Follow-up Form

HTMCP – Diffuse Large B-Cell Lymphoma (DLBCL)

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)*	☐ Living *(Additional Follow-up Forms Due Annually)* ☐ Deceased ☐ 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). 5 *If the patient was lost to follow-up or died after enrollment, additional follow-up forms are not required.*
*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). 2897020 (month), 2897022 (day), 2897024 (year) *Note: The day of Last Contact is not required.*
*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. 2975722 (month), 2975724 (day), 2975726 (year) *Note: The day of Last Known Alive is not required.*
*4	Date of Death	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	If the patient is deceased, provide the date of death. 2897026, (month) 2897028 (day), 2897030 (year) *Note: The day of Death is not required.*
5	Cause of Death Only complete if patient is deceased.	☐ Cancer Related ☐ Non-Cancer Related ☐ Unknown ☐ Other (please specify)	Indicate the patient's cause of death. 2554674
6	Other Cause of Death Only complete if "other" is selected above.	_____	If the patient's cause of death was not included in the provided list, specify the patient's cause of death. 2004150
Patient Status (Regarding Submitted Tumor)			
*7	Tumor Status *(at time of last contact)*	☐ Tumor free ☐ With tumor ☐ 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. 2759550
*8	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy *for the tumor submitted for HTMCP.* 2005312
*9	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy *for the tumor submitted for HTMCP*. 3397567

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10	Measure of Success of Outcome at the Completion of Initial First Course Treatment	☐ Progressive Disease ☐ Complete Response ☐ Stable Disease ☐ Unknown ☐ Partial Response ☐ Not Applicable (treatment ongoing)	Indicate the patient's measure of success after the initial first course of treatment. 2786727
11	Results of PET Scan Performed within 2 Months after Treatment	☐ Positive ☐ Negative ☐ Indeterminate ☐ Not Performed	Provide the results of the PET Scan which was performed to identify the absence or presence of disease within two months after the completion of the first course of treatment. 2603749

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?	☐ 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.
Ii	Type of New Tumor Event	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ 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
iii	Anatomic Site of New Tumor Event	☐ Bone ☐ Retroperitoneum ☐ Lung ☐ Lymph Node(s) ☐ Liver ☐ Other, specify	Indicate the site of this new tumor event. 3108271
iv	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
v*	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)
vi	Diagnostic Evidence of Recurrence / Relapse (check all that apply)	☐ Biopsy w/Histologic Confirmation ☐ Convincing Imaging (i.e. CT, PET, MRI) ☐ Positive Biomarker(s)	Indicate the procedure or testing method used to diagnose tumor recurrence or relapse. 2786205
vii	Additional Surgery for New Tumor Event	☐ Yes ☐ Unknown ☐ No	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	☐ Yes ☐ Unknown ☐ No	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
ix	Additional Treatment of New Tumor Event Pharmaceutical Therapy	☐ Yes ☐ Unknown ☐ No	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.