Follow Up: Ovary

V4.10

Tissue Source Site (TSS) Name: _____ TSS Identifier: _____ TSS Unique Patient #: _____

Completed By: _____ Completion Date (MM/DD/YYYY):_____

Form Notes: *A Follow-up Form is to be completed for any of the following reasons: 1) For each additional new tumor event identified at the time of enrollment or follow-up submission; or 2) 12 months after a case is shipped to the Biospecimen Core Resource (BCR) for cases that have qualified. All information provided on this form includes activity from the "Date of Last Contact" provided on the TCGA Enrollment Form to the most recent date of contact with the patient. This form should only be completed by the Tissue Source Site if updated information can be provided to TCGA. Questions regarding this form should be directed to 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 is 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 being performed.

Question#	Data Element Label	Data Entry Alternatives	CDE ID With 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	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	Reason For Follow-up Form Submission	☐ Scheduled (Routine) Follow-up Submission ☐ Additional New Tumor Event	3233305 Indicate the reason for submission of this follow-up form. If scheduled follow-up, complete entire form. If additional new tumor event, complete only questions pertaining to new tumor.
3	Is This Patient Lost to Follow-up?	☐ Yes ☐ No	61333 Indicate whether the patient is lost to follow-up as defined by the ACoS Commission on Cancer. This only includes cases where updated information has not been collected within the last 15 months. If the patient is lost to follow-up, the remaining questions may be left unanswered. ***Note: If the patient is deceased and a TCGA Follow-up Form has not yet been completed, the answer to this question should be "No" and the remaining applicable questions should be completed.***
Primary Treatment			
4	Adjuvant Post-operative Radiation Therapy	☐ Yes ☐ No ☐ Unknown	2005312 Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***Note: If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed***.
5	Adjuvant Post-operative Chemotherapy	☐ Yes ☐ No ☐ Unknown	2756823 Indicate whether the patient had adjuvant/ post-operative Chemotherapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.***
6	Adjuvant Post-Operative Immunotherapy	☐ Yes ☐ No ☐ Unknown	2756814 Indicate whether the patient had adjuvant/ post-operative Immunotherapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.***
7	Adjuvant Post-Operative Hormone Therapy	☐ Yes ☐ No ☐ Unknown	2199669 Indicate whether the patient had adjuvant/ post-operative Hormone Therapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.***

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8	Adjuvant Post-Operative Targeted Molecular Therapy	☐ Yes ☐ No ☐ Unknown	2785850 Indicate whether the patient had adjuvant/ post-operative Targeted Molecular Therapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.***
9	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.
Patient Status			
10	Vital Status	☐ Living ☐ Deceased	5 Indicate whether the patient was living or deceased at the date of last contact.
Date Of Last Contact			
11	Month Of Last Contact	☐☐ (MM)	2897020 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.***
12	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 is deceased.***
13	Year Of Last Contact	☐☐☐☐ (YYYY)	2897024 Provide the year 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.***
14	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	3008273 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Last Contact. ***Note 1: Do not answer this question if the patient is deceased.*** ***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.***
Date of Death		☐ Not Applicable (Patient is Alive)	
15	Month of Death	☐☐ (MM)	2897026 If the patient is deceased, provide the month of death.
16	Day of Death	☐☐ (DD)	2897028 If the patient is deceased, provide the day of death.
17	Year of Death	☐☐☐☐ (YYYY)	2897030 If the patient is deceased, provide the year of death.
18	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	3165475 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Death. ***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.***
19	Tumor Status	☐ Tumor Free ☐ Unknown Tumor Status ☐ With Tumor	2759550 Indicate whether the patient was tumor/disease free from the tumor submitted for TCGA at the date of last contact or death.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Tumor Progression			
20	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.
21	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.
22	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.
23	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.
24	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 ***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.***
Tumor Recurrence			
25	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.
26	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.
27	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.
28	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.
29	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 ***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.***
New Tumor Event: Please verify that new tumor event information has not previously been reported on the Enrollment Form or on a prior Follow-up Form			
30	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	3121376 Indicate whether the patient had a new tumor event (e.g. remote resection, recurrent, or new primary tumor) after their initial treatment for the tumor submitted to TCGA. ***Note: If the patient had multiple new tumor events, a follow-up form should be completed for each new tumor event.***
Date of New Tumor Event After Initial Treatment			
31	Month of New Tumor Event After Initial Treatment	☐☐ (MM)	3104044 If the patient had a new tumor event, provide the month of diagnosis for this new tumor event.
32	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.
33	Year of New Tumor Event After Initial Treatment	☐☐☐☐ (YYYY)	3104046 If the patient had a new tumor event, provide the year of diagnosis for this new tumor event.

34	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event	_____	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. ***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.***
35	Site Of First Tumor Recurrence	☐ Metastasis ☐ Loco-regional and Metastasis ☐ Loco-regional	2791194 Description of tumor first recurrence in reference to extent of disease
36	Method Of Diagnosis First Recurrence	☐ Imaging study ☐ First seen at further surgery ☐ Molecular marker(s) ☐ Other method (please specify) ☐ Physical examination	2786205 Text name of the procedure or testing method used to diagnose tumor recurrence.
37	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.
38	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 loco-regional tumor event in question.
Date Additional Surgery for New Tumor Event – Loco–Regional ☐ Not Applicable			
39	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.
40	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.
41	Year of Additional Surgery for New Tumor Event **Loco-Regional Procedure**	☐☐☐☐ (YYYY)	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.
42	Number of Days from Date of Initial Pathologic 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 to the date of additional surgery for new tumor event (Local-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.***
43	Additional Surgery for New Tumor Event **Metastasis Procedure**	☐ 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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Date of Additional Surgery for New Tumor Event Metastasis		☐ Not Applicable (No Surgical Procedure for Metastatic Tumor Event)	
44	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.
45	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.
46	Year of Additional Surgery for New Tumor Event **Metastasis Procedure**	☐☐☐☐ (YYYY)	2897042 If the patient had surgery for the new metastatic tumor event, provide the year of surgery for this new metastatic tumor event.
47	Number of Days from Date of Initial Pathologic 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 Treatment			
48	Additional Treatment of New Tumor Event **Radiation Therapy**	☐ Yes ☐ No ☐ Unknown	3008761 Indicate whether the patient received radiation treatment for this new tumor event.
49	Additional Treatment of New Tumor Event **Chemotherapy**	☐ Yes ☐ No ☐ Unknown	2650626 Indicate whether the patient received Chemotherapy treatment for this new tumor event.
50	Additional Treatment of New Tumor Event **Immunotherapy**	☐ Yes ☐ No ☐ Unknown	2759828 Indicate whether the patient received Immunotherapy for this new tumor event.
51	Additional Treatment of New Tumor Event **Hormone Therapy**	☐ Yes ☐ No ☐ Unknown	2650646 Indicate whether the patient received Hormone Therapy for this new tumor event.
52	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.
53	Measure of Success of Outcome at the Completion of this Follow-up Submission	☐ Progressive Disease ☐ Complete Response ☐ Partial Response ☐ Not Applicable ☐ Stable Disease ☐ Unknown	3104050 Provide the patient's outcome of treatment up to the point of the current follow-up data submission

Comments:

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_____

Principal Investigator Name: _____ Principal Investigator Signature: _____

Date Signed (MM/DD/YYYY): _____