Enrollment Form

Uterine Carcinosarcoma (UCS)

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	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
2	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
3	Month of Birth	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month the patient was born. 2896950
4	Day of Birth	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	Provide the day the patient was born. 2896952
5	Year of Birth	_____	Provide the year the patient was born. 2896954
6	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
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

Enrollment Form

Uterine Carcinosarcoma (UCS)

#	Data Element	Entry Alternatives	Working Instructions
8	Has the patient ever taken menopausal hormone therapy?	☐ Current User ☐ Former User ☐ Never Used ☐ Unknown	Indicate whether the patient, at any time, used menopausal hormone therapy. 3012813
9	Has the patient ever taken oral contraceptives?	☐ Current User ☐ Former User ☐ Never Used ☐ Unknown	Indicate whether the patient, at any time, used oral contraceptives. 3104217
10	Has the patient ever taken Tamoxifen?	☐ Current User ☐ Former User ☐ Never Used ☐ Unknown	Indicate whether the patient, at any time, used Tamoxifen. 3104234
11	Hypertension	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient has a history of hypertension. 2183378
12	Has the patient ever been diagnosed with diabetes by a physician?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient has, at any time, been diagnosed with diabetes by a physician. This includes borderline and gestational diabetes. 2716085
13	Number of full term pregnancies	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4+ ☐ Unknown	Provide the number of full term pregnancies the patient has had. 3012512
14	Has the patient had colorectal cancer?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient has a history of colorectal cancer. 2684753
15	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
16	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
17	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

Enrollment Form
Uterine Carcinosarcoma (UCS)

#	Data Element	Entry Alternatives	Working Instructions
18	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
19	History of Other 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.
20	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.
21	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
22	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553
23	Month of Last Contact	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	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
24	Day of Last Contact	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	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). 2897022
25	Year of Last Contact	_____	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). 2897024
26	Month of Death	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient is deceased, provide the month of death. 2897026
27	Day of Death	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient is deceased, provide the day of death. 2897028
28	Year of Death	_____	If the patient is deceased, provide the year of death. 2897030

Enrollment Form
Uterine Carcinosarcoma (UCS)

#	Data Element	Entry Alternatives	Working Instructions
29	Measure of Success of Outcome ***at the Completion of Initial First Course Treatment***	☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Not Applicable (Treatment Ongoing) ☐ Unknown	Indicate the patient's measure of success after their primary treatment including surgery and adjuvant therapies. 2786727
30	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.
31	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.

Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
32	Primary Site of Disease	☐ Uterus	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. 2735776
33	Anatomic Organ Subdivision	☐ Endometrium ☐ Myometrium ☐ Lower uterine segment/ Isthmus uteri ☐ Fundus uteri ☐ Unknown - Uterus, NOS	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor that yielded the sample submitted for TCGA. 2735776 The tumor submitted for TCGA must be located in the endometrium; indicate other involvement, as initially diagnosed.
34	Histological Subtype	☐ Uterine Carcinosarcoma / Malignant Mixed Mullerian Tumor (MMMT) NOS ☐ Uterine Carcinosarcoma / MMMT: Heterologous Type ☐ Uterine Carcinosarcoma / MMMT: Homologous Type	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. 3081934
35	Month of Initial Pathologic Diagnosis	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956
36	Day of Initial Pathologic Diagnosis	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896958
37	Year of Initial Pathologic Diagnosis	_____	Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896960
38	Method of Initial Pathologic Diagnosis	☐ Office endometrial biopsy ☐ Dilation and curettage procedure ☐ Tumor resection ☐ Cytology ☐ Fine needle aspiration biopsy ☐ Core needle biopsy ☐ Incision biopsy ☐ Excisional biopsy ☐ Other, specify below	Provide the procedure used to initially diagnose the patient. 2757941
39	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

Enrollment Form

Uterine Carcinosarcoma (UCS)

#	Data Element	Entry Alternatives	Working Instructions
40	Surgical Approach	☐ Minimally invasive ☐ Open	Indicate whether the procedure used to diagnose the patient was minimally invasive (e.g. laparoscopic) or open (e.g. surgery). 2429840
41	Peritoneal Washing	☐ Positive ☐ Negative ☐ Not Performed	If performed, provide the results of peritoneal cytology. 61384
42	Percent of Tumor Invasion	_____**(%)**	Using the patient's pathology/laboratory report, provide the percent of tumor invasion. This value is calculated by dividing the depth of the myometrial thickness by the depth of the myometrial invasion. 3104403
43	FIGO Staging System *(Publication Date Used for Staging)*	☐ 1988 ☐ 2009	Using the patient's pathology/laboratory report, provide the FIGO staging system used to stage the patient. 3114049
44	FIGO Stage	☐ I ☐ IA ☐ IB ☐ IC ☐ II ☐ IIA ☐ IIB ☐ III ☐ IIIA ☐ IIIB ☐ IIIC ☐ IIIC1 ☐ IIIC2 ☐ IV ☐ IVA ☐ IVB	Using the patient's pathology/laboratory report, provide the FIGO stage given to the patient at the time of diagnosis. 3225684
45	Residual Tumor	☐ 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. ☐ Unknown	Using the patient's pathology/laboratory report, provide the Residual Tumor code. 3104061
Pelvic Node Status			
46	Total Number of Pelvic Lymph Node Removed	_____	Provide the number of pelvic lymph nodes removed. If no pelvic lymph nodes were removed, enter "0" and skip the remaining pelvic lymph node questions. 3104458
47	Number of Pelvic Lymph Nodes Positive by H&E Light Microscopy	_____	Provide the number of pelvic lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3151830
48	Number of Pelvic Lymph Nodes Positive by IHC Keratin Staining	_____	Provide the number of pelvic lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3151829
49	Total Number of Pelvic Lymph Nodes Positive	_____	Provide the total number of pelvic lymph nodes positive (by either H&E or IHC staining). 3151828
Aortic Node Status			
50	Total Number of Aortic Lymph Nodes Removed	_____	Provide the number of aortic lymph nodes removed. If no aortic lymph nodes were removed, enter "0" and skip the remaining aortic lymph node questions. 3104460
51	Number of Aortic Lymph Nodes Positive by H&E Light Microscopy	_____	Provide the number of aortic lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3151832
52	Number of Aortic Lymph Nodes Positive by IHC Keratin Staining	_____	Provide the number of aortic lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3151831

Enrollment Form
Uterine Carcinosarcoma (UCS)

#	Data Element	Entry Alternatives	Working Instructions
53	Total Number of Aortic Lymph Nodes Positive	_____	Provide the total number of aortic lymph nodes positive (by either H&E or IHC staining). 3151827

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
20	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.
21	Type of New Tumor Event	☐ Locoregional Recurrence *Presence of a new tumor in the same location as the TCGA submitted tumor, after the patient was disease free* ☐ Distant Metastasis *Presence of a new tumor in a different location as the TCGA submitted tumor, after the patient was disease free* ☐ Progression of Disease *Progression of the pre-existing tumor*	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology as the tumor submitted to TCGA. 3119721
22	Site of New Tumor Event	☐ Abdomen ☐ Bone ☐ Brain ☐ Liver ☐ Lung ☐ Lymph Node ☐ Pelvis ☐ Unknown ☐ Other, specify	Indicate the site of this new tumor event. 3108271
23	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
24	Month of New Tumor Event	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. 3104044
25	Day of New Tumor Event	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
26	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
27	Additional treatment for New Tumor Event: *Surgery*	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
28	Month of Additional Surgery for New Tumor Event	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612
29	Day of Additional Surgery for New Tumor Event	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient had surgery for the new tumor event, provide the day this surgery was performed. 3427613

Enrollment Form

Uterine Carcinosarcoma (UCS)

#	Data Element	Entry Alternatives	Working Instructions
30	Year of Additional Surgery for New Tumor Event	_____	If the patient had surgery for the new tumor event, provide the year this surgery was performed. 3427614
31	Procedure Type for New Tumor Event	☐ Excisional Biopsy ☐ Incisional Biopsy ☐ Surgical Resection ☐ Unknown ☐Other Method, Specify Below	If the patient had surgery for the new tumor event, provide the type of procedure performed for this tumor. 3125097
32	Other Procedure Type for New Tumor Event	_____	If the procedure for the new tumor event was not included in the list provided, indicate the type of procedure performed. 3125102
33	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
34	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
35	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