



ACRIN 6685

Registration / Randomization

ACRIN Study 6685  
PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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

## DEMOGRAPHICS

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

1. Name of institutional person registering this case \_\_\_\_\_ [1]
3. Is the participant eligible for this study? [3]  
☐ 1 No ☐ 2 Yes
4. Date the study-specific consent form was signed (mm-dd-yyyy) **(Must be prior to study entry)** \_\_\_\_-\_\_\_\_-\_\_\_\_ [4]
5. Participant's Initials (*last, first*) (*L, F*) \_\_\_\_\_ [5]
6. Verifying physician (Site PI) \_\_\_\_\_ [6]
8. Date of birth (*mm-dd-yyyy*) \_\_\_\_-\_\_\_\_-\_\_\_\_ [8]
9. Ethnicity [9]  
☐ 1 Hispanic or Latino ☐ 3 Not reported  
☐ 2 Not Hispanic or Latino ☐ 9 Unknown
11. Gender [11] ☐ 1 Male ☐ 2 Female
12. Participant's country of residence **(if other, complete Q12a)** [12]  
☐ 1 United States ☐ 3 Other  
☐ 2 Canada ☐ 9 Unknown  
  
12a. Other country, specify (completed if Q12 is coded "other") \_\_\_\_\_ [18]
13. Zip Code **(5 digit code, US residents)** \_\_\_\_\_ [13]
14. Participant's insurance status [14]  
☐ 0 Other ☐ 5 Medicaid and Medicare  
☐ 1 Private Insurance ☐ 6 Military or Veteran's Administration  
☐ 2 Medicare ☐ 7 Self Pay  
☐ 3 Medicare and Private Insurance ☐ 8 No means of payment  
☐ 4 Medicaid ☐ 9 Unknown/Decline to answer
15. Will any component of the participant's care be given at a military or VA facility? [15]  
☐ 1 No ☐ 2 Yes ☐ 9 Unknown
16. Calendar base date [Date of registration] (*mm-dd-yyyy*) \_\_\_\_-\_\_\_\_-\_\_\_\_ [16]
17. Date of registration (*mm-dd-yyyy*) \_\_\_\_-\_\_\_\_-\_\_\_\_ [17]  
  
Race (check all that apply) ☐ =1 No, ☒ =2 Yes
  19. ☐ American Indian or Alaskan Native [19]
  20. ☐ Asian [20]
  21. ☐ Black or African American [21]
  22. ☐ Native Hawaiian or other Pacific Islander [22]
  23. ☐ White [23]
  24. ☐ Unknown [24]
  44. ☐ Not reported [55]

**A0****ACRIN 6685  
Registration/Eligibility Checklist**

ACRIN Study 6685

**PLACE LABEL HERE**

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? <sup>[28]</sup>  
☐ 1 No ☐ 2 Yes
26. Does the participant have histological confirmation of a first time diagnosed SCC head & neck? <sup>[29]</sup>  
☐ 1 No ☐ 2 Yes
27. Is unilateral or bilateral neck dissection planned for the patient's care? <sup>[30]</sup>  
☐ 1 No ☐ 2 Yes
28. Has the participant had CT or MR images taken within six (6) weeks prior to enrollment? <sup>[54]</sup>  
☐ 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)? <sup>[32]</sup>  
☐ 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? <sup>[53]</sup>  
☐ 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? <sup>[33]</sup>  
☐ 1 No ☐ 2 Yes
31. Does the participant have one of the following? <sup>[56]</sup>  
☐ Oral cavity cancer <sup>[34]</sup>  
☐ Oropharynx cancer, including base of tongue and tonsil <sup>[35]</sup>  
☐ Larynx cancer <sup>[36]</sup>  
☐ Supraglottic cancer <sup>[37]</sup>  
☐ None of the above
- 31a. List any second primary: \_\_\_\_\_ <sup>[57]</sup>
32. Is the participant willing to provide a written informed consent? <sup>[38]</sup>  
☐ 1 No ☐ 2 Yes

**A0****ACRIN 6685  
Registration/Eligibility Checklist**

ACRIN Study 6685

**PLACE LABEL HERE**

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? <sup>[39]</sup>  
☐ 1 No ☐ 2 Yes
34. Does the patient have sinonasal carcinoma? <sup>[40]</sup>  
☐ 1 No ☐ 2 Yes
35. Does the patient have tumors in the head and neck that are not SCC? <sup>[41]</sup>  
☐ 1 No ☐ 2 Yes
36. Does the patient have salivary gland malignancies? <sup>[42]</sup>  
☐ 1 No ☐ 2 Yes
37. Does the patient have thyroid cancer? <sup>[43]</sup>  
☐ 1 No ☐ 2 Yes
38. Does the patient have advanced skin cancer? <sup>[44]</sup>  
☐ 1 No ☐ 2 Yes
39. Does the patient have nasopharyngeal carcinoma? <sup>[45]</sup>  
☐ 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? <sup>[58]</sup>  
☐ 1 No ☐ 2 Yes
41. Is the patient not a candidate for surgery due to an underlying medical condition? <sup>[47]</sup>  
☐ 1 No ☐ 2 Yes
43. Is the patient's weight > than PET/CT table weight limit? <sup>[52]</sup>  
☐ 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 <sup>[49]</sup>\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
Date form completed (mm-dd-yyyy) <sup>[50]</sup>\_\_\_\_\_  
Initials of Person(s) completing this form <sup>[51]</sup>



**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** <sup>[12]</sup>

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

5c.

☐
**Soft Tissue** <sup>[13]</sup>

- 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** <sup>[14]</sup>

- |                        |                          |
|------------------------|--------------------------|
| 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** <sup>[16]</sup>

- |                          |                           |
|--------------------------|---------------------------|
| 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** <sup>[18]</sup>

- 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. ☐

**ACRIN Study 6685**  
**PLACE LABEL HERE**

**Institution** \_\_\_\_\_ **Institution No.** \_\_\_\_\_

**Participant Initials** \_\_\_\_\_ **Case No.** \_\_\_\_\_

**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]

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





**ACRIN 6685**  
**FDG-PET/CT Staging of Head and**  
**Neck Cancer**  
**CT 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. ☐

**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]

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

\_\_\_\_\_  
Initials of person entering data onto the web [88]



ACRIN 6685

FDG-PET/CT Staging of  
Head and Neck Cancer

**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:** <sup>[1]</sup>

- ☐ 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:** \_\_\_\_\_<sup>[2]</sup> / \_\_\_\_\_<sup>[3]</sup> / \_\_\_\_\_<sup>[4]</sup> (mm/dd/yyyy)

**Cause of death** <sup>[5]</sup>

- ☐ 1 Disease Progression
- ☐ 88 Other, specify \_\_\_\_\_<sup>[6]</sup>
- ☐ 5 Adverse Event / Side Effects / Complications
- ☐ 6 Protocol violation: (*check all that apply*)
  - ☐ Did not meet eligibility<sup>[7]</sup>
  - ☐ Technical problems<sup>[8]</sup>
  - ☐ Related to study visits<sup>[9]</sup>
  - ☐ Related to imaging<sup>[10]</sup>
  - ☐ Related to randomization<sup>[11]</sup>
  - ☐ Other<sup>[12]</sup> (*specify below*)
- ☐ 8 Study terminated by sponsor
- ☐ 88 Other (*specify reason below*)

DSe1=7 Disease progression

Specify reason: \_\_\_\_\_<sup>[13]</sup>

**2. Date of disposition:** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ (mm/dd/yyyy) <sup>[14]</sup>

**3. Did the investigator review and sign off on the participant's disposition?** <sup>[15]</sup>

- ☐ 1 No
- ☐ 2 Yes

**Comments:** \_\_\_\_\_<sup>[16]</sup>

\_\_\_\_\_<sup>[17]</sup>  
Initials of person completing the form

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_<sup>[18]</sup>  
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 \_\_\_\_\_



## Imaging Agent: FDG

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

### Exam Data

1. Planned time point: <sup>[1]</sup>

☐ Visit 2

2. Was imaging agent administered? <sup>[2]</sup>

☐ No (Initial & date form) ☐ Yes

3. Imaging agent name: <sup>[3]</sup>

☒ FDG

4. Administration date: <sup>[4]</sup>

\_\_\_\_ - \_\_\_\_ - \_\_\_\_ (mm-dd-yyyy)

### Imaging Agent Procurement

5. Identification number (Lot #): <sup>[5]</sup> \_\_\_\_\_

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

6a. Method: <sup>[7]</sup> \_\_\_\_\_

6b. Supplier: <sup>[8]</sup> \_\_\_\_\_

### Administration Information

7. Route of administration: <sup>[9]</sup>

☒ IV

8. Activity in full syringe before injection:

\_\_\_\_ . \_\_\_\_ mCi <sup>[10]</sup>

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

\_\_\_\_ : \_\_\_\_ (military time) <sup>[11]</sup>

☐ Unknown <sup>[12]</sup>

9. Time of injection:

\_\_\_\_ : \_\_\_\_ (military time) <sup>[13]</sup>

☐ Unknown <sup>[14]</sup>

10. Residual activity in syringe after injection:

\_\_\_\_ . \_\_\_\_ mCi <sup>[15]</sup>

☐ Unknown <sup>[16]</sup>  
(if unk, skip to Q12)

10a. Time of assay of residual activity after injection:

\_\_\_\_ : \_\_\_\_ (military time) <sup>[17]</sup>

☐ Unknown <sup>[18]</sup>

11. Net activity administered (Dosage Amount):

\_\_\_\_ . \_\_\_\_ mCi <sup>[19]</sup>

12. Site of injection: <sup>[20]</sup>

☐ Right antecubital ☐ Left antecubital  
☐ Right wrist ☐ Left wrist  
☐ Right foot ☐ Left foot  
☐ Indwelling central catheter ☐ Unknown  
☐ Other, specify <sup>[21]</sup> \_\_\_\_\_

13. Any infiltration at injection site noted? <sup>[22]</sup>

☐ 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 <sup>[23]</sup>

\_\_\_\_ - \_\_\_\_ - \_\_\_\_  
Date form completed (mm-dd-yyyy) <sup>[24]</sup>

**F1****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
o 1= Positive [44]	o Positive [45]
o 2= Negative	o Negative
o 3= Completely resected	o Completely resected
o 99= Unknown	o Unknown

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

ACRIN Study 6685

**PLACE LABEL HERE**If this is a revised or corrected form, please ☒ box. ☐

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 _____	____-____-____ [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

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

ACRIN Study 6685  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**GENERAL IMAGING INFORMATION****1. Was endoscopy performed** <sup>[1]</sup>

- ☐ No (*skip to Q2*)  
☐ Yes

**1a. Where was the endoscopy performed?** <sup>[2]</sup>

- ☐ Office (*flexible*)  
☐ OR (*direct*)

**2. Is there evidence of vocal cord paralysis?** <sup>[3]</sup>

- ☐ No  
☐ Yes

**3. Was a diagnostic MRI performed within 6 weeks of enrollment?** <sup>[62]</sup>

- ☐ No  
☐ Yes

**4. Was a diagnostic CT performed within 6 weeks of enrollment?** <sup>[63]</sup>

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

**4a. Was the CT obtained from a PET/CT?** <sup>[6]</sup>

- ☐ No  
☐ Yes

**5. Subject weight** \_\_\_\_\_ **kg** <sup>[7]</sup>

☐ Unknown <sup>[8]</sup>

**6. Subject height** \_\_\_\_\_ **cm** <sup>[9]</sup>

☐ Unknown <sup>[10]</sup>

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

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

**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 <sup>[17]</sup>  
☐ Lateral <sup>[18]</sup>  
☐ Superior <sup>[19]</sup>  
☐ Inferior <sup>[20]</sup>

**8. Primary Tumor Invasion** (check all that apply)

- ☐ Muscle Invasion <sup>[21]</sup>  
☐ Bone Invasion <sup>[22]</sup>  
☐ Cartilage Invasion <sup>[23]</sup>  
☐ Nerve Involvement <sup>[24]</sup>  
☐ Fixed Vocal Cord <sup>[25]</sup>  
☐ Superficial invasion <sup>[26]</sup>  
☐ No invasion <sup>[27]</sup>

**9. Lateralization of Tumor** <sup>[28]</sup>

- ☐ Right  
☐ Left  
☐ Bilateral  
☐ Midline

**10. Which side of the neck is N0?** <sup>[29]</sup>

- ☐ 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]

**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	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:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_ [58]

\_\_\_\_\_ [59]  
Initials of person completing the form

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

\_\_\_\_\_ [61]  
Initials of person entering data onto the web



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 ☒ 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? <sup>[12]</sup>

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

1a. Was the test negative? <sup>[13]</sup>

- ☐ No  
☐ Yes

2. Did the patient consent to blood collection? <sup>[15]</sup>

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

2a. Was blood collected? <sup>[16]</sup>

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

2b. If no, will blood be collected prior to surgery? <sup>[17]</sup>

- ☐ No  
☐ Yes

3. Date of PET/CT scan: \_\_\_\_-\_\_\_\_-\_\_\_\_ (mm-dd-yyyy) <sup>[14]</sup>4. Reader ID         <sup>[1]</sup>5. Image quality <sup>[2]</sup>

- ☐ 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 <sup>[3]</sup>  
☐ Artifacts <sup>[4]</sup>  
☐ Contrast Media <sup>[5]</sup>  
☐ DICOM Header <sup>[6]</sup>  
☐ Lost Images <sup>[7]</sup>  
☐ Poor S/N <sup>[8]</sup>  
☐ Incomplete anatomic coverage <sup>[9]</sup>  
☐ Other, <sup>[10]</sup> specify: \_\_\_\_\_ <sup>[11]</sup>

6. Did the study include a dedicated head and neck acquisition? <sup>[18]</sup>

- ☐ No  
☐ Yes

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

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

## 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 <sup>[35]</sup>  
☐ Lateral <sup>[36]</sup>  
☐ Superior <sup>[37]</sup>  
☐ Inferior <sup>[38]</sup>

## 8. Primary Tumor Invasion (check all that apply)

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

9. Lateralization of Tumor <sup>[46]</sup>

- ☐ 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 (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

### 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 (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

## 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 2 T2 3 T3 4 T4 5 TX	1 N0 2 N1 3 N2a 4 N2b 5 N2c 6 N3 7 NX	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]

**M4****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"/>
<b>Total</b>	[88]	[89]			

**19. Other involved areas:** \_\_\_\_\_ [90]**Comments:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_ [91]

\_\_\_\_\_  
Initials of person completing the form [92]\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
Date form completed (mm-dd-yyyy) [93]\_\_\_\_\_  
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** <sup>[1]</sup>

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

**2. Date of surgery** \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (mm-dd-yyyy) <sup>[2]</sup>**3. HPV testing** <sup>[3]</sup>

- ☐ Positive  
☐ Equivocal  
☐ Negative  
☐ Not done

**4. P16 test results** <sup>[4]</sup>

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

\_\_\_\_\_  
Initials of person(s) completing this form <sup>[5]</sup>\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_  
Date form completed (mm-dd-yyyy) <sup>[6]</sup>

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?** <sup>[1]</sup>☐ 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?** <sup>[2]</sup>☐ Records not available from outside institution☐ Specimen lost or unavailable for review☐ Specimen inadequate☐ Unknown☐ Other, specify \_\_\_\_\_ <sup>[3]</sup>**2. Date specimen was obtained** \_\_\_\_\_ <sup>[4]</sup>  
(mm-dd-yyyy)**3. Date of pathology review** \_\_\_\_\_ <sup>[5]</sup>  
(mm-dd-yyyy)**4. How many primary tumors were identified?** \_\_\_\_\_ <sup>[6]</sup>**5. Primary Tumor** (List up to 3 primary tumors)

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

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 <sup>[16]</sup>☐ Lateral <sup>[17]</sup>☐ Superior <sup>[18]</sup>☐ Inferior <sup>[19]</sup>**6. Primary Tumor Invasion** (check all that apply)☐ Muscle Invasion <sup>[20]</sup>☐ Bone Invasion <sup>[21]</sup>☐ Cartilage Invasion <sup>[22]</sup>☐ Nerve Involvement <sup>[23]</sup>☐ Fixed Vocal Cord <sup>[24]</sup>☐ Superficial invasion <sup>[25]</sup>☐ No invasion <sup>[26]</sup>**7. Were clear margins obtained?** <sup>[27]</sup>☐ No☐ Yes**8. Histologic Grade (G)** <sup>[28]</sup>☐ GX Grade cannot be assessed☐ G1 Well differentiated☐ G2 Moderately differentiated☐ G3 Poorly differentiated☐ G4 Undifferentiated**9. HPV testing** <sup>[153]</sup>☐ Positive☐ Equivocal☐ Negative☐ Not done**10. P16 test results** <sup>[154]</sup>☐ 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]
<b>Total</b>		[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]
<b>Total</b>		[143]	[144]					

12. Other involved areas: \_\_\_\_\_ [145]

13. Pathologic Stage:

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

Code Table for Q13		
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]

# ACRIN 6685

## FDG-PET/CT Staging of Head and Neck Cancer

# PET/CT Central Interpretation Form

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

ACRIN Study 6685

**PLACE LABEL HERE**

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 <sup>[12]</sup>

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



# ACRIN 6685 PET/CT Central Interpretation Form

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]

ACRIN Study 6685

PLACE LABEL HERE

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)** <sup>[1]</sup>

- ☐ 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: \_\_\_\_\_ <sup>[2]</sup>

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

- ☐ 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)** <sup>[4]</sup>

- ☐ 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

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

ACRIN Study 6685  
PLACE LABEL HERE

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

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]

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

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

\_\_\_\_\_  
Investigator Signature

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?** <sup>[1]</sup>

- ☐ 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?** <sup>[2]</sup>

- ☐ Records not available from outside institution  
☐ Specimen lost or unavailable for review  
☐ Specimen inadequate  
☐ Unknown  
☐ Other, specify \_\_\_\_\_ <sup>[3]</sup>

**2. Date specimen was obtained** \_\_\_\_\_ <sup>[4]</sup>  
(mm-dd-yyyy)**3. Date of pathology review** \_\_\_\_\_ <sup>[5]</sup>  
(mm-dd-yyyy)**4. How many primary tumors were identified?** \_\_\_\_\_ <sup>[6]</sup>**5. Primary Tumor** (List up to 3 primary tumors)

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

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 <sup>[16]</sup>  
☐ Lateral <sup>[17]</sup>  
☐ Superior <sup>[18]</sup>  
☐ Inferior <sup>[19]</sup>

**6. Primary Tumor Invasion** (check all that apply)

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

**7. Were clear margins obtained?** <sup>[27]</sup>

- ☐ No  
☐ Yes

**8. Histologic Grade (G)** <sup>[28]</sup>

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

**9. HPV testing** <sup>[153]</sup>

- ☐ Positive  
☐ Equivocal  
☐ Negative  
☐ Not done

**10. P16 test results** <sup>[154]</sup>

- ☐ 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]

Code Table for Q13		
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	5. N2c	
	6. N3	
	7. NX	
	4. N2b	

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. ☐**ACRIN Study 6685  
PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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]

**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**

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

**ACRIN Study 6685**  
**PLACE LABEL HERE**

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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 2. T2 3. T3 4. T4	1. N0 2. N1 3. N2a 4. N2b	5. N2c 6. N3 7. NX 1. M0 2. M1 3. MX



**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** <sup>[36]</sup>

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

**8. Level I** <sup>[37]</sup>

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

**9. Level II** <sup>[38]</sup>

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

**Comments:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_ <sup>[32]</sup>

\_\_\_\_\_  
Initials of person completing the form <sup>[33]</sup>

\_\_\_\_ - \_\_\_\_ - \_\_\_\_ <sup>[34]</sup>  
Date form completed (mm-dd-yyyy)

\_\_\_\_\_  
Initials of person entering data onto the web <sup>[35]</sup>



ACRIN 6685

FDG - PET/CT Staging of Head and Neck Cancer  
PET/CT Central Reader Adjudication FormACRIN 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	<div><div><input type="radio"/> Positive</div><div><input type="radio"/> Negative</div><div><input type="checkbox"/> Not reviewed</div></div> <div><div>[7]</div><div></div><div>[8]</div></div>	<div><div><input type="radio"/> Positive</div><div><input type="radio"/> Negative</div><div><input type="checkbox"/> Not reviewed</div></div> <div><div>[9]</div><div></div><div>[10]</div></div>

4. Are Distant Metastases present? [11]

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

**Dedicated Head & Neck PET/CT**

5.

	Left	Right
Overall visual assessment	<div><div><input type="radio"/> Positive</div><div><input type="radio"/> Negative</div><div><input type="checkbox"/> Not reviewed</div></div>	<div><div><input type="radio"/> Positive</div><div><input type="radio"/> Negative</div><div><input type="checkbox"/> Not reviewed</div></div>

6. Date of Imaging [17]

\_\_\_\_ - \_\_\_\_ - \_\_\_\_

COMMENTS: \_\_\_\_\_

\_\_\_\_\_  
[18]\_\_\_\_\_  
Initials of person(s) responsible for the data [19]\_\_\_\_\_  
Date form completed (mm-dd-yyyy) [20]\_\_\_\_\_  
Initials of person(s) completing form [21]





**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** <sup>[1]</sup>

☐ Visit 2

**2. Imaging Agent Name** <sup>[2]</sup>

☐ FDG

**3. Was imaging exam completed?** <sup>[4]</sup>

☐ 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:** <sup>[5]</sup>

☐ Scheduling problem

☐ Claustrophobia

☐ Adverse event (complete AE form)

☐ Equipment failure

☐ Blood glucose level

☐ Participant death

☐ Participant refusal

☐ Participant withdrew consent

☐ Unknown

☐ Medical reason

☐ Progressive disease

☐ Other, specify: \_\_\_\_\_ <sup>[6]</sup>

☐ Injection site complications

☐ Imaging agent not administered

**4. Date of imaging:** <sup>[7]</sup> (mm-dd-yyyy)

\_\_\_\_ - \_\_\_\_ - \_\_\_\_

**5. Weight**

\_\_\_\_ . \_\_\_\_ kg <sup>[8]</sup>

☐ Unknown <sup>[9]</sup>

**6. Height**

\_\_\_\_ cm <sup>[10]</sup>

☐ Unknown <sup>[11]</sup>

**Patient Preparation**

☐ Not Done <sup>[12]</sup>

**1. Duration of fasting pre-imaging:**

\_\_\_\_ hours (up to time of injection) <sup>[13]</sup> ☐ Unknown <sup>[14]</sup>

**2. Blood glucose before injection of FDG** <sup>[15]</sup>

(record value measured before injection)

\_\_\_\_ mg/dl ☐ Unknown <sup>[16]</sup>

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

\_\_\_\_ : \_\_\_\_ ☐ Unknown <sup>[18]</sup>

**3. Was Foley catheter in place for study?** <sup>[19]</sup>

☐ No (complete Q4-Q5) ☐ Yes (skip to next section)

**4. Patient voided immediately pre-imaging?** <sup>[20]</sup>

☐ No ☐ Yes ☐ Unknown

**5. Patient voided immediately post-imaging?** <sup>[21]</sup>

☐ No ☐ Yes ☐ Unknown



ACRIN 6685  
FDG - PET/CT  
PET/CT Local Technical Assessment Form

ACRIN Study 6685  
PLACE LABEL HERE

Imaging Agent: **FDG**

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**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]



ACRIN 6685  
FDG - PET/CT  
PET/CT Local Technical Assessment Form

ACRIN Study 6685  
PLACE LABEL HERE

Imaging Agent: **FDG**

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

Institution \_\_\_\_\_ Institution No. \_\_\_\_\_

Participant Initials \_\_\_\_\_ Case No. \_\_\_\_\_

**PET Emission Scan**

☐ Not Done<sup>[56]</sup>

1. Acquisition mode<sup>[57]</sup>      ☐ 2D      ☐ 3D

2. Number of bed positions scanned   <sup>[58]</sup>

PET Emission Scan:

Start Time (military time)

Stop Time (military time)

3a.   :  <sup>[60]</sup>

3b.   :  <sup>[61]</sup>

Reconstructed Images:

4. Pixel Size:  .   mm<sup>[62]</sup>

5. Thickness:  .   mm<sup>[63]</sup>

**Adverse Events**

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

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

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

☐ No      ☐ Yes

\_\_\_\_\_<sup>[84]</sup>  
Initials of person completing this form

\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_<sup>[85]</sup>  
Date form completed (mm-dd-yyyy)



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: <sup>[1]</sup> ☐ Visit 2

2. Is the participant a known diabetic? <sup>[2]</sup> ☐ 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? <sup>[3]</sup>

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

☐ A sulfonylurea, <sup>[4]</sup> drug name \_\_\_\_\_ <sup>[5]</sup> given \_\_\_\_\_ <sup>[6]</sup> hours before FDG

☐ Metformin <sup>[7]</sup> given \_\_\_\_\_ <sup>[8]</sup> hours before FDG

☐ Other oral agent (s) <sup>[9]</sup> drug name \_\_\_\_\_ <sup>[10]</sup> given \_\_\_\_\_ <sup>[11]</sup> hours before FDG  
drug name \_\_\_\_\_ <sup>[12]</sup> given \_\_\_\_\_ <sup>[13]</sup> hours before FDG

☐ Short-acting insulin <sup>[14]</sup> given, \_\_\_\_\_ <sup>[15]</sup> hours before FDG, given (check one) <sup>[16]</sup> ☐ Intravenously  
*Record 99 if hours unknown* ☐ Subcutaneously  
☐ Inhaled

☐ Intermediate or long-acting insulin <sup>[17]</sup> given \_\_\_\_\_ <sup>[18]</sup> hours before FDG

☐ Insulin Pump <sup>[19]</sup> (check one) <sup>[20]</sup> ☐ On during FDG injection and uptake period  
☐ Off during FDG injection and uptake period, off \_\_\_\_\_ <sup>[21]</sup> hours before FDG

☐ Other injectable agent <sup>[22]</sup> specify \_\_\_\_\_ <sup>[23]</sup> given \_\_\_\_\_ <sup>[24]</sup> hours before FDG

☐ Unknown <sup>[25]</sup> *Record 99 if hours unknown*

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

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

☐ A benzodiazepine to decrease brown fat FDG uptake, <sup>[27]</sup> drug name \_\_\_\_\_ <sup>[28]</sup>

☐ A beta-blocker to decrease brown fat FDG uptake, <sup>[29]</sup> drug name \_\_\_\_\_ <sup>[30]</sup>

☐ A diuretic to decrease urinary tract activity, <sup>[31]</sup> drug name \_\_\_\_\_ <sup>[32]</sup>

☐ Sedation or anesthesia <sup>[33]</sup>

☐ Other drug(s), <sup>[34]</sup> drug name (s) \_\_\_\_\_ <sup>[35]</sup>

☐ Unknown <sup>[36]</sup>

4. Is the participant currently being treated with corticosteroids? <sup>[37]</sup> ☐ No ☐ Yes ☐ Unknown

Taken \_\_\_\_\_ <sup>[38]</sup> hours before FDG

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

Agent Name: \_\_\_\_\_ <sup>[40]</sup>

Given approximately \_\_\_\_\_ days ago <sup>[41]</sup>

☐ Unknown <sup>[42]</sup>

\_\_\_\_\_  
Initials of Person(s) Completing this Form <sup>[43]</sup>

\_\_\_\_\_  
Date form completed (mm-dd-yyyy) <sup>[44]</sup>