

Enrollment Form Mesothelioma

Instructions: The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial diagnosis to the most recent date of contact with the patient (“Date of Initial Pathologic Diagnosis” and “Date of Last Contact” on this form).

Questions regarding this form should be directed to the Tissue Source Site’s primary Clinical Outreach Contact at the BCR.

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 cannot answer the question because the answer is not known at the TSS. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should be selected by the TSS if it is known that the information being requested cannot be obtained. If for example, a test was not performed the results of that test cannot be provided because it was “Not Evaluated.”

Tissue Source Site (TSS): _____ TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By (Interviewer Name on OpenClinica): _____ Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
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 for the specific purpose of TCGA, 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 TCGA contract was executed, the tissue has been collected retrospectively. 3088528

Patient Information

#	Data Element	Entry Alternatives	Working Instructions
Date of Birth			
3	Date of Birth	_____ <i>Month Day Year</i>	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
4	Gender	<input type="checkbox"/> Female <input type="checkbox"/> Male	Provide the patient's gender using the defined categories. 2200604
5	Race	<input type="checkbox"/> American Indian or Alaska Native <i>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.</i> <input type="checkbox"/> Asian <i>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.</i> <input type="checkbox"/> White <i>A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.</i> <input type="checkbox"/> Black or African American <i>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.”</i> <input type="checkbox"/> Native Hawaiian or other Pacific Islander <i>A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</i>	Provide the patient's race using the defined categories. 2192199

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#	Data Element	Entry Alternatives	Working Instructions
		<input type="checkbox"/> Not Evaluated <i>Not provided or available.</i> <input type="checkbox"/> Unknown <i>Could not be determined or unsure.</i>	
6	Ethnicity	<input type="checkbox"/> Not Hispanic or Latino <i>A person not meeting the definition of Hispanic or Latino.</i> <input type="checkbox"/> Hispanic or Latino <i>A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.</i> <input type="checkbox"/> Not Evaluated <i>Not provided or available.</i> <input type="checkbox"/> Unknown <i>Could not be determined or unsure.</i>	Provide the patient's ethnicity using the defined categories. 2192217
7	History of Other Malignancy	<input type="checkbox"/> Yes <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 TCGA. If the patient has any history, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for TCGA. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736 <i>If this question cannot be answered because the answer is unknown, please contact the BCR.</i> <i>If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.</i>
8	Neo-adjuvant (pre-operative) therapy for tumor submitted for TCGA	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the resection of the tumor that yielded the sample submitted for TCGA. 3382737 <i>Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the resection of the sample submitted for TCGA is exclusionary.</i>
9	Was pleurodesis performed prior to cancer sample procurement?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received pleurodesis prior to the resection of the tumor submitted for TCGA. 3646078
10	If pleurodesis was performed, was it performed at least 90 days prior to the cancer sample procurement?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If the patient received pleurodesis, indicate whether the procedure was performed at least 90 days prior to the resection of the tumor sample submitted for TCGA. 3646080
11	Tumor Status <i>(at time of last contact or death)</i>	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
12	Vital Status <i>(at date of last contact)</i>	<input type="checkbox"/> Living <input type="checkbox"/> Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
Date of Last Contact <i>(If patient is living)</i>			
13	Date of Last Contact	_____ <i>Month Day Year</i>	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)

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#	Data Element	Entry Alternatives	Working Instructions										
Date of Death													
14	Date of Death	_____ <i>Month Day Year</i>	If the patient is deceased, provide the date of death. <u>2897026</u> (Month), <u>2897028</u> (Day), <u>2897030</u> (Year)										
Patient Occupation and Asbestos Exposure													
15	Asbestos Exposure	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient has asbestos exposure prior to the diagnosis of the tumor submitted for TCGA. <u>1253</u>										
16	Type of Asbestos Exposure	<input type="checkbox"/> Chrysotile <input type="checkbox"/> Crocidolite <input type="checkbox"/> Anthophyllite <input type="checkbox"/> Actinolite <input type="checkbox"/> Amosite <input type="checkbox"/> Tremolite <input type="checkbox"/> Erionite <input type="checkbox"/> Unknown	If the patient had a known exposure to asbestos, indicate the type of asbestos exposure. <u>3629989</u>										
17	Source of First Asbestos Exposure	<input type="checkbox"/> Occupational <input type="checkbox"/> Secondary <input type="checkbox"/> Unknown	If the patient had a known exposure to asbestos, indicate the source of the asbestos exposure. <u>3629990</u>										
18	Age at First Asbestos Exposure	_____ Years	If the patient had known occupational and/or environmental asbestos exposure, indicate the patient's age at their first exposure. <u>3629991</u>										
19	Number of Years of Asbestos Exposure	_____ Years	If the patient had known occupational and/or environmental asbestos exposure, indicate the number of years of exposure. <u>3629992</u>										
20	Age at Last Asbestos Exposure	_____ Years	If the patient had a known exposure to asbestos, provide the age at last asbestos exposure. <u>3629993</u>										
21	Primary Occupation	<input type="checkbox"/> Asbestos Mining <input type="checkbox"/> Construction <input type="checkbox"/> Automotive <input type="checkbox"/> Welding <input type="checkbox"/> Unknown <input type="checkbox"/> Other (please specify)	Provide the occupation in which the patient was employed for the majority of their working years. <u>3259240</u>										
22	Other Primary Occupation	_____	If the patient's primary occupation was not included in the list provided, specify the occupation in which the patient was employed for the majority of their working years. <u>5714</u>										
23	Years Worked in Industry	_____ Years	Provide the number of years the patient was employed in their primary occupation. <u>2435424</u>										
24	Family History of Cancer	<input type="checkbox"/> Spouse <table border="1" style="display: inline-table; vertical-align: middle; margin-left: 10px;"> <tr> <td style="width: 10%;"></td> <td style="width: 15%;">Mesothelioma</td> <td style="width: 15%;">Uveal Melanoma</td> <td style="width: 15%;">Melanoma</td> <td style="width: 15%;">Other (specify)</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>		Mesothelioma	Uveal Melanoma	Melanoma	Other (specify)						If the patient has a family history of cancer, provide the type of cancer of the patient's relative and their relationship to the patient. <u>2783641</u> (relative), <u>3838107</u> (type of cancer), <u>2691192</u> (other type of cancer),
			Mesothelioma	Uveal Melanoma	Melanoma	Other (specify)							
		<input type="checkbox"/> Child											
		<input type="checkbox"/> Parent											
		<input type="checkbox"/> Sibling											
		<input type="checkbox"/> Grandparent											
<input type="checkbox"/> Unknown													
<input type="checkbox"/> _____													

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#	Data Element	Entry Alternatives	Working Instructions
25	Performance Status Scale: Karnofsky Score	<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, but is able to care for most of his/her needs <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 is not imminent. <input type="checkbox"/> 20 – Very sick, hospitalization indicated. Death not imminent <input type="checkbox"/> 10 – Moribund, fatal processes progressing rapidly <input type="checkbox"/> 0 – Dead <input type="checkbox"/> Unknown <input type="checkbox"/> Not Evaluated	Indicate the patient's Karnofsky performance status score at the time provided for the "Performance Status Score: Timing" question below. 2003853
26	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG)	<input type="checkbox"/> 0 – Asymptomatic <input type="checkbox"/> 1 – Symptomatic but fully ambulatory <input type="checkbox"/> 2 – Symptomatic but in bed less than 50% of the day <input type="checkbox"/> 3 – Symptomatic and in bed more than 50% of the day <input type="checkbox"/> 4 – Bedridden <input type="checkbox"/> Unknown <input type="checkbox"/> Not Evaluated	Indicate the patient's ECOG performance status score at the time provided for the "Performance Status Score: Timing" question below. 88
27	Performance Status Score: Timing	<input type="checkbox"/> Pre-Operative <input type="checkbox"/> Post-Adjuvant <input type="checkbox"/> Pre-Adjuvant <input type="checkbox"/> Other	Provide the time reference for the Karnofsky score and/or the ECOG score using the defined categories. 2792763
28	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>IF the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.</i> 2005312
29	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>IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i> 3397567

Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
30	Primary Site of Disease	<input type="checkbox"/> Pleura	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
31	Laterality	<input type="checkbox"/> Left <input type="checkbox"/> Right <input type="checkbox"/> Bilateral	If applicable, indicate the laterality of the tumor that yielded the biospecimen submitted to for TCGA. 827
32	Histologic Subtype	<input type="checkbox"/> Epithelioid mesothelioma <input type="checkbox"/> Sarcomatoid mesothelioma <input type="checkbox"/> Desmoplastic mesothelioma <input type="checkbox"/> Biphasic mesothelioma <input type="checkbox"/> Diffuse malignant mesothelioma, NOS	Indicate the confirmed diagnosis of the tumor submitted for TCGA. 3081934

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#	Data Element	Entry Alternatives	Working Instructions
Date of Initial Pathologic Diagnosis			
33	Date of Initial Pathologic Diagnosis	____ / ____ / ____ <i>Month Day Year</i>	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (Month), 2896958 (Day), 2896960 (Year)
AJCC Staging			
34	AJCC Cancer Staging Edition Used At Initial Diagnosis	<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 answer the following questions (#s 40-44). 2722309
35	Primary Tumor (T) <i>(per Staging Edition Indicated)</i>	<input type="checkbox"/> TX <input type="checkbox"/> T1b <input type="checkbox"/> T0 <input type="checkbox"/> T2 <input type="checkbox"/> T1 <input type="checkbox"/> T3 <input type="checkbox"/> T1a <input type="checkbox"/> T4	Provide the AJCC T category of the primary tumor at initial diagnosis 3045435
36	Regional Nodes (N) <i>(per Staging Edition Indicated)</i>	<input type="checkbox"/> NX <input type="checkbox"/> N2 <input type="checkbox"/> N0 <input type="checkbox"/> N3 <input type="checkbox"/> N1	Provide the AJCC N category at initial diagnosis 3203106
37	Distant Metastasis (M) <i>(per Staging Edition Indicated)</i>	<input type="checkbox"/> MX <input type="checkbox"/> M0 <input type="checkbox"/> M1	Provide the AJCC M category at initial diagnosis. 3045439
38	Tumor Stage <i>(per Staging Edition Indicated in)</i>	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> IA <input type="checkbox"/> III <input type="checkbox"/> IB <input type="checkbox"/> IV	Provide the overall AJCC stage at initial diagnosis. 3203222
39	Residual Tumor	<input type="checkbox"/> RX <input type="checkbox"/> R2 <input type="checkbox"/> R0 <input type="checkbox"/> Unknown <input type="checkbox"/> R1	Using the patient's pathology/laboratory report, select the tissue margin status at time of surgical resection. 2608702
Tests Performed			
40	Serum mesothelin (SM) <i>(prior to treatment)</i>	_____ (nmol/L)	Provide the patient's serum mesothelin level prior to treatment. 3629985
41	Serum mesothelin (SM) Lower Limit	_____ (nmol/L)	Provide the institution's lower serum mesothelin limit. 3629986
42	Serum mesothelin (SM) Upper Limit	_____ (nmol/L)	Provide the institution's upper serum mesothelin limit. 3629987
43	Creatinine <i>(prior to treatment)</i>	_____ (mg/dL)	Provide the patient's creatinine level prior to treatment. 58318
44	Creatinine Lower Limit	_____ (mg/dL)	Provide the institution's lower creatinine limit. 2234697
45	Creatinine Upper Limit	_____ (mg/dL)	Provide the institution's upper creatinine limit. 2004064
46	Maximum SUV of Pleura <i>(prior to treatment)</i>	_____	Provide patient's maximum standardized update value (SUV) of the Pleura. 2716767
47	Detection Method of Mesothelioma	<input type="checkbox"/> Cytology <input type="checkbox"/> Biopsy <input type="checkbox"/> Thorascopy <input type="checkbox"/> Thoracentesis	Indicate the method used to detect the patient's mesothelioma. 3629988

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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.

#	Data Element	Entry Alternatives	Working Instructions
48	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 the date of initial diagnosis. For mesothelioma, recurrent tumor is local progression in or adjacent to the original cavity and metastatic means disease outside the original pleural cavity. 3121376 <i>If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.</i>
<i>Date of New Tumor Event after Initial Treatment</i>			
49	Date of New Tumor Event	_____ <i>Month Day Year</i>	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)
50	Type of New Tumor Event	<input type="checkbox"/> Intrapleural Progression <input type="checkbox"/> Distant Metastasis <input type="checkbox"/> New Primary Tumor	Indicate whether the patient's new tumor event was progression in the same pleura, a distant metastasis or a new primary tumor. 3119721
60	Site of New Tumor Event	<input type="checkbox"/> Bone <input type="checkbox"/> Lung <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Ipsilateral pleura <input type="checkbox"/> Contralateral pleura <input type="checkbox"/> Abdomen <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____	If the patient had a new tumor event, provide the site of this tumor. 3108271
61	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
62	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 tumor event in question. 3427611
<i>Date of Additional Surgery for New Tumor Event (when applicable)</i>			
63	Date of Additional Surgery for New Tumor Event	_____ <i>Month Day Year</i>	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (Month), 3427613 (Day), 3427614 (Year)
64	Additional treatment for 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
65	Additional treatment for 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 or Designee Signature

 Print Name

 _____/_____/_____
 Date