		Enrollment: Ovary	V4.30	
Tissue Sou	rce Site (TSS) Name:	TSS Identifier:TSS	5 Unique Patient #:	
Completed By: Completion Date (MM/DD/YYYY):				
Form Notes: An Enrollment Form should be completed for each TCGA qualified case upon qualification notice from the BCR. All information provided on this forr include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient. Questions regarding this form should be di the Tissue Source Site's (TSS) primary Clinical Outreach Contact at the BCR The following definitions for the use of "Unknown" and "Not Evaluated" on this form are as follows: Unknown: This answer option should only be selected if the TSS cannot answer the question because the answer is not known at the TSS. If this answer option selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing the reason why the answer is unknown Not Evaluated: This answer option should be selected by the TSS if it is known that the information being requested cannot be obtained due to the test not be performed.				
Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions	
1	Has this TSS received permission from NCI to provide time intervals as a substitute for requested dates on this form?	□ Yes □ No	Please note that time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box to the left. Note 1: Provided time intervals must begin with the date of initial pathologic diagnosis. (i.e., biopsy or resection) Note 2: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.	
2	Primary Site of Disease*	Ovary Omentum Peritoneum (Ovary)	2735776 Using the patient's pathology/laboratory report select the anatomic site of disease of the tumor submitted for TCGA.	
3	Histological Subtype*	Serous Cystadenocarcinoma	 2831122 Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. Note: The following subtypes are synonyms for "Serous Cystadenocarcinoma" and they are acceptable. All other subtypes not listed are excluded from this study. Serous carcinoma Serous adenocarcinoma Papillary Serous carcinoma Serous Papillary cystoadenocarcinoma Serous Papillary adenocarcinoma 	
4	Anatomic Site	Right Left Bilateral	2008006 Using the patient's pathology/laboratory report, select the anatomic site of the tumor used for TCGA.	
5	Is this a Prospective Tissue Collection?	□ Yes □ No	3088492 Indicate whether the TSS providing tissue is contracted for prospective tissue collection. Note: If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively.	
6	Is this a Retrospective Tissue Collection?	□ Yes □ No	3088528 Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. Note: If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively.	
7	Gender*	Male Female	2200604 Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.	

Enrollment: Ovary



Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
8	Month of Birth*	(MM)	2896950 Provide the month the patient was born.
9	Day of Birth	(DD)	2896952 Provide the day the patient was born
10	Year of Birth*		2896954 Provide the year the patient was born
11	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth		3008233 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Birth. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
12	Race	 American Indian or Alaska Native (A person having origins in any of the original peoples of North/ South America (including Central America), and maintains tribal affiliation or community attachment) Asian (A person having origins in any of the original peoples of the Far East, Southeast Asia, or Indian subcontinent, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam) White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa) Black or African American (A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American") Native Hawaiian or other Pacific Islander (A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands) Not Evaluated (Not provided or available) Unknown (Could not be determined or unsure) 	2192199 Provide the patient's race using the defined categories.
13	Ethnicity	 Not Hispanic or Latino (A person not meeting the definition for Hispanic or Latino) Hispanic or Latino (A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race) Not Evaluated (Not provided or available) Unknown (Could not be determined or unsure) 	2192217 Provide the patient's ethnicity using the defined categories
14	Jewish Religion/Heritage	Ashkenazi Not Evaluated Sephardic Unknown	2200537 Name for Jewish heritage categories for a patient/participant on a clinical trial.



Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
15	Has the Patient Had Any Prior Cancer Diagnosed?*	 No History of Prior Malignancy History of Synchronous / Bilateral Malignancy 	3382736 Indicate whether the patient has a history of prior malignancies. Note 1: If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. Note 2: If the patient has any history of prior malignancies, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for TCGA. If the patient has a history of multiple diagnoses of basal and/or squamous cell skin cancers, complete an "Other Malignancy Form" for the first diagnosis for each of these types.
16	History of Neo-Adjuvant Treatment to Tumor Specimen Submitted for TCGA*	 No Radiation Prior to Sample Procurement Pharmaceutical Treatment Prior to Sample Procurement Both Pharmaceutical and Radiation Treatment Prior to Sample Procurement 	3382737 Indicate whether the patient received therapy for this cancer prior to sample procurement of the tumor submitted for TCGA. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instructions. <i>Note: Systemic treatment and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to procurement of the sample submitted for TCGA are exclusionary.</i>
Date of Initia	Pathologic Diagnosis		2806056
17	Month of Initial Pathological Diagnosis*	(MM)	2896956 Provide the month the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
18	Day of Initial Pathological Diagnosis	(DD)	2896958 Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
19	Year of Initial Pathological Diagnosis*		2896960 Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
20	Method of Initial Pathologic Diagnosis	Cytology Excisional biopsy Fine needle aspiration biopsy Tumor resection Incisional biopsy Other method (please specify)	2757941 Indicate the procedure utilized to procure the tissue which was used for the original diagnosis of the tissue submitted to TCGA
21	Other Method of Initial Pathological Diagnosis		2757948 Indicate the other method utilized to procure the tissue which was used for the original diagnosis of the tissue submitted to TCGA.
22	Vital Status*	Living Deceased	5 Indicate whether the patient was living or deceased at the date of last contact.
Date of Last 0	Contact		2897020
23	Month of Last Contact	ШП (ММ)	Provide the month of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). Note: Do not answer this question if the patient is deceased.
24	Day of Last Contact	(DD)	2897022 Provide the day of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). Note: Do not answer this question if the patient



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Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Question	Data Element Laber		is deceased.
			is acceused.
			2897024
			Provide the year of last contact with the patient
			(as reported by the patient, medical provider,
25	Year of Last Contact		family member, or caregiver).
			Note: Do not answer this question if the patient
			is deceased.
			3008273
			Provide the number of days from the date the patient was initially diagnosed pathologically
			with the disease to the date of Last Contact. Do
	Number of Days from		not answer this question if the patient is
26	Date of Diagnosis to Date		deceased.
20	of Last Contact		Note: Do not answer this question if the patient
			is deceased. Note: Only provide Interval data if you have
			received permission from the NCI to provide
			time intervals as a substitute for requested
			dates on this form.
Date of Deat	h	Not Applicable (Patient is Alive)	
			2897026
27	Month of Death	ШШ (ММ)	If the patient is deceased, provide the month of
			death.
			2897028
28	Day of Death		If the patient is deceased, provide the day of
			death. 2897030
29	Year of Death		If the patient is deceased, provide the year of
			death.
			3165475
			Provide the number of days from the date the
	Number of Days from		patient was initially diagnosed pathologically
30	Date of Diagnosis to Date		with the disease to the date of Death. Note: Only provide Interval data if you have
	of Death		received permission from the NCI to provide
			time intervals as a substitute for requested
			dates on this form.
			2759550
31	Tumor Status	Unknown Tumor Status	Indicate whether the patient was tumor/disease
			free at the date of last contact or death. 62343
			Assignment of TNM categories into groups used
			to select and evaluate therapy, estimate
			prognosis and calculate end results.
		Ц ів	<u>I:</u> Tumor limited to ovaries (one or both)
			no tumor on ovarian surface. No malignant cells
			in ascites or peritoneas washings.
			IB: Tumor limited to both ovaries; capsules
	Tumor Stage		intact, no tumor on ovarian surface. No
32	(Pathological) Ovary		malignant cells in ascites or peritoneal washings.
	FIGO Staging System		IC: Tumor limited to one or both ovaries with
			any of the following: capsule ruptured, tumor on
			ovarian surface, malignant cells in ascites or
			peritoneal washings.
			II: Tumor involves one or both ovaries with
		Пив	pelvic extension.
			IIA: Extension and/or implants on uterus and/or
			tube(s). No malignant cells in ascites or
			peritoneal washings.
			IIB: Extension to other pelvic tissues. No



Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Question #	Data Element Label		 malignant cells in ascites or peritoneal washings. IIC: Pelvic extension (2a or 2b) with malignant cells in ascites or peritoneal washings. III: Tumor involves one or both ovaries with microscopically confirmed peritoneal metastasis outside the pelvis and/or regional lymph node metastasis. IIIA: Microscopic peritoneal metastasis beyond pelvis. IIIB: Macroscopic peritoneal metastasis beyond pelvis 2cm or less in greatest dimension. IIIC: Peritoneal metastasis beyond pelvis more than 2cm in greatest dimension and/or regional lymph node metastasis. IV: Distant metastasis (any T, any N, M1): cancer has spread to inside the liver, lungs or other organs located outside of the peritoneal cavity (excludes peritoneal metastasis).
33	Tumor Grade	□ G1 □ G4 □ G2 □ GX □ G3 □ GB	2785839 Using the patient's pathology/laboratory report, select the tumor grade of the tumor submitted to TCGA.
34	Residual Tumor	RX R1 R0 R2	2608702 Indicate the status of a tissue margin submitted for TCGA following surgical resection as defined by the American Joint Committee on Cancer (AJCC).
35	Tumor Residual Disease (for the max diameter of the largest remaining tumor nodule)	□ No Macroscopic disease □ 11-20 mm □ 1-10 mm □ >20 mm	2785858 Category to represent the size in millimeters of the largest remaining nodule of ovarian carcinoma.
36	Vascular Invasion	Yes INO Unknown	64358 Indicate if large vessel or venous invasion was pathologically present in the tumor specimen submitted to TCGA
37	Lymphatic Invasion	Yes INO Unknown	64171 Indicate if malignant cells are pathologically present in small or thin walled vessels suggesting lymphatic involvement in the tumor submitted to TCGA.
Prognostic/P	redictive/Lifestyle Features f	or Tumor Prognosis or Responsiveness to Treatment	
38	Performance Status Score: Karnofsky Score	 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 30 Severely disabled 20 Very sick; requiring hospitalization 	2003853 Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient.

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Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions		
		 10 Moribund; fatal processes progressing rapidly 0 Dead Not Evaluated Unknown 			
39	Performance Status Score: Eastern Cooperative Oncology Group	 Asymptomatic 1 Symptomatic, but fully ambulatory 2 Symptomatic, in bed less than 50% of day 3 Symptomatic, in bed more than 50% of day, but not bed-ridden 4 Bed-ridden Not Evaluated Unknown 	88 Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient.		
40	Performance Status Score: Timing	Pre-OperativePost-AdjuvantUnknownPre-AdjuvantOtherNot Evaluated	2792763 Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories.		
Primary Trea	tment				
41	Adjuvant Post-operative Radiation Therapy	 Yes No Unknown 	2005312 Indicate whether the patient had adjuvant/ post- operative Radiation Therapy. If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.		
42	Adjuvant Post-Operative Chemotherapy	 Yes No Unknown 	2756823 Indicate whether the patient had adjuvant/ post- operative Chemotherapy. If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.		
43	Adjuvant Post-Operative Immunotherapy	Yes No Unknown	2756814 Indicate whether the patient had adjuvant/ post- operative Immunotherapy. If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.		
44	Adjuvant Post-Operative Hormone Therapy	Yes No Unknown	2199669 Indicate whether the patient had adjuvant/ post- operative Hormone Therapy. If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.		
45	Adjuvant Post-Operative Targeted Molecular Therapy	Yes No Unknown	2785850 Indicate whether the patient had adjuvant/ post- operative Targeted Molecular Therapy. If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.		
46 Tumor Progre	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies)	Progressive Disease Complete Response Stable Disease Not Applicable Partial Response Unknown	2786727 Provide the patient's response to their initial first course treatment.		



Outstien #	Data Floment Label	Data Entry Altern	ativos		CDE ID With Working Instructions
Question #	Data Element Label	Data Entry Altern	latives		CDE ID With Working Instructions
47	Tumor Progression After Initial Treatment	Yes	🗆 No	Unknown	3479887 Indicate whether the patient had a tumor progression after their initial treatment for the tumor submitted to TCGA.
48	Month of Tumor Progression After Initial Treatment		(MM)		2897014 If the patient had a tumor progression, provide the month of diagnosis for this new tumor event.
49	Day of Tumor Progression After Initial Treatment		(DD)		2897016 If the patient had a tumor progression, provide the day of diagnosis for this new tumor event.
50	Year of Tumor Progression After Initial Treatment		(YYYY)		2897018 If the patient had a tumor progression, provide the year of diagnosis for this new tumor event.
51	Number of Days from Date of Initial Pathologic Diagnosis to Date of Tumor Progression After Initial Treatment				3165480 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of tumor progression after initial treatment <i>Note: Only provide Interval data if you have</i> <i>received permission from the NCI to provide</i> <i>time intervals as a substitute for requested</i> <i>dates on this form.</i>
Tumor Recur	rence				
52	Tumor Recurrence After Initial Treatment	Yes	🗆 No	Unknown	3479892 Indicate whether the patient had a tumor Recurrence after their initial treatment for the tumor submitted to TCGA.
53	Month of Tumor Recurrence After Initial Treatment		(MM)		2896991 If the patient had a tumor recurrence, provide the month of diagnosis for this new tumor event.
54	Day of Tumor Recurrence After Initial Treatment		(DD)		2897006 If the patient had a tumor recurrence, provide the day of diagnosis for this new tumor event.
55	Year of Tumor Recurrence After Initial Treatment		(YYYY)		2897008 If the patient had a tumor recurrence, provide the year of diagnosis for this new tumor event.
56	Number of Days from Date of Initial Pathologic Diagnosis to Date of Tumor Recurrence After Initial Treatment				3479874 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of tumor recurrence after initial treatment Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
					t and prior to submission of the Enrollment Form. If
the patient di	d not have a new tumor ever	nt, or if the TSS does	s not know, indicate this in	the first question below; and	d then skip the remainder of this form. 3121376
57	New Tumor Event After Initial Treatment	YesNoUnknown			Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after their initial treatment for the tumor submitted to TCGA. <i>Note: If the patient had multiple new tumor</i> <i>events, a follow-up form should be completed</i> <i>for each new tumor event.</i>
Date of New	Tumor Event After Initial Tre	eatment 🛛 N	Not Applicable		
58	Month of New Tumor Event After Initial		(MM)		3104044 If the patient had a new tumor event, provide the month of diagnosis for this new tumor



Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions	
	Treatment		event.	
59	Day of New Tumor Event After Initial Treatment	(DD)	3104042 If the patient had a new tumor event provide the day of diagnosis for this new tumor event.	
60	Year of New Tumor Event After Initial Treatment		3104046 If the patient had a new tumor event provide the year of diagnosis for this new tumor event.	
61	Number of Days from Date of Diagnosis to Date of New Tumor Event After Initial Treatment		3392464 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.	
62	Site Of First Tumor Recurrence	Metastasis Loco-regional and Metastasis	2791194 Description of tumor first recurrence in reference to extent of disease	
63	Method Of Diagnosis First Recurrence	Physical examination First seen at further surgery Imaging study Other method (please specify) Molecular marker(s) Other method (please specify)	2786205 Text name of the procedure or testing method used to diagnose tumor recurrence.	
64	Other Method Of Diagnosis First Recurrence		2786210 Text description of a method of diagnosing recurrent neoplastic disease that is different than the options previously specified.	
65	Additional Surgery for New Tumor Event Loco-Regional Procedure	Yes No Unknown	3008755 Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question.	
Date of Addit	tional Surgery for New Tumo	r Event Loco-Regional		
66	Month of Additional Surgery for New Tumor Event Loco-Regional Procedure	(MM)	2897032 If the patient had surgery for the new loco- regional tumor event provide the month of surgery for this new loco-regional tumor event.	
67	Day of Additional Surgery for New Tumor Event Loco-Regional Procedure	(DD)	2897034 If the patient had surgery for the new loco- regional tumor event provide the day of surgery for this new loco-regional tumor event.	
68	Year of Additional Surgery for New Tumor Event Loco-Regional Procedure		2897036 If the patient had surgery for the new loco- regional tumor event provide the year of surgery for this new loco-regional tumor event.	
69	Number of Days from Date of Initial Diagnosis to Date of Additional Surgery for New Tumor Event Loco-Regional Procedure		3408572 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event (loco-regional). Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.	
70	Additional Surgery for New Tumor Event Metastasis Procedure tional Surgery for New Tumo	Yes No Unknown	3008757 Using the patient's medical records indicate whether the patient had surgery for the new metastatic tumor event in question.	



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a		Data Entry Alternatives CDE ID With Working Instructions			
Question #	Data Element Label	Data Entry Altern	latives		CDE ID With Working Instructions
71	Month of Additional Surgery for New Tumor Event Metastasis Procedure		(MM)		2897038 If the patient had surgery for the new metastatic tumor event provide the month of surgery for this new metastatic tumor event.
72	Day of Additional Surgery for New Tumor Event Metastasis Procedure		(DD)		2897040 If the patient had surgery for the new metastatic tumor event provide the day of surgery for this new metastatic tumor event.
73	Year of Additional Surgery for New Tumor Event Metastasis Procedure		(ҮҮҮҮ)		2897042 If the patient had surgery for the new metastatic tumor event provide the year of surgery for this new metastatic tumor event.
74	Number of Days from Date of Initial Diagnosis to Date of Additional Surgery for New Tumor Event Metastasis Procedure				3408682 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event (metastasis) Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
Additional Tr	eatment	•			÷
75	Additional treatment of New Tumor Event Radiation Therapy	Yes	□ No	Unknown	3008761 Indicate whether the patient received Radiation Therapy for this new tumor event.
76	Additional Treatment of New Tumor Event Chemotherapy	Yes	No No	Unknown	2650626 Indicate whether the patient received Chemotherapy for this new tumor event.
77	Additional Treatment of New Tumor Event Immunotherapy	□ Yes	🗆 No	Unknown	2759828 Indicate whether the patient received Immunotherapy for this new tumor event.
78	Additional Treatment of New Tumor Event Hormone Therapy	☐ Yes	🗆 No	Unknown	2650646 Indicate whether the patient received Hormone Therapy for this new tumor event.
79	Additional Treatment of New Tumor Event Targeted Molecular Therapy	Yes	🔲 No	Unknown	2786150 Indicate whether the patient received Targeted Molecular Therapy or this new tumor event.

Comments:

Principal Investigator Name: ______ Principal Investigator Signature: ______

Date Signed (MM/DD/YYYY):