

Follow-Up Form

Uterine Carcinosarcoma (UCS)

Instructions: The Follow-up Form is to be completed 12 months after a case enters the Biospecimen Core Resource (BCR). 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. Please direct any questions to the Clinical Outreach team 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 on OpenClinica): _____ Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1	Is this Patient Lost to Follow-up?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the patient is lost to follow-up, as defined by the ACoS Commission on Cancer. This only includes cases where updated follow-up information has not been collected within the past 15 months and all efforts to contact the patient have been exhausted (this includes reviewing the Social Security death index). If the patient is lost to follow-up, the remaining questions can be left unanswered. 61333 <i>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.</i>

Follow-Up Information

#	Data Element	Entry Alternatives	Working Instructions
2	Adjuvant (Post-Operative) Radiation Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. 2005312 <i>If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.</i>
3	Adjuvant (Post-Operative) Pharmaceutical Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. 3397567 <i>If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i>
4	Has the patient ever taken menopausal hormone therapy?	<input type="checkbox"/> Current User <input type="checkbox"/> Former User <input type="checkbox"/> Never Used <input type="checkbox"/> Unknown	Indicate whether the patient, at any time, used menopausal hormone therapy. 3012813
5	Has the patient ever taken oral contraceptives?	<input type="checkbox"/> Current User <input type="checkbox"/> Former User <input type="checkbox"/> Never Used <input type="checkbox"/> Unknown	Indicate whether the patient, at any time, used oral contraceptives. 3104217
6	Has the patient ever taken Tamoxifen?	<input type="checkbox"/> Current User <input type="checkbox"/> Former User <input type="checkbox"/> Never Used <input type="checkbox"/> Unknown	Indicate whether the patient, at any time, used Tamoxifen. 3104234
7	Hypertension	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient has a history of hypertension. 2183378

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8	Has the patient ever been diagnosed with diabetes by a physician?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient has, at any time, been diagnosed with diabetes by a physician. This includes borderline and gestational diabetes. 2716085
9	Number of full term pregnancies	<input type="checkbox"/> 0 <input type="checkbox"/> 3 <input type="checkbox"/> 1 <input type="checkbox"/> 4+ <input type="checkbox"/> 2 <input type="checkbox"/> Unknown	Provide the number of full term pregnancies the patient has had. 3012512
10	Has the patient had colorectal cancer?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient has a history of colorectal cancer. 2684753
11	Tumor Status (at time of last contact or death)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
12	Vital Status (at date of last contact)	<input type="checkbox"/> Living <input type="checkbox"/> Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
13	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)
14	Date of Death	____/____/____ (month)* (day) (year)*	If the patient is deceased, provide the date of death. 2897026 (month) 2897028 (day), 2897030 (year)
15	Measure of success of outcome <i>at the completion of initial first course treatment</i>	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Stable Disease <input type="checkbox"/> Partial Response <input type="checkbox"/> Complete Response <input type="checkbox"/> Not Applicable (Treatment Ongoing) <input type="checkbox"/> Unknown	Provide the patient's response to their initial first course treatment. 2786727

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
16	New Tumor Event After Initial Treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.
17	Type of New Tumor Event	<input type="checkbox"/> Locoregional Recurrence <i>Presence of a new tumor in the same location as the TCGA submitted tumor, after the patient was disease free</i> <input type="checkbox"/> Distant Metastasis <i>Presence of a new tumor in a different location as the TCGA submitted tumor, after the patient was disease free</i> <input type="checkbox"/> Progression of Disease <i>Progression of the pre-existing tumor</i>	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
18	Site of New Tumor Event	<input type="checkbox"/> Abdomen <input type="checkbox"/> Lymph Node <input type="checkbox"/> Bone <input type="checkbox"/> Pelvis <input type="checkbox"/> Brain <input type="checkbox"/> Unknown <input type="checkbox"/> Liver <input type="checkbox"/> Other, specify <input type="checkbox"/> Lung	Indicate the site of this new tumor event. 3108271
19	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

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#	Data Element	Entry Alternatives	Working Instructions
<u>20</u>	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)
<u>21</u>	Additional treatment for New Tumor Event: <i>Surgery</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
<u>22</u>	Month of Additional Surgery for New Tumor Event	____/____/____ (month)* (day) (year)*	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612 (month) , 3427613 (day) , 3427614 (year)
<u>23</u>	Procedure Type for New Tumor Event	<input type="checkbox"/> Excisional Biopsy <input type="checkbox"/> Incisional Biopsy <input type="checkbox"/> Surgical Resection <input type="checkbox"/> Unknown <input type="checkbox"/> Other Method, Specify Below	If the patient had surgery for the new tumor event, provide the type of procedure performed for this tumor. 3125097
<u>24</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. 3125102
<u>25</u>	Residual Tumor <i>After surgery for New Tumor Event</i>	<input type="checkbox"/> RX: The presence of residual tumor or margin status cannot be assessed. <input type="checkbox"/> R0: No residual tumor and negative microscopic margins in resected specimen. <input type="checkbox"/> R1: Microscopic residual tumor. No gross residual disease but positive microscopic margins. <input type="checkbox"/> 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
<u>26</u>	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
<u>27</u>	Additional treatment for New Tumor Event: <i>Pharmaceutical Therapy</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

Principal Investigator or Designee Signature_____
Print Name____/____/_____
Date