

Follow-Up Form

Testicular

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 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 a 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. If for example, a test was not performed the results of that test cannot be provided because it was "Not Evaluated."

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?	☐ Yes ☐ 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

2*	Post-Orchiectomy Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had post-orchietomy radiation therapy. <i>IF the patient did have post-orchietomy radiation, the Radiation Supplemental Form should be completed.</i> 2005312																								
3*	Post-Orchiectomy Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had post-orchietomy pharmaceutical therapy. <i>IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i> 3397567																								
4*	Post-Orchiectomy Retroperitoneal Lymph Node Dissection	☐ Yes – prior to chemotherapy ☐ Yes – after chemotherapy ☐ No ☐ Unknown	Indicate whether the patient had a retroperitoneal lymph node dissection. 3953323																								
5a*	Measure of Success of Outcome at the Completion of Initial First Course Treatment <i>Including Orchiectomy, Radiation, Chemotherapy and RPLND</i>	☐ No Measureable Tumor or Tumor Markers ☐ Normalization of Tumor Markers, but Residual Tumor Mass ☐ Elevated Tumor Markers and Residual Mass ☐ Progressive Tumor Mass and Tumor Markers ☐ Unknown	Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies). 2786727																								
5b	Molecular Marker(s) Used to Determine Outcome at the Completion of Initial First Course Treatment	<table border="1"> <thead> <tr> <th>Marker</th><th>Elevated</th><th>Normal</th><th>Progressed</th></tr> </thead> <tbody> <tr> <td>Lactate Dehydrogenase (LDH)</td><td></td><td></td><td></td></tr> <tr> <td>Human Chorionic Gonadotropin (HCG)</td><td></td><td></td><td></td></tr> <tr> <td>Alpha-Fetoprotein (AFP)</td><td></td><td></td><td></td></tr> <tr> <td>Luteinizing Hormone (LH)</td><td></td><td></td><td></td></tr> <tr> <td>Testosterone</td><td></td><td></td><td></td></tr> </tbody> </table>	Marker	Elevated	Normal	Progressed	Lactate Dehydrogenase (LDH)				Human Chorionic Gonadotropin (HCG)				Alpha-Fetoprotein (AFP)				Luteinizing Hormone (LH)				Testosterone				If the patient's outcome, at the completion of initial first course treatment, was measured by a tumor marker(s), indicate the tumor marker(s) measured and the result of each of the tests. 3953322
Marker	Elevated	Normal	Progressed																								
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6	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
7*	Vital Status (at date of last contact)	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
Date of Last Contact (If patient is living)			
8*	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)
Date of Death			
9	Date of Death	____ / ____ / ____ (month)* (day) (year)*	If the patient is deceased, provide the date of death. 2897026 (month), 2897028 (day), 2897030 (year)
10	Cause of Death	☐ Testicular Germ Cell Tumor (TGCT) ☐ Other Malignancy (not TGCT related) ☐ Other Non-Malignant Disease ☐ Death not Caused by Disease ☐ Unknown Cause of Death	Indicate the patient's cause of death. 2554674
11	Source of Death Information	☐ Death Certificate ☐ Medical Record ☐ Autopsy ☐ Death Index ☐ Physician ☐ Relative or Friend ☐ Other	Indicate the source used to identify the patient's cause of death. 2390921
12	Performance Status Scale: Karnofsky Score (To be taken prior to surgery/treatment)	☐ 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 and assistance ☐ 30 – Severely disabled, hospitalization indicated. Death is not imminent. ☐ 20 – Very sick, hospitalization indicated. Death not imminent ☐ 10 – Moribund, fatal processes progressing rapidly ☐ 0 – Dead ☐ Unknown ☐ Not Evaluated	Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient. 2003853
13	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) (To be taken prior to surgery/treatment)	☐ 0 – Asymptomatic ☐ 1 – Symptomatic but fully ambulatory ☐ 2 – Symptomatic but in bed less than 50% of the day ☐ 3 – Symptomatic and in bed more than 50% of the day ☐ 4 – Bedridden ☐ Unknown ☐ Not Evaluated	Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient. 88

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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
14*	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.
15	Type of New Tumor Event	☐ Metachronous Testicular Tumor ☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary 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
16	Site of New Tumor Event	☐ Brain ☐ Testis ☐ Lung ☐ Mediastinum ☐ Liver ☐ Lymph Node(s) ☐ RPLN ☐ Other, specify	Indicate the site of this new tumor event. 3108271
17	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
18	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)

Time Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form.

Please 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.

i	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: The time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box. Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection).
ii	Number of Days from Date of Initial Pathological Diagnosis to Date of Last Contact	_____ days	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. 3008273
iii	Number of Days from Date of Initial Pathological Diagnosis to Date of Death	_____ days	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 3165475
iv	Number of Days from Date of Initial Pathological Diagnosis to Date of New Tumor Event After Initial Treatment	_____ days	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 new tumor event after initial treatment. 3392464

Principal Investigator or Designee Signature

Print Name

____/____/_____
Date