

Follow-Up Form Cervical (CESC)

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	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 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). 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	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 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.

Follow-Up Information

#	Data Element	Entry Alternatives	Working Instructions
3	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
4	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
5	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
6	Vital Status (at date of last contact)	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553

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7	Month of Last Contact	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient is living, provide the month of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 Do not answer if patient is deceased.
8	Day of Last Contact	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient is living, provide the day of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897022 Do not answer if patient is deceased.
9	Year of Last Contact	_____	If the patient is living, provide the year of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897024 Do not answer if patient is deceased.
10	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	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 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.
11	Month of Death	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient is deceased, provide the month of death. 2897026
12	Day of Death	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient is deceased, provide the day of death. 2897028
13	Year of Death	_____	If the patient is deceased, provide the year of death. 2897030
14	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	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 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.
15	Cause of Death	☐ Cervical cancer ☐ Unknown ☐ Other cause(s), specify	Indicate the patient's cause of death. 2554674
16	Other Cause of Death	_____	If the patient's cause of death was not included in the provided list, specify the patient's cause(s) of death. 2004150

Performance Status and Measure of Success

17	Performance Status: Eastern Cooperative Oncology Group (ECOG)	☐ 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	Using the patient's medical records, provide the ECOG performance status score at the time provided in the following question. 88
18	Performance Status: Timing	☐ Preoperative ☐ Pre-adjuvant therapy ☐ Post-adjuvant therapy ☐ Other, specify	Indicate the time point of the documented ECOG performance score provided above. 2792763

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#	Data Element	Entry Alternatives	Working Instructions
19	Other Performance Status Scale	_____	If the status of the patient during the last documented ECOG performance score was not included in the provided list, specify the patient's status. 3151756
20	Month of Performance Status	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	Provide the month of the last documented ECOG performance score. 3121370
21	Day of Performance Status	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	Provide the day of the last documented ECOG performance score. 3121372
22	Year of Performance Status	_____	Provide the year of the last documented ECOG performance score. 3121374
23	Measure of success of outcome <i>at the completion of initial first course treatment (including surgery)</i>	☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Unknown ☐ Not Applicable (Treatment Ongoing)	Indicate the patient's measure of success after their primary treatment including surgery and adjuvant therapies. 2786727
24	What was the measure of success <i>at Date of Last Contact provided on this form?</i>	☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Unknown	Indicate the patient's measure of success at the Date of Last Contact provided on this form. 3033278

Treatment Information

#	Data Element	Entry Alternatives	Working Instructions
Radiation Therapy (Brachytherapy and External Radiation)			
25	If patient did not complete radiation, provide the primary reason why it was not given or not completed.	☐ Adverse event/complications ☐ Scheduling problems ☐ Participant refusal ☐ Not done per treating physicians discretion ☐ Other, specify ☐ Unknown	If the patient did not receive radiation indicate the reason treatment was not administered. 2733266
26	Other Reason Radiation Not Given or Not Completed	_____	If the reason the patient did not receive radiation is not included in the provided list, specify the reason. 2733267
27	If patient received brachytherapy, indicate the type.	☐ LDR ☐ HDR ☐ Other, specify	If the patient received brachytherapy, indicate the type administered. If the patient did not receive brachytherapy, skip all related questions. 2966127
28	Other Type of Brachytherapy	_____	If the type of brachytherapy the patient received is not included in the provided list, specify the type administered. 3150976
29	If patient received brachytherapy, provide the total dose to point A	_____ cGy	Indicate the total dose (cGy) of brachytherapy to point A the patient received. 3151100
30	If patient received external radiation, indicate type of external radiation.	☐ 3D Conformal ☐ IMRT ☐ External Beam ☐ Unknown ☐ Other, specify	If the patient received external radiation, indicate the type administered. If the patient did not receive external radiation, skip all related questions. 61468
31	Other Type of External Radiation	_____	If the type of external radiation the patient received is not included in the provided list, specify the type administered. 2195477

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#	Data Element	Entry Alternatives	Working Instructions
32	Total Dose to Pelvis/Pelvic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to pelvis/pelvic nodes. 3006
33	Total Dose to Paraaortic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to paraaortic nodes. 3151106
Concurrent Chemotherapy			
34	Was chemotherapy given concurrent to radiation after tissue procurement?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received chemotherapy concurrent to radiation treatment after tissue procurement. 2539220
35	If patient did not complete chemotherapy concurrent to radiation, provide the primary reason why it was not given or not completed.	☐ Adverse event/complications ☐ Scheduling problems ☐ Participant refusal ☐ Not done per treating physicians discretion ☐ Unknown ☐ Other, specify	If the patient did not receive chemotherapy concurrent to radiation treatment indicate the reason treatment was not administered. 3151120
36	Other Reason Chemotherapy Not Given concurrent to Radiation	_____	If the reason the patient did not receive chemotherapy concurrent to radiation treatment is not included in the provided list, specify the reason. 3151824
<u>37</u>	If patient received concurrent chemotherapy, indicate type of concurrent chemotherapy. (Check all that apply)	☐ Cisplatin ☐ Carboplatin ☐ Other, specify	If the patient received chemotherapy concurrent to radiation treatment, indicate the type administered. If the patient did not receive external radiation, skip all related questions. 2007212
<u>38</u>	Other Type of Concurrent Chemotherapy	_____	If the type of chemotherapy given concurrent to radiation treatment is not included in the provided list, specify the type administered. 2426129
<u>39</u>	Concurrent Chemotherapy Dose	_____	Indicate the dose of the concurrent chemotherapy the patient received. Include the unit of measure. 3166172 and 3065815
<u>40</u>	Concurrent Chemotherapy Frequency	☐ Every hour ☐ 5 times daily ☐ 4 times daily ☐ 3 times daily ☐ 2 times daily ☐ Every 24 hours ☐ Every other day ☐ Twice a week ☐ Once weekly	Indicate the frequency the concurrent chemotherapy was received. 2179580
<u>41</u>	Concurrent Chemotherapy Number of Total Doses	_____	Indicate the total number of doses the patient received the concurrent chemotherapy. 2180805

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.

#	Data Element	Entry Alternatives	Working Instructions
42	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.
<u>43</u>	Type of New Tumor Event	☐ 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. 3119721

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#	Data Element	Entry Alternatives	Working Instructions
<u>44</u>	Site of New Tumor Event	☐ Cervix ☐ Head & Neck ☐ Lung ☐ Vulvar ☐ Anus ☐ Other, specify ☐ Unknown ☐ Not Applicable	If the patient had a new tumor event, provide the site of this tumor. 3108271
<u>45</u>	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
<u>46</u>	Month of New Tumor Event	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. 3104044
<u>47</u>	Day of New Tumor Event	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
<u>48</u>	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
<u>49</u>	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	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. 3392464 <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>
<u>50</u>	Method of Pathologic Diagnosis for New Tumor Event	☐ Cytology ☐ Tumor Resection ☐ Other, specify	Indicate the method used to pathologically diagnose the new tumor event. 3151113
<u>51</u>	Other Method of Pathologic Diagnosis for New Tumor Event	_____	If the pathologic method used to diagnose the new tumor event is not included in the provided list, specify the method used. 3151116
<u>52</u>	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
<u>53</u>	Month of Additional Surgery for New Tumor Event	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612
<u>54</u>	Day of Additional Surgery for New Tumor Event	☐ 01 ☐ 08 ☐ 14 ☐ 20 ☐ 26 ☐ 02 ☐ 09 ☐ 15 ☐ 21 ☐ 27 ☐ 03 ☐ 10 ☐ 16 ☐ 22 ☐ 28 ☐ 04 ☐ 11 ☐ 17 ☐ 23 ☐ 29 ☐ 05 ☐ 12 ☐ 18 ☐ 24 ☐ 30 ☐ 06 ☐ 13 ☐ 19 ☐ 25 ☐ 31 ☐ 07	If the patient had surgery for the new tumor event, provide the day this surgery was performed. 3427613
<u>55</u>	Year of Additional Surgery for New Tumor Event	_____	If the patient had surgery for the new tumor event, provide the year this surgery was performed. 3427614
<u>56</u>	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event	_____	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). 3008335 <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>

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#	Data Element	Entry Alternatives	Working Instructions
<u>57</u>	Residual Tumor <i>After surgery for New Tumor Event</i>	☐ RX: The presence of residual tumor or margin status cannot be assessed. ☐ R0: No residual tumor and negative microscopic margins in resected specimen. ☐ R1: Microscopic residual tumor. No gross residual disease but positive microscopic margins. ☐ 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>58</u>	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
<u>59</u>	Additional treatment for New Tumor Event: <i>Pharmaceutical Therapy</i>	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

 Principal Investigator or Designee Signature

 Print Name

 ____/____/_____
 Date