

Instructions: The TCGA treatment forms (Pharmaceutical and Radiation) act as supplemental forms to the Follow-up form and are due at the time the Follow-up form is submitted to the BCR. However, if the patient has completed treatment or if the patient is deceased, these forms can be submitted to the BCR at the time the Enrollment form is submitted.

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 on OpenClinica): _____ Completed Date: _____

General 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Please note that the time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box.</p> <p>Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection). 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.</p>

Treatment Information

#	Data Element	Entry Alternatives	Working Instructions
2	Radiation Type	<input type="checkbox"/> External <i>(e.g. 3D Conformal, Cyberknife, External Beam, IMRT)</i> <input type="checkbox"/> Internal <i>(e.g. Brachytherapy, 90yttrium, Tandem & Ovoids)</i> <input type="checkbox"/> Systemic <i>(e.g. I-131)</i> <input type="checkbox"/> Unknown	<p>Indicate the type of radiation therapy administered to the patient. 2842944</p> <p>A separate Radiation Therapy form should be used for each type of treatment regimen.</p>
3	Location of Radiation Treatment	<input type="checkbox"/> Primary Tumor Field <input type="checkbox"/> Regional Site <input type="checkbox"/> Distant Site <input type="checkbox"/> Local Recurrence <input type="checkbox"/> Distant Recurrence <input type="checkbox"/> Unknown	<p>Indicate the location to which radiation therapy was administered. 2793522</p> <p>If radiation treatment was given to multiple locations, complete a separate Radiation Therapy form for each location.</p>
4	Total Dose	_____	<p>Provide the total dose of radiation therapy administered to the patient's tumor location referenced above. 2721441</p>
5	Units	<input type="checkbox"/> Gy (Gray) <input type="checkbox"/> cGy (Centigray) <input type="checkbox"/> mCi (Millicurie)	<p>Provide the unit of measurement used to calculate the corresponding total dose of radiation therapy given to the patient for the tumor location referenced above. 61446</p>

Radiation Supplemental Form

#	Data Element	Entry Alternatives	Working Instructions
6	Total Number of Fractions	_____	Provide the total number of radiation therapy sessions (fractions) which the patient completed to receive the required radiation dose to primary treatment fields. 61465
Date of Start of Radiation Therapy			
7	Month Radiation Therapy Started	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	Provide the month that radiation therapy was started. 2897100
8	Day Radiation Therapy Started	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	Provide the day that radiation therapy was started. 2897102
9	Year Radiation Therapy Started	_____	Provide the year that radiation therapy was started. 2897104
10	Number of Days from Date of Initial Pathologic Diagnosis to Date of Radiation Therapy Started	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of start of radiation therapy. 3008313 <i>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>
11	Radiation Therapy Ongoing	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether radiation therapy is ongoing. 2842745 <i>If therapy ongoing, date of therapy end should not be completed.</i>
Date of Therapy End			
12	Month Radiation Therapy Ended	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	Provide the month that radiation therapy was completed/ ended. 2897106
13	Day Radiation Therapy Ended	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	Provide the day that radiation therapy was completed/ ended. 2897108
14	Year Radiation Therapy Ended	_____	Provide the year that radiation therapy was completed/ ended. 2897110
15	Number of Days from Date of Initial Pathologic Diagnosis to Date Radiation Therapy Ended	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of end of radiation therapy. 3008333 <i>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>
16	Measure of Best Response of Treatment	<input type="checkbox"/> Complete Response <input type="checkbox"/> Partial Response <input type="checkbox"/> Stable Disease <input type="checkbox"/> Progressive Disease <input type="checkbox"/> Not Applicable (Therapy Ongoing) <input type="checkbox"/> Unknown	Indicate the patient's outcome (response) at the end of this treatment regimen. 2857291

Principal Investigator or Designee Signature

Print Name

Date