		Enroliment: Head & Neck	V4.3
Tissue Sour	rce Site (TSS) Name:	TSS Identifier:TSS	S Unique Patient #:
Completed	Ву:	Completion Date (MM/DD/YYYY):	
include activit the Tissue Sou The following Unknown: Th selected for a Not Evaluated performed.	y from the Date of Initial Pati urce Site's (TSS) primary Clinic definitions for the use of "U his answer option should only question that is part of the d: This answer option should	completed for each TCGA qualified case upon qualification notice from the hologic Diagnosis to the most recent Date of Last Contact with the patient. al Outreach Contact at the BCR nknown" and "Not Evaluated" on this form are as follows: be selected if the TSS cannot answer the question because the answer is TCGA required data set, the TSS must complete a discrepancy note providi be selected by the TSS if it is known that the information being requested	Questions regarding this form should be directed to not known at the TSS. If this answer option is ing the reason why the answer is unknown. d cannot be obtained due to the test not being
Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
1	Has this TSS received permission from 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.
Patient Inform	nation		
2	Primary Site of Disease*	Head/Neck	2735776 Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA.
3	Histological Subtype*	Head & Neck Squamous Cell Carcinoma Head & Neck Squamous Cell Carcinoma Spindle Cell Variant Head & Neck Squamous Cell Carcinoma, Basaloid Type	3081934 Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. <i>Note: All other subtypes not listed are excluded</i> <i>from this study.</i>
4	Anatomic Organ Sub- division	Oral Cavity Floor of Mouth Tonsil Lip Hard Palate Base of tongue Oral Tongue Buccal Mucosa Hypopharynx Alveolar Ridge Oropharynx Larynx	3108203 Using the patient's pathology/laboratory report select the anatomic organ subdivision for the tumor submitted to TCGA.
5	Laterality of Site	Left I Midline Right	3130361 Using the patient's pathology/laboratory report and/or medical record, designate the side of the body from which this tumor, submitted for TCGA, originated.
6	Is this a Prospective Tissue Collection?	□ Yes □ No	3088492 Indicate whether the TSS providing tissue is contracted for prospective tissue collection. Note: If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively.
7	Is this a Retrospective Tissue Collection?	Yes No	3088528 Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. Note: If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively.
8	Gender*	Male Female	2200604 Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.

Tissue Sour	ce Site (TSS) Name:	TSS Identifier:TSS	Unique Patient #:
Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date of Birth			
9	Month of Birth*	(MM)	2896950 Provide the month the patient was born.
10	Day of Birth	(DD)	2896952 Provide the day the patient was born
11	Year of Birth*		2896954 Provide the year the patient was born
12	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth		3008233 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Birth. 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.
13	Race	 American Indian or Alaska Native (A person having origins in any of the original peoples of North/ South America (including Central America), and maintains tribal affiliation or community attachment) Asian (A person having origins in any of the original peoples of the Far East, Southeast Asia, or Indian subcontinent, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam) White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa) Black or African American (A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American") Native Hawaiian or other Pacific Islander (A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands) Not Evaluated (Not provided or available) Unknown (Could not be determined or unsure) 	2192199 Provide the patient's race using the defined categories.
14	Ethnicity	 Onknown (could not be determined or disarte) Not Hispanic or Latino (A person not meeting the definition for Hispanic or Latino) Hispanic or Latino (A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race) Not Evaluated (Not provided or available) Unknown (Could not be determined or unsure) 	2192217 Provide the patient's ethnicity using the defined categories

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

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
15	Has the Patient Had Any Prior Cancer Diagnosed?*	 No History of Prior Malignancy History of Synchronous / Bilateral Malignancy 	3382736 Indicate whether the patient has a history of prior malignancies. Note 1: If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. Note 2: If the patient has any history of prior malignancies, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for TCGA. If the patient has a history of multiple diagnoses of basal and/or squamous cell skin cancers, complete an "Other Malignancy Form" for the first diagnosis for each of these types.
16	History of Neo-Adjuvant Treatment to Tumor Specimen Submitted for TCGA*	 No Radiation Prior to Sample Procurement Pharmaceutical Treatment Prior to Sample Procurement Both Pharmaceutical and Radiation Treatment Prior to Sample Procurement 	3382737 Indicate whether the patient received therapy for this cancer prior to sample procurement of the tumor submitted for TCGA. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instructions. Note: Systemic treatment and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to procurement of the sample submitted for TCGA are exclusionary.
Date of Initia	Pathologic Diagnosis (Tumo	r Associated with Tissue Procurement for TCGA)	
17	Month of Initial Pathological Diagnosis*	(MM)	2896956 Provide the month the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
18	Day of Initial Pathological Diagnosis	(DD)	2896958 Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
19	Year of Initial Pathological Diagnosis*		2896960 Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
20	Lymph Node Neck Dissection	Yes No	2238421 Indicate whether a lymph node neck dissection was performed.
21	Method of Lymph Node Dissection LEFT	 Functional (Limited) Neck Dissection Modified Radical Neck Dissection Radical Neck Dissection 	3113989 If lymph node dissection was performed for head and neck cancer, indicate the method of lymph node neck dissection that was performed on the left side of the neck.
22	Method of Lymph Node Dissection RIGHT	 Functional (Limited) Neck Dissection Modified Radical Neck Dissection Radical Neck Dissection 	3124514 If lymph node dissection was performed for head and neck cancer, indicate the method of lymph node neck dissection that was performed on the right side of the neck.
23	Were Lymph Nodes Examined at the time of Primary Presentation?	Yes No	2200396 Indicate whether any lymph nodes were examined at the time of the primary resection for the tumor submitted to TCGA
24	Number of Lymph Nodes Examined		3 Provide the number of lymph nodes pathologically assessed if one or more lymph nodes were removed.

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

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
25	Number of Lymph Nodes Positive by H&E Light Microscopy		3086388 Provide the number of lymph nodes identified as positive through hematoxylin and eosin (H&E) staining and light microscopy.
26	Number of Lymph Nodes Positive for micrometastasis by IHC Keratin Staining ONLY		3086383 Provide the number of lymph nodes identified as positive through keratin immunohistochemistry (IHC) staining.
27	Margin Status	 Negative(Tumor > 2mm from Specimen Surface) Close (Tumor < or = 2mm from Specimen Surface) Positive (Tumor on Specimen Surface) 	3114007 Using the patient's pathology/laboratory report indicate the margin status results following examination of tissue margin(s) for the presence of disease.
28	p53 gene analysis	Normal Unknown Abnormal Not Evaluated	3124938 Indicate the results of p53 gene analysis.
29	EGFR amplification status	Amplified Unknown Unamplified Not Evaluated	3124957 Indicate the status of EGFR amplification.
30	Vital Status*	Living Deceased	5 Indicate whether the patient was living or deceased at the date of last contact.
Date of Last C	Contact		
31	Month of Last Contact	(MM)	2897020 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.
32	Day of Last Contact		2897022 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.
33	Year of Last Contact		2897024 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.
34	Number of Days from Date of 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	<u> </u>	Not Applicable (Patient is Alive)	
35	Month of Death	(MM)	2897026 If the patient is deceased, provide the month of death.
36	Day of Death	(DD)	2897028 If the patient is deceased, provide the day of death.
37	Year of Death		2897030 If the patient is deceased, provide the year of death.

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

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions	
38	Number of Days from Date of 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.
39	Tumor Status	Tumor Free With Tumor	Unknown Tumor Status	2759550 Indicate whether the patient was tumor/disease free at the date of last contact or death.

AJCC Stagi	AJCC Staging Instructions:						
	For Head & Neck tumors the clinical stage of the patient's tumor prior to surgery and the edition of the AJCC Staging Handbook are REQUIRED. In addition, it is						
strongly reco	mmended that the patholog	ical stage be included when applicabl	е				
40	AJCC Cancer Staging Handbook Edition*	 First Edition (1978-1983) Second Edition (1984-1988) Third Edition (1989-1992) Fourth Edition (1993-1997) 	 Fifth Edition (1998-200 Sixth Edition (2003-200 Seventh Edition (2010 	2722309 1009) Indicate the AJCC Cancer Staging Edition that			
41	Clinical Spread: Primary Tumor (cT)*	□ TX □ T1 □ T0 □ T2 □ Tis		2179725Using the patient's medical record in conjunctionT4aclinical T (primary tumor) as defined by theT4bAmerican Joint Committee on Cancer (AJCC).Note: The clinical staging components areREQUIRED for all head & neck cases.			
42	Clinical Spread: Lymph Nodes (cN)*	□ NX □ N1 □ N0 □ N2	— —	2179723 Using the patient's medical record in conjunction with any biopsy reports, select the code for the clinical N (regional lymph nodes) as defined by N3 the American Joint Committee on Cancer (AJCC). Note: The clinical staging components are <u>REQUIRED for all head & neck cases.</u>			
43	Clinical Spread: Distant Metastases (cM)*	Пмх	мо	2179720 Using the patient's medical record, identify the clinical absence or presence of distant spread or metastases and select the code for the clinical M (distant metastases) as defined by the American Joint Committee on Cancer (AJCC). Note: The clinical staging components are <u>REQUIRED</u> for all head & neck cases.			
44	Clinical Tumor Stage*	Stage I Stage	L Stage	definitive treatment, select the clinical stage as defined by the American Joint Committee on			

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Tissue Sour	rce Site (TSS) Name:	TSS Identifier: TS	S Unique Patient #:
Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
45	Pathologic Spread: Primary Tumor (pT)	TX T1 T4 T0 T2 T4a Tis T3 T4b	3045435 Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC). Note: The pathologic staging components are strongly recommended for all applicable head & neck cases.
46	Pathologic Spread : Lymph Nodes (pN)	□ NX □ N1 □ N2a □ N2c □ N0 □ N2 □ N2b □ N3	3065858 Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC). Note: The pathologic staging components are strongly recommended for all applicable head & neck cases.
47	Pathologic Spread : Distant Spread: Distant Metastases (pM)	П мх П мо П м1	3045439 Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the code for the clinical or pathological pM (metastasis) as defined by the American Joint Committee on Cancer (AJCC). Note: The pathologic staging components are strongly recommended for all applicable head & neck cases.
48	Pathological Tumor Stage	Stage I Stage III Stage IVB Stage II Stage IVA Stage IVC	3065862 Using the patient's pathology/laboratory report, in conjunction with the patient's medical record select the stage defined by the American Joint Committee on Cancer (AJCC). Note: The pathologic staging components are strongly recommended for all applicable head & neck cases.
Prognostic/P	redictive/Lifestyle Features f	or Tumor Prognosis or Responsiveness to Treatment	
49	Presence of Pathological Nodal Extra-capsular Spread	No Extranodal Extension Microscopic Extension Gross Extension	3108215 Using the patient's pathology/laboratory report, indicate if extracapsular (extranodal) extension is present in the tumor submitted for TCGA.
50	Tumor Grade*	G1 Well differentiated G4 Undifferentiated G2 Moderately differentiated GX Grade cannot be assessed G3 Poorly differentiated GX Grade cannot be assessed	2785839 Using the patient's pathology/laboratory report, select the tumor grade of the tumor submitted to TCGA.
51	Lymphovascular Invasion (LVI)	□ Yes □ No	64727 Indicate if lymphovascular invasion is pathologically present in the tumor submitted to TCGA. <i>Note: Lymphovascular invasion is defined as</i> <i>large vessel (vascular) invasion or small, thin- walled (lymphatic) invasion in a tumor</i> <i>specimen.</i>
52	Perineural Invasion Present	Yes No	64181 Indicate if perineural invasion or infiltration of tumor or cancer is pathologically present in tumor submitted to TCGA.
53	HPV Status by p16 Testing	Negative Unknown Positive Not Evaluated	3108263 Indicate the results of p16 testing used to identify the presence or absence of HPV (Human Papilloma Virus) in the tumor submitted to TCGA.

Tissue Sou	Tissue Source Site (TSS) Name: TSS Identifier:		ntifier: TSS	Unique Patient #:
Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions
54	HPV Status by ISH Testing	 Negative Positive 	Unknown Not Evaluated	3108261 Indicate the results of ISH testing used to identify the presence or absence of HPV (Human Papilloma Virus) in the tumor submitted to TCGA.
55	Tobacco Smoking History Indicator*	 Lifelong Non-smoker (<100 cigar Current smoker (includes daily si occasional smokers) Current reformed smoker for > 1 Current reformed smoker for <1 (less than or equal to 15 years) Current reformed smoker, durat Smoking History not Documented 	mokers and non-daily smokers (or 15 years (greater than 15 years) 5 years ion not specified	2181650 Indicate the patient's current smoking status or smoking history as self reported by the patient.
56	Year of Onset of Tobacco Smoking			2228604 f the patient is a current or reformed smoker, indicate the year in which the patient began smoking.
57	Year of Quitting Tobacco Smoking			2228610 If the patient is a reformed smoker, indicate the year in which the patient quit smoking.
58	Number Pack Years Smoked			2955385 Indicate the lifetime tobacco exposure of the patient. Number of pack years is defined as the number of cigarettes smoked per day times (x) the number of years smoked divided (/) by 20.
59	Alcohol History Documented?	Yes No		2201918 Indicate if the patient's alcohol history is documented.
60	Frequency of Alcohol Consumption	days/week		3114013 Indicate the average number of days each week that the patient consumes an alcoholic beverage.
61	Amount of Alcohol Consumption Per Day	drinks/day		3124961 Indicate the average number of alcoholic beverages that a person consumes per day.
Primary Treat	tment			
62	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.
63	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.
64	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies)	 Progressive Disease Stable Disease Partial Response 	Complete Response	2786727 Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies).

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

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
		this section if the patient had a new tumor event after tissue procurement a	
the patient di	d not have a new tumor even	t, or if the TSS does not know, indicate this in the first question below; and t	•
65	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.
Date of New	L Tumor Event After Initial Tre	atment	jor each new tanior event.
66	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.
67	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.
68	Year of New Tumor Event After Initial Treatment		3104046 If the patient had a new tumor event, provide the year of diagnosis for this new tumor event.
69	Number of Days from Date of 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.
70	Site of New Tumor Event	Oral Cavity Hypopharynx Cervical Lymph node Oropharynx Larynx Distant Metastasis (specify)	3108271 Indicate the site of this new tumor event, as it relates to the tissue submitted for TCGA.
71	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.
72	Type of New Tumor Event(Check all that apply)	 Locoregional Recurrence 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.
73	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.
74	Additional Surgery for New Tumor Event Loco- Regional Procedure	Yes I No I 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 Addit	ional Surgery for New Tumo	r Event Loco-Regional	
75	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.
76	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.
77	Year of Additional Surgery for New Tumor Event Loco-Regional		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.

Tissue Source Site (TSS) Name	Tissue	Source	Site	(TSS)) Name
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e: ______ TSS Identifier: ______ TSS Unique Patient #: ____

Question #	Data Element Label	Data Entry Altern	atives		CDE ID With Working Instructions
78	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.
79	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 Addit	tional Surgery for New Tumo	r Event Metastasis			
80	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.
81	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.
82	Year of Additional Surgery for New Tumor Event Metastasis		(ҮҮҮҮ)		2897042 If the patient had surgery for the new metastatic tumor event, provide the year of surgery for this new metastatic tumor event.
83	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					
84	Additional treatment of New Tumor Event Radiation Therapy	☐ Yes	🗋 No	Unknown	3008761 Indicate whether the patient received radiation treatment for this new tumor event.
85	Additional Treatment of New Tumor Event Pharmaceutical Therapy	Yes	□ No	Unknown	2650646 Indicate whether the patient received pharmaceutical treatment for this new tumor event.

Comments:

Principal Investigator Name: ______ Principal Investigator Signature: ______

Date Signed (MM/DD/YYYY):