Enrollment Form
Cervical (CESC)

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 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 Contact" 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
4	Date of Birth	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	Provide the date the patient was born. 2896950 (month), 2896952 (day), 2896954 (year) *Note: The day of Birth is not required.*
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	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604

#	Data Element	Entry Alternatives	Working Instructions
7	Menopause Status *(at time of diagnosis)*	☐ Premenopausal *<6 months since LMP AND no prior bilateral oophorectomy AND not on estrogen replacement* ☐ Perimenopausal *6-12 months since last menstrual period* ☐ Postmenopausal *Prior bilateral oophorectomy OR >12 months since LMP with no prior oophorectomry* ☐ Indeterminate or Unknown ☐ Not Evaluated	Using the patient's medical records, indicate menopause status at the time the patient was diagnosed with the malignancy submitted for TCGA. 2957270
8	Height *(at time of diagnosis)*	_____(cm)	Provide the patient's height (in centimeters) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 649
9	Weight *(at time of diagnosis)*	_____(kg)	Provide the patient's weight (in kilograms) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 651
10	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
11	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
12	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.
13	History of Neo-adjuvant Treatment for Sample Submitted for TCGA	☐ Yes ☐ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737 Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the collection of the sample submitted for TCGA is exclusionary.
14	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
15	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553
16	Date of Last Contact	___ ___ / ___ ___ / ___ ___ ___ ___ (month) (day) (year)	If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (month), 2897022 (day), 2897024 (year) *Note:* Do not answer if patient is deceased. *The day of Last Contact is not required.*
17	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.
18	Date of Death	___ ___ / ___ ___ / ___ ___ ___ ___ (month) (day) (year)	If the patient is deceased, provide the month of death. 2897026, (month) 2897028 (day), 2897030 (year) *Note: The day of Death is not required.*
19	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.
20	Cause of Death	☐ Cervical cancer ☐ Other cause(s), specify ☐ Unknown	Indicate the patient's cause of death. 2554674
21	Other Cause of Death	_____	If the patient's cause of death was not included in the provided list, specify the patient's cause(s) of death. 2004150
History of Pregnancies and Contraceptive Use			
22	Use of Hormonal Contraceptives	☐ Current User ☐ Former User ☐ Never Used ☐ Unknown	Indicate whether the patient has used or is currently using hormonal contraceptives. 3104217

#	Data Element	Entry Alternatives		Working Instructions
23	Total Number of Pregnancies	_____		Provide the total number of times the patient conceived and became pregnant. This should include all of the pregnancies under the question "Number of Pregnancies by Outcome Type" and current pregnancies. 2005341
24	Number of Pregnancies by Outcome Type *(Complete all that apply)*	**Pregnancy Type**	**Number of Pregnancies**	
		Live Birth *(single or multiple births)*	_____	Provide the number of times the patient had successful pregnancies that resulted in the live birth of at least one child. 2005342
		Miscarriage	_____	Provide the number of times the patient conceived and became pregnant, but did not carry fetus to term due to natural occurrences or problems during the pregnancy. 2180637
		Induced Abortion	_____	Provide the number of times the patient conceived and became pregnant, but did not carry fetus to term due to medical intervention to end the pregnancy. 2180648
		Ectopic Pregnancy	_____	Provide the number of times the patient conceived and become pregnant, but did not carry the fetus to term due to an ectopic pregnancy. 2261915
		Stillbirth *(early fetal death)*	_____	Indicate the number of times the patient conceived and become pregnant, but the pregnancy ended with stillbirth. 2183304
		Unknown	_____	Provide the number of times the patient was known to be pregnant, but the outcome of the pregnancy was unknown.
25	Pregnant at Time of Diagnosis	☐ Yes ☐ No		Indicate whether the patient was pregnant at the time of initial diagnosis. 3012573
Smoking History				
26	Tobacco smoking history indicator	☐ Lifelong non-smoker (<100 cigarettes smoked in lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for > 15 years ☐ 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
27	Age of onset tobacco smoking	___ ___ Years of Age		Provide the age in years when the patient began smoking cigarettes. 2178045 If the patient is a lifelong non-smoker, do not answer this question.
28	Year of quitting tobacco smoking	___ ___ ___ ___ (YYYY)		Provide the year the patient quit smoking. 2228610 If the patient is a lifelong non-smoker or if the patient has not quit smoking, do not answer this question.
29	Number of Pack Years Smoked	___ ___ 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.
History of Immunosuppressive Disease				

#	Data Element	Entry Alternatives	Working Instructions
30	History of Immunosuppressive Disease *(Check all that apply)*	☐ HIV ☐ Organ Transplant ☐ Chronic Systemic Steroid Use ☐ Unknown ☐ Not Evaluated ☐ Other, specify	If the patient has had any history of immunosuppressive disease(s), provide the patient's medical history. If the patient's disease is not provided in the list, select "other" and provide the specific disease in the following question. 3151446
31	Other Immunosuppressive Disease	_____	Specify any history of immunosuppressive disease that is not included in the list provided. 3151449
Performance Status and Measure of Success			
32	Performance Status: Eastern Cooperative Oncology Group (ECOG)	☐ 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	Using the patient's medical records, provide the ECOG performance status score at the time provided in the following question. 88
33	Performance Status: Timing	☐ Preoperative ☐ Pre-adjuvant therapy ☐ Post-adjuvant therapy ☐ Other, specify	Indicate the time point of the documented ECOG performance score provided above. 2792763
34	Other Performance Status Scale: Timing	_____	If the status of the patient during the last documented ECOG performance score was not included in the provided list, specify the patient's status. 3151756
35	Date of Performance Status	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	Provide the date of the last documented ECOG performance score. 3121370 (month), 3121372 (day), 3121374 (year) *Note: The day of Performance Status is not required.*
36	Measure of success of outcome *at the completion of initial first course treatment (including surgery)*	☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Unknown ☐ Not Applicable (Treatment Ongoing)	Indicate the patient's measure of success after their primary treatment including surgery and adjuvant therapies. 2786727

Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
Pathologic Diagnosis Information			
37	Primary Site of Disease	☐ Cervix	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
38	Histological Subtype	☐ Cervical Squamous Cell Carcinoma ☐ Endocervical type of Adenocarcinoma ☐ Endocervical Adenocarcinoma of the Usual Type ☐ Mucin-depleted Adenocarcinoma ☐ Endometrioid Adenocarcinoma of Endocervix ☐ Mucinous Adenocarcinoma of Endocervical Type ☐ Adenosquamous Carcinoma	Using the patient's pathology/laboratory report, select the histology of the tumor submitted for TCGA. 3081934
39	Keratinization in Squamous Cell Carcinoma	☐ Keratinizing squamous cell carcinoma ☐ Non-keratinizing squamous cell carcinoma	If the patient had squamous cell carcinoma, indicate whether the tumor has any keratinizing squamous cell carcinoma using the patient's pathology/laboratory report. Keratinizing tumors have at least one well-formed keratin pearl. All other patters are non-keratinizing. 3151599

#	Data Element	Entry Alternatives	Working Instructions
40	Tumor Grade	☐ G1 Well Differentiated ☐ G2 Moderately Differentiated ☐ G3 Poorly Differentiated ☐ G4 Undifferentiated ☐ GX Grade cannot be assessed	Using the patient's pathology/laboratory report, select the tumor grade. 2785839
41	Date of Initial Pathologic Diagnosis	___ ___ / ___ ___ / ___ ___ ___ ___ (month) (day) (year)	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (month), 2896958 (day), 2896960 (year) *Note: The day of Initial Pathologic Diagnosis is not required.*
42	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.
43	Method of Initial Pathologic Diagnosis	☐ Cytology ☐ Biopsy (cervical, CT-guided or other) ☐ Cone biopsy/ LEEP ☐ Lymph node sampling or dissection ☐ Other, specify	Provide the procedure used to initially diagnose the patient. 2757941 Please note that this method is referring to the procedure performed on the Date of Initial Pathologic Diagnosis, provided in the previous question.
44	Other Method of Pathologic Diagnosis	_____	If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948
45	If hysterectomy was performed, what type was it?	☐ Hysterectomy not performed ☐ Simple ☐ Radical (modified or not modified) ☐ Other, specify	Indicate whether a hysterectomy was performed at diagnosis. If a hysterectomy was performed, indicate the type. 2647164
46	Other Type of Hysterectomy	_____	If the type of hysterectomy performed was not included in the list provided, please provide the type of hysterectomy performed. 3151506
47	If hysterectomy was performed, were there involved pathologic margins?	☐ Macroscopic parametrial involvement ☐ Microscopic parametrial involvement ☐ Positive bladder margin ☐ Positive vaginal margin ☐ Unknown ☐ Other, specify	If a hysterectomy was performed, provide the patient's margin involvement after surgery. 3151541
48	Other Involved Pathologic Margins	_____	If the margin involvement was not included in the provided list, describe the pathologic margins. 3151544
49	Pelvic Extension Comment	_____	Using the patient's pathology/laboratory report, provide comments regarding any tumor extension to the pelvic wall. 3151605
50	Pathologic Lymphovascular Invasion	☐ Present ☐ Absent ☐ Unknown	Using the patient's pathology/laboratory report, indicate the presence or absents of pathologic lymphovascular invasion. 2008052
51	Corpus Involvement	☐ Present ☐ Absent ☐ Unknown	The corpus uteri is the part of the uterus above the isthmus, comprising about two thirds of the non-pregnant organ. To have a connection by participation or association or use; sharing in an activity or process. 3151610
Lymph Node Status			
52	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
53	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3
54	Number of Lymph Nodes Positive by H&E	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy.

#	Data Element	Entry Alternatives	Working Instructions
	light microscopy		3086388
55	Number of Lymph Nodes Positive by IHC Keratin Staining only	_____	Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3086383
56	Pathologic Positive Lymph Node Location(s) *(Check all that apply)*	☐ Pelvic (external iliac, internal iliac, obturator) ☐ Common iliac ☐ Paraaortic ☐ Supraclavicular ☐ Unknown ☐ Other, specify	Using the patient's pathology/laboratory report, provide the location(s) of any positive lymph nodes. 3151519
57	Other Positive Lymph Node	_____	If the location of positive lymph nodes was not included in the list provide, please provide the location of positive lymph nodes. 3151522
AJCC Staging			
58	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 select the AJCC Cancer Staging Edition used to answer the following questions. 2722309
59	Pathologic Spread: Primary Tumor (pT)	☐ TX ☐ T1b ☐ T2a2 ☐ T0 ☐ T1b1 ☐ T2b ☐ Tis ☐ T1b2 ☐ T3 ☐ T1 ☐ T2 ☐ T3a ☐ T1a ☐ T2a ☐ T3b ☐ T1a1 ☐ T2a1 ☐ T4 ☐ T1a2	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
60	Pathologic Spread: Regional Nodes (pN)	☐ NX ☐ N0 ☐ N1	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
61	Pathologic Distant Spread: Distant Metastasis (M)	☐ MX ☐ M0 ☐ M1	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
62	FIGO Staging System *(Publication Date Used for Staging)*	☐ 1988 ☐ 1995 ☐ 2009	Using the patient's pathology/laboratory report, provide the FIGO staging system used to stage the patient. 3114049
63	FIGO Stage	☐ Stage I ☐ Stage IIA1 ☐ Stage IA ☐ Stage IIA2 ☐ Stage IA1 ☐ Stage IIB ☐ Stage IA2 ☐ Stage III ☐ Stage IB ☐ Stage IIIA ☐ Stage IB1 ☐ Stage IIIB ☐ Stage IB2 ☐ Stage IV ☐ Stage II ☐ Stage IVA ☐ Stage IIA ☐ Stage IVB	Using the patient's pathology/laboratory report, provide the FIGO stage given to the patient at the time of diagnosis. 3225684

Tests Performed

64	Date of FED-PET or PET / CT	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	If the patient's medical records indicate the patient had a FED-PET or PET/CT, provide the month of the FED-PET or PET/CT. 3151498 (month), 3151499 (day), 3151500 (year)

65	Cervix SUV Results	_____	If the patient's medical records indicate the patient had a FED-PET or PET/CT, provide the cervix standardized update value (SUV). 3151615
66	FED-PET or PET / CT Results *(Check all that apply)*	**Anatomic Site** / **Present** / **Absent** / **Unknown** Pelvic Nodes Paraaortic Nodes Supraclavicular Nodes Parametrium Bladder Extra-Pelvic Metastatic Disease	If the patient's medical records indicate the patient had a FED-PET or PET/CT, provide the results for each applicable anatomic site. 3151497
67	Date of MRI	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	If the patient's medical records indicate the patient had an MRI, provide the date of the MRI. 3151491 (month), 3151492 (day), 3151493 (year)
68	MRI Results *(Check all that apply)*	**Anatomic Site** / **Present** / **Absent** / **Unknown** Pelvic Nodes Paraaortic Nodes Supraclavicular Nodes Parametrium Bladder Extra-Pelvic Metastatic Disease	If the patient's medical records indicate the patient had a MRI, provide the results for each applicable anatomic site. 3151441
69	Date of CT	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	If the patient's medical records indicate the patient had an MRI, provide the date of the MRI. 3151134 (month), 3151132 (day), 3151133 (year)
70	CT Results *(Check all that apply)*	**Anatomic Site** / **Present** / **Absent** / **Unknown** Pelvic Nodes Paraaortic Nodes Supraclavicular Nodes Parametrium Bladder Extra-Pelvic Metastatic Disease	If the patient's medical records indicate the patient had a CT, provide the results for each applicable anatomic site. 3151439
71	HPV *(List all types)*	☐ HPV 16 ☐ HPV 18 ☐ Other HPV Type ☐ None	If the patient's medical records indicate human papillomavirus (HPV), provide the HPV type. 2922649
72	Other HPV Type(s)	_____	If the patient's medical records indicate human papillomavirus (HPV) and the type is not included in the provided list, please describe the HPV type. 3166168
73	Method of HPV Typing	☐ PCR ☐ Qiagen-digene #C2 ☐ Roche - linear array ☐ Other (please specify)	Indicate the method used for HPV typing. 3151457
74	Other Method of HPV Typing	_____	If the method used for HPV typing is not included in the provided list, please describe the method used. 3151460
75	PCR Primer Pairs	☐ MY09/MY11 ☐ PGMY09/PGMY11 ☐ Roche - linear array ☐ SPF10-LiPA ☐ GP5+/GP6+ ☐ Other (please specify)	Indicate the PCR primer pairs used. 3151487

76	Other PCR Primer Pairs	_____	If the PCR primer pairs used are not included in the provided list, please describe the PCR primer pairs used. 3151490
77	Squamous Cellular Carcinoma Antigen (SCCA) Tumor Marke	_____ µg/µL	Provide the patient's squamous cellular carcinoma antigen (SCCA) tumor marker results. 3151234
78	Date of SCCA Performed	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	Provide the date SCCA was performed. 3151235 (month), 3151236 (day), 3151237 (year)

Treatment Information

#	Data Element	Entry Alternatives	Working Instructions
79	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
80	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
Radiation Therapy (Brachytherapy and External Radiation)			
81	If patient did not complete radiation, provide the primary reason why it was not given or not completed.	☐ Adverse event/complications ☐ Scheduling problems ☐ Participant refusal ☐ Not done per treating physicians discretion ☐ Other, specify ☐ Unknown	If the patient did not receive radiation indicate the reason treatment was not administered. 2733266
82	Other Reason Radiation Not Given or Not Completed	_____	If the reason the patient did not receive radiation is not included in the provided list, specify the reason. 2733267
83	If patient received brachytherapy, indicate the type.	☐ LDR ☐ HDR ☐ Other, specify	If the patient received brachytherapy, indicate the type administered. If the patient did not receive brachytherapy, skip all related questions. 2966127
84	Other Type of Brachytherapy	_____	If the type of brachytherapy the patient received is not included in the provided list, specify the type administered. 3150976
85	If patient received brachytherapy, provide the total dose to point A.	_____ cGy	Indicate the total dose (cGy) of brachytherapy to point A the patient received. 3151100
86	If patient received external radiation provide type of external radiation	☐ 3D Conformal ☐ IMRT ☐ External Beam ☐ Unknown ☐ Other, specify	If the patient received external radiation, indicate the type administered. If the patient did not receive external radiation, skip all related questions. 61468
87	Other Type of External Radiation	_____	If the type of external radiation the patient received is not included in the provided list, specify the type administered. 2195477
88	Total Dose to Pelvis/Pelvic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to pelvis/pelvic nodes. 3006
89	Total Dose to Paraaortic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to paraaortic nodes. 3151106
Concurrent Chemotherapy			

#	Data Element	Entry Alternatives	Working Instructions
90	Was chemotherapy given concurrent to radiation after tissue procurement?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received chemotherapy concurrent to radiation treatment after tissue procurement. 2539220
91	If patient did not complete chemotherapy concurrent to radiation, provide the primary reason why it was not given or not completed.	☐ Adverse event/complications ☐ Scheduling problems ☐ Participant refusal ☐ Not done per treating physicians discretion ☐ Other, specify ☐ Unknown	If the patient did not receive chemotherapy concurrent to radiation treatment indicate the reason treatment was not administered. 3151120
92	Other Reason Chemotherapy Not Given concurrent to Radiation	_____	If the reason the patient did not receive chemotherapy concurrent to radiation treatment is not included in the provided list, specify the reason. 3151824
93	If patient received concurrent chemotherapy, indicate type of concurrent chemotherapy. *(Check all that apply)*	☐ Cisplatin ☐ Carboplatin ☐ Other, specify	If the patient received chemotherapy concurrent to radiation treatment, indicate the type administered. If the patient did not receive external radiation, skip all related questions. 2007212
94	Other Type of Concurrent Chemotherapy	_____	If the type of chemotherapy given concurrent to radiation treatment is not included in the provided list, specify the type administered. 2426129
95	Concurrent Chemotherapy Dose	_____	Indicate the dose of the concurrent chemotherapy the patient received. Include the unit of measure. 3166172 and 3065815
96	Concurrent Chemotherapy Frequency	☐ Every hour ☐ 5 times daily ☐ 4 times daily ☐ 3 times daily ☐ 2 times daily ☐ Every 24 hours ☐ Every other day ☐ Twice a week ☐ Once weekly	Indicate the frequency the concurrent chemotherapy was received. 2179580
97	Concurrent Chemotherapy Number of Total Doses	_____	Indicate the total number of doses the patient received the concurrent chemotherapy. 2180805

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.*

#	Data Element	Entry Alternatives	Working Instructions
98	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 initial treatment. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
99	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
100	Site of New Tumor Event	☐ Cervix ☐ Head & Neck ☐ Lung ☐ Vulvar ☐ Anus ☐ Other, specify ☐ Unknown ☐ Not Applicable	If the patient had a new tumor event, provide the site of this tumor. 3108271
101	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

#	Data Element	Entry Alternatives	Working Instructions
102	Date 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)
103	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.
104	Method of Pathologic Diagnosis for New Tumor Event	☐ Cytology ☐ Tumor Resection ☐ Other, specify	Indicate the method used to pathologically diagnose the new tumor event. 3151113
105	Other Method of Pathologic Diagnosis for New Tumor Event	_____	If the pathologic method used to diagnose the new tumor event is not included in the provided list, specify the method used. 3151116
106	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
107	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)
108	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.
109	Residual Tumor *After surgery for New Tumor Event*	☐ RX: The presence of residual tumor or margin status cannot be assessed. ☐ R0: No residual tumor and negative microscopic margins in resected specimen. ☐ R1: Microscopic residual tumor. No gross residual disease but positive microscopic margins. ☐ R2: Macroscopic residual tumor. Grossly visible residual disease.	Using the patient's pathology/laboratory report, select the residual tumor status after the surgical resection for the new tumor event. 3104061
110	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
111	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 or Designee Signature | Print Name | Date