ACRIN 6685

Staging of Head and Neck Cancer: Assessment of FDG-PET/CT
and the Impact on N0 Neck Surgical Treatment

CRF Set

ACRIN 6685

Registration / Randomization

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

ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ **Institution No.** ____________

Participant Initials ____________ **Case No.** ____________

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]
   O 1 No O 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]
   O 1 Hispanic or Latino
   O 2 Not Hispanic or Latino
   O 3 Not reported
   O 9 Unknown

11. Gender [11] O 1 Male O 2 Female

12. Participant's country of residence **(if other, complete Q12a)** [12]
   O 1 United States
   O 2 Canada
   O 3 Other
   O 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]
   O 0 Other
   O 1 Private Insurance
   O 2 Medicare
   O 3 Medicare and Private Insurance
   O 4 Medicaid
   O 5 Medicaid and Medicare
   O 6 Military or Veteran's Administration
   O 7 Self Pay
   O 8 No means of payment
   O 9 Unknown/Decline to answer

15. Will any component of the participant's care be given at a military or VA facility? [15]
   O 1 No O 2 Yes O 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]

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ACRIN 6685
Registration/Eligibility Checklist

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ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ Institution No. ____________

Participant Initials ____________ Case No. ____________

INCLUSION CRITERIA

25. Is the participant ≥ 18 years of age? [28]
    O 1 No O 2 Yes

26. Does the participant have histological confirmation of a first time diagnosed SCC head & neck? [29]
    O 1 No O 2 Yes

27. Is unilateral or bilateral neck dissection planned for the patient's care? [30]
    O 1 No O 2 Yes

28. Has the participant had CT or MR images taken within six (6) weeks prior to enrollment? [54]
    O 1 No O 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]
    O 1 No O 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]
    O 1 No O 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]
    O 1 No O 2 Yes

31. Does the participant have one of the following? [56]
    O Oral cavity cancer
    O Oropharynx cancer, including base of tongue and tonsil
    O Larynx cancer
    O Supraglottic cancer
    O None of the above

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

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

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ACRIN 6685
Registration/Eligibility Checklist

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ACRIN Study 6685
PLACE LABEL HERE

Institution ________ **Institution No.** ________

Participant Initials ________ **Case No.** ________

EXCLUSION CRITERIA

33. Is the patient pregnant and/or breast feeding? [39]
    O 1 No O 2 Yes

34. Does the patient have sinonasal carcinoma? [40]
    O 1 No O 2 Yes

35. Does the patient have tumors in the head and neck that are not SCC? [41]
    O 1 No O 2 Yes

36. Does the patient have salivary gland malignancies? [42]
    O 1 No O 2 Yes

37. Does the patient have thyroid cancer? [43]
    O 1 No O 2 Yes

38. Does the patient have advanced skin cancer? [44]
    O 1 No O 2 Yes

39. Does the patient have nasopharyngeal carcinoma? [45]
    O 1 No O 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]
    O 1 No O 2 Yes

41. Is the patient not a candidate for surgery due to an underlying medical condition? [47]
    O 1 No O 2 Yes

43. Is the patient's weight > than PET/CT table weight limit? [52]
    O 1 No O 2 Yes

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

____-____-________ [50]
Date form completed *(mm-dd-yyyy)*

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

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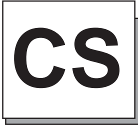

ACRIN 6685 Coversheet for Quality of Life Questionnaires

ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ Institution No. ____________

Participant Initials ____________ Case No. ____________

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

Instructions: This coversheet represents the first page of the Quality of Life (QOL) questionnaires and is completed by a Research Associate each time a participant is scheduled to complete any of the QOL questionnaires. This form is submitted via the ACRIN website. Submit paper form only in the event of a revised or corrected form via fax to ACRIN Data Management.

1. **Timepoint for this questionnaire** [1]
   - O Baseline
   - O 30 days post-surgery
   - O 1 year post-surgery
   - O 2 years post-surgery

Questionnaire Compliance

2. **Did participant answer any questionnaire items?** [2]
   - O No (answer Q2a, initial and date form)
   - O Yes, date questionnaire completed:

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

   2a. If no, please state reason: [4]
   - O Participant refused
   - O Participant ill or hospitalized
   - O Participant deceased
   - O Participant out of the country
   - O Incorrect contact information
   - O Telephone disconnected
   - O Participant unable to be contacted
   - O Form not available in participants language
   - O Other, specify: ____________ [5]

3. **Which questionnaires were completed?**
   (mark all that apply)
   - ☐ QL - HUI3 [6]
   - ☐ QM - SF - 36 v2 [7]
   - ☐ QN - UW - QOL v4 [8]
   - ☐ QO - HUI23 [25]

4. **Indicate the language of the QOL questionnaire by participant:** [9]
   - O English
   - O Spanish
   - O Other, specify ____________ [10]

5. **Did the participant require any assistance in completing the questionnaire?** [11]
   - O No (skip to Q6)
   - O Yes
   - O Unknown (skip to Q6)

   5a. Specify the person who assisted the participant in completing the questionnaire: [12]
   - O Staff member
   - O Family
   - O Other, specify: ____________ [13]
   - O Unknown

   5b. Extent of assistance (check all that apply):
   - ☐ Read items to participant [14]
   - ☐ Marked items per participant's response [15]
   - ☐ Interpreted items for participant [16]
   - ☐ Other, [17] specify: ____________ [18]
   - ☐ Unknown [19]

6. **Specify method of completion:** [20]
   - O At appointment
   - O By mail (include mailed questionnaire brought to the site completed)
   - O By telephone
   - O Unknown

Comments: ____ [21]

____________ [22]
Initials of person entering data onto web

____-____-______ [23]
Date form completed *(mm-dd-yyyy)*

____________ [24]
Initials of person responsible for data

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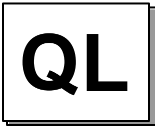

ACRIN 6654
NLST
Annual Health Status
Questionnaire (SF-36v2™, EQ-5D)

ACRIN Study 6654

PLACE LABEL HERE

Institution ______________ Institution No. ______________

Participant Initials ______________ Case No. ______________

Participant Instructions: As part of the study, we are interested in your views about your health. Please answer every question by marking your answer as indicated. If you are unsure about how to answer a question, give the best answer you can. Return this questionnaire to the NLST research associate once you have completed it.

Part 1 SF-36v2

1. In general, would you say your health is: (check the circle that best describes your answer)

Excellent	Very good	Good	Fair	Poor
O 1	O 2	O 3	O 4	O 5

2. *Compared to one year ago*, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
O 1	O 2	O 3	O 4	O 5

3. The following questions are about activities you might do during a typical day. *Does your health now limit* you in these activities? If so, how much?

(mark an X in a circle on each line)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3a. *Vigorous activities,* such as running, lifting heavy objects, participating in strenuous sports	O 1	O 2	O 3
3b. *Moderate activities,* such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O 1	O 2	O 3
3c. Lifting or carrying groceries	O 1	O 2	O 3
3d. Climbing *several* flights of stairs	O 1	O 2	O 3
3e. Climbing *one* flight of stairs	O 1	O 2	O 3
3f. Bending, kneeling, or stooping	O 1	O 2	O 3
3g. Walking *more than a mile*	O 1	O 2	O 3
3h. Walking *several hundred yards*	O 1	O 2	O 3
3i. Walking *one hundred yards*	O 1	O 2	O 3
3j. Bathing or dressing yourself	O 1	O 2	O 3

QL

ACRIN Study 6654

PLACE LABEL HERE

Institution ______________ Institution No. ______________

Participant Initials ______________ Case No. ______________

4. During the *past 4 weeks,* how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of your physical health*?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
4a. Cut down on the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
4b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
4c. Were limited in the *kind* of work or other activities	O 1	O 2	O 3	O 4	O 5
4d. Had *difficulty* performing the work or other activities (for example, it took extra effort)	O 1	O 2	O 3	O 4	O 5

5. During the *past 4 weeks*, how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
5a. Cut down the *amount of time* you spent on work or other activities	O 1	O 2	O 3	O 4	O 5
5b. *Accomplished less* than you would like	O 1	O 2	O 3	O 4	O 5
5c. Did work or activities *less carefully than usual*	O 1	O 2	O 3	O 4	O 5

6. During the past 4 *weeks*, to what *extent* has your *physical health or emotional problems* interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

7. How much *bodily* pain have you had during the *past 4 weeks*?

None	Very Mild	Mild	Moderate	Severe	Very Severe
O 1	O 2	O 3	O 4	O 5	O 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

QL

ACRIN Study 6654

PLACE LABEL HERE

Institution ______________ Institution No. ______________

Participant Initials ______________ Case No. ______________

9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*…

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
9a. Did you feel full of life?	O 1	O 2	O 3	O 4	O 5
9b. Have you been very nervous?	O 1	O 2	O 3	O 4	O 5
9c. Have you felt so down in the dumps that nothing could cheer you up?	O 1	O 2	O 3	O 4	O 5
9d. Have you felt calm and peaceful?	O 1	O 2	O 3	O 4	O 5
9e. Did you have a lot of energy?	O 1	O 2	O 3	O 4	O 5
9f. Have you felt downhearted and depressed?	O 1	O 2	O 3	O 4	O 5
9g. Did you feel worn out?	O 1	O 2	O 3	O 4	O 5
9h. Have you been happy?	O 1	O 2	O 3	O 4	O 5
9i. Did you feel tired?	O 1	O 2	O 3	O 4	O 5

10. During the *past 4 weeks*, how much of the time has your *physical health* or *emotional problems* interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
O 1	O 2	O 3	O 4	O 5

11. How TRUE or FALSE is *each* of the following statements for you?

	Definitely true	**Mostly true**	**Don't know**	**Mostly false**	**Definitely false**
11a. I seem to get sick a little easier than other people	O 1	O 2	O 3	O 4	O 5
11b. I am as healthy as anybody I know	O 1	O 2	O 3	O 4	O 5
11c. I expect my health to get worse	O 1	O 2	O 3	O 4	O 5
11d. My health is excellent	O 1	O 2	O 3	O 4	O 5

QL

ACRIN Study 6654

PLACE LABEL HERE

Institution ____________ Institution No. ____________

Participant Initials ____________ Case No. ____________

1. MOBILITY

☐ 1 I have no problems in walking about

☐ 2 I have some problems in walking about

☐ 3 I am confined to bed

2. SELF-CARE

☐ 1 I have no problems with self-care

☐ 2 I have some problems washing or dressing myself

☐ 3 I am unable to wash or dress myself

3. USUAL ACTIVITIES (e.g., work, study, housework, family or leisure activities)

☐ 1 I have no problems with performing my usual activities

☐ 2 I have some problems with performing my usual activities

☐ 3 I am unable to perform my usual activities

4. PAIN/DISCOMFORT

☐ 1 I have no pain or discomfort

☐ 2 I have moderate pain or discomfort

☐ 3 I have extreme pain or discomfort

5. ANXIETY/DEPRESSION

☐ 1 I am not anxious or depressed

☐ 2 I am moderately anxious or depressed

☐ 3 I am extremely anxious or depressed

Please check that you have completed every question then sign and date below.

____________ **Participants signature**

__ __ - __ __ - 2 0 0 __ **Date form completed (mm-dd-yyyy)**

____________ **Signature of person responsible for data**

____________ **Signature of person entering data onto web**

ACRIN 6685
FDG-PET/CT Staging of Head and Neck Cancer
Blood Collection 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 blood collected day of PET/CT?** [1]
   - O No
   - O Yes (skip to Q3)

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

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

   2a. Reason blood was not collected *(check only one)* [5]
   - O Scheduling problem
   - O Patient refusal
   - O Medical contraindication
   - O Patient death
   - O Other, specify ______________________ [6]
   - O 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]
   - O No
   - O Yes

7. **What temperature was blood stored at?** O Positive O Negative [16]

   ______________________ °C [11]

Comments: ____

____

____ [12]

______________________________ [13]
Initials of person responsible for the data

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

______________________________ [15]
Initials of person entering data onto the web

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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

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ACRIN Study 6685
PLACE LABEL HERE

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

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

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

6. ☐ **Histology** [18]

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

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BX

Revision ☐

ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ Institution No. ____________

Participant Initials ____________ Case No. ____________

COMMENTS: ____

____

____

____ [20]

____________________ [21]
Initials of person responsible for the data

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

____________________ [23]
Initials of person entering data onto the web

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

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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]
   - O No (*skip to Q4*)
   - O Yes *(Complete Q3a)*

   3a. **Was the CT read independent of the PET?** [4]
   - O No
   - O Yes

4. **Image quality** [5]
   - O Adequate
   - O Suboptimal
   - O 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]
   - O No *(Skip to Q6)*
   - O Yes *(Skip to Q5a)*

   5a. **Type of oral contrast used** [16]
   - O Positive contrast agent
   - O Negative contrast agent

6. **IV contrast used?** [17]
   - O No *(Skip to Q7)*
   - O 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)	88. Other (specify in comments)
9. Hard Palate	

   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]
   - O Right
   - O Left
   - O Bilateral
   - O Midline

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

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ACRIN Study 6685
PLACE LABEL HERE

Institution ______________ **Institution No.** ______________

Participant Initials ______________ **Case No.** ______________

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]	[44] ☐ No ☐ Yes	[45] ☐ No ☐ Yes	[46] ☐
IB	[47]	[48]	[49] ☐ No ☐ Yes	[50] ☐ No ☐ Yes	[51] ☐
IIA	[52]	[53]	[54] ☐ No ☐ Yes	[55] ☐ No ☐ Yes	[56] ☐
IIB	[57]	[58	[59] ☐ No ☐ Yes	[60] ☐ No ☐ Yes	[61] ☐
III	[62]	[63]	[64] ☐ No ☐ Yes	[65] ☐ No ☐ Yes	[66] ☐
IV	[67]	[68]	[69] ☐ No ☐ Yes	[70] ☐ No ☐ Yes	[71] ☐
V	[72]	[73]	[74] ☐ No ☐ Yes	[75] ☐ No ☐ Yes	[76] ☐
VI	[77]	[78]	[79] ☐ No ☐ Yes	[80] ☐ No ☐ Yes	[81] ☐
Total	[82]	[83]			

15. Other involved areas: ______________ [84]

Comments: ____

____

____ [85]

______________________________ [86]
Initials of person completing the form

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

______________________________ [88]
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ACRIN 6685
FDG-PET/CT Staging of Head and Neck Cancer
FDG Administration Treatment Exposure Form

ACRIN Study 6685
PLACE LABEL HERE

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]
o Visit 2

2. Was imaging agent administered?[2]
o No (Initial & date form) o 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] o Prepared in-house (provide method by which agent is synthesized, complete Q6a)
o Obtained from outside supplier (complete Q6b)

6a. Method:[7] ____________

6b. Supplier:[8] ____________

Administration Information

7. Route of administration:[9] ● IV

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

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

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

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

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

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

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

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

____
Initials of person who completed form[23]

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

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ACRIN 6685 Clinical Assessment Follow-up Form

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ACRIN Study 6685

PLACE LABEL HERE

Institution ________ Institution No. ________

Participant Initials ________ Case No. ________

1. Timepoint for this follow-up? [1]
- O One year post-surgery
- O Two year post-surgery
- O 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]
- O No (*Complete Q4a)*
- O Yes

4a. Reason not completed: [7]
- O The participant refused
- O Patient lost to follow-up
- O Unable to contact treating physician
- O Records not available
- O 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]
- O Alive
- O Dead *(complete Q6a)*
- O Unknown

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

7. Most recent interim treatments:

	Start Date	Stop Date
XrT	[19] ____-____-____	[20] ____-____-____ [21] ☐ Ongoing
Chemotherapy	[22] ____-____-____	[23] ____-____-____ [24] ☐ Ongoing
Surgery	[25] ____-____-____	
Other, specify [26] ________	[27] ____-____-____	[28] ____-____-____ [29] ☐ Ongoing

8. Initial primary disease status at this assessment: [30]
- O 1 Recurrent disease
- O 2 Disease-free
- O 3 Persistent disease
- O 99 Unknown

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

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 [44]	Right [45]
o Positive	o Positive
o Negative	o Negative
o Completely resected	o Completely resected
o Unknown	o Unknown

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ACRIN 6685 Clinical Assessment Follow-up Form

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ACRIN Study 6685
PLACE LABEL HERE

Institution ______________ Institution No. ______________
Participant Initials ______________ Case No. ______________

10a. Site(s) of metastastic 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)		
[46]	LUNG	___-___-___ [47]	[48]	[49]	[50]
[51]	LYMPH NODES (distant)	___-___-___ [52]	[53]	[54]	[55]
[56]	LIVER	___-___-___ [57]	[58]	[59]	[60]
[61]	BONE	___-___-___ [62]	[63]	[64]	[65]
[66]	CNS (BRAIN)	___-___-___ [67]	[68]	[69]	[70]
[71]	OTHER, Specify__________ [72]	___-___-___ [73]	[74]	[75]	[76]

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

O No
O 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

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

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ACRIN Study 6685
PLACE LABEL HERE

Institution ______________ Institution No. ________

Participant Initials ________ Case No. ________

GENERAL IMAGING INFORMATION

1. **Was endoscopy performed** [1]
   O No (*skip to Q2*)
   O Yes

   1a. **Where was the endoscopy performed?** [2]
   O Office *(flexible)*
   O OR *(direct)*

2. **Is there evidence of vocal cord paralysis?** [3]
   O No
   O Yes

3. **Was a diagnostic MRI performed within 6 weeks of enrollment?** [62]
   O No
   O Yes

4. **Was a diagnostic CT performed within 6 weeks of enrollment?** [63]
   O No *(Skip to Q5)*
   O Yes *(Complete Q4a)*

   4a. **Was the CT obtained from a PET/CT?** [6]
   O No
   O Yes

5. **Subject weight** ___ ___ ___ . ___ **kg** [7]
   ☐ Unknown [8]

6. **Subject height** ___ ___ ___ **cm** [9]
   ☐ Unknown [10]

CLINICAL EXAMINATION

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

	Location	Histology SCC?
1.	[11]	☐ No ☐ Yes [12]
2.	[13]	☐ No ☐ Yes [14]
3.	[15]	☐ No ☐ 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]
   O Right
   O Left
   O Bilateral
   O Midline

10. **Which side of the neck is N0?** [29]
   O Right
   O Left
   O Both sides
   O Neither side

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ACRIN 6685

FDG-PET/CT Staging of Head and Neck Cancer

Initial Evaluation Form

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ACRIN Study 6685

PLACE LABEL HERE

Institution ______ **Institution No.** ______

Participant Initials ______ **Case No.** ______

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]	☐ [32]
IB	[33]	[34]	☐ [35]
IIA	[36]	[37]	☐ [38]
IIB	[39]	[40]	☐ [41]
III	[42]	[43]	☐ [44]
IV	[45]	[46]	☐ [47]
V	[48]	[49]	☐ [50]
VI	[51]	[52]	☐ [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 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

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

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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. ☐

GENERAL IMAGING INFORMATION

1. **Reader ID** |_|_|_|_|_|_|_| [1]

2. **Date of MRI scan** ____-____-______ *(mm-dd-yyyy)* [2]

3. **Image quality** [3]
   - O Adequate
   - O Suboptimal
   - O 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]
   - O No
   - O Yes

   4a. **Was T-1 weighted post-contrast imaging performed?** [14]
   - O No
   - O Yes

   4b. **Was T2 weighted imaging performed?** [15]
   - O No
   - O Yes

   4c. **Was FLAIR imaging performed?** [16]
   - O No
   - O Yes

   4d. **Was diffusion-weighted or diffusion tensor imaging performed?** [17]
   - O No
   - O Yes

5. **Subject weight** ____ ____ ____ . ____ **kg** [18]
   (measured on day of scan) ☐ Unknown [19]

6. **Was contrast used?** [20]
   - O No *(Skip to Q12)*
   - O Yes

7. **Time of injection (military time)** ____ ____ : ____ ____ [21]

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]
    - O Magnevist
    - O Omniscan
    - O ProHance
    - O OptiMark
    - O MultiHance
    - O 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]

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

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ACRIN Study 6685
PLACE LABEL HERE

Institution ________ **Institution No.** ________
Participant Initials ________ **Case No.** ________

16. Lateralization of Tumor [46]
- O Right
- O Left
- O Bilateral
- O 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] ☐No ☐ Yes	[51] ☐No ☐ Yes	[52] ☐
IB	[53]	[54]	[55] ☐No ☐ Yes	[56] ☐No ☐ Yes	[57] ☐
IIA	[58]	[59]	[60] ☐No ☐ Yes	[61] ☐No ☐ Yes	[62] ☐
IIB	[63]	[64]	[65] ☐No ☐ Yes	[66] ☐No ☐ Yes	[67] ☐
III	[68]	[69]	[70] ☐No ☐ Yes	[71] ☐No ☐ Yes	[72] ☐
IV	[73]	[74]	[75] ☐No ☐ Yes	[76] ☐No ☐ Yes	[77] ☐
V	[78]	[79]	[80] ☐No ☐ Yes	[81] ☐No ☐ Yes	[82] ☐
VI	[83]	[84]	[85] ☐No ☐ Yes	[86] ☐No ☐ Yes	[87] ☐
Total	[88]	[89]			

19. Other involved areas: ____________ [90]

Comments: ______________________________________ [91]

____________ [92]
Initials of person completing the form

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

____________ [94]
Initials of person entering data onto the web

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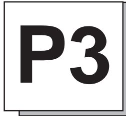

ACRIN 6685

Pathology Report Review Form

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ACRIN Study 6685
PLACE LABEL HERE

Institution ________________ **Institution No.** ____________

Participant Initials ____________ **Case No.** ______________

1. **Pathology report available** [1]
   - O No (if no initial and date form)
   - O Yes

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

3. **HPV testing** [3]
   - O Positive
   - O Equivocal
   - O Negative
   - O Not done

4. **P16 test results** [4]
   - O Strongly diffusely positive
   - O Strongly focally positive
   - O Weakly focally positive
   - O Negative
   - O Not done

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

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

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ACRIN 6685
Local Pathology Form

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ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ Institution No. ________

Participant Initials________ Case No. ________

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

1a. If not, what is the reason that data is unavailable? [2]
- O Records not available from outside institution
- O Specimen lost or unavailable for review
- O Specimen inadequate
- O Unknown
- O 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]	☐No ☐ Yes [9]
2.	[10]	[11]	☐No ☐ Yes [12]
3.	[13]	[14]	☐No ☐ 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]
- ☐ Cart ilage Invasion [22]
- ☐ Nerve Involvement [23]
- ☐ Fixed Vocal Cord [24]
- ☐ Superficial invasion [25]
- ☐ No invasion [26]

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

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

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

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

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ACRIN 6685
Local Pathology Form

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ACRIN Study 6685
PLACE LABEL HERE

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	☐ [158]	[29]	[30]	[31]	[32]	☐No ☐ Yes [33]	☐No ☐ Yes [34]	☐No ☐ Yes [35]
IB	☐ [159]	[36]	[37]	[38]	[39]	☐No ☐ Yes [40]	☐No ☐ Yes [41]	☐No ☐ Yes [42]
IIA	☐ [160]	[43]	[44]	[45]	[46]	☐No ☐ Yes [47]	☐No ☐ Yes [48]	☐No ☐ Yes [49]
IIB	☐ [161]	[50]	[51]	[52]	[53]	☐No ☐ Yes [54]	☐No ☐ Yes [55]	☐No ☐ Yes [56]
III	☐ [162]	[57]	[58]	[59]	[60]	☐No ☐ Yes [61]	☐No ☐ Yes [62]	☐No ☐ Yes [63]
IV	☐ [163]	[64]	[65]	[66]	[67]	☐No ☐ Yes [68]	☐No ☐ Yes [69]	☐No ☐ Yes [70]
V	☐ [164]	[71]	[72]	[73]	[74]	☐No ☐ Yes [75]	☐No ☐ Yes [76]	☐No ☐ Yes [77]
VI	☐ [165]	[78]	[79]	[80]	[81]	☐No ☐ Yes [82]	☐No ☐ Yes [83]	☐No ☐ 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	☐ [166]	[87]	[88]	[89]	[90]	☐No ☐ Yes [91]	☐No ☐ Yes [92]	☐No ☐ Yes [93]
IB	☐ [167]	[94]	[95]	[96]	[97]	☐No ☐ Yes [98]	☐No ☐ Yes [99]	☐No ☐ Yes [100]
IIA	☐ [168]	[101]	[102]	[103]	[104]	☐No ☐ Yes [105]	☐No ☐ Yes [106]	☐No ☐ Yes [107]
IIB	☐ [169]	[108]	[109]	[110]	[111]	☐No ☐ Yes [112]	☐No ☐ Yes [113]	☐No ☐ Yes [114]
III	☐ [170]	[115]	[116]	[117]	[118]	☐No ☐ Yes [119]	☐No ☐ Yes [120]	☐No ☐ Yes [121]
IV	☐ [171]	[122]	[123]	[124]	[125]	☐No ☐ Yes [126]	☐No ☐ Yes [127]	☐No ☐ Yes [128]
V	☐ [172]	[129]	[130]	[131]	[132]	☐No ☐ Yes [133]	☐No ☐ Yes [134]	☐No ☐ Yes [135]
VI	☐ [173]	[136]	[137]	[138]	[139]	☐No ☐ Yes [140]	☐No ☐ Yes [141]	☐No ☐ 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 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

Comments: ____________ [149]

____________ [150]
Initials of person responsible for data

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

____________ [152]
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ACRIN 6685

FDG-PET/CT Staging of Head and Neck Cancer

PET/CT Central Interpretation Form

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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]
   - O Adequate
   - O Suboptimal *(complete Q3a, then continue with form)*
   - O 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]
   - O Whole body PET/CT
   - O 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]
   - o Right
   - o Left
   - o Bilateral
   - o Midline

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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	O No O Yes [169]

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

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]

O No *(Skip to Q11)*
O Yes *(Complete Q10a)*
O 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]

O No
O Yes, specify ____________ [156]

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 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: ____________

____________ [160,174, 175, 176]

____________ [161]
Initials of person responsible for data

___-___-___ [162]
Date form completed

____________ [163]
Initials of person completing form

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Central Pathology Review Form

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Participant Initials ____________ Case No. ____________

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

   1a. **If not, what is the reason that data is unavailable?** [2]
   - O Records not available from outside institution
   - O Specimen lost or unavailable for review
   - O Specimen inadequate
   - O Unknown
   - O 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]	☐ No ☐ Yes [9]
2.	[10]	[11]	☐ No ☐ Yes [12]
3.	[13]	[14]	☐ No ☐ 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]
- ☐ Cart ilage Invasion [22]
- ☐ Nerve Involvement [23]
- ☐ Fixed Vocal Cord [24]
- ☐ Superficial invasion [25]
- ☐ No invasion [26]

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

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

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

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

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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	☐ [158]	[29]	[30]	[31]	[32]	☐No ☐ Yes [33]	☐No ☐ Yes [34]	☐No ☐ Yes [35]
IB	☐ [159]	[36]	[37]	[38]	[39]	☐No ☐ Yes [40]	☐No ☐ Yes [41]	☐No ☐ Yes [42]
IIA	☐ [160]	[43]	[44]	[45]	[46]	☐No ☐ Yes [47]	☐No ☐ Yes [48]	☐No ☐ Yes [49]
IIB	☐ [161]	[50]	[51]	[52]	[53]	☐No ☐ Yes [54]	☐No ☐ Yes [55]	☐No ☐ Yes [56]
III	☐ [162]	[57]	[58]	[59]	[60]	☐No ☐ Yes [61]	☐No ☐ Yes [62]	☐No ☐ Yes [63]
IV	☐ [163]	[64]	[65]	[66]	[67]	☐No ☐ Yes [68]	☐No ☐ Yes [69]	☐No ☐ Yes [70]
V	☐ [164]	[71]	[72]	[73]	[74]	☐No ☐ Yes [75]	☐No ☐ Yes [76]	☐No ☐ Yes [77]
VI	☐ [165]	[78]	[79]	[80]	[81]	☐No ☐ Yes [82]	☐No ☐ Yes [83]	☐No ☐ 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	☐ [166]	[87]	[88]	[89]	[90]	☐No ☐ Yes [91]	☐No ☐ Yes [92]	☐No ☐ Yes [93]
IB	☐ [167]	[94]	[95]	[96]	[97]	☐No ☐ Yes [98]	☐No ☐ Yes [99]	☐No ☐ Yes [100]
IIA	☐ [168]	[101]	[102]	[103]	[104]	☐No ☐ Yes [105]	☐No ☐ Yes [106]	☐No ☐ Yes [107]
IIB	☐ [169]	[108]	[109]	[110]	[111]	☐No ☐ Yes [112]	☐No ☐ Yes [113]	☐No ☐ Yes [114]
III	☐ [170]	[115]	[116]	[117]	[118]	☐No ☐ Yes [119]	☐No ☐ Yes [120]	☐No ☐ Yes [121]
IV	☐ [171]	[122]	[123]	[124]	[125]	☐No ☐ Yes [126]	☐No ☐ Yes [127]	☐No ☐ Yes [128]
V	☐ [172]	[129]	[130]	[131]	[132]	☐No ☐ Yes [133]	☐No ☐ Yes [134]	☐No ☐ Yes [135]
VI	☐ [173]	[136]	[137]	[138]	[139]	☐No ☐ Yes [140]	☐No ☐ Yes [141]	☐No ☐ 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 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

14. Agree with Local Pathology assessment? [174]

O No
O Yes

Comments: ____ [149]

______________________________ [150]
Initials of person responsible for data

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

______________________________ [152]
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FDG-PET/CT Staging of Head and Neck Cancer

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Participant Initials ____________ **Case No.** ____________

Participant Instructions: As part of the study, we are interested in your views about your health. Please answer every question by marking your answer as indicated. If you are unsure about how to answer a question, give the best answer you can. Return this questionnaire to the research associate once you have completed it.

This part of the questionnaire asks about your health and quality of life **over the past four weeks** Please answer all of the questions by selecting one choice for each question.

1. In general, would you say your health is: (mark with an X) [1]

Excellent	Very good	Good	Fair	Poor
O 1	O 2	O 3	O 4	O 5

2. *Compared to one year ago*, how would you rate your health in general *now*?[2]

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
O 1	O 2	O 3	O 4	O 5

3. The following questions are about activities you might do during a typical day. *Does your health now limit* you in these activities? If so, how much?

(mark an X in a circle on each line)

	Yes, limited a lot	Yes, limited a little	No, not limited at all
3a. *Vigorous activities,* such as running, lifting heavy objects, participating in strenuous sports [3]	O 1	O 2	O 3
3b. *Moderate activities,* such as moving a table, pushing a vacuum cleaner, bowling, or playing golf[4]	O 1	O 2	O 3
3c. Lifting or carrying groceries [5]	O 1	O 2	O 3
3d. Climbing *several* flights of stairs [6]	O 1	O 2	O 3
3e. Climbing *one* flight of stairs [7]	O 1	O 2	O 3
3f. Bending, kneeling, or stooping [8]	O 1	O 2	O 3
3g. Walking *more than a mile*[9]	O 1	O 2	O 3
3h. Walking *several hundred yards* [10]	O 1	O 2	O 3
3i. Walking *one hundred yards* [11]	O 1	O 2	O 3
3j. Bathing or dressing yourself[12]	O 1	O 2	O 3

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4. During the *past 4 weeks,* how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of your physical health*?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
4a. Cut down on the *amount of time* you spent on work or other activities [13]	O 1	O 2	O 3	O 4	O 5
4b. *Accomplished less* than you would like [14]	O 1	O 2	O 3	O 4	O 5
4c. Were limited in the *kind* of work or other activities [15]	O 1	O 2	O 3	O 4	O 5
4d. Had *difficulty* performing the work or other activities (for example, it took extra effort) [16]	O 1	O 2	O 3	O 4	O 5

5. During the *past 4 weeks*, how much of the time have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
5a. Cut down the *amount of time* you spent on work or other activities [17]	O 1	O 2	O 3	O 4	O 5
5b. *Accomplished less* than you would like [18]	O 1	O 2	O 3	O 4	O 5
5c. Did work or activities *less carefully than usual* [19]	O 1	O 2	O 3	O 4	O 5

6. During the past 4 *weeks*, to what *extent* has your *physical health or emotional problems* interfered with your normal social activities with family, friends, neighbors, or groups? [20]

Not at all	Slightly	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

7. How much *bodily* pain have you had during the *past 4 weeks*? [21]

None	Very Mild	Mild	Moderate	Severe	Very Severe
O 1	O 2	O 3	O 4	O 5	O 6

8. During the *past 4 weeks*, how much did *pain* interfere with your normal work (including both work outside the home and housework)? [22]

Not at all	A little bit	Moderately	Quite a bit	Extremely
O 1	O 2	O 3	O 4	O 5

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9. These questions are about how you feel and how things have been with you **during the past 4 weeks.** For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*…

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
9a. Did you feel full of life? [23]	O 1	O 2	O 3	O 4	O 5
9b. Have you been very nervous? [24]	O 1	O 2	O 3	O 4	O 5
9c. Have you felt so down in the dumps that nothing could cheer you up? [25]	O 1	O 2	O 3	O 4	O 5
9d. Have you felt calm and peaceful? [26]	O 1	O 2	O 3	O 4	O 5
9e. Did you have a lot of energy? [27]	O 1	O 2	O 3	O 4	O 5
9f. Have you felt downhearted and depressed? [28]	O 1	O 2	O 3	O 4	O 5
9g. Did you feel worn out? [29]	O 1	O 2	O 3	O 4	O 5
9h. Have you been happy? [30]	O 1	O 2	O 3	O 4	O 5
9i. Did you feel tired? [31]	O 1	O 2	O 3	O 4	O 5

10. During the *past 4 weeks*, how much of the time has your *physical health* or *emotional problems* interfered with your social activities (like visiting with friends, relatives, etc.)? [32]

All of the the time	Most of the time	Some of the time	A little of the time	None of the time
O 1	O 2	O 3	O 4	O 5

11. How TRUE or FALSE is *each* of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
11a. I seem to get sick a little easier than other people [33]	O 1	O 2	O 3	O 4	O 5
11b. I am as healthy as anybody I know [34]	O 1	O 2	O 3	O 4	O 5
11c. I expect my health to get worse [35]	O 1	O 2	O 3	O 4	O 5
11d. My health is excellent [36]	O 1	O 2	O 3	O 4	O 5

Please check that you have completed every question then sign and date below.

______________________ [37]
Participant's Initials

_______-_______-____________ [38]
Date form completed (mm-dd-yyyy)

______________________ [39]
Initials of person responsible for data

______________________ [40]
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FDG-PET/CT Staging of Head and Neck Cancer

(UW-QOL v4))of Washington Quality of Life Questionnaire (UW-QOL v4))

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Participant Instructions: As part of the study, we are interested in your views about your health. Please answer every question by marking your answer as indicated. If you are unsure about how to answer a question, give the best answer you can. Return this questionnaire to the research associate once you have completed it.

This part of the questionnaire asks about your health and quality of life **over the past seven days.** Please answer all of the questions by selecting one choice for each question

1. Which one of the following best describes your level of **Pain** within the past week? [1]
   - O I have no pain.
   - O There is mild pain not needing medication.
   - O I have moderate pain - requires regular medication (e.g. paracetamol).
   - O I have severe pain controlled only by prescription medicine (e.g. morphine).
   - O I have severe pain, not controlled by medication.

2. Which one of the following best describes your **Appearance** within the past week? [2]
   - O There is no change in my appearance.
   - O The change in my appearance is minor.
   - O My appearance bothers me but I remain active.
   - O I feel significantly disfigured and limit my activities due to my appearance.
   - O I cannot be with people due to my appearance.

3. Which one of the following best describes your **Activity** level within the past week? [3]
   - O I am as active as I have ever been.
   - O There are times when I can't keep up my old pace, but not often.
   - O I am often tired and have slowed down my activities although I still get out.
   - O I don't go out because I don't have the strength.
   - O I am usually in bed or chair and don't leave home.

4. Which one of the following best describe the amount of **Recreation** time spent within the past week? [4]
   - O There are no limitations to recreation at home or away from home.
   - O There are a few things I can't do but I still get out and enjoy life.
   - O There are many times when I wish I could get out more, but I'm not up to it.
   - O There are severe limitations to what I can do, mostly I stay at home and watch TV.
   - O I can't do anything enjoyable.

5. Which one of the following best describes your **Swallowing** abilities within the past week? [5]
   - O I can swallow as well as ever.
   - O I cannot swallow certain solid foods.
   - O I can only swallow liquid food.
   - O I cannot swallow because it "goes down the wrong way" and chokes me.

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6. Which one of the following best describes your **Chewing** abilities within the past week? [6]
   - O I can chew as well as ever.
   - O I can eat soft solids but cannot chew some foods.
   - O I cannot even chew soft solids.

7. Which one of the following best describes your **Speech** abilities within the past week? [7]
   - O My speech is the same as always.
   - O I have difficulty saying some words but I can be understood over the phone.
   - O Only my family and friends can understand me.
   - O I cannot be understood.

8. Which one of the following best describes your ability to use your **Shoulder** with the past week? [8]
   - O I have no problem with my shoulder.
   - O My shoulder is stiff but it has not affected my activity or strength.
   - O Pain or weakness in my shoulder has caused me to change my work / hobbies.
   - O I cannot work or do my hobbies due to problems with my shoulder.

9. Which one of the following best describes your sense of **Taste** within the past week? [9]
   - O I can taste food normally.
   - O I can taste most foods normally.
   - O I can taste some foods.
   - O I cannot taste any foods.

10. Which one of the following best describes the amount of **Saliva** you have had within the past week? [10]
    - O My saliva is of normal consistency.
    - O I have less saliva than normal, but it is enough.
    - O I have too little saliva.
    - O I have no saliva.

11. Which one of the following best describes your **Mood** within the past week? [11]
    - O My mood is excellent and unaffected by my cancer.
    - O My mood is generally good and only occasionally affected by my cancer.
    - O I am neither in a good mood nor depressed about my cancer.
    - O I am somewhat depressed about my cancer.
    - O I am extremely depressed about my cancer.

12. Which one of the following best describes your level of **Anxiety** within the past week? [12]
    - O I am not anxious about my cancer.
    - O I am a little anxious about my cancer.
    - O I am anxious about my cancer.
    - O I am very anxious about my cancer.

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Which issues have been the most important to you <u>during the past 7 days</u>? Tick ☑ **up to 3 boxes.**

☐ Pain [13]	☐ Swallowing [17]	☐ Taste [21]
☐ Appearance [14]	☐ Chewing [18]	☐ Saliva [22]
☐ Activity [15]	☐ Speech [19]	☐ Mood [23]
☐ Recreation [16]	☐ Shoulder [20]	☐ Anxiety [24]

GENERAL QUESTIONS

Compared to the month before you developed cancer, how would you rate your health-related quality of life? (Tick one box: ☑) [25]

☐ Much better
☐ Somewhat better
☐ About the same
☐ Somewhat worse
☐ Much worse

In general, would you say your **health-related quality of life** <u>during the past 7 days</u> has been: (Tick one box: ☑) [26]

☐ Outstanding
☐ Very good
☐ Good
☐ Fair
☐ Poor
☐ Very poor

Overall quality of life includes not only physical and mental health, but also many other factors, such as family, friends, spirituality, or personal leisure activities that are important to your enjoyment of life. Considering everything in your life that contributes to your personal well-being, rate your **overall quality of life** <u>during the past 7 days</u>. (Tick one box: ☑) [27]

☐ Outstanding
☐ Very good
☐ Good
☐ Fair
☐ Poor
☐ Very poor

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ACRIN 6685
Health Status Questionnaire

ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ **Institution No.** ____________
Participant Initials ____________ **Case No.** ____________

Please describe any other issues (medical or nonmedical) that are important to your quality of life and have not been adequately addressed by our questions (you may attach additional sheets if needed).

COMMENTS:

____

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____ [28,29,30]

Please check that you have completed every question then sign and date below.

____________________ [31]
Participant's Initials

_____-_____-________ [32]
Date form completed (mm-dd-yyyy)

____________________ [33]
Initials of person responsible for data

____________________ [34]
Initials of person entering data onto web

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ACRIN 6685
FDG-PET/CT Staging of Head and Neck Cancer
HUI23 Multi-Attribute Health Status Classification System

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

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

Participant Instructions: As part of the study, we are interested in your views about your health. Please answer every question by marking your answer as indicated. If you are unsure about how to answer a question, give the best answer you can. Return this questionnaire to the research associate once you have completed it.
This part of the questionnaire asks about your health and quality of life **over the past four weeks.** Please answer all of the questions by selecting one choice for each question.

1. Which one of the following best describes your ability, during the past four weeks, to see well enough to read ordinary newsprint? [1]
- O Able to see well enough without glasses or contact lenses.
- O Able to see well enough with glasses or contact lenses.
- O Unable to see well enough, even with glasses or contact lenses.
- O Unable to see at all.

2. Which one of the following best describes your ability, during the past four weeks, to see well enough to recognize a friend on the other side of the street? [2]
- O Able to see well enough without glasses or contact lenses.
- O Able to see well enough with glasses or contact lenses.
- O Unable to see well enough, even with glasses or contact lenses.
- O Unable to see at all.

3. Which one of the following best describes your ability, during the past four weeks, to hear what was said in a group conversation with at least three other people? [3]
- O Able to hear what is said without a hearing aid.
- O Able to hear what is said with a hearing aid.
- O Unable to hear what was said, even with a hearing aid.
- O Unable to hear what was said, but did not wear a hearing aid.
- O Unable to hear at all.

4. Which one of the following best describes your ability, during the past four weeks, to hear what was said in a conversation with one other person in a quiet room? [4]
- O Able to hear what is said without a hearing aid.
- O Able to hear what is said with a hearing aid.
- O Unable to hear what was said, even with a hearing aid.
- O Unable to hear what was said, but did not wear a hearing aid.
- O Unable to hear at all.

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ACRIN 6685
Health Status Questionnaire

ACRIN Study 6685
PLACE LABEL HERE

Institution ________ Institution No. ________

Participant Initials ________ Case No. ________

5. Which one of the following best describes your ability, during the past four weeks, to be understood when speaking your own language with people who do not know you? [5]

O Able to be understood completely.
O Able to be understood partially.
O Unable to be understood.
O Unable to speak at all.

6. Which one of the following best describes your ability, during the past four weeks, to be understood when speaking with people who know you well? [6]

O Able to be understood completely.
O Able to be understood partially.
O Unable to be understood.
O Unable to speak at all.

7. Which one of the following best describes how you have been feeling during the past four weeks? [7]

O Happy and interested in life.
O Somewhat happy.
O Somewhat unhappy.
O Very unhappy.
O So unhappy that life is not worthwhile.

8. Which one of the following best describes the pain and discomfort you have experienced during the past four weeks? [8]

O Free of pain and discomfort.
O Mild to moderate pain that prevents no activities.
O Moderate pain or discomfort that prevented some activities.
O Moderate to severe pain or discomfort that prevented some activities.
O Severe pain or discomfort that prevented most activities.

9. Which one of the following best describes your ability, during the past four weeks, to walk? NOTE: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker. [9]

O Able to walk around the neighborhood without difficulty and without walking equipment.
O Able to walk around the neighborhood with difficulty; but did not require walking equipment or the help of another person.
O Able to walk around the neighborhood with walking equipment, but without the help of another person.
O Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood.
O Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood.
O Unable to walk at all.

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ACRIN 6685 Health Status Questionnaire

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

10. Which one of the following best describes your ability, during the past four weeks, to use your hands and fingers? NOTE: Special tools refers to hooks for buttoning clothes, gripping devices for opening jars or lifting small items, and other devices to compensate for limitations of hands or fingers. [10]

O Full use of two hands and ten fingers.

O Limitations in the use of hands or fingers, but did not require special tools or the help of another person.

O Limitations in the use of hands or fingers, independent with use of special tools (does not require the help of another person).

O Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools).

O Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools).

O Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools).

11. Which one of the following best describes your ability, during the past four weeks, to remember things? [11]

O Able to remember most things.

O Somewhat forgetful.

O Very forgetful.

O Unable to remember anything at all.

12. Which one of the following best describes your ability, during the past four weeks, to think and solve day to day problems? [12]

O Able to think clearly and solve day to day problems.

O Had a little difficulty when trying to think and solve day to day problems.

O Had some difficulty when trying to think and solve day to day problems.

O Had great difficulty when trying to think or solve day to day problems.

O Unable to think or solve day to day problems.

13. Which one of the following best describes your ability, during the past four weeks, to perform basic activities? [13]

O Eat, bathe, dress, and use the toilet normally.

O Eat, bathe, dress, or use the toilet independently, but with difficulty.

O Required mechanical equipment to eat, bathe, dress, or use the toilet independently.

O Required the help of another person to eat, bathe, dress, or use the toilet.

14. Which one of the following best describes how you have been feeling during the past four weeks? [14]

O Generally happy and free from worry.

O Occasionally fretful, angry, irritable, anxious, or depressed.

O Often fretful, angry, irritable, anxious, or depressed.

O Almost always fretful, angry, irritable, anxious, or depressed.

O Extremely fretful, angry, irritable, anxious, or depressed; to the point of needing professional help.

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ACRIN 6685
Health Status Questionnaire

ACRIN Study 6685
PLACE LABEL HERE

Institution ______________ Institution No. ______________

Participant Initials ______________ Case No. ______________

15. Which one of the following best describes the pain or discomfort you have experienced during the past four weeks? [15]

O Free of pain and discomfort.

O Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities.

O Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities.

O Frequent pain or discomfort. Frequent disruption of normal activities. Discomfort required prescription narcotics for relief.

O Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities.

Please check that you have completed every question then sign and date below.

______________________ [16]
Participant's Initials

____-____-______ [17]
Date form completed (mm-dd-yyyy)

______________________ [18]
Initials of person responsible for data

______________________ [19]
Initials of person entering data onto web

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ACRIN 6685

Serum Transmittal 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. Specimen Review:

	Specimen ID Number	Hemolyzed?	Is serum red?	Volume sufficient?
1	[1]	O No O Yes [2]	O No O Yes [3]	O No O Yes [4]
2	[5]	O No O Yes [6]	O No O Yes [7]	O No O Yes [8]
3	[9]	O No O Yes [10]	O No O Yes [11]	O No O Yes [12]
4	[13]	O No O Yes [14]	O No O Yes [15]	O No O Yes [16]
5	[17]	O No O Yes [18]	O No O Yes [19]	O No O Yes [20]
6	[21]	O No O Yes [22]	O No O Yes [23]	O No O Yes [24]
7	[25]	O No O Yes [26]	O No O Yes [27]	O No O Yes [28]
8	[29]	O No O Yes [30]	O No O Yes [31]	O No O Yes [32]

2. Initials of Serum Bank staff: ____________ [33]

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ACRIN 6685

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

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

ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ Institution No. ____________

Participant Initials____________ Case No. ____________

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	[7] O Positive O Negative ☐ Not reviewed [8]	[9] O Positive O Negative ☐ Not reviewed [10]

4. **Are Distant Metastases present?** [11]
   - O No
   - O Yes
   - O Indeterminate
   - ☐ Not reviewed [12]

Dedicated Head & Neck PET/CT

5.

	Left	Right
Overall visual assessment	[13] O Positive O Negative ☐ Not reviewed [14]	[15] O Positive O Negative ☐ Not reviewed [16]

COMMENTS: ____ [17]

______________________ [18]
Initials of person(s) responsible for the data

____-____-______ [19]
Date form completed (mm-dd-yyyy)

______________________ [20]
Initials of person(s) completing form

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

ACRIN Study 6685
PLACE LABEL HERE

Institution ________________ **Institution No.** ________________

Participant Initials ________________ **Case No.** ________________

Imaging Agent: FDG

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

Exam Data

1. Clinical trial time point [1]
o Visit 2

2. Imaging Agent Name[2]
o FDG

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

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

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

5. Weight
☐☐☐ . ☐ kg[8]
☐ Unknown[9]

6. Height
☐☐☐ **cm**[10]
☐ Unknown[11]

Patient Preparation

☐ Not Done[12]

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

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

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

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

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

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

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

ACRIN Study 6685
PLACE LABEL HERE

Institution ____________ Institution No. ____________
Participant Initials ____________ Case No. ____________

Imaging Agent: FDG

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

3. Scanner used for this exam:

3a. Manufacturer

______________________________[27]

3b. Manufacturer model name/or number

______________________________[28]

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

_____ - ______ - ____________(mm-dd-yyyy)

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

o No o Yes

CT Image Acquisition or Transmission Scan

☐ Not Done[37]

1. Type of attenuation correction used?[38]
- o CT (complete Q2 thru 6)
- o Ge-68 Segmentation (complete Q7)
- o Cs-137 Segmentation (complete Q7)

2. Was oral contrast administered?[39]
- o No (skip to Q3)
- o Yes, if used specify type:[40] o Positive o Negative

2a. Amount [41] |__|__|__|__| ml ☐ Unknown[42]

3. Was IV contrast administered?[43]
- o No (skip to Q4)
- o 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]

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

ACRIN Study 6685
PLACE LABEL HERE

Institution ________ Institution No. ________

Participant Initials ________ Case No. ________

Imaging Agent: FDG

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

PET Emission Scan

☐ Not Done[56]

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

2. Number of bed positions scanned ☐☐[58]

PET Emission Scan:

Start Time (military time)

3a. ☐☐ : ☐☐ [60]

Stop Time (military time)

3b. ☐☐ : ☐☐ [61]

Reconstructed Images:

4. Pixel Size: ☐ . ☐☐ mm[62]

5. Thickness: ☐ . ☐☐ mm[63]

Adverse Events

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

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

________________ [84]
Initials of person completing this form

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

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ACRIN 6685

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

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

ACRIN Study 6685 Case #

PLACE LABEL HERE

Institution ____________ Institution No. ____________

Participant Initials ____________ Case No. ____________

1. **Clinical trial time point:** [1] O Visit 2
2. **Is the participant a known diabetic?** [2] O No O Yes
   Were any drugs taken by the participant or administered to the participant on the day of PET study for control of blood glucose level? [3]
   O No O Yes, check drug(s) used O Unknown
   - ☐ A sulfonylurea, [4] drug name ____________ [5] given ___ ___ [6] hours before FDG
   - ☐ Metformin [7] given ___ ___ [8] hours before FDG
   - ☐ Other oral agent (s) [9] drug name ____________ [10] given ___ ___ [11] hours before FDG
     drug name ____________ [12] given ___ ___ [13] hours before FDG
   - ☐ Short-acting insulin [14] given, ___ ___ [15] hours before FDG, given (check one) [16] O Intravenously O Subcutaneously O Inhaled
     Record 99 if hours unknown
   - ☐ Intermediate or long-acting insulin [17] given ___ ___ [18] hours before FDG
   - ☐ Insulin Pump [19] *(check one)* [20] O On during FDG injection and uptake period
     O Off during FDG injection and uptake period, off ___ ___ [21] hours before FDG
   - ☐ Other injectable agent [22] specify ____________ [23] given ___ ___ [24] hours before FDG
     Record 99 if hours unknown
   - ☐ Unknown [25]
3. **Were any drugs administered as part of the PET imaging procedure?** [26] *In addition to any listed in Q2a*
   O No O Yes, check drug(s) used: O Unknown
   - ☐ A benzodiazepine to decrease brown fat FDG uptake, [27] drug name ____________ [28]
   - ☐ A beta-blocker to decrease brown fat FDG uptake, [29] drug name ____________ [30]
   - ☐ A diuretic to decrease urinary tract activity, [31] drug name ____________ [32]
   - ☐ Sedation or anesthesia [33]
   - ☐ Other drug(s), [34] drug name (s) ____________ [35]
   - ☐ Unknown [36]
4. **Is the participant currently being treated with corticosteroids?** [37] O No O Yes O Unknown
   Taken ___ ___ [38] hours before FDG
5. **Has the participant received a bone marrow stimulating agent in the last 2 months?** [39] O No O Yes, provide; O Unknown
   Agent Name: ____________ [40]
   Given approximately ___ ___ days ago [41]
   ☐ Unknown [42]

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

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

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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?** [12]
   - O No *(Skip to Q2)*
   - O Yes *(Complete Q1a)*
   - O Not applicable *(Skip to Q2)*

   1a. **Was the test negative?** [13]
   - O No
   - O Yes

2. **Did the patient consent to blood collection?** [15]
   - O No *(Skip to Q3)*
   - O Yes *(Complete Q2a)*

   2a. **Was blood collected?** [16]
   - O No (complete Q2b)
   - O Yes (skip to Q3)

   2b. **If no, will blood be collected prior to surgery?** [17]
   - O No
   - O Yes

3. **Date of PET/CT scan:** ____-____-______ *(mm-dd-yyyy)* [14]

4. **Reader ID** ☐☐☐☐☐☐☐ [1]

5. **Image quality** [2]
   - O Adequate
   - O Suboptimal *(complete Q5a, then continue with form)*
   - O Uninterpretable *(complete Q5a, then initial and date form)*

   5a. **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]

6. **Did the study include a dedicated head and neck acquisition?** [18]
   - O No
   - O Yes

7. **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 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 [35]
- ☐ Lateral [36]
- ☐ Superior [37]
- ☐ Inferior [38]

8. **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]

9. **Lateralization of Tumor** [46]
   - o Right
   - o Left
   - o Bilateral
   - o Midline

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ACRIN 6685
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. ____________

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

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

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]

O No *(Skip to Q13)*
O Yes *(Complete Q12a)*
O 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]

O No
O Yes, specify ____________ [156]

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

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57F=B **,)

:8; !D9 H#7 H GHU[ ]b[cZ
<YUX UbX BYW_ 7 UbWYf
DfY!Gi f[YfmiD Ubb]b[: cfa

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

57F=B Gh Xm**,)
PLACE LABEL HERE
=bgh]hi h]cb ________ =bgh]hi h]cb Bc" ________
DUf h]W]dUbh =b]h]U g ________ 7 UgY Bc" ________

DUfh%

DfY!D9 H#7 H F Yj]Yk

%" Df]a Uf mih a cf (list up to 3 primary tumors)

	@cWUh]cb
%"	[1]
&"	[2]
' "	[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	

%U" =ZUj Yc Uf f]X[Y]bX]WUhY cWUh]cb (mark all that apply)

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

&" D UbbYX BcXU X]ggYWh]cbg (check levels to be dissected)

☐ not Marked, ☑ Marked

	@Yzh	F][\ h
=5	[8]	[9]
=6	[10]	[11]
==5	[12]	[13]
==6	[14]	[15]
===	[16]	[17]
=J	[18]	[19]
J	[20]	[21]
J=	[22]	[23]

DUfh&

DcgH!D9 H#7 H F Yj]Yk

' " K Yf Y D9 H#7 H]a U[Yg f Yj]Yk YX3 [24]

- O No
- O Yes

(" K Ug bc XU X]ggYWh]cb d Ub W Ub[YX VUgYX cb D9 H#7 H Z]bX]b[g3 [25]

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

(U" K \ Uh k Ug W Ub[YX VYWUi gY cZ D9 H#7 H Z]bX]b[g3 [26]

- O Side
- O Level
- O Both

) " K Yf Y X]gHUbh a YHUgHUgYg gYYb cb D9 H#7 H3 [27]

- O No
- O Yes

* " K] bcXU X]ggYWh]cb gh] VY dYf Zcfa YX3 [28]

- O No (initial and date form)
- O Yes

+" D UbbYX BcXU 8]ggYWh]cbg UZhYf D9 H#7 H f Yj]Yk 3 (check levels dissected)

☐ not Marked, ☑ Marked

	@Yzh	F][\ h
=5	[29]	[30]
=6	[31]	[32]
==5	[33]	[34]
==6	[35]	[36]
===	[37]	[38]
=J	[39]	[40]
J	[41]	[42]
J=	[43]	[44]

7ca a Ybhg. ________________________ [45]

________________________ [46]
Initials of person completing the form

______-______-______ [47]
Date form completed (mm-dd-yyyy)

________________________ [48]
Initials of person entering data onto the web