Enrollment Form

HTMCP – Diffuse Large B-Cell Lymphoma (DLBCL)

Instructions: *The Enrollment 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 for qualified cases upon qualification notice from the Office of Cancer Genomics (OCG).*

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
General Information			
*1	Is this a prospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected after the date the HTMCP contract was executed, the tissue has been collected prospectively. 3088492
*2	Is this a retrospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the HTMCP contract was executed, the tissue has been collected retrospectively. 3088528
Patient Information			
Demographic Information			
*3	Date of Birth	___ ___ / ___ ___ / ___ ___ ___ ___ (month) (day) (year)	Provide the date the patient was born. 2896950 (month), 2896952 (day), 2896954 (year) *Note: The day of Birth is not required.*
*4	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
*5	Race *(check all that apply)*	☐ American Indian or Alaska Native ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ Not Evaluated ☐ Unknown	Provide the patient's race using the defined categories. 2192199 American Indian or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. Asian: A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. White: A person having origins in any of the original peoples of the four Europe, the Middle East, or North Africa. Black or African American: A person having origins in any of any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." Native Hawaiian or other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Not Evaluated: Not provided or available Unknown: Could not be determined or unsure
6	Ethnicity	☐ Not Hispanic or Latino ☐ Hispanic or Latino ☐ Not Evaluated ☐ Unknown	Provide the patient's ethnicity using the defined categories. 2192217 Not Hispanic or Latino: A person not meeting the definition of Hispanic or Latino. Hispanic or Latino: A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race. Not Evaluated: Not provided or available Unknown: Could not be determined or unsure
7	Height *(at time of diagnosis)*	_____(cm)	Provide the patient's height (in centimeters) at the time the patient was diagnosed with the tumor submitted for HTMCP. 649
8	Weight *(at time of diagnosis)*	_____(kg)	Provide the patient's weight (in kilograms) at the time the patient was diagnosed with the tumor submitted for HTMCP. 651

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Survival Information			
*9	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
†10	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.*
*11	Date of 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.*
†12	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.*
13	Cause of Death Only complete if patient is deceased	☐ Cancer Related ☐ Unknown ☐ Non-Cancer Related ☐ Other (please specify)	Indicate the patient's cause of death. 2554674
14	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(s) of death. 2004150
Patient Status (Regarding Submitted Tumor)			
*15	Did the patient receive neo-adjuvant therapy for the tumor submitted for HTMCP?	☐ Yes *(exclusion criterion)* ☐ No	Indicate whether the patient received treatment (radiation, pharmaceutical, or both) prior to the procurement of the sample submitted for HTMCP. 3382737 *If the answer to this question is "yes", the submitted case is excluded.*
*16	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown Tumor Status	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
17	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) *(At the time of diagnosis)*	☐ 0: Asymptomatic ☐ 1: Symptomatic, but fully ambulatory ☐ 2: Symptomatic, in bed less than 50% of day ☐ 3: Symptomatic, in bed more than 50% of day. ☐ 4: Bed-ridden ☐ Unknown ☐ Not Evaluated	Provide the Eastern Cooperative Oncology Group (ECOG) performance status of the patient at the time of diagnosis. 88
18	Performance Status Score: Karnofsky Score *(At the time of diagnosis)*	☐ 100: Normal, no complaints, no evidence of disease ☐ 90: Able to carry on normal activity; minor signs or symptoms of disease ☐ 80: Normal activity with effort; some signs or symptoms of disease ☐ 70: Cares for self, unable to carry on normal activity or to do active work ☐ 60: Requires occasional assistance; but is able to care for most of his/her needs ☐ 50: Requires considerable assistance and frequent medical care ☐ 40: Disabled, requires special care and assistance ☐ 30: Severely disabled, hospitalization indicated. Death not imminent ☐ 20: Very sick, hospitalization ☐ 10: Moribund, fatal processes progressing rapidly ☐ 0: Dead ☐ Unknown ☐ Not Evaluated	Provide the Karnofsky Score performance status of the patient at the time of diagnosis. 2003853
19	Tumor Response	☐ Progressive Disease ☐ Partial Response ☐ Stable Disease ☐ Complete Response	Indicate the patient's measure of success after their primary treatment including surgery and adjuvant therapies. 2786727
*20	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
*21	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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#	Data Element	Entry Alternatives	Working Instructions
22	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
Smoking History			
23	Tobacco Smoking History Indicator *(at time of diagnosis)*	☐ 1: Lifelong Non-Smoker ☐ 2: Current Smoker ☐ 3: Current Reformed Smoker for > 15 years ☐ 4: Current Reformed Smoker for <= 15 years ☐ 5: Current Reformed Smoker (duration not specified) ☐ Smoking Status not Documented	Indicate the patient's history of tobacco smoking including their smoking status at diagnosis using the defined categories. If the patient is or was a lifelong non-smoker, skip the additional smoking questions. 2181650
24	Age of Onset of Tobacco Smoking	____ ____ years	Provide the age in years when the patient began smoking cigarettes. 2178045
25	Year of Quitting Tobacco Smoking	____ ____ ____ ____ (YYYY)	Provide the year the patient quit smoking. 2228610
26	Number of Pack Years Smoked *(at time of diagnosis)*	____ ____ ____ ____ pack years	Provide the number of pack years the patient smoked. This is calculated using the number of cigarettes smoked per day times the number of years smoked, divided by 20. For example, if the patient smoked 5 cigarettes per day times 10 years divided by 20, the patient would have 2.5 pack years (e.g. 5x10/20=2.5). 2955385
History of Disease			
HIV Status			
*27	Is patient HIV positive?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient is HIV positive. 2180464
†28	Date of HIV Diagnosis (if known)	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)	Provide the month the patient was diagnosed with HIV. 3579640 (month), 3579644 (day), 3579643 (year) *Note: The day of HIV Diagnosis is not required.*
29	Nadir CD4 Counts	_____ (cells/mm³)	Provide the patient's Nadir CD4 counts, which are the lowest CD4 counts the patient has had. 2684395
†30	CD4 Counts at Diagnosis of the Submitted Malignancy	_____ (cells/mm³)	Provide the patient's CD4 Counts at the time the patient was diagnosed with the malignancy submitted for the HTMCP study. 2922654
†31	HIV RNA load at Diagnosis of Submitted Malignancy	_____ (counts/mL)	Provide the HIV RNA load (also known as the "viral load") at the time the patient was diagnosed with the malignancy submitted for the HTMCP study. 2922674
32	Prior AIDS Defining Conditions	☐ Candidiasis of bronchi, trachea or lungs ☐ Candidiasis, esophageal ☐ CMV other than liver, spleen or nodes, onset at age >1month ☐ CMV retinitis ☐ Coccidioidomycosis, disseminated or extrapulmonary ☐ Cryptococcosis, extrapulmonary ☐ Cryptosporidiosis, chronic intestinal ☐ Encephalopathy, HIV-related ☐ Herpes simplex: chronic ulcers (> 1 month's duration) or bronchitis, pneumonitis or esophagitis (onset at age > 1 month) ☐ Histoplasmosis, disseminated or extrapulmonary ☐ Isosporiasis, chronic intestinal (> 1 mon) ☐ Mycobacterium avium complex or Mycobacterium kansasii disseminated or extrapulmonary ☐ Mycobacterium tuberculosis of any site, pulmonary, disseminated or extrapulmonary ☐ Mycobacterium, other species or unidentified species, disseminated or extrapulmonary ☐ Nocardiosis ☐ Pneumocystis jirovecii pneumonia ☐ Pneumonia, recurrent ☐ Progressive multifocal leukoencephalopathy ☐ Salmonella septicemia, recurrent ☐ Toxoplasmosis of the brain, onset at age >1month ☐ Wasting syndrome, due to HIV	Prior to the malignancy submitted for the HTMCP study, provide any AIDS defining conditions. 2679581

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#	Data Element	Entry Alternatives					Working Instructions
33	Co-Infections *(serology data/viral load if available)*	**Test**	**Results**				Using the list provided, indicate whether the patient had any co-infections by providing the results of each of the tests listed.
			Pos	Neg	Inconclusive	Not Tested	
		HBV					2180456
		HCV					2695021
		HPV					2230033
		KSHV /HHV8					3335773
†34	HAART Treatment Prior to Diagnosis of Submitted Malignancy	☐ Yes ☐ No ☐ Unknown					Indicate whether the patient received Highly Active Antiretroviral Therapy (HAART) treatment prior to the diagnosis of the malignancy submitted for the HTMCP study. 3335156
†35	HAART Treatment at Time of Diagnosis of Submitted Malignancy	☐ Yes ☐ No ☐ Unknown					Indicate whether the patient received Highly Active Antiretroviral Therapy (HAART) treatment at the time of the diagnosis of the malignancy submitted for the HTMCP study. 2922679
36	CDC HIV Risk Group(s)	☐ Homosexual or bisexual contact ☐ Heterosexual contact ☐ IV drug user ☐ Transfusion recipient ☐ Hemophiliac ☐ Other					Indicate whether the patient has a history of any of the listed HIV Risk Groups as defined by the Center for Disease Control (CDC). 2542215
Prior Malignancies							
*37	Has this patient at any time in their life had a prior diagnosis of a malignant neoplasm?	☐ Yes *(exclusion criterion)* ☐ No					Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for HTMCP. 3382736 *If the answer to this question is "yes", the submitted case is excluded. This exclusion does not apply if the patient only has a history of non-melanoma skin cancer, in situ carcinoma or Kaposi's Sarcoma*
38	Type of Prior Malignancies	_____					If the patient has had a prior diagnosis of a malignant neoplasm, provide the type of prior malignancy. 2718428
Prior Immunological Disease							
39	Patient History of Prior Immunological Disease	☐ Rheumatoid Arthritis ☐ Sjogren's Syndrome ☐ Systemic Lupus Erythematosus ☐ Crohn's Disease ☐ Ulcerative Colitis ☐ Hashimoto's Thyroiditis ☐ Other (please specify) ☐ Unknown					Indicate whether the patient has a history of any of the listed immunological diseases. 3233628
40	Patient History of Other Prior Immunological Disease Only complete if "other" is selected above.	_____					If the patient has a history of immunological disease and the disease is not listed in the previous question, provide the name of the disease(s). 3233629
41	Patient History of Prior Immunosuppressive Therapy for Immunological Disease	☐ Methotrexate ☐ Azathioprine ☐ None	☐ Cyclophosphamide ☐ Anti-TNF therapy ☐ Other (please specify) ☐ Unknown				If the patient received immunosuppressive therapy for the immunological disease selected in the previous question, provide the type of immunosuppressive therapy given. 3233638
42	Other History of Prior Immunosuppressive Therapy for Immunological Disease Only complete if "other" is selected above.	_____					If the patient has a history of immunosuppressive therapy for immunological disease and the immunosuppressive therapy is not listed in the previous question, provide the name of the immunosuppressive therapy(s). 2873928
Prior Infectious Disease							
43	Patient History of Relevant Prior Infectious Disease	☐ Hepatitis B ☐ Hepatitis C ☐ H. Pylori	☐ Other (please specify) ☐ Unknown				Indicate whether the patient has a history of any of the listed infectious diseases. 3233642
44	Patient History of Other Relevant Infectious Disease Only complete if "other" is selected above.	_____					If the patient has a history of relevant prior disease that was not included in the list, provide the infectious disease. 3233643

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#	Data Element	Entry Alternatives	Working Instructions
Pathologic Diagnosis			
*45	Histological Subtype	☐ Diffuse Large B-cell Lymphoma (DLBCL) NOS (any anatomic site, nodal or extra nodal) ☐Primary Mediastinal (thymic) Large B-cell Lymphoma ☐ Primary DLBCL of the CNS ☐ Primary cutaneous DLBCL, leg type ☐ EBV Positive DLBCL of the Elderly ☐ DLBCL Associated with Chronic Inflammation	Using the patient's final diagnostic pathology report, provide the most detailed histological subtype available. 3081934
46	Percent Follicular Component	☐ < or = 10% ☐ > 10%	Using the pathology report, indicate the percentage of the follicular component within the diffuse large B-cell lymphoma sample that was removed from the patient. 3232840
*47	Site of Nodal Involvement at Diagnosis *(Please check all that apply)*	☐ Axillary ☐ Cervical ☐ Epitrochlear ☐ Femoral ☐ Iliac ☐ Iliac-common ☐ Iliac-external ☐ Inguinal ☐ Mediastinal ☐ Mesenteric ☐ Occipital ☐ Para aortic ☐ Parotid ☐ Popliteal ☐ Retroperitoneal ☐ Splenic ☐ Supraclavicular ☐ Submandibular ☐ No Known Nodal Involvement	Using the patient's medical record check all applicable boxes to identify the lymph node chain(s) that were involved by diffuse large B-cell lymphoma at the time of initial diagnosis. 2180591
*48	Site(s) of Extranodal Involvement At Diagnosis *(Please check all that apply)*	☐ Adrenal ☐ Bone ☐ Bone Marrow ☐ Breast ☐ Neck ☐ Peripheral Blood ☐ Skin ☐ Soft Tissue *(muscle, ligaments, subcutaneous)* **Central Nervous System** ☐ Brain ☐ Cerebrospinal Fluid ☐ Epidural ☐ Leptomeninges **ENT & Eye** ☐ Intraocular ☐ Larynx ☐ Trachea ☐ Nasal Soft Tissue ☐ Nasopharynx ☐ Oropharynx ☐ Parotid Gland ☐ Peri orbital Soft Tissue ☐ Salivary Gland ☐ Sinus ☐ Thyroid **Gastrointestinal/ Abdominal** ☐ Ascites/ Peritoneum ☐ Appendix ☐ Colon ☐ Esophagus ☐ Stomach ☐ Gall Bladder ☐ Small Intestine ☐ Liver ☐ Pancreas ☐ Rectum **Genito-urinary Tract** ☐ Epididymis ☐ Kidney ☐ Ovary ☐ Prostate ☐ Testes ☐ Uterus **Mediastinal/ Intra-thoracic** ☐ Heart ☐ Lung ☐ Mediastinal Soft Tissue ☐ Pericardium ☐ Pleura/Pleural Effusion ☐ Other Extranodal Site ☐ No Known Extranodal Involvement	Using the patient's medical record check all applicable boxes to identify the anatomic location of all site(s) of extranodal involvement by diffuse large B-cell lymphoma at the time of initial diagnosis. 3427536
†49	Other Specified Site of Extranodal Involvement at Diagnosis *(For Primary Clinical Involvement)* Only complete if "other" is selected above.	_____	If there is extranodal tumor involvement of other specified sites not included on the provided list, specify the other anatomic site(s) of extranodal involvement. 3234303
50	Number of Extranodal Sites of Involvement Above *(to calculate the IPI)*	_____	Provide the total number of extranodal sites with lymphoma involvement. Use the previous two questions to determine this number. This information, along with other data provided, will be used to calculate the International Prognostic Index (IPI). 3233242

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#	Data Element	Entry Alternatives		Working Instructions
51	Maximum Tumor Bulk *(Dimension)*	_____ (cm)		After review of the entire medical record, record the length of the largest dimension/ diameter of a tumor, regardless of anatomical plane. 64215
*52	Anatomic Site of Maximum Tumor Bulk *(Select one anatomic site from listing above)*	**Lymph Nodes** ☐ Axillary ☐ Cervical ☐ Epitrochlear ☐ Femoral ☐ Iliac ☐ Iliac-common ☐ Iliac-external ☐ Inguinal ☐ Mediastinal ☐ Mesenteric ☐ Occipital ☐ Para aortic ☐ Parotid ☐ Popliteal ☐ Retroperitoneal ☐ Splenic ☐ Supraclavicular ☐ Submandibular **Extralnodal** ☐ Adrenal ☐ Bone ☐ Bone Marrow ☐ Breast ☐ Neck ☐ Peripheral Blood ☐ Skin ☐ Soft Tissue *(muscle, ligaments, subcutaneous)* **Central Nervous System** ☐ Brain ☐ Cerebrospinal Fluid ☐ Epidural ☐ Lepomeninges **ENT & Eye** ☐ Intraocular ☐ Larynx ☐ Trachea ☐ Nasal Soft Tissue	☐ Nasopharynx ☐ Oropharynx ☐ Parotid Gland ☐ Peri-orbital Soft Tissue ☐ Salivary Gland ☐ Sinus ☐ Thyroid **Gastrointestinal/ Abdominal** ☐ Ascites/ Peritoneum ☐ Appendix ☐ Colon ☐ Esophagus ☐ Stomach ☐ Gallbladder ☐ Small Intestine ☐ Liver ☐ Pancreas ☐ Rectum **Genito-urinary Tract** ☐ Epididymis ☐ Kidney ☐ Ovary ☐ Prostate ☐ Testes ☐ Uterus **Mediastinal/ Intra-thoracic** ☐ Heart ☐ Lung ☐ Mediastinal Soft Tissue ☐ Pericardium ☐ Pleura/Pleural Effusion ☐ Other Extranodal site	Using the list of sites above, provide the anatomic site of the maximum tumor bulk. 3639616
Pathologic Diagnosis and Surgical Resection				
*53	Date of Initial Pathologic Diagnosis	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)		Provide the date the patient was initially diagnosed pathologically with the malignancy submitted for HTMCP. This may or may not be the date of the surgical resection that yielded the tumor sample submitted for HTMCP. 2896956 (month), 2896958 (day), 2896960 (year) *Note: The day of Initial Pathologic Diagnosis is not required.*
*54	Method of Initial Pathologic Diagnosis	☐ Biopsy ☐ Surgical Resection ☐ Other (please specify) ☐ Unknown		Provide the method of the initial pathologic diagnosis. This is the method used on the date provided above. 2757941
†55	Other Method of Initial Pathologic Diagnosis Only complete if "other" is selected above.	_____		If the method of initial pathologic diagnosis is not included in the list above, provide the method used. 2757948
56	Date of Surgical Resection	____ ____ / ____ ____ / ____ ____ ____ ____ (month) (day) (year)		Provide the date of the surgical resection that yielded the tumor sample submitted for HTMCP. Depending on the method of initial pathologic diagnosis, this could be the same date provided for the previous question asking for the pathologic diagnosis date. 3008197 (month), 3008195 (day), 3008199 (year)
Lymph Node Status				
57	Were Lymph Nodes Examined at the Time of Primary Resection?	☐ Yes ☐ No ☐ Unknown		Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
58	Number of Lymph Nodes	_____		Provide the number of lymph nodes examined, if one or more

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#	Data Element	Entry Alternatives	Working Instructions
	Examined Only complete if "yes" is selected above.		lymph nodes were removed. 3
59	Number of Lymph Nodes Positive by H&E light microscopy only Only complete if "yes" is selected above.	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3086388
60	Number of Lymph Nodes Positive by IHC Keratin Staining only Only complete if "yes" is selected above.	_____	Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3086383
61	Pathologic Positive Lymph Node Location(s) *(Check all that apply)* Only complete if "yes" is selected above.	☐ Pelvic (external iliac, internal iliac, obturator) ☐ Common iliac ☐ Paraaortic ☐ Supraclavicular ☐ Unknown ☐ Other, specify	Using the patient's pathology/laboratory report, provide the location(s) of any positive lymph nodes. 3151519
62	Other Positive Lymph Node Only complete if "yes" is selected above.	_____	If the location of positive lymph nodes was not included in the list provided, please provide the location of positive lymph nodes. 3151522
Staging and Histology of Bone Marrow			
*63	Clinical Tumor Stage *(Follow Ann Arbor Criteria)*	☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV	Using the Ann Arbor criteria, provide the clinical stage that was used to treat the patient. 5615604
*64	Are "B" Symptoms Present?	☐ Yes ☐ No	Using the patient's medical record, indicate whether there is documentation of "B" symptoms. *Note: "B" symptoms are defined as unexplained fevers, drenching night sweats, or unexplained weight loss of more than 10% of usual body weight in the six months prior to lymphoma diagnosis.* 2902402
*65	Lymphomatous Involvement of Extranodal "E" Site?	☐ Yes ☐ No	Using the patient's medical record, indicate whether there is documentation of extranodal site involvement. *Note: If the answer is "Yes", the anatomic site(s) of extranodal involvement should be included inextranodal site question above.* 3364582
*66	Pathological Tumor Stage	☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV	Using the Ann Arbor criteria, provide the pathologic stage that was used to treat the patient. 5615605
67	Presence of Malignant Cells in Bone Marrow by Histology	☐ Yes ☐ No ☐ Unknown	Indicate if malignant cells are histologically Confirmed in the patient's bone marrow. 2180550
68	Histology of Bone Marrow Samples	☐ Concordant Histology ☐ Disconcordant Histology ☐ Unknown	If malignant cells are present in the bone marrow at the time of initial staging workup, determine if the histologic diagnosis of the bone marrow is concordant with the previously diagnosed DLBCL. 3233401
Tests Performed			
LDH Level (at the time of staging)			
*69	LDH Level	_____(IU)	Record the result of the LDH lab test performed during the staging workup. 2798766

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*70	LDH Level Upper Limit for Normal at Facility	_____(IU)	Record the upper limit of the normal range of the LDH lab test performed at the reporting facility. 2597015
Genetic Testing			
71	Immunophenotyping	(+) (-) Indeterminant ☐ CD19 ☐ CD10 > 30% ☐ BCL2 ☐ P53 > 20% ☐ CD20 ☐ MUM1 > 30% ☐ CD138 ☐ CD22 ☐ BCL6 > 30% ☐ CD23 ☐ CD79a ☐ PAX5 ☐ CD5 ☐ HHV8 ☐ CD30 ☐ Cytoplasmic lg ☐ CD15 ☐ Surface lg ☐ EBER ☐ Cyclin D1 ☐ ALK	Indicate all tests performed for immunophenotypic analysis in order to classify clonal subgroups. 3234614 (Test), 3234626 (Result)
72	B-cell Immunophenotype Methodology	☐ Immunohystochemistry ☐ Flow Cytometry ☐ Unknown	If B-cell genotype was performed, indicate the testing method used. 64540
73	Immunophenotyping MIB-1 *(Percent Positive; 4+ Scale)*	☐ 0-25% ☐ 51-75% ☐ 26-50% ☐ 76-100%	Provide the percentage range of MIB-1 positive cells identified through immunophenotypic analysis. 3233414
74	Methodology Used to Determine B-Cell Genotype	☐ PCR ☐ Southern ☐ Not Performed	If B-cell genotype was performed, indicate the testing method used. 3233449
75	B-Cell Genotype: IgH	☐ Clonal ☐ Non-Clonal ☐ Not Tested	If B-cell genotype was performed, indicate the results of the IgH. 3233560
76	B-Cell Genotype: IgK	☐ Clonal ☐ Non-Clonal ☐ Not Tested	If B-cell genotype was performed, indicate the results of the IgK. 3233565
Genetic Abnormalities			
77	Genetic Abnormalities	N G L T A O C-MYC ☐ ☐ ☐ ☐ ☐ ☐ BCL2 ☐ ☐ ☐ ☐ ☐ ☐ BCL6 ☐ ☐ ☐ ☐ ☐ ☐ ALK ☐ ☐ ☐ ☐ ☐ ☐ C-REL ☐ ☐ ☐ ☐ ☐ ☐ 9p21 ☐ ☐ ☐ ☐ ☐ ☐ CCND1 ☐ ☐ ☐ ☐ ☐ ☐ MALT1 ☐ ☐ ☐ ☐ ☐ ☐	Indicate all genetic abnormalities for which the patient was tested. 3234675, 3234680 N = Normal T = Translocation G = Gain L = Loss A = Amplification O = Other
78	Other Genetic Abnormalities *(please specify)* Only complete if "other" is selected above.	N G L T A O _____ ☐ ☐ ☐ ☐ ☐ ☐ _____ ☐ ☐ ☐ ☐ ☐ ☐ _____ ☐ ☐ ☐ ☐ ☐ ☐ _____ ☐ ☐ ☐ ☐ ☐ ☐	Specify any other genetic abnormalities not in the provided list for which the patient was tested. 3234685
79	Other Results of Testing for Genetic Abnormalities *(please specify)* Only complete if "O" is selected	Other Results C-MYC BCL2 BCL6 ALK	Specify any other results of testing for genetic abnormalities not in the provided list. 4459354

#	Data Element	Entry Alternatives	Working Instructions
	above.	C-REL 9p21 CCND1 MALT1 _____ _____ _____ _____	
80	Methodology Used to Identify Genetic Abnormalities Only complete if patient had a genetic abnormality.	1 2 3 4 5 C-MYC ☐ ☐ ☐ ☐ ☐ BCL2 ☐ ☐ ☐ ☐ ☐ BCL6 ☐ ☐ ☐ ☐ ☐ ALK ☐ ☐ ☐ ☐ ☐ C-REL ☐ ☐ ☐ ☐ ☐ 9p21 ☐ ☐ ☐ ☐ ☐ CCND1 ☐ ☐ ☐ ☐ ☐ MALT1 ☐ ☐ ☐ ☐ ☐ Other ☐ ☐ ☐ ☐ ☐	If the patient was tested for a specific genetic abnormality, indicate the testing method used to perform each analysis. 3234684 Methodology Code: 1 = PCR 2 = Southern Blot 3 = FISH 4 = Cytogenetics 5 = Other, Please specify
81	Other Methodology Used in Testing for Genetic Abnormalities Only complete if patient had a genetic abnormality.	Other Methodology C-MYC BCL2 BCL6 ALK C-REL 9p21 CCND1 MALT1 Other	Specify any other methodology not in the provided list used for testing genetic abnormalities. 4459355
82	Methodology Used to Determine EBV Status of Malignant Cells	☐ EBER in situ Hybridization ☐ LMP Immunohistochemistry ☐ EBV PCR	If the patient's EBV status was positive, provide the testing method used to determine the EBV status of the malignant cells. 3233656
83	EBV Status of Malignant Cells	☐ Positive ☐ Negative ☐ Not Performed	Provide the result of the lab test to detect the presence of Epstein/Barr Virus antibody in the patient. 2003961
84	If EBV status is positive, provide the percent positive. *(does not include background positives)* Only complete if "positive" is selected above.	_____(%)	If the patient's EBV status was positive, provide the percentage of EBV positive malignant cells. Do not include the number of background positives. 3233649
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 ☐ Lung ☐ Liver ☐ Retroperitoneum ☐ Lymph Node(s) ☐ 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

Enrollment Form

HTMCP – Diffuse Large B-Cell Lymphoma (DLBCL)

#	Data Element	Entry Alternatives	Working Instructions
†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 ☐ No ☐ 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 for New Tumor Event Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
ix	Additional Treatment for New Tumor Event Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616
Patient Status			
*85	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 information has not been collected within the last 15 months. If the patient is lost to follow-up, the remaining questions may be left unanswered. 61333 *If the patient is lost to follow-up or deceased at the time of enrollment, follow-up forms are not required.*

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.