

Enrollment Form

HTMCP – Lung

V1.39 093015

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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input type="checkbox"/> 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) <i>Note: The day of Birth is not required.</i>
*4	Gender	<input type="checkbox"/> Female <input type="checkbox"/> Male	Provide the patient's gender using the provided categories. 2200604
*5	Race (check all that apply)	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> Not Evaluated <input type="checkbox"/> 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	<input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Evaluated <input type="checkbox"/> 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 (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 (kilograms) at the time the patient was diagnosed with the tumor submitted for HTMCP. 651
Survival Information			
*9	Vital Status (at date of last contact)	<input type="checkbox"/> Living <input type="checkbox"/> Deceased	Indicate whether the patient was living or deceased at the date of last contact.

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#	Data Element	Entry Alternatives	Working Instructions
			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) <i>Note: The day of Last Contact is not required.</i>
*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) <i>Note: The day of Last Known Alive is not required.</i>
*12	Date of Death	____/____/____ (month) (day) (year)	If the patient is deceased, provide the date of death. 2897026 , (month) 2897028 (day), 2897030 (year) <i>Note: The day of Death is not required.</i>
13	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. 2554674
14	Other Cause of Death <i>Only complete if "other" is selected in #14.</i>	_____	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)			
*15	Did the patient receive neo-adjuvant therapy for the tumor submitted for HTMCP?	<input type="checkbox"/> Yes (<i>exclusion criterion</i>) <input type="checkbox"/> No	Indicate whether the patient received treatment (radiation, pharmaceutical, or both) prior to the procurement of the sample submitted for HTMCP. 3382737 <i>If the answer to this question is "yes", the submitted case is excluded.</i>
*16	Tumor Status (at time of last contact or death)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> 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
Performance Scores			
17	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) (At time of Diagnosis)	<input type="checkbox"/> 0: Asymptomatic <input type="checkbox"/> 1: Symptomatic, but fully ambulatory <input type="checkbox"/> 2: Symptomatic, in bed less than 50% of day <input type="checkbox"/> 3: Symptomatic, in bed more than 50% of day <input type="checkbox"/> 4: Bed-ridden <input type="checkbox"/> Unknown <input type="checkbox"/> 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 time of Diagnosis)	<input type="checkbox"/> 100: Normal, no complaints, no evidence of disease <input type="checkbox"/> 90: Able to carry on normal activity; minor signs or symptoms of disease <input type="checkbox"/> 80: Normal activity with effort; some signs or symptoms of disease <input type="checkbox"/> 70: Cares for self, unable to carry on normal activity or to do active work <input type="checkbox"/> 60: Requires occasional assistance <input type="checkbox"/> 50: Requires considerable assistance and frequent medical care <input type="checkbox"/> 40: Disabled, requires special care and assistance <input type="checkbox"/> 30: Severely disabled, hospitalization indicated. Death not imminent <input type="checkbox"/> 20: Very sick, hospitalization <input type="checkbox"/> 10: Moribund, fatal processes progressing rapidly <input type="checkbox"/> 0: Dead <input type="checkbox"/> Unknown <input type="checkbox"/> Not Evaluated	Provide the Karnofsky Score performance status of the patient at the time of diagnosis. 2003853
19	Tumor Response	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Stable Disease <input type="checkbox"/> Partial Response <input type="checkbox"/> 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	<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> . 2005312
*21	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> . 3397567
Smoking History			
22	Tobacco Smoking History	<input type="checkbox"/> 1: Lifelong Non-Smoker	Indicate the patient's history of tobacco smoking including their

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	Indicator <i>(at time of diagnosis)</i>	<input type="checkbox"/> 2: Current Smoker <input type="checkbox"/> 3: Current Reformed Smoker for > 15 years <input type="checkbox"/> 4: Current Reformed Smoker for ≤15 years <input type="checkbox"/> 5: Current Reformed Smoker (duration not specified) <input type="checkbox"/> Smoking Status not Documented	smoking status at diagnosis using the defined categories. If the patient is or was a lifelong non-smoker, skip the additional smoking questions. 2181650
23	Age of Onset Tobacco History Indicator	_____ years	Provide the age in years when the patient began smoking cigarettes. 2178045
24	Year of Quitting Tobacco Smoking	_____ (YYYY)	Provide the year the patient quit smoking. 2228610
25	Number of Pack Years Smoked <i>(at time of diagnosis)</i>	_____ 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
Patient History of Disease			
HIV Status			
*26	Is this patient HIV positive?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient is HIV positive. 2180464
†27	Date of HIV Diagnosis	_____/_____/_____ (month) (day) (year)	Provide the date the patient was diagnosed with HIV. 3579640 (month), 3579644 (day), 3579643 (year) <i>Note: The day of HIV Diagnosis is not required.</i>
28	Nadir CD4 Counts	_____ (cells/mm ³)	Provide the patient's Nadir CD4 counts, which are the lowest CD4 counts the patient has had. 2684395
†29	CD4 Counts at Diagnosis of the Submitted Malignancy	_____ (cells/mm ³)	Provide the patient's CD4 Counts at the time the patient was diagnosed with the malignancy submitted for the HTMCP study. 2922654
†30	HIV RNA load at Diagnosis of Submitted Malignancy	_____	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
31	Prior AIDS Defining Conditions	<input type="checkbox"/> Candidiasis of bronchi, trachea or lungs <input type="checkbox"/> Candidiasis, esophageal <input type="checkbox"/> CMV other than liver, spleen or nodes, onset at age >1month <input type="checkbox"/> CMV retinitis <input type="checkbox"/> Coccidioidomycosis, disseminated or extrapulmonary <input type="checkbox"/> Cryptococcosis, extrapulmonary <input type="checkbox"/> Cryptosporidiosis, chronic intestinal <input type="checkbox"/> Encephalopathy, HIV-related <input type="checkbox"/> Herpes simplex: chronic ulcers (> 1 month's duration) or bronchitis, pneumonitis or esophagitis (onset at age > 1 month) <input type="checkbox"/> Histoplasmosis, disseminated or extrapulmonary <input type="checkbox"/> Isosporiasis, chronic intestinal (> 1 mon) <input type="checkbox"/> Mycobacterium avium complex or Mycobacterium kansasii disseminated or extrapulmonary <input type="checkbox"/> Mycobacterium tuberculosis of any site, pulmonary, disseminated or extrapulmonary <input type="checkbox"/> Mycobacterium, other species or unidentified species, disseminated or extrapulmonary <input type="checkbox"/> Nocardiosis	Prior to the malignancy submitted for the HTMCP study, provide any AIDS defining conditions 2679581

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		<input type="checkbox"/> Pneumocystis jirovecii pneumonia <input type="checkbox"/> Pneumonia, recurrent <input type="checkbox"/> Progressive multifocal leukoencephalopathy <input type="checkbox"/> Salmonella septicemia, recurrent <input type="checkbox"/> Toxoplasmosis of the brain, onset at age >1 month <input type="checkbox"/> Wasting syndrome, due to HIV	
32	Co-Infections (<i>serology data/viral load if available</i>)	Test	Results
		Pos	Neg
		Inconclusive	Not Tested
		28. HBV	2180456
			2695021
			2230033
			3335773
†33	HAART Treatment Prior to Diagnosis of Submitted Malignancy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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
†34	HAART Treatment at Time of Diagnosis of Submitted Malignancy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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
35	CDC HIV Risk Group	<input type="checkbox"/> Homosexual or bisexual contact <input type="checkbox"/> Heterosexual contact <input type="checkbox"/> IV drug user <input type="checkbox"/> Transfusion recipient <input type="checkbox"/> Hemophiliac <input type="checkbox"/> 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			
*36	Has this patient at any time in their life had a prior diagnosis of a malignant neoplasm?	<input type="checkbox"/> Yes (<i>exclusion criterion</i>) <input type="checkbox"/> 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 <i>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.</i>
37	Type of Prior Malignancies <i>Only complete if "yes" is selected in #37.</i>	_____	If the patient has had a prior diagnosis of a malignant neoplasm, provide the type of prior malignancy. 2718428
Prior Immunological Disease			
38	Patient History of Prior Immunological Disease	<input type="checkbox"/> Rheumatoid Arthritis <input type="checkbox"/> Sjogren's Syndrome <input type="checkbox"/> Systemic Lupus Erythematosus <input type="checkbox"/> Crohn's Disease <input type="checkbox"/> Ulcerative Colitis <input type="checkbox"/> Hashimoto's Thyroiditis <input type="checkbox"/> Other, please specify <input type="checkbox"/> Unknown	Indicate whether the patient has a history of any of the listed immunological diseases. 3233628
39	Other History of Prior Immunological Disease <i>Only complete if "other" is selected in #39.</i>	_____	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
40	Patient History of Prior Immunosuppressive Therapy for Immunological Disease	<input type="checkbox"/> Methotrexate <input type="checkbox"/> Cyclophosphamide <input type="checkbox"/> Azathioprine <input type="checkbox"/> Anti-TNF therapy <input type="checkbox"/> None <input type="checkbox"/> Other <input type="checkbox"/> Unknown	If the patient received immunosuppressive therapy for the immunological disease selected in the previous question, provide the type of immunosuppressive therapy given. 3233638
41	Other History of Prior Immunosuppressive Therapy for Immunological Disease	_____	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).

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#	Data Element	Entry Alternatives	Working Instructions
	Only complete if "other" is selected in #41.		2873928
Prior Infectious Disease			
42	Patient History of Relevant Prior Infectious Disease	<input type="checkbox"/> Hepatitis B <input type="checkbox"/> Hepatitis C <input type="checkbox"/> H. Pylori <input type="checkbox"/> Other <input type="checkbox"/> Unknown	Indicate whether the patient has a history of any of the listed infectious disease. 3233642
43	Patient History of Other Relevant Infectious Disease Only complete if "other" is selected in #43.	_____	If the patient has a history of relevant prior disease that was not included in the list, provide the infectious disease. 3233643
Pathologic Information			
*44	Histological Subtype	<input type="checkbox"/> Non-Small Cell Lung Cancer (NOS) <input type="checkbox"/> Large cell carcinoma; Specify <input type="checkbox"/> Large cell neuroendocrine carcinoma <input type="checkbox"/> Small Cell Lung Cancer Squamous Cell Carcinoma <input type="checkbox"/> Squamous Cell Carcinoma; NOS <input type="checkbox"/> Squamous Cell Carcinoma; Keratinizing <input type="checkbox"/> Squamous Cell Carcinoma; Non-keratinizing <input type="checkbox"/> Small Cell Squamous Cell <input type="checkbox"/> Basaloid Squamous Cell Adenocarcinoma <input type="checkbox"/> Adenocarcinoma; NOS <input type="checkbox"/> Bronchoalveolar carcinoma/AIS; non-mucinous <input type="checkbox"/> Bronchoalveolar carcinoma/AIS; mucinous <input type="checkbox"/> Minimally invasive adenocarcinoma <input type="checkbox"/> Lepidic predominant adenocarcinoma <input type="checkbox"/> Adenocarcinoma; Mixed Subtype; NOS <input type="checkbox"/> Invasive mucinous adenocarcinoma <input type="checkbox"/> Adenosquamous <input type="checkbox"/> Special type; specify	Using the patient's final diagnostic pathology report, provide the most detailed histological subtype available. 3081934
†45	Other Histological Subtype	_____	If the histological subtype is not included in the provided list, specify the histological subtype of the tumor that is being submitted. 3124492
*46	Organ of Origin	<input type="checkbox"/> Lung	Using the patient's pathology/laboratory report, select the organ where the disease originated. 3427536
*47	Laterality	<input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Bilateral	Using the patient's pathology/laboratory report, select the laterality of the disease. Include all areas of invasion. 827
*48	Anatomic Organ Subdivision (Check all that apply)	<input type="checkbox"/> Upper Lobe <input type="checkbox"/> Middle Lobe (right only) <input type="checkbox"/> Lower Lobe <input type="checkbox"/> Bronchus <input type="checkbox"/> Mediastinal <input type="checkbox"/> Other (please specify)	Using the patient's pathology/laboratory report, select the anatomic organ subdivision(s) of the disease. Include all areas of invasion. 2008006
†49	Other Anatomic Organ Subdivision Only complete if "other" is selected in #48	_____	If the anatomic organ subdivision was not included in the provided, indicate the anatomic organ subdivision of the disease. 2584114
Pathologic Diagnosis and Surgical Resection			
*50	Date of Initial Pathologic Diagnosis	_____/_____/_____ (month) (day) (year)	Provide the date the patient was initially pathologically diagnosed 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) <i>Note: The day of Initial Pathologic Diagnosis is not required.</i>

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#	Data Element	Entry Alternatives	Working Instructions		
*51	Method of Initial Pathologic Diagnosis	<input type="checkbox"/> Fine Needle Aspiration Biopsy <input type="checkbox"/> Incisional Biopsy <input type="checkbox"/> Excisional Biopsy <input type="checkbox"/> Surgical Resection <input type="checkbox"/> Other (please specify) <input type="checkbox"/> Unknown	Provide the method of the initial pathologic diagnosis. 2757941 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.		
†52	Other Method of Initial Pathologic Diagnosis <i>Only complete if "other" is selected in #51.</i>	_____	If the method of initial pathologic diagnosis is not included in the list above, provide the method used. 2757948		
53	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)		
54	Residual Tumor	<input type="checkbox"/> RX: Margins not assessed <input type="checkbox"/> R0: Negative margins <input type="checkbox"/> R1: Microscopic positive margins <input type="checkbox"/> R2: Macroscopic positive margins <input type="checkbox"/> Not Evaluated	Using the defined categories, indicate the patient's residual tumor margins after their final surgery. 2608702		
Lymph Node Status					
55	Were Lymph Nodes Examined at the Time of Primary Resection?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396		
56	Number of Lymph Nodes Examined <i>Only complete if "yes" is selected in #55.</i>	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3		
57	Number of Lymph Nodes Positive by H&E light microscopy only <i>Only complete if "yes" is selected in #55.</i>	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3086388		
58	Number of Lymph Nodes Positive by IHC Keratin Staining only <i>Only complete if "yes" is selected in #55.</i>	_____	Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining. 3086383		
59	Pathologic Positive Lymph Node Location(s) <i>(Check all that apply)</i> <i>Only complete if "yes" is selected in #55.</i>	<input type="checkbox"/> Pelvic (external iliac, internal iliac, obturator) <input type="checkbox"/> Common iliac <input type="checkbox"/> Paraaortic <input type="checkbox"/> Supraclavicular <input type="checkbox"/> Unknown <input type="checkbox"/> Other, please specify	Using the patient's pathology/laboratory report, provide the location(s) of any positive lymph nodes. 3151519		
60	Other Positive Lymph Node <i>Only complete if "yes" is selected in #55.</i>	_____	If the location of positive lymph nodes was not included in the list provided, please provide the location of positive lymph nodes. 3151522		
AJCC Staging					
†61	Primary Tumor (T)	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> Clinical <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> T1 <input type="checkbox"/> T1a <input type="checkbox"/> T1b <input type="checkbox"/> T2 <input type="checkbox"/> T2a <input type="checkbox"/> T2b <input type="checkbox"/> T3 <input type="checkbox"/> T4 </td> <td style="width: 50%; vertical-align: top;"> Pathologic <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> T1 <input type="checkbox"/> T1a <input type="checkbox"/> T1b <input type="checkbox"/> T2 <input type="checkbox"/> T2a <input type="checkbox"/> T2b <input type="checkbox"/> T3 <input type="checkbox"/> T4 </td> </tr> </table>	Clinical <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> T1 <input type="checkbox"/> T1a <input type="checkbox"/> T1b <input type="checkbox"/> T2 <input type="checkbox"/> T2a <input type="checkbox"/> T2b <input type="checkbox"/> T3 <input type="checkbox"/> T4	Pathologic <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> T1 <input type="checkbox"/> T1a <input type="checkbox"/> T1b <input type="checkbox"/> T2 <input type="checkbox"/> T2a <input type="checkbox"/> T2b <input type="checkbox"/> T3 <input type="checkbox"/> T4	Using the patient's medical records, select the primary tumor category (T) used to determine the patient's final AJCC stage. 3440328 (clinical), 3045435 (pathologic) <i>Clinical and/or pathologic staging can be selected, but pathologic staging is preferred.</i>
Clinical <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> T1 <input type="checkbox"/> T1a <input type="checkbox"/> T1b <input type="checkbox"/> T2 <input type="checkbox"/> T2a <input type="checkbox"/> T2b <input type="checkbox"/> T3 <input type="checkbox"/> T4	Pathologic <input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> T1 <input type="checkbox"/> T1a <input type="checkbox"/> T1b <input type="checkbox"/> T2 <input type="checkbox"/> T2a <input type="checkbox"/> T2b <input type="checkbox"/> T3 <input type="checkbox"/> T4				
†62	Regional Lymph Nodes (N)	<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> Clinical <input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2 </td> <td style="width: 50%; vertical-align: top;"> Pathologic <input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2 </td> </tr> </table>	Clinical <input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2	Pathologic <input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2	Using the patient's medical records, select the patient's regional lymph node category (N) used to determine the patient's final AJCC stage. 3440330 (clinical), 3203106 (pathologic) <i>Clinical and/or pathologic staging can be selected, but pathologic</i>
Clinical <input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2	Pathologic <input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N1 <input type="checkbox"/> N2				

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#	Data Element	Entry Alternatives	Working Instructions																						
		<input type="checkbox"/> N3 <input type="checkbox"/> N3	<u>staging is preferred.</u>																						
*63	Distant Metastasis (M)	<table border="0"> <tr> <td>Clinical</td> <td>Pathologic</td> </tr> <tr> <td><input type="checkbox"/> MX</td> <td><input type="checkbox"/> MX</td> </tr> <tr> <td><input type="checkbox"/> M0</td> <td><input type="checkbox"/> M0</td> </tr> <tr> <td><input type="checkbox"/> M1</td> <td><input type="checkbox"/> M1</td> </tr> <tr> <td><input type="checkbox"/> M1a</td> <td><input type="checkbox"/> M1a</td> </tr> <tr> <td><input type="checkbox"/> M1b</td> <td><input type="checkbox"/> M1b</td> </tr> </table>	Clinical	Pathologic	<input type="checkbox"/> MX	<input type="checkbox"/> MX	<input type="checkbox"/> M0	<input type="checkbox"/> M0	<input type="checkbox"/> M1	<input type="checkbox"/> M1	<input type="checkbox"/> M1a	<input type="checkbox"/> M1a	<input type="checkbox"/> M1b	<input type="checkbox"/> M1b	Using the patient's medical records, select the patient's distant metastasis category (M) used to determine the patient's final AJCC stage. 3440331 (clinical), 3045439 (pathologic) Clinical and/or pathologic staging can be selected, but pathologic staging is preferred.										
Clinical	Pathologic																								
<input type="checkbox"/> MX	<input type="checkbox"/> MX																								
<input type="checkbox"/> M0	<input type="checkbox"/> M0																								
<input type="checkbox"/> M1	<input type="checkbox"/> M1																								
<input type="checkbox"/> M1a	<input type="checkbox"/> M1a																								
<input type="checkbox"/> M1b	<input type="checkbox"/> M1b																								
*64	Overall Stage	<table border="0"> <tr> <td>Clinical</td> <td>Pathologic</td> </tr> <tr> <td><input type="checkbox"/> Stage I</td> <td><input type="checkbox"/> Stage I</td> </tr> <tr> <td><input type="checkbox"/> Stage IA</td> <td><input type="checkbox"/> Stage IA</td> </tr> <tr> <td><input type="checkbox"/> Stage IB</td> <td><input type="checkbox"/> Stage IB</td> </tr> <tr> <td><input type="checkbox"/> Stage II</td> <td><input type="checkbox"/> Stage II</td> </tr> <tr> <td><input type="checkbox"/> Stage IIA</td> <td><input type="checkbox"/> Stage IIA</td> </tr> <tr> <td><input type="checkbox"/> Stage IIB</td> <td><input type="checkbox"/> Stage IIB</td> </tr> <tr> <td><input type="checkbox"/> Stage III</td> <td><input type="checkbox"/> Stage III</td> </tr> <tr> <td><input type="checkbox"/> Stage IIIA</td> <td><input type="checkbox"/> Stage IIIA</td> </tr> <tr> <td><input type="checkbox"/> Stage IIIB</td> <td><input type="checkbox"/> Stage IIIB</td> </tr> <tr> <td><input type="checkbox"/> Stage IV</td> <td><input type="checkbox"/> Stage IV</td> </tr> </table>	Clinical	Pathologic	<input type="checkbox"/> Stage I	<input type="checkbox"/> Stage I	<input type="checkbox"/> Stage IA	<input type="checkbox"/> Stage IA	<input type="checkbox"/> Stage IB	<input type="checkbox"/> Stage IB	<input type="checkbox"/> Stage II	<input type="checkbox"/> Stage II	<input type="checkbox"/> Stage IIA	<input type="checkbox"/> Stage IIA	<input type="checkbox"/> Stage IIB	<input type="checkbox"/> Stage IIB	<input type="checkbox"/> Stage III	<input type="checkbox"/> Stage III	<input type="checkbox"/> Stage IIIA	<input type="checkbox"/> Stage IIIA	<input type="checkbox"/> Stage IIIB	<input type="checkbox"/> Stage IIIB	<input type="checkbox"/> Stage IV	<input type="checkbox"/> Stage IV	Using the patient's medical records, select the final AJCC stage. 3440332 (clinical), 3203222 (pathologic) Clinical and/or pathologic staging can be selected, but pathologic staging is preferred.
Clinical	Pathologic																								
<input type="checkbox"/> Stage I	<input type="checkbox"/> Stage I																								
<input type="checkbox"/> Stage IA	<input type="checkbox"/> Stage IA																								
<input type="checkbox"/> Stage IB	<input type="checkbox"/> Stage IB																								
<input type="checkbox"/> Stage II	<input type="checkbox"/> Stage II																								
<input type="checkbox"/> Stage IIA	<input type="checkbox"/> Stage IIA																								
<input type="checkbox"/> Stage IIB	<input type="checkbox"/> Stage IIB																								
<input type="checkbox"/> Stage III	<input type="checkbox"/> Stage III																								
<input type="checkbox"/> Stage IIIA	<input type="checkbox"/> Stage IIIA																								
<input type="checkbox"/> Stage IIIB	<input type="checkbox"/> Stage IIIB																								
<input type="checkbox"/> Stage IV	<input type="checkbox"/> Stage IV																								
*65	AJCC Staging Edition Used to Stage the Patient	<input type="checkbox"/> 1 st Edition (1978-1983) <input type="checkbox"/> 2 nd Edition (1984-1988) <input type="checkbox"/> 3 rd Edition (1989-1992) <input type="checkbox"/> 4 th Edition (1993-1997) <input type="checkbox"/> 5 th Edition (1998-2002) <input type="checkbox"/> 6 th Edition (2003-2009) <input type="checkbox"/> 7 th Edition (2010-present)	Please select the AJCC cancer staging edition used to determine the T, N, M, and stage provided. 2722309																						

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 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	<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						
iii	Anatomic Site of New Tumor Event	<table border="0"> <tr> <td><input type="checkbox"/> Bone</td> <td><input type="checkbox"/> Retroperitoneum</td> </tr> <tr> <td><input type="checkbox"/> Lung</td> <td><input type="checkbox"/> Lymph Node(s)</td> </tr> <tr> <td><input type="checkbox"/> Liver</td> <td><input type="checkbox"/> Other, specify</td> </tr> </table>	<input type="checkbox"/> Bone	<input type="checkbox"/> Retroperitoneum	<input type="checkbox"/> Lung	<input type="checkbox"/> Lymph Node(s)	<input type="checkbox"/> Liver	<input type="checkbox"/> Other, specify	Indicate the site of this new tumor event. 3108271
<input type="checkbox"/> Bone	<input type="checkbox"/> Retroperitoneum								
<input type="checkbox"/> Lung	<input type="checkbox"/> Lymph Node(s)								
<input type="checkbox"/> Liver	<input type="checkbox"/> Other, specify								
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						
tv	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)	<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						

Patient Status

Enrollment Form
HTMCP – Lung

V1.39 093015

#	Data Element	Entry Alternatives	Working Instructions
*66	Is This Patient Lost to Follow-up?	<input type="checkbox"/> Yes <input type="checkbox"/> 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 <i>If the patient is lost to follow-up or deceased at the time of enrollment, follow-up forms are not required.</i>

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.