form completed (mm-dd-yyyy) [151]

Initials of person entering data onto the web [152]

S1

ACRIN 6685 FDG-PET/CT Staging of Head and Neck Cancer Pre-Surgery Planning Form

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

Part 1

Pre-PET/CT Review

1. Primary tumor (list up to 3 primary tumors)

	Location	
1.		[1]
2.		[2]
3.		[3]

Code Table for Q1

1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	88. Other (specify in comments)
9. Hard Palate	

1a. If alveolar ridge indicate location (mark all that apply)

- Anterior [4]
 Lateral [5]
 Superior [6]
 Inferior [7]

2. Planned Nodal dissections (check levels dissected)

not Marked, Marked

	Left	Right
IA	[8]	[9]
IB	[10]	[11]
IIA	[12]	[13]
IIB	[14]	[15]
III	[16]	[17]
IV	[18]	[19]
V	[20]	[21]
VI	[22]	[23]

ACRIN Study 6685 PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Part 2

Post-PET/CT Review

3. Were PET/CT images reviewed? [24]

- No
 Yes

4. Was nodal dissection plan changed based on PET/CT findings? [25]

- No (Skip to Q5)
 Yes (Complete Q4a)

4a. What was changed because of PET/CT findings? [26]

- Side
 Level
 Both

5. Were distant metastases seen on PET/CT? [27]

- No
 Yes

6. Will nodal dissection still be performed? [28]

- No (initial and date form)
 Yes

7. Planned Nodal Dissections after PET/CT review? (check levels dissected)

not Marked, Marked

	Left	Right
IA	[29]	[30]
IB	[31]	[32]
IIA	[33]	[34]
IIB	[35]	[36]
III	[37]	[38]
IV	[39]	[40]
V	[41]	[42]
VI	[43]	[44]

Comments: _____

_____ [45]

_____ [46]

Initials of person completing the form

_____ [47]

Date form completed (mm-dd-yyyy)

_____ [48]

Initials of person entering data onto the web



ACRIN 6685
FDG-PET/CT Staging of
Head and Neck Cancer
Post-Surgery Form

ACRIN Study **6685**
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

1. Was Surgery performed? [1]

- No (complete Q1a, then initial and date form)
- Yes (skip to Q2)

1a. Reason surgery not performed: (check only one) [2]

- Scheduling Problem
- Participant refusal
- Medical contraindication
- Participant withdrew consent
- Progressive disease/ palliation
- Participant Death
- Adverse Event
- Other, specify _____ [3]

2. Date of surgery _____ - _____ - _____ (mm-dd-yyyy) [4]

3. Primary tumor (list up to 3 primary tumors)

	Location	
1.		[5]
2.		[6]
3.		[7]

Code Table for Q3	
1. Tongue (tip)	10. Buccal Mucosa
2. Tongue (lateral)	11. Tonsil
3. Tongue (base)	12. Hypopharynx
4. Floor of Mouth (anterior)	13. Larynx (supraglottic)
5. Floor of Mouth (lateral)	14. Larynx (glottic)
6. Alveolar Ridge	15. Larynx (subglottic)
7. Retromolar Trigone (maxillar)	16. Larynx (transglottic)
8. Retromolar Trigone (mandibular)	88. Other (specify in comments)
9. Hard Palate	

3a. If alveolar ridge, indicate location (mark all that apply)

- Anterior [8]
- Lateral [9]
- Superior [10]
- Inferior [11]

4. Nodal dissection performed (check levels dissected)

- Not Marked, Marked

	Left	Right
IA	[12]	[13]
IB	[14]	[15]
IIA	[16]	[17]
IIB	[18]	[19]
III	[20]	[21]
IV	[22]	[23]
V	[24]	[25]
VI	[26]	[27]

5. Other involved areas _____ [28]

6. Clinical Stage

T Stage	N Stage	M Stage
[29]	[30]	[31]

Code Table for Q6			
T Stage	N Stage		M Stage
1. T1	1. N0	5. N2c	1. M0
2. T2	2. N1	6. N3	2. M1
3. T3	3. N2a	7. NX	3. MX
4. T4	4. N2b		



ACRIN 6685
FDG-PET/CT Staging of
Head and Neck Cancer
Post-Surgery Form

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Pathology Submission

7. Level IA ^[36]

- Left and/or right submitted separately
- Submitted as midline
- Not dissected

8. Level I ^[37]

- A and/or B submitted separately
- A and B submitted together
- Not dissected

9. Level II ^[38]

- A and/or B submitted separately
- A and B submitted together
- Not dissected

Comments: _____

_____ ^[32]

_____ ^[33]
 Initials of person completing the form

____ - ____ - _____ ^[34]
 Date form completed (mm-dd-yyyy)

_____ ^[35]
 Initials of person entering data onto the web



ACRIN 6685

FDG - PET/CT Staging of Head and Neck Cancer
PET/CT Central Reader Adjudication Form

ACRIN Study 6685
PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Instructions: Please complete only the highlighted questions.

General Imaging Information

1. Adjudicator's Reader ID _____ [1]

2. Series to be adjudicated (check all that apply)

- WB PET/CT Left neck (Complete Q3 "left") [2]
- WB PET/CT Right neck (Complete Q3 "right") [3]
- WB PET/CT Distant mets (Complete Q4) [4]
- Dedicated Head & Neck PET/CT Left neck (Complete Q5 "left") [5]
- Dedicated Head & Neck PET/CT Right neck (Complete Q5 "right") [6]

WB PET/CT

3. Overall PET/CT visual neck assessment

	Left	Right
Overall visual assessment	<input type="radio"/> Positive [7] <input type="radio"/> Negative <input type="checkbox"/> Not reviewed [8]	<input type="radio"/> Positive [9] <input type="radio"/> Negative <input type="checkbox"/> Not reviewed [10]

4. Are Distant Metastases present? [11]

- No
- Yes
- Indeterminate
- Not reviewed [12]

Dedicated Head & Neck PET/CT

5.

	Left	Right
Overall visual assessment	<input type="radio"/> Positive [13] <input type="radio"/> Negative <input type="checkbox"/> Not reviewed [14]	<input type="radio"/> Positive [15] <input type="radio"/> Negative <input type="checkbox"/> Not reviewed [16]

6. Date of Imaging [17]

_____ - _____ - _____

COMMENTS: _____

_____ [18]

_____ [19]
Initials of person(s) responsible for the data

_____ [20]
Date form completed (mm-dd-yyyy)

_____ [21]
Initials of person(s) completing form



Imaging Agent: FDG

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

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

Exam Data

1. Clinical trial time point ^[1]

Visit 2

2. Imaging Agent Name ^[2]

FDG

3. Was imaging exam completed? ^[4]

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

Claustrophobia ^[5]

Adverse event (complete AE form)

Equipment failure

Blood glucose level

Participant death

Participant refusal

Participant withdrew consent

Unknown

Medical reason

Progressive disease

Other, specify: _____ ^{6]}

Injection site complications

Imaging agent not administered

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

____ - ____ - _____

5. Weight

____ . ____ kg ^[8]

Unknown ^[9]

6. Height

____ cm ^[10]

Unknown ^[11]

Patient Preparation

Not Done ^[12]

1. Duration of fasting pre-imaging:

____ hours (up to time of injection) ^[13] Unknown ^[14]

2. Blood glucose before injection of FDG ^[15]

(record value measured before injection)

____ . ____ mg/dl Unknown ^[16]

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

____ : ____ Unknown ^[18]

3. Was Foley catheter in place for study? ^[19]

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



Imaging Agent: **FDG**

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

Scanner

Not Done [22]

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

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

3. Scanner used for this exam:

3a. Manufacturer

_____ [27]

3b. Manufacturer model name/or number

_____ [28]

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

____ - ____ - ____ (mm-dd-yyyy)

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

No Yes

CT Image Acquisition or Transmission Scan

Not Done [37]

1. Type of attenuation correction used? [38]

- CT (complete Q2 thru 6)
- Cs-137 Segmentation (complete Q7)
- Ge-68 Segmentation (complete Q7)

2. Was oral contrast administered? [39]

- No (skip to Q3)
- Yes, if used specify type: [40] Positive Negative

2a. Amount [41]

____|____|____|____ ml Unknown [42]

3. Was IV contrast administered? [43]

- No (skip to Q4)
- Yes

3a. Amount [44]

____|____|____|____ ml Unknown [45]

3b. Time of injection [46]

____|____ : ____|____ (military time) Unknown [47]

4. kVp

____|____|____|____ [48]
 Unknown [49]

5. mAs

____|____|____|____ [50]
 Unknown [51]

6. Slice Thickness of reconstructed images

____|____ . ____|____ mm [52]
 Unknown [53]

7. Length of Transmission Scan:

____|____|____|____ (minutes) [54] Unknown [55]



Imaging Agent: FDG

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

PET Emission Scan

Not Done ^[56]

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

2. Number of bed positions scanned ^[58]

PET Emission Scan:

Start Time (military time)

Stop Time (military time)

3a. : ^[60]

3b. : ^[61]

Reconstructed Images:

4. Pixel Size: . mm ^[62]

5. Thickness: . mm ^[63]

Adverse Events

1. Any adverse events related to imaging to report for this timepoint? ^[82]
 No (initial and date form) Yes (Submit AE form)

2. Does this event meet the criteria of a serious adverse event? ^[83]
 No Yes

 Initials of person completing this form ^[84]

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



ACRIN 6685
FDG-PET/CT Staging of Head and Neck Cancer
FDG-PET Imaging-Related Drug History

ACRIN Study 6685

Case #

PLACE LABEL HERE

Institution _____ Institution No. _____

Participant Initials _____ Case No. _____

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

1. **Clinical trial time point:** ^[1] Visit 2

2. **Is the participant a known diabetic?** ^[2] No 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]

No Yes, check drug(s) used Unknown

A sulfonylurea, ^[4] drug name _____ ^[5] given _____ ^[6] hours before FDG

Metformin ^[7] given _____ ^[8] hours before FDG

Other oral agent (s) ^[9] drug name _____ ^[10] given _____ ^[11] hours before FDG
 drug name _____ ^[12] given _____ ^[13] hours before FDG

Short-acting insulin ^[14] given, _____ ^[15] hours before FDG, given (check one) ^[16] Intravenously
Record 99 if hours unknown Subcutaneously
 Inhaled

Intermediate or long-acting insulin ^[17] given _____ ^[18] hours before FDG

Insulin Pump ^[19] (check one) ^[20] On during FDG injection and uptake period
 Off during FDG injection and uptake period, off _____ ^[21] hours before FDG

Other injectable agent ^[22] specify _____ ^[23] given _____ ^[24] 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*

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

Taken _____ ^[38] hours before FDG

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