Enrollment Form Endometrial (UCEC)

V4.03 070612

_Completed Date: _____

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): _____

Gene	eneral 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. <u>3088492</u>					
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. <u>3088528</u>					

Patient Information

#	Data Element	Entr	y Alternatives		Working Instructions
4	Month of Birth	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	□ 08	□ 10 □ 11 □ 12	Provide the month the patient was born. <u>2896950</u>
5	Day of Birth	$ \begin{array}{c ccccc} & 0 & 1 & 0 & 0 \\ & 0 & 2 & 0 & 0 \\ & 0 & 1 & 0 \\ & 0 & 4 & 1 & 1 \\ & 0 & 5 & 1 & 2 \\ & 0 & 6 & 1 & 3 \\ & 0 & 7 & 0 \\ \end{array} $	14 20 15 21 16 22 17 23 18 24 19 25	□ 26 □ 27 □ 28 □ 29 □ 30 □ 31	Provide the day the patient was born. 2896952
6	Year of Birth			_	Provide the year the patient was born. <u>2896954</u>

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#	Data Element	Entry Alternatives	Working Instructions
7	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. <u>3008233</u> 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.
8	Gender	☐ Female □ Male	Provide the patient's gender using the defined categories. <u>2200604</u>
9	Menopause Status (at time of diagnosis)	 Premenopausal G months since LMP AND no prior bilateral oophorectomy AND not on estrogen replacement Perimenopausal G-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. <u>2957270</u>
10	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. <u>3012813</u>
11	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
12	Has the patient ever taken Tamoxifen?	 □ Current User □ Former User □ Never Used □ Unknown 	Indicate whether the patient, at any time, used Tamoxifen. 3104234
13	Hypertension	☐ Yes □ No □ Unknown	Indicate whether the patient has a history of hypertension. 2183378
14	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
15	Number of full term pregnancies	□ 0 □ 1 □ 2 □ 3 □ 4+ □ Unknown	Provide the number of full term pregnancies the patient has had. <u>3012512</u>
16	Has the patient had colorectal cancer?	□ Yes □ No □ Unknown	Indicate whether the patient has a history of colorectal cancer. <u>2684753</u>
17	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.
18	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. <u>651</u>

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#	Data Element	Entry Alternatives	Working Instructions Provide the patient's race using the defined categories.
19	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 Africa American." Native Hawaiian or other Pacific Islander:	<u>2192199</u>
20	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.
21	History of Other Malignancy	□ Yes □ No	Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior or synchronous to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior or synchronous 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. <u>3382736</u> 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.
22	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. <u>3382737</u> 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.
23	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
24	Vital Status (at date of last contact)	□ Living □ Deceased	Indicate whether the patient was living or deceased at the date of last contact. <u>5</u>
25	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). <u>2897020</u> Do not answer if patient is deceased.

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#	Data Element		Entr	w Altorn	ativac		Working Instructions
#	Data Element	D 01		y Alterna 14		2 6	If the patient is living, provide the day of last contact with the
26	Day of Last Contact	 01 02 03 04 05 06 07 	 00 09 10 11 12 13 	 14 15 16 17 18 19 	□ 21 □ 22 □ 23 □ 24 □ 25	□ 20 □ 27 □ 28 □ 29 □ 30 □ 31	patient (as reported by the patient, medical provider, family member, or caregiver). 2897022 Do not answer if patient is deceased.
27	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). <u>2897024</u> Do not answer if patient is deceased.
28	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. <u>3008273</u> 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.
29	Month of Death	□ 01 □ 02 □ 03	□ 04 □ 05 □ 06		08	□ 10 □ 11 □ 12	If the patient is deceased, provide the month of death. <u>2897026</u>
30	Day of Death	 01 02 03 04 05 06 07 	 08 09 10 11 12 13 	 14 15 16 17 18 19 	 20 21 22 23 24 25 	□ 26 □ 27 □ 28 □ 29 □ 30 □ 31	If the patient is deceased, provide the day of death. <u>2897028</u>
31	Year of Death						If the patient is deceased, provide the year of death. $\frac{2897030}{2897030}$
32	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. <u>3165475</u> 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.
33	Measure of Success of Outcome <i>at the</i> <i>Completion of Initial</i> <i>First Course Treatment</i>	□ Stable □ Partia □ Comp	essive Dise e Disease al Respons olete Resp pplicable own	se onse	ent Ongo	ing)	Indicate the patient's measure of success after their primary treatment including surgery and adjuvant therapies. <u>2786727</u>
34	Adjuvant (Post- Operative) Radiation Therapy	□ Yes □ No □ Unkn	own				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.
35	Adjuvant (Post- Operative) Pharmaceutical Therapy	□ Yes □ No □ Unkno	own				Indicate whether the patient had adjuvant/ post- operative pharmaceutical therapy. <u>3397567</u> If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
Patho	ologic/Prognostic Inform	ation					

#	Data Element	Entry Alternatives	Working Instructions
36	Primary Site of Disease	 Endometrium Other, specify below 	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. <u>2735776</u> The tumor submitted for TCGA must be located in the endometrium; indicate other involvement, as initially diagnosed.

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#	Data Element	Entry Alternatives	Working Instructions
37	Other Primary Site		If the primary site of disease on the pathology/laboratory report is not available or does not specifically match the provided sites, describe the site(s) of disease. <u>2584114</u>
38	Histological Subtype	 Endometrioid endometrial adenocarcinoma Serous endometrial adenocarcinoma Mixed serous and endometrioid 	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. <u>Mixed serous and endometrioid</u> : A case mixed with $\geq 10\%$ serous AND $\geq 10\%$ endometrioid. NOTE : If a case is mixed with something other than serous or endometrioid it must be $\leq 10\%$ (i.e. 1-9%). <u>3081934</u>
39	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. <u>2896956</u>
40	Day of Initial Pathologic Diagnosis	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. <u>2896958</u>
41	Year of Initial Pathologic Diagnosis		Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. <u>2896960</u>
42	Age at Initial Diagnosis		 Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. <u>2006657</u> 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	 Office endometrial biopsy Dilation and curettage procedure Tumor resection Cytology Fine needle aspiration biopsy Core needle biopsy Incisional biopsy Excisional biopsy Other, specify below 	Provide the procedure used to initially diagnose the patient. 2757941
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. <u>2757948</u>
45	Surgical Approach	Minimally invasiveOpen	Indicate whether the procedure used to diagnose the patient was minimally invasive (e.g. laparoscopic) or open (e.g. surgery). <u>2429840</u>
46	Peritoneal Washing	 Positive Negative Not Performed 	If performed, provide the results of peritoneal cytology. 61384
47	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. <u>3104403</u>
48	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

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#	Data Element	Entry Alternati	ves	Working Instructions
49	FIGO Stage	I IIB IA III IB IIIA IC IIIB II IIIC IIA IIIC	☐ IIIC2 ☐ IV ☐ IVA ☐ IVB	Using the patient's pathology/laboratory report, provide the FIGO stage given to the patient at the time of diagnosis. <u>3225684</u>
50	Residual Tumor	 RX: The presence of residual t status cannot be assessed. R0: No residual tumor and neg margins in resected specimen. R1: Microscopic residual tumor residual disease but positive mic R2: Macroscopic residual tumor residual disease. Unknown 	gative microscopic or. No gross roscopic margins.	Using the patient's pathology/laboratory report, provide the Residual Tumor code. <u>3104061</u>
51	Tumor Grade	□ Grade 1 □ Grade 2 □ Grade 3		Using the patient's pathology/laboratory report, provide the patients Tumor Grade. 3104227 If the tumor in question was histologically classified as a Serous Endometrial Adenocarcinoma, and a Tumor Grade is not stated on the pathology report, please select "Grade 3" for these cases.
Pelv	vic Node Status			
52	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. <u>3104458</u>
53	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. <u>3151830</u>
54	Number of Pelvic Lymph Nodes Positive by IHC Keratin Staining			Provide the number of pelvic lymph nodes positive through keratin immunohistochemistry (IHC) staining. <u>3151829</u>
55	Total Number of Pelvic Lymph Nodes Positive			Provide the total number of pelvic lymph nodes positive (by either H&E or IHC staining). <u>3151828</u>
Aor	tic Node Status			
56	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. <u>3104460</u>
57	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. <u>3151832</u>
58	Number of Aortic Lymph Nodes Positive by IHC Keratin Staining			Provide the number of aortic lymph nodes positive through keratin immunohistochemistry (IHC) staining. <u>3151831</u>
59	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.

#	Data Element	Entry Alternatives	Working Instructions
60	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. <u>3121376</u> If the patient did not have a new tumor event or if this is unknown the remaining questions can be skinned

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Event

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27					t Form l (UCEC)	V4.03 070612
Data Element		Entr	y Alterna	atives		Working Instructions
Type of New Tumor Event	🗖 Distar	egional R it Metasta Primary T	ecurrenco Isis			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
Site of New Tumor Event	LungBoneLiver			Brain Unknow Other, sp		Indicate the site of this new tumor event. <u>3108271</u>
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. <u>3128033</u>
Month of New Tumor Event	□ 01 □ 02 □ 03	□ 04 □ 05 □ 06		08	□ 10 □ 11 □ 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. <u>3104044</u>
Day of New Tumor Event	 01 02 03 04 05 06 07 	 08 09 10 11 12 13 	 14 15 16 17 18 19 	 20 21 22 23 24 25 	□ 26 □ 27 □ 28 □ 29 □ 30 □ 31	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. <u>3104042</u>
Year of New Tumor Event	_					If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. <u>3104046</u>
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. <u>3392464</u> 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 for New Tumor Event: <i>Surgery</i>	□ Yes □ No □ Unkno	own				Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
Month of Additional Surgery for New Tumor Event	□ 01 □ 02 □ 03	□ 04 □ 05 □ 06		08	□ 10 □ 11 □ 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. <u>3427612</u>
Day of Additional Surgery for New Tumor Event	 01 02 03 04 05 06 07 	 08 09 10 11 12 13 	 14 15 16 17 18 19 	□ 20 □ 21 □ 22 □ 23 □ 24 □ 25	□ 26 □ 27 □ 28 □ 29 □ 30 □ 31	If the patient had surgery for the new tumor event, provide the day this surgery was performed. <u>3427613</u>
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
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). <u>3008335</u> Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested

dates on this form.

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#	Data Element	Entry Alternatives	Working Instructions
<u>73</u>	Procedure Type for New Tumor Event	□ Cytology □ Tumor Resection □Other Method, Specify Below	If the patient had surgery for the new tumor event, provide the type of procedure performed for this tumor. <u>3125097</u>
<u>74</u>	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. <u>3125102</u>
75	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. Unknown 	Using the patient's pathology/laboratory report, select the residual tumor status after the surgical resection for the new tumor event. <u>3104061</u>
<u>76</u>	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. <u>3427615</u>
<u>77</u>	Additional treatment for New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. <u>3427616</u>

Principal Investigator or Designee Signature

Print Name

_ ___/ ____ / ____ ___ ___ Date