

Follow-up Form HTMCP – Lung

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"/> Cancer Related <input type="checkbox"/> Non-Cancer Related <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 or death)	<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	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Complete Response <input type="checkbox"/> Stable Disease <input type="checkbox"/> Unknown	Indicate the patient's measure of success after the initial first course of treatment. <u>2786727</u>

