

Enrollment Form

Thymoma (THYM)

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 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 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 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: _____

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
3*	Date of Birth	____/____/____ (month)* (day) (year)*	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	Height (at time of diagnosis)	_____ (cm)	Provide the patient's height (cm) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 649
6	Weight (at time of diagnosis)	_____ (kg)	Provide the patient's weight (kg) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 651
7*	Race	<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 far 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.

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#	Data Element	Entry Alternatives	Working Instructions
8	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.
9*	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 had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. 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 If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. 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.
10*	History of Neo-adjuvant Treatment for Sample 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 collection of the sample submitted for TCGA. 3382737 Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the collection of the sample submitted for TCGA is exclusionary. Note: Pharmaceutical treatment includes chemotherapy, immunotherapy, hormonal therapy, and targeted molecular therapy.
11*	Tumor Status (at time of last contact or death)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
12*	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. 2939553
13*	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: Please do not answer if patient is deceased.
14*	Date of Death	____ / ____ / ____ (month)* (day) (year)*	If the patient is deceased, provide the date of death. 2897026 , (month) 2897028 (day), 2897030 (year)
15*	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 TCGA</i> . 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
16*	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 TCGA</i> . 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed. Note: Pharmaceutical treatment includes chemotherapy, immunotherapy, hormonal therapy, and targeted molecular therapy.
17*	Adjuvant (Post-Operative) Ablation or Embolization Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the patient had adjuvant/ post-operative ablation or embolization therapy <i>for the tumor submitted for TCGA</i> . 3172120 If the patient did have ablation/embolization treatment for this new tumor event, the Ablation/Embolization Supplemental Form should be completed.

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Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
18*	Primary Site of Disease	<input type="checkbox"/> Thymus <input type="checkbox"/> Anterior Mediastinum	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
19*	Histologic Subtype (check all that apply)	<input type="checkbox"/> Type A <input type="checkbox"/> Type AB <input type="checkbox"/> Type B1 <input type="checkbox"/> Type B2 <input type="checkbox"/> Type B3 <input type="checkbox"/> Thymic carcinoma (Type C)	Using the patient's pathology/laboratory report, select the histologic subtype of the tumor submitted for TCGA. 3081934
20*	Method of Initial Pathologic Diagnosis	<input type="checkbox"/> Surgical Resection <input type="checkbox"/> Core Biopsy <input type="checkbox"/> Aspiration Biopsy <input type="checkbox"/> Other	Provide the procedure used to initially diagnose the patient. 2757941
21	Other Method of Initial Pathologic Diagnosis	_____	If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948
22*	Date of Initial Pathologic Diagnosis	____/____/____ (month)* (day) (year)*	Provide the date the patient was initially diagnosed with the malignancy submitted for TCGA. This may or may not be the date of the surgical resection that yielded the tumor sample submitted for TCGA. 2896956 (month), 2896958 (day), 2896960 (year) <i>Note: The day of Initial Pathologic Diagnosis is not required.</i>
23*	Masaoka Staging	<input type="checkbox"/> I- Grossly & microscopically encapsulated <input type="checkbox"/> IIa - Microscopically capsular invasion <input type="checkbox"/> IIb - Macroscopic invasion into surrounding thymic or fatty tissue <input type="checkbox"/> III- Macroscopic invasion into neighboring organ <input type="checkbox"/> IVa- Pleural or pericardial metastasis <input type="checkbox"/> IVb - Lymphogenous or hematogenous metastasis	Using the patient's pathology/laboratory report, indicate the patient's Masaoka stage. 3952848
24*	Does the patient have a history of myasthenia gravis?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient has a known history of myasthenia. 3950458
25*	Myasthenia Class	<input type="checkbox"/> Not Available <input type="checkbox"/> Class I- any ocular weakness <input type="checkbox"/> Class II- Mild weakness (non- ocular muscles) <input type="checkbox"/> Class III - Moderate Weakness (non- ocular muscles) <input type="checkbox"/> Class IV- Severe (non- ocular muscles) <input type="checkbox"/> Class V- Intubation	Using the patient's pathology/laboratory report, indicate the tumor's myasthenia section. 3952852

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
26*	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 <i>If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.</i>
<u>27</u>	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, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology as the tumor submitted to TCGA. 3119721

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#	Data Element	Entry Alternatives	Working Instructions
<u>28</u>	Anatomic Site of New Tumor Event	<input type="checkbox"/> Pleura <input type="checkbox"/> Pericardium <input type="checkbox"/> Lung <input type="checkbox"/> Bone <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Other, specify _____	Indicate the site of this new tumor event. 3108271
<u>29</u>	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
<u>30</u>	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
<u>31</u>	Additional treatment for New Tumor Event: <i>Surgery</i>	<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
<u>32</u>	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	<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
<u>33</u>	Additional treatment for New Tumor Event: <i>Pharmaceutical Therapy</i>	<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 <i>Note: Pharmaceutical treatment includes chemotherapy, immunotherapy, hormonal therapy, and targeted molecular therapy.</i>

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Time Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form.

- Please Note: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.

#	Question	Entry Alternatives	Working Instructions
i	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Please Note: Provided time intervals must begin with the date of initial pathologic diagnosis.
ii	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth. 3008233
iii	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of last contact. 3008273
iv	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death. 3165475
v	Age at Initial Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657
vi	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. 3392464

Principal Investigator or Designee Signature

Print Name

____/____/_____
Date (Month/Day/Year)

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.