

Follow-up Form

HTMCP – Cervical

Instructions: The Follow-up Form should be completed for each qualified case in the HIV+ Tumor Characterization Project (HTMCP) study. The Tissue Source Site (TSS) should complete the form 12 months after the sample is submitted for HTMCP. In addition, the OCG project office will request this information again at 24-months after this date. Questions regarding this form should be directed to the Clinical Data Collection Operation & Database (CDCOD) or OCG.

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 HTMCP 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 in OpenClinica): _____ Completed Date: _____

#	Data Element	Entry Alternatives	Working Instructions
Patient Information			
Patient Status			
*1	Patient Status (at completion of this form)	<input type="checkbox"/> Living (Additional Follow-up Forms Due Annually) <input type="checkbox"/> Deceased <input type="checkbox"/> Lost to follow-up	Indicate whether the patient was living or deceased at the date of last contact, or has been 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 death records). <u>5</u> <i>If the patient was lost to follow-up or died after enrollment, additional follow-up forms are not required.</i>
†2	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). <u>2897020</u> (month), <u>2897022</u> (day), <u>2897024</u> (year) <i>Note: The day of Last Contact is not required.</i>
*3	Date Last Known Alive	____/____/____ (month) (day) (year)	Indicate the last date the patient was known to be alive, regardless of whether the patient, medical provider, family member or caregiver was contacted. <u>2975722</u> (month), <u>2975724</u> (day), <u>2975726</u> (year) <i>Note: The day of Last Known Alive is not required.</i>
†4	Date of Death	____/____/____ (month) (day) (year)	If the patient is deceased, provide the date of death. <u>2897026</u> , (month) <u>2897028</u> (day), <u>2897030</u> (year) <i>Note: The day of Death is not required.</i>
5	Cause of Death <i>Only complete if patient is deceased.</i>	<input type="checkbox"/> Cervical Cancer <input type="checkbox"/> Unknown <input type="checkbox"/> Other (please specify)	Indicate the patient's cause of death. <u>2554674</u>
6	Other Cause of Death <i>Only complete if "other" is selected above.</i>	_____	If the patient's cause of death was not included in the provided list, specify the patient's cause of death. <u>2004150</u>
Patient Status (Regarding Submitted Tumor)			
*7	Tumor Status (at time of last contact)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> Unknown	Indicate whether the patient was tumor/disease free (i.e. free of the malignancy that yielded the sample submitted for the HTMCP study) at the date of last contact or death. <u>2759550</u>
*8	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 <i>for the tumor submitted for HTMCP.</i> <u>2005312</u>
*9	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 <i>for the tumor submitted for HTMCP.</i> <u>3397567</u>
10	Measure of Success of Outcome at the Completion of Initial First Course Treatment	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Stable Disease <input type="checkbox"/> Partial Response <input type="checkbox"/> Complete Response <input type="checkbox"/> Unknown <input type="checkbox"/> Not Applicable (treatment ongoing)	Indicate the patient's measure of success after their primary treatment including surgery and adjuvant therapies. <u>2786727</u>

Follow-up Form

HTMCP – Cervical

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Treatment Information			
Radiation Therapy (Brachytherapy and External Radiation)			
11	If patient did not complete radiation, provide the primary reason why it was not given or not completed.	<input type="checkbox"/> Adverse event/complications <input type="checkbox"/> Scheduling problems <input type="checkbox"/> Participant refusal <input type="checkbox"/> Not done per treating physicians discretion <input type="checkbox"/> Other, specify <input type="checkbox"/> Unknown	If the patient did not receive radiation indicate the reason treatment was not administered. 2733266
12	Other Reason Radiation Not Given or Not Completed <i>Only complete if "other" is selected above.</i>	_____	If the reason the patient did not receive radiation is not included in the provided list, specify the reason. 2733267
13	If patient received brachytherapy, indicate the type.	<input type="checkbox"/> LDR <input type="checkbox"/> HDR <input type="checkbox"/> Other, specify	If the patient received brachytherapy, indicate the type administered. If the patient did not receive brachytherapy, skip all related questions. 2966127
14	Other Type of Brachytherapy <i>Only complete if "other" is selected above.</i>	_____	If the type of brachytherapy the patient received is not included in the provided list, specify the type administered. 3150976
15	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
16	If patient received external radiation, indicate type of external radiation.	<input type="checkbox"/> 3D Conformal <input type="checkbox"/> IMRT <input type="checkbox"/> External Beam <input type="checkbox"/> Unknown <input type="checkbox"/> 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
17	Other Type of External Radiation <i>Only complete if "other" is selected above.</i>	_____	If the type of external radiation the patient received is not included in the provided list, specify the type administered. 2195477
18	Total Dose to Pelvis/Pelvic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to pelvis/pelvic nodes. 3006
19	Total Dose to Paraaortic Nodes	_____ cGy	Indicate the total dose (cGy) of external radiation the patient received to paraaortic nodes. 3151106
Concurrent Chemotherapy			
20	Was chemotherapy given concurrent to radiation after tissue procurement?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received chemotherapy concurrent to radiation treatment after tissue procurement. 2539220
21	If patient did not complete chemotherapy concurrent to radiation, provide the primary reason why it was not given or not completed.	<input type="checkbox"/> Adverse event/complications <input type="checkbox"/> Scheduling problems <input type="checkbox"/> Participant refusal <input type="checkbox"/> Not done per treating physicians discretion <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify	If the patient did not receive chemotherapy concurrent to radiation treatment, indicate the reason treatment was not administered. 3151120
22	Other Reason Chemotherapy Not Given concurrent to Radiation <i>Only complete if "other" is selected above.</i>	_____	If the reason the patient did not receive chemotherapy concurrent to radiation treatment is not included in the provided list, specify the reason. 3151824
23	If patient received concurrent chemotherapy, indicate type of concurrent chemotherapy. <i>(Check all that apply)</i>	<input type="checkbox"/> Cisplatin <input type="checkbox"/> Carboplatin <input type="checkbox"/> 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
24	Other Type of Concurrent Chemotherapy <i>Only complete if "other" is selected above.</i>	_____	If the type of chemotherapy given concurrent to radiation treatment is not included in the provided list, specify the type administered. 2426129

Follow-up Form

HTMCP – Cervical

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25	Concurrent Chemotherapy Dose	_____	Indicate the dose of the concurrent chemotherapy the patient received. Include the unit of measure. 3166172 and 3065815
26	Concurrent Chemotherapy Frequency	<input type="checkbox"/> Every hour <input type="checkbox"/> 5 times daily <input type="checkbox"/> 4 times daily <input type="checkbox"/> 3 times daily <input type="checkbox"/> 2 times daily <input type="checkbox"/> Every 24 hours <input type="checkbox"/> Every other day <input type="checkbox"/> Twice a week <input type="checkbox"/> Once weekly	Indicate the frequency the concurrent chemotherapy was received. 2179580
27	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.			
*i	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
tii	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)
iii	Type of New Tumor Event	<input type="checkbox"/> Locoregional Recurrence <input type="checkbox"/> Distant Metastasis <input type="checkbox"/> New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence or a distant metastasis of the tissue submitted for HTMCP; or a new primary tumor. 3119721
iv	Anatomic Site of New Tumor Event	<input type="checkbox"/> Bone <input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Retroperitoneum <input type="checkbox"/> Lymph Node(s) <input type="checkbox"/> Other, specify	Indicate the site of this new tumor event. 3108271
v	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
vi	Diagnostic Evidence of Recurrence / Relapse (check all that apply)	<input type="checkbox"/> Biopsy w/Histologic Confirmation <input type="checkbox"/> Convincing Imaging (i.e. CT, PET, MRI) <input type="checkbox"/> Positive Biomarker(s)	Indicate the procedure or testing method used to diagnose tumor recurrence or relapse. 2786205
vii	Additional Surgery for New Tumor Event	<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 metastatic tumor event in question. 3427611
viii	Additional Treatment of New Tumor Event Radiation Therapy	<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
ix	Additional Treatment of New Tumor Event Pharmaceutical Therapy	<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 (*Printed Name*)

 Principal Investigator (*Signature*)

 Date

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.