Enrollment Form
Esophageal

Instructions: *The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity and known history from the date of initial diagnosis to the most recent date of contact with the patient ("Date of Initial Pathologic Diagnosis" and "Date of Last Contant" on this form).*

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. 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 a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By *(Interviewer Name in OpenClinica)*: _____Completed Date: _____

General Information

#	Data Element	Entry Alternatives	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	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. *Provided time intervals must begin with the date of initial pathologic diagnosis (e.g. biopsy).* *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	Is this a prospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. 3088492
3	Is this a retrospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. 3088528

Patient Information

#	Data Element	Entry Alternatives			Working Instructions
Date of Birth					
4*	Date of Birth	___ ___ Month	___ ___ Day	___ ___ ___ ___ Year	Provide the date the patient was born. 2896950(month), 2896952(day), 2896954 (year)
5	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	_____			Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth. 3008233 *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.*
6	Country of Birth	_____			Provide the country where the patient was born. 2183279

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#	Data Element	Entry Alternatives	Working Instructions
7*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
8	Height *(at time of diagnosis)*	_____(cm)	Provide the patient's height (centimeters) at the time the patient was diagnosed with the tumor submitted for TCGA. 649
9	Weight *(at time of diagnosis)*	_____(kg)	Provide the patient's weight (kilograms) at the time the patient was diagnosed with the tumor submitted for TCGA. 651
10	Country Where Cancer Sample was Procured	_____	Provide the country where the tissue submitted for TCGA was procured. 3203072
11	State/Province of Sample Procurement	_____	Provide the name of the state, province or country where the sample submitted for TCGA was procured. 2179603
12	City of Cancer Sample Procurement	_____	Provide the name of the city where the sample submitted for TCGA was procured 3203075
13*	Race	☐ American Indian or Alaska Native *A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.* ☐ Asian *A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, 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 the far Europe, the Middle East, or North Africa.* ☐ Black or African American *A person having origins in any of 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.*	Provide the patient's race using the defined categories. 2192199
14	Ethnicity	☐ Not Hispanic or Latino: *A person not meeting the definition of 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.*	Provide the patient's ethnicity using the defined categories. 2192217

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#	Data Element	Entry Alternatives	Working Instructions
15*	History of Prior Malignancy	☐ Yes ☐ No	Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736 *If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA.* *If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.*
16*	Neo-adjuvant Therapy (Pre-Operative) Therapy For Tumor Submitted for TCGA	☐ Yes ☐ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the tumor that yielded the sample submitted for TCGA. 3382737 *Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the collection of the sample submitted for TCGA is exclusionary.*
17*	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
18*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
Date of Last Contact *(If patient is living)*			
19*	Date of Last Contact	___ ___ Month; ___ ___ Day; ____ ____ ____ ____ Year	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). 2897020 (month), 2897022 (day), 2897024(year) *Do not answer if patient is deceased.*
20	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	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 last contact. 3008273 *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			
21*	Date of Death	___ ___ Month; ___ ___ Day; ____ ____ ____ ____ Year	If the patient is deceased, provide the month of death. 2897026(month), 2897028(day), 2897030 (year)
22	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	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 death. 3165475 *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 History of Tobacco and Alcohol Use			
23	Tobacco Smoking History Indicator	☐ 1-Lifelong non-smoker (<100 cigarettes smoked in lifetime) ☐ 2-Current smoker (includes daily and non-daily smokers) ☐ 3-Current reformed smoker (duration not specified) ☐ 4-Current reformed smoker for > 15 years ☐ 5-Current reformed smoker for ≥ 15 years ☐ Smoking History not Documented	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories. If the patient is a lifelong non-smoker, skip the additional smoking questions. 2181650
24	Age at Onset of Tobacco	_____	Provide the age in years when the patient began smoking cigarettes.

#	Data Element	Entry Alternatives	Working Instructions
	Smoking		2178045 *If the patient is a lifelong non-smoker, do not answer this question.*
25	Year of Quitting Tobacco Smoking	___ ___ ___ ___ (YYYY)	Provide the year the patient quit smoking. 2228610 *If the patient is a current smoker or a lifelong non-smoker, do not answer this question.*
26	Number of Pack Years Smoked	___ ___ Pack Years	Provide the number of pack years the patient smoked. This is calculated using the number of cigarettes smoked per day times the number of years smoked, divided by 20. For example, if a patient smoked 5 cigarettes per day times 10 years divided by 20, the patient would have 2.5 pack years (e.g. 5 x 10/ 20=2.5). 2955385 *If the patient is a lifelong non-smoker, do not answer this question.*
27	Was the patient's alcohol history documented?	☐ Yes ☐ No	Indicate whether the patient's alcohol history is documented. 3440205
28	Frequency of Alcohol Consumption	___ Days per Week	Provide the number of days per week that the patient consumes alcohol. 3114013 *If the patient's alcohol history is not documented, do not answer this question.*
29	Amount of Alcohol Consumption per Day	___ ___ Drinks per Day	Provide the number of drinks the patient consumes per day. 3124961 *If the patient's alcohol history is not documented, do not answer this question.*
Patient History of Esophageal and Gastric Disease			
30	Did the patient have a prior clinical diagnosis of reflux disease?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a prior clinical diagnosis of reflux disease. 3203079
31	If the patient was clinically diagnosed with reflux disease, how was the patient treated? *Check all that apply*	☐ Medically Treated ☐ Surgically Treated ☐ No Treatment ☐ Unknown	If the patient was clinically diagnosed with reflux disease, indicated how the patient was treated. 3440206 *If the patient did not have a prior clinical diagnosis of reflux disease or if this is unknown, do not answer this question.*
32	Previous or current diagnosis of H. pylori infection?	☐ Current ☐ Previous ☐ Never ☐ Unknown	Indicate whether the subject was previously or is currently diagnosed with H. Pylori. 3440211
33	How was the patient initially diagnosed with esophageal cancer?	☐ Screening ☐ Surveillance ☐ Symptomatic ☐ Unknown	Provide the method used to initially diagnose this patient with esophageal cancer. 3440213
34	Prior to the diagnosis of the esophageal tumor submitted for TCGA, was the patient clinically diagnosed with Barrett's esophagus?	☐ Yes-USA ☐ Yes-UK ☐ No ☐ Unknown	Indicate whether the subject was previously or is currently diagnosed with Barrett's Esophagus. 3440212
35	If the patient had a clinical diagnosis of Barrett's esophagus, were goblet cells present?	☐ Yes ☐ No ☐ Unknown	If the patient was clinically diagnosed with Barrett's Esophagus, indicate whether there were goblet cells present. 3440216 *If the patient did not have a clinical diagnosis of Barrett's Esophagus or if this is unknown, do not answer this question.*

#	Data Element	Entry Alternatives	Working Instructions
36	Family History of Esophageal and/or Gastric Cancer in First Degree Relative *(parents, siblings, or children)*	☐ Yes ☐ No ☐ Unknown	Indicate whether the subject has a first degree relative (parents, siblings, or children) with a history of esophageal cancer. 3440217
37	Number of First Degree Relatives who have been Diagnosed with Esophageal and/or Gastric Cancer	_____	Indicate the number of first degree relatives (parents, siblings, children) who have been diagnosed with esophageal cancer. 3440229 *If it is not known whether the patient had a family history of esophageal and/or gastric cancer, do not answer this question.*

Primary Tumor Pathologic/ Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
38*	Primary Site of Disease	☐ Esophagus	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
39*	In which third of the esophagus is the tumor **centered**? *Check only one.*	☐ Proximal ☐ Mid ☐ Distal	Using the patient's pathology/laboratory report, indicate where the tumor submitted for TCGA is centered. 3295805
40*	In which third(s) of the esophagus is the tumor **involved**? *Check all that apply.*	☐ Proximal ☐ Mid ☐ Distal	Using the patient's pathology/laboratory report, indicate the involved locations of the tumor submitted for TCGA. 3295806
41*	Histological Type	☐ Esophagus Adenocarcinoma, NOS ☐ Esophagus Squamous Cell Carcinoma	Using the patient's pathology/laboratory report, select the histology and/or subtype. 3081934
42	Esophageal Columnar Metaplasia Present	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had esophageal columnar metaplasia present. 3440218
43	Goblet Cells of Esophageal Columnar Mucosa Present (i.e. Possible Specialized Barrett's Esophagus Mucosa)	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had intestinal metaplasia with goblet cells present. 3440219
44	Degree of Dysplasia within the Non-cancerous Esophageal Columnar Mucosa	☐ Negative/ no dysplasia ☐ Indefinite for dysplasia ☐ Low grade dysplasia ☐ High grade dysplasia ☐ Unknown	Provide the patient's degree of dysplasia. 3440917
45*	Tumor Grade	☐ GX – Unknown ☐ G1 – Well Differentiated ☐ G2 – Moderately Differentiated ☐ G3 – Poorly Differentiated ☐ G4 – Undifferentiated	Using the patient's pathology/laboratory report, select the tumor grade for the specimen submitted for TCGA. 2785839
Date and Method of Initial Pathologic Diagnosis			
46*	Date of Initial Pathologic Diagnosis	___ ___ Month ___ ___ Day ___ ___ ___ ___ Year	Provide the month the patient was initially diagnosed with the malignancy submitted for TCGA. 2896956(month), 2896958(day), 2896960(year)
47	Age at Initial Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657 *Only complete this question 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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#	Data Element	Entry Alternatives	Working Instructions
48	Method of Initial Pathologic Diagnosis	☐ Endoscopic Biopsy ☐ Transurethral Resection (TURBT) ☐ Other, specify	Provide the procedure used to initially diagnose the patient. 2757941
49	Other Method of Initial Pathologic Diagnosis	_____	If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948
Lymph Node Status			
50	Was there radiographic evidence suggesting spread to the lymph nodes?	☐ Yes ☐ No ☐ Unknown	Indicate whether there was radiographic evidence of lymph nodes for this patient. 3440228
51	Were lymph nodes examined at the time of primary resection?	☐ Yes ☐ No ☐ Unknown	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
52	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3 *If lymph nodes were not examined for this patient at the time of the primary resection, or if this is unknown, do not answer this question.*
53	Number of Lymph Nodes Positive by H&E light microscopy	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3086388 *If lymph nodes were not examined for this patient at the time of the primary resection, or if this is unknown, do not answer this question.*
54	Number of Lymph Nodes Positive by IHC Keratin Staining only	_____	Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3086383 *If lymph nodes were not examined for this patient at the time of the primary resection, or if this is unknown, do not answer this question.*
AJCC Staging *If the patient did not undergo surgery, the following questions should be completed.*			
55*	AJCC Cancer Staging Edition *(used for clinical staging)*	☐ 1st Edition *(1978-1983)* ☐ 2nd Edition *(1984-1988)* ☐ 3rd Edition *(1989-1992)* ☐ 4th Edition *(1993-1997)* ☐ 5th Edition *(1998-2002)* ☐ 6th Edition *(2003-2009)* ☐ 7th Edition *(2010-present)*	Please provide the AJCC Cancer Staging Edition used to answer the following clinical staging questions. 2722309
56*	Clinical T Stage *At time of biopsy*	☐ TX ☐ T1 ☐ T4 ☐ T0 ☐ T2 ☐ T4a ☐ Tis ☐ T3 ☐ T4b	Using the patient's medical records, select the code for the clinical T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3440328
57*	Clinical N Stage *At time of biopsy*	☐ NX ☐ N1 ☐ N3 ☐ N0 ☐ N2	Using the patient's medical records, select the code for the clinical N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3440330
58*	Clinical M Stage *At time of biopsy*	☐ MX ☐ M1 ☐ M1b ☐ M0 ☐ M1a	Using the patient's medical records, select the code for the clinical M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3440331
59*	Clinical Stage *At time of biopsy*	☐ Stage 0 ☐ Stage III ☐ Stage I ☐ Stage IIIA ☐ Stage IA ☐ Stage IIIB ☐ Stage IB ☐ Stage IIIC ☐ Stage II ☐ Stage IV ☐ Stage IIA ☐ Stage IVA ☐ Stage IIB ☐ Stage IVB	Using the patient's medical records, select the stage defined by the American Joint Committee on Cancer (AJCC). 3440332

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#	Data Element	Entry Alternatives	Working Instructions
60	Will The Patient Undergo Surgery For This Tumor?	☐ Yes ☐ No ☐ Surgery Already Performed ☐ Unknown	Indicate whether the patient has had surgery for this tumor. 3440231
61	If Surgery Was Already Performed, Was Treatment Given Prior To Surgery?	☐ No treatment ☐ Chemotherapy ☐ Radiation ☐ Chemotherapy & Radiation ☐ Unknown	If the patient has already undergone surgery, indicate whether the patient received treatment prior to the surgery. 3440232
AJCC Staging *The following staging questions should be answered for* ***the pathologic staging done after the patient had surgery****.* *If the patient did not undergo surgery, additional questions should be answered for this patient (see questions 67-73).*			
62*	AJCC Cancer Staging Edition	☐ 1st Edition *(1978-1983)* ☐ 2nd Edition *(1984-1988)* ☐ 3rd Edition *(1989-1992)* ☐ 4th Edition *(1993-1997)* ☐ 5th Edition *(1998-2002)* ☐ 6th Edition *(2003-2009)* ☐ 7th Edition *(2010-present)*	Please use the AJCC Cancer Staging Edition used to answer the following pathologic staging questions. 2722309
63*	Pathologic Spread *(for Cystectomy Specimen):* Primary Tumor (pT) *Please provide as much information as possible.*	☐ TX ☐ T1 ☐ T4 ☐ T0 ☐ T2 ☐ T4a ☐ Tis ☐ T3 ☐ T4b ☐ Unknown	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3045435
64*	Pathologic Spread *(for Cystectomy Specimen)*: Regional Nodes (pN)	☐ NX ☐ N1 ☐ N3 ☐ N0 ☐ N2 ☐ Unknown	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3203106
65*	Distant Spread: Distant Metastasis (M)	☐ MX ☐ M1 ☐ M1b ☐ M0 ☐ M1a ☐ Unknown	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3045439
66*	Tumor Stage	☐ Stage 0 ☐ Stage IIA ☐ Stage IIIC ☐ Stage I ☐ Stage IIB ☐ Stage IV ☐ Stage IA ☐ Stage III ☐ Stage IVA ☐ Stage IB ☐ Stage IIIA ☐ Stage IVB ☐ Stage II ☐ Stage IIIB ☐ Unknown	Using the patient's pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3203222
67*	Residual Tumor *(at time of initial surgery)*	☐ RX ☐ R1 ☐ Unknown ☐ R0 ☐ R2	Using the patient's pathology/laboratory report, select the tissue margin a status at time of surgical resection. 2608702
68	Performance Status Scale: Karnofsky Score ***(To be taken prior to surgery / treatment.)***	☐ 100 – Normal, no complaints, no evidence of disease ☐ 90 – Able to carry on normal activity; minor signs or symptoms of disease ☐ 80 – Normal activity with effort; some signs or symptoms of disease ☐ 70 – Cares for self, unable to carry on normal activity or to do active work ☐ 60 – Requires occasional assistance, but is able to care for most of his/her needs ☐ 50 – Requires considerable assistance and frequent medical care ☐ 40 – Disabled, requires special care and assistance ☐ 30 – Severely disabled, hospitalization indicated. Death is not imminent. ☐ 20 – Very sick, hospitalization indicated. Death not imminent ☐ 10 – Moribund, fatal processes progressing rapidly ☐ 0 – Dead ☐ Unknown ☐ Not Evaluated	Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient at the time of the diagnosis of the tumor submitted for TCGA. 2003853

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#	Data Element	Entry Alternatives	Working Instructions
69	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) ***(To be taken prior to surgery / treatment.)***	☐ 0 – Asymptomatic ☐ 1 – Symptomatic but fully ambulatory ☐ 2 – Symptomatic but in bed less than 50% of the day ☐ 3 – Symptomatic and in bed more than 50% of the day ☐ 4 – Bedridden ☐ Unknown ☐ Not Evaluated	Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient at the time of the diagnosis of the tumor submitted for TCGA. 88
70*	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***IF the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed***. 2005312
71*	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. ***IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed***. 3397567

New Tumor Event Information *Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.*

Note: The New Tumor Event section on OpenClinica can be completed multiple times, if the patient had multiple New Tumor Events.

#	Data Element	Entry Alternatives	Working Instructions
72*	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after the date of initial diagnosis. 3121376 *If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.*
Date of New Tumor Event after Initial Treatment			
73*	Month of New Tumor Event	___ ___ ___ ___ ___ ___ ___ ___ Month Day Year	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (month), 3104042 (day), 3104046 (year)
74	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	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. 3392464 *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.*
75	Type of New Tumor Event	☐ Locoregional/Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. 3119721
76	Site of New Tumor Event	☐ Brain ☐ Lung ☐ Bone ☐ Liver ☐ Other, specify	Indicate the site of this new tumor event. 3108271
77	Other Site of New Tumor Event	_____	If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033
78	Diagnostic Evidence of New Tumor Event	☐ Biopsy w/ Histologic Confirmation ☐ Convincing Imaging ☐ Positive Biomarker(s)	Indicate the procedure or testing method used to diagnose this new tumor event. 2786205

#	Data Element	Entry Alternatives	Working Instructions
79	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
Date of Additional Surgery for New Tumor Event (when applicable)			
80	Date of Additional Surgery for New Tumor Event	___ ___ ___ ___ ____ ____ ____ ____ Month Day Year	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (month), 3427613 (day), 3427614 (year)
81	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event	_____	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). 3008335 *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.*
82	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
83	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

Principal Investigator Signature Date

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.