Enrollment Form

Melanoma of the Uveal Tract

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 melanoma 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?	☐ Yes ☐ 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?	☐ 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 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	____ ____/ ____ ____/ ____ ____ ____ ____ *Month* *Day* *Year*	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
4	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
5	Height *(at time of diagnosis)*	_____(cm)	Provide the patient's height (in centimeters) 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 (in kilograms) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 651

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#	Data Element	Entry Alternatives	Working Instructions
7*	Race	☐ 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.*	Provide the patient's race using the defined categories. 2192199
8	Eye Color	☐ Amber ☐ Blue ☐ Brown ☐ Gray ☐ Green ☐ Hazel ☐ Red & Violet ☐ Other ☐ Unknown	Provide the patient's eye color. 3870394
9	Ethnicity	☐ 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.*	Provide the patient's ethnicity using the defined categories. 2192217
10*	History of Other Malignancy *(Non-melanoma malignancies only)*	☐ Yes ☐ No	Indicate whether the patient has a history of non-melanoma malignancies. 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 *If this question cannot be answered because the answer is unknown, please contact the BCR.* *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.*
11*	History of neo-adjuvant (pre-operative) therapy for tumor submitted for TCGA	☐ Yes ☐ 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 *Mitotane prior to surgery is an exclusionary criterion for this study* *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.*
12	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550

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#	Data Element	Entry Alternatives	Working Instructions
13*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
Date of Last Contact *(If patient is living)*			
14*	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)
Date of Death			
15*	Date of Death	___ ___/ ___ ___/ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
16	Cause of Death	☐ Metastatic Uveal Melanoma ☐ Other Malignancy, please specify ☐ Other Non-Malignant Disease, please specify ☐ Death not Caused by Disease* ☐ Unknown Cause of Death	If the patient is deceased, indicate the patient's cause of death. 2554674 * Death not caused by disease is an accidental or unexpected death (e.g. car accident).
17	Other Cause of Death	_____	If the patient's cause of death is not uveal melanoma and the cause of death is known, please describe the cause. 2004150
Pathologic/Prognostic Information **PLEASE NOTE:** ***The following questions should be answered for the entire tumor that yielded the sample submitted for TCGA.***			
18*	Anatomic Site of Disease *(check all that apply)*	☐ Choroid ☐ Ciliary body ☐ Iris	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
19*	Tumor Morphology	**Melanoma of the Uveal Tract** *Epithelioid Cell*: ☐ 0% ☐ 1-30% ☐ 31-60% ☐ 61-90% ☐ > 90% *Spindle Cell*: ☐ 0% ☐ 1-30% ☐ 31-60% ☐ 61-90% ☐ > 90%	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. Cell Type (3081934) and Percentage (3729984) *Samples with a nevus histology are exclusionary.*
20	Chromosomal Alterations *(check all that apply)*	☐ Chromosome 1 loss ☐ Chromosome 3 loss ☐ Chromosome 6p gain ☐ Chromosome 8q gain ☐ Unknown	Using the patient's medical records, indicate whether any of the listed chomrosomal alterations where identified for the patient. 2760451
21	Gene Expression Profile *(check all that apply)*	☐ Class 1 ☐ Class 1a ☐ Class 1b ☐ Class 2 ☐ Unknown	Using the patient's medical records, indicate the patient's gene expression profile. 3870395
22	PET/CT Standardized Uptake Values (SUV)	_____	If the patient received positron emission tomography/ computed tomograph (PET/CT), provide the patient's standardized uptake values. 3133999
23	Mitotic Count	_____ (mm^2)	Using the patient's pathology/laboratory report, indicate the number of mitotic figures per 40 high-power fields. 3227319
24	Presence of Extravascular Matrix Patterns	☐ Loops ☐ Loops Forming Networks ☐ Other Complex Patterns ☐ Unknown	Using the patient's pathology/laboratory report, indicate whether there was a presence of the listed extravascular matrix patterns. 3874271
25	Microvascular Density (MVD)	_____ (mm^2)	Using the patient's pathology/laboratory report, provide the microvasular density of the tumor that yielded the submitted sample. 3874272

#	Data Element	Entry Alternatives	Working Instructions
26	Tumor Infiltrating Lymphocytes	☐ Few ☐ Moderate Numbers ☐ Many ☐ Unknown	Using the patient's pathology/laboratory report, indicate the amount of tumor infiltrating lymphocytes. 3870441
27	Tumor Infiltrating Macrophages	☐ Few ☐ Moderate Numbers ☐ Many ☐ Unknown	Using the patient's pathology/laboratory report, indicate the amount of tumor infiltrating macrophages. 3874291
28	Tumor Basal Diameter	_____ mm	Using the patient's pathology/laboratory report or clinical records, provide the tumor basal diameter of the entire tumor that yielded the TCGA sample. 3870453
29	Tumor Basal Diameter Measurement	☐ Pathologic Measurement ☐ Echographic Measurement	Using the patient's pathology/laboratory report or clinical records, provide the tumor basal diameter measurement of the entire tumor that yielded the TCGA sample. 3870439
30	Tumor Thickness	_____ mm	Using the patient's pathology/laboratory report or clinical records, provide the tumor thickness of the entire tumor that yielded the TCGA sample. 2479403
31	Tumor Thickness Measurement	☐ Pathologic Measurement ☐ Echographic Measurement	Using the patient's pathology/laboratory report or clinical records, provide the tumor thickness measurement of the entire tumor that yielded the TCGA sample. 3870440
32	Extrascleral Extension	☐ Yes ☐ No ☐ Unknown	Using the patient's pathology/laboratory report or clinical records, indicate whether there was extrascleral extension. 3874292
33	Size of Extranocular Nodule	☐ ≤ 5mm ☐ > 5mm	Using the patient's pathology/laboratory report or clinical records, indicate whether the size of the extranocular nodule. 3874294
34	Shape of Tumor *(pathologic or clinical)*	☐ Mushroom ☐ Dome ☐ Diffuse ☐ Undescribed/Unknown	Using the patient's pathology/laboratory report or clinical records, indicate the shape of the tumor. 3870445
Date and Method of Initial Pathologic Diagnosis			
35*	Date of Initial Pathologic Diagnosis	___ ___/ ___ ___/ ___ ___ ___ ___ *Month* *Day* *Year*	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (Month), 2896958 (Day), 2896960 (Year)
36	Method of Initial Pathologic Diagnosis	☐ Enucleation ☐ Local Resection (Exoresection; wall resection) ☐ Endoresection ☐ Other Method, (please specify)	Provide the procedure used to initially diagnose the patient. 2757941 *Please note that this method is referring to the procedure performed on the Date of Initial Pathologic Diagnosis, provided in the previous question.*
37	Other Method of Pathologic Diagnosis	_____	If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948
AJCC Staging			
38*	AJCC Cancer Staging Edition	☐ 1st Edition *(1978-1983)* ☐ 2nd Edition *(1984-1988)* ☐ 3rd Edition *(1989-1992)* ☐ 4th Edition *(1993-1997)* ☐ 5th Edition *(1998-2002)* ☐ 6th Edition *(2003-2009)* ☐ 7th Edition *(2010-present)*	Please select the AJCC Cancer Staging Edition used to answer the following questions. 2722309

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39	Primary Tumor (T)	**Clinical** ☐ TX ☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T2a ☐ T2b ☐ T2c ☐ T2d ☐ T3 ☐ T3a ☐ T3b ☐ T3c ☐ T3d ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ T4e **Pathologic** ☐ TX ☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T2a ☐ T2b ☐ T2c ☐ T2d ☐ T3 ☐ T3a ☐ T3b ☐ T3c ☐ T3d ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d ☐ T4e	Using the patient's medical records, or pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3440328 (Clinical) 3045435 (Pathologic)
40	Regional Lymph Nodes (N)	**Clinical** ☐ NX ☐ N0 ☐ N1 ☐ N2 **Pathologic** ☐ NX ☐ N0 ☐ N1 ☐ N2	Using the patient's medical records, or pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3440330 (Clinical) 3203106 (Pathologic)
41	Distant Metastasis (M)	**Clinical** ☐ MX ☐ M0 ☐ M1 ☐ M1a ☐ M1b ☐ M1c **Pathologic** ☐ MX ☐ M0 ☐ M1 ☐ M1a ☐ M1b ☐ M1c	Using the patient's medical records, or pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3440331 (Clinical) 3045439 (Pathologic)
42	Overall Stage (*Prognostic Group*)	**Clinical** ☐ Stage I ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV **Pathologic** ☐ Stage I ☐ Stage IIA ☐ Stage IIB ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	Using the patient's medical records, or pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3440332 (Clinical) 3203222 (Pathologic)
Regional and Distant Spread			
43	Metastatic Site *(check all that apply)*	☐ Liver ☐ Cutaneous ☐ Lymph node ☐ Lung ☐ Bone ☐ Other, specify ☐ None	If the patient had a metastatic tumor at the time of initial diagnosis of the tumor submitted for TCGA, provide the site of the metastasis. If there was more than one metastatic site, select all that apply. 62835
44	Other Metastatic Site	_____	If the site of the metastasis was not included in the list provided, please provide the site. 3135371
45	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. *IF the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.* 2005312
46	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. *IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.* 3397567

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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.*

Note: The New Tumor Event section on OpenClinica can be completed multiple times, if the patient had multiple New Tumor Events.

#	Data Element	Entry Alternatives	Working Instructions
47*	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 the date of initial diagnosis. 3121376 *If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.*
Date of New Tumor Event after Initial Treatment			
48	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)
49	Type of New Tumor Event	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. 3119721
50	Site of New Tumor Event	☐ Bone ☐ Breast ☐ Cutaneous ☐ Liver ☐ Lung ☐ Lymph node ☐ Prostate ☐ Other, specify ☐ None	If the patient had a new tumor event, provide the site of this tumor. 3108271
51	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
52	Histological Type	_____	Using the patient's pathology/laboratory report, select the histology and/or subtype of the new tumor event. 4500217
53	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
Date of Additional Surgery for New Tumor Event (when applicable)			
54	Date of Additional Surgery for New Tumor Event	___ ___/ ___ ___/ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (Month), 3427613 (Day), 3427614 (Year)
55	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
56	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

_____ _____ ___ ___/ ___ ___/ ___ ___ ___ ___

Principal Investigator or Designee Signature | Print Name | Month/Day/Year