Follow Up: Head & Neck

V4.0

Tissue Source Site (TSS) Name: _____ TSS Identifier: _____ TSS Unique Patient #: _____

Completed By: _____ Completion Date (MM/DD/YYYY): _____

Form Notes: *A Follow-up Form is to be completed for any of the following reasons:*
1) For each additional new tumor event identified at the time of enrollment or follow-up submission; or
2) 12 months after a case is shipped to the Biospecimen Core Resource (BCR) for cases that have qualified. All information provided on this form includes activity from the "Date of Last Contact" provided on the TCGA Enrollment Form to the most recent date of contact with the patient. This form should only be completed by the Tissue Source Site if updated information can be provided to TCGA. Questions regarding this form should be directed to the Tissue Source Site's (TSS) primary Clinical Outreach Contact at the BCR.

The following definitions for the use of "Unknown" and "Not Evaluated" on this form are as follows:

Unknown: This answer option should only be selected if the TSS cannot answer the question because the answer is not known at the TSS. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing the reason why the answer is unknown.

Not evaluated: This answer option should be selected by the TSS if it is known that the information being requested cannot be obtained due to the test not being performed.

Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
1	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?*	☐ Yes ☐ No	Please note that time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box to the left. ***Note 1: Provided time intervals must begin with the date of initial pathologic diagnosis. (i.e., biopsy or resection)*** ***Note 2: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
2	Reason for Follow-Up Form Submission?	☐ Scheduled (Routine) Follow-up Submission ☐ Additional New Tumor Event	3233305 Indicate the reason for submission of this follow-up form. If scheduled follow-up, complete entire form. ***Note: If additional new tumor event, complete only questions pertaining to new tumor.***
3	Is This Patient Lost to Follow-up?	☐ Yes ☐ No	61333 Indicate whether the patient is lost to follow-up as defined by the ACoS Commission on Cancer. This only includes cases where updated information has not been collected within the last 15 months. If the patient is lost to follow-up, the remaining questions may be left unanswered. ***Note: If the patient is deceased and a TCGA Follow-up Form has not yet been completed, the answer to this question should be "No" and the remaining applicable questions should be completed.***
Primary Treatment			
4	Adjuvant Post-Operative Radiation Therapy	☐ Yes ☐ No ☐ Unknown	2005312 Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***Note: If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.***
5	Adjuvant Post-Operative Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	2785850 Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.***
6	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies)	☐ Progressive Disease ☐ Complete Response ☐ Stable Disease ☐ Not Applicable ☐ Partial Response ☐ Unknown	2786727 Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies).
Patient Status			
7	Vital Status*	☐ Living ☐ Deceased	2939553 Indicate whether the patient was living or deceased at the date of last contact.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date of Last Contact			
8	Month of Last Contact	☐☐ (MM)	2897020 If the patient is living, provide the month of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). ***Note: Do not answer this question if the patient is deceased.***
9	Day of Last Contact	☐☐ (DD)	2897022 If the patient is living, provide the day of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). ***Note: Do not answer this question if the patient is deceased.***
10	Year of Last Contact	☐☐☐☐ (YYYY)	2897024 If the patient is living, provide the year of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). ***Note: Do not answer this question if the patient is deceased.***
11	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	3008273 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Last Contact. Do not answer this question if the patient is deceased. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
Date of Death		☐ Not Applicable (Patient is Alive)	
12	Month of Death	☐☐ (MM)	2897026 If the patient is deceased, provide the month of death.
13	Day of Death	☐☐ (DD)	2897028 If the patient is deceased, provide the day of death.
14	Year of Death	☐☐☐☐ (YYYY)	2897030 If the patient is deceased, provide the year of death.
15	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	3165475 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Death. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
16	Tumor Status	☐ Tumor Free ☐ Unknown Tumor Status ☐ With Tumor	2759550 Indicate whether the patient was tumor/disease free at the date of last contact or death.
New Tumor Event : *Instructions: Please verify that new tumor event information has not previously been reported on the Enrollment Form or on a Prior Follow-up Form.*			
17	New Tumor Event After Initial Treatment *	☐ Yes ☐ No ☐ Unknown	3121376 Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after their initial treatment for the tumor submitted to TCGA. ***Note: If the patient had multiple new tumor events, a follow-up form should be completed for each new tumor event.***

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Date of New Tumor Event			
18	Month of New Tumor Event After Initial Treatment	☐☐ (MM)	3104044 If the patient had a new tumor event, provide the month of diagnosis for this new tumor event.
19	Day of New Tumor Event After Initial Treatment	☐☐ (DD)	3104042 If the patient had a new tumor event, provide the day of diagnosis for this new tumor event.
20	Year of New Tumor Event After Initial Treatment	☐☐☐☐ (YYYY)	3104046 If the patient had a new tumor event, provide the year of diagnosis for this new tumor event.
21	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	3392464 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
22	Site of New Tumor Event	☐ Oral Cavity ☐ Larynx ☐ Oropharynx ☐ Cervical Lymph node ☐ Hypopharynx ☐ Distant Metastasis (specify)	3108271 Indicate the site of this new tumor event, as it relates to the tissue submitted for TCGA.
23	Site of New Tumor Event Specific Location	_____	3128033 If the tumor site is not included in the list for the question above, designate the site of this new tumor event.
24	Type of New Tumor Event(Check all that apply)	☐ Locoregional Recurrance ☐ Distant Metastasis ☐ New Primary Tumor	3119721 Indicate whether the patient's new tumor event was a loco-regional recurrence or a distant metastasis of the tissue submitted for TCGA; or a new primary tumor.
25	Diagnostic Evidence of Recurrence/ Relapse(Check all that apply)	☐ Biopsy with Histologic Confirmation ☐ Convincing Imaging (i.e. CT/PET/MRI) ☐ Positive Biomarker(s)	2786205 Indicate the procedure or testing method used to diagnose tumor recurrence or relapse.
26	Additional Surgery for New Tumor Event Loco-Regional Procedure	☐ Yes ☐ No ☐ Unknown	3008755 Using the patient's medical records, indicate whether the patient had surgery for the new loco-regional tumor event in question.
Date of Additional Surgery for New Tumor Event Loco-Regional			
27	Month of Additional Surgery for New Tumor Event Loco-Regional	☐☐ (MM)	2897032 If the patient had surgery for the new loco-regional tumor event, provide the month of surgery for this new loco-regional tumor event.
28	Day of Additional Surgery for New Tumor Event Loco-Regional	☐☐ (DD)	2897034 If the patient had surgery for the new loco-regional tumor event, provide the day of surgery for this new loco-regional tumor event.
29	Year of Additional Surgery for New Tumor Event Loco-Regional	☐☐☐☐ (YYYY)	2897036 If the patient had surgery for the new loco-regional tumor event, provide the year of surgery for this new loco-regional tumor event.
30	Number of Days from Date of Initial Diagnosis to Date of Additional Surgery for New Tumor Event Loco-Regional	_____	3408572 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event (loco-regional). ***Note: Only provide Interval data if you have received permission from the NCI to provide time***

			intervals as a substitute for requested dates on this form.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
31	Additional Surgery for New Tumor Event Metastasis Procedure	☐ Yes ☐ No ☐ Unknown	3008757 Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question.
Date of Additional Surgery for New Tumor Event Metastasis			
32	Month of Additional Surgery for New Tumor Event Metastasis	☐☐ (MM)	2897038 If the patient had surgery for the new metastatic tumor event, provide the month of surgery for this new metastatic tumor event.
33	Day of Additional Surgery for New Tumor Event Metastasis	☐☐ (DD)	2897040 If the patient had surgery for the new metastatic tumor event, provide the day of surgery for this new metastatic tumor event.
34	Year of Additional Surgery for New Tumor Event Metastasis	☐☐☐☐ (YYYY)	2897042 If the patient had surgery for the new metastatic tumor event, provide the year of surgery for this new metastatic tumor event.
35	Number of Days from Date of Initial Diagnosis to Date of Additional Surgery for New Tumor Event Metastasis	_____	3408682 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event (metastasis). ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
Additional Treatment			
37	Additional treatment of New Tumor Event Radiation Therapy	☐ Yes ☐ No ☐ Unknown	3008761 Indicate whether the patient received radiation treatment for this new tumor event.
38	Additional Treatment of New Tumor Event Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	2650646 Indicate whether the patient received pharmaceutical treatment for this new tumor event.
39	Measure of Success of Outcome at the Completion of this Follow-up Submission *	☐ Progressive Disease ☐ Stable Disease ☐ Complete Response ☐ Not Applicable ☐ Partial Response ☐ Unknown	3104050 Provide the patient's outcome of treatment up to the point of the current follow-up data submission

Comments:

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Principal Investigator Name: _____ Principal Investigator Signature: _____

Date Signed (MM/DD/YYYY): _____