

Initial Case Quality Control Form

Melanoma of the Uveal Tract

Instructions: This form should be completed for all cases submitted for TCGA, prior to the shipment of samples to the BCR.

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

Tissue Source Site (TSS) acknowledges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen biospecimen is consistent with the primary diagnosis reported by the TSS through histopathology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, the TSS authorizes the BCR to report these patient results to the TSS by means of a formal report in confidential email format for the quality assurance program of the TSS to address.

Tissue Source Site (TSS): _____ TSS ID: _____ TSS Unique Patient ID: _____ Interviewer Name: _____ Interview Date ____/____/____

#	Question	Entry Alternatives	Working Instructions
Tumor Information <i>The following questions should be answered based on the sample submitted for TCGA and the pathology review of the frozen slide prepared for TCGA.</i>			
	Histological Subtype	<input type="checkbox"/> Uveal Melanoma	Indicate the histologic subtype for the tumor sample being submitted to TCGA. 3081934
1	Tumor Morphology	<div style="display: flex; justify-content: space-between;"> <div> <i>Epithelioid Cell</i> <input type="checkbox"/> 0% <input type="checkbox"/> 1-30% <input type="checkbox"/> 31-60% <input type="checkbox"/> 61-90% <input type="checkbox"/> > 90% </div> <div> <i>Spindle Cell</i> <input type="checkbox"/> 0% <input type="checkbox"/> 1-30% <input type="checkbox"/> 31-60% <input type="checkbox"/> 61-90% <input type="checkbox"/> > 90% </div> </div>	Indicate the confirmed histologic diagnosis of the submitted tumor, based on the pathology review of the frozen slide prepared for TCGA. 3284266 , 3729984 Note: Samples with a nevus histology are exclusionary.
2	Tumor Type	<input type="checkbox"/> Primary (primary untreated malignant biospecimen)	Indicate the type of tumor submitted for TCGA. 3288124 All submitted biospecimens should NOT have systemic treatment prior to procurement.
3	Anatomic Site of Frozen Biospecimen (check all that apply)	<input type="checkbox"/> Choroid <input type="checkbox"/> Ciliary body <input type="checkbox"/> Iris	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. 4132152
4	Laterality	<input type="checkbox"/> Left <input type="checkbox"/> Right	Indicate the laterality of the frozen tumor biospecimen submitted for TCGA. 827
5	Date of Cancer Sample Procurement	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>_____ Month</div> <div>_____ Day</div> <div>_____ Year</div> </div>	Provide the date of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008197 (Month), 3008195 (Day), 3008199 (Year)
8	Method of Cancer Sample Procurement	<input type="checkbox"/> Enucleation <input type="checkbox"/> Local Resection (Exoresection; wall resection) <input type="checkbox"/> Endoresection <input type="checkbox"/> Other Method, (please specify)	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514
9	Other Method of Cancer Sample Procurement	_____	If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure. 2006730

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#	Question	Entry Alternatives	Working Instructions
10	Country Where Cancer Sample was Procured		Provide the country where the tissue submitted for TCGA was procured. 3203072
11	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> <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 race using the defined categories. 2192199
12	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
13	Vessel Used	<input type="checkbox"/> Cryovial <input type="checkbox"/> Biospecimen Storage Bag <input type="checkbox"/> Cassette <input type="checkbox"/> Cryomold <input type="checkbox"/> Other, specify	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. 3081940
14	Other Vessel Used		If the vessel used to ship the tissue to the BCR is not included in the provided list, specify the vessel used. 3288137
15	Is tumor sample being submitted for macrodissection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the tumor sample submitted to the BCR is intended to undergo macrodissection after the BCR receives the sample. 3521908
16	Was sample prescreened at site?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the sample submitted to the BCR was prescreened at the TSS. 3081942
Tumor Slides Submitted			
<u>17</u>	Types of Slides Submitted <i>Check all that apply</i>	<input type="checkbox"/> Physical Top Slide <input type="checkbox"/> Digital Top Slide Image <input type="checkbox"/> Physical FFPE Slide <input type="checkbox"/> Digital FFPE Slide Image	Indicate the type(s) of slide(s) submitted to the BCR. 3521909 Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface

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#	Question	Entry Alternatives	Working Instructions
18	Slide/Digital Image ID #	_____	Provide the slide ID for each slide (physical and digital image) submitted to the BCR. 2321277
Tumor Sample Information <i>If the TSS is submitting multiple pieces of the same primary tumor for this case; complete the following information for each piece of tumor sent to the BCR.</i>			
19	Tumor Identifier	_____	Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. 3288096
20	Weight of Frozen Tumor	_____ (mg) <i>(0.2cm³ (0.6cm * 0.6cm * 0.6cm)) = ~200mg</i>	Provide the weight of the tumor sample submitted for TCGA. 3081946
21	Tumor Nuclei %	_____ (%)	Provide the percent of tumor nuclei for the sample submitted for TCGA. <i>Check with the BCR to confirm the current acceptable TCGA metrics.</i> 2841225
22	Necrosis %	_____ (%)	Provide the percent of necrosis for the sample submitted for TCGA. <i>Check with the BCR to confirm the current acceptable TCGA metrics.</i> 2841237
Normal Information A normal control must be present to qualify.			
23	Type(s) of Normal Control <i>Check all that apply</i>	<input type="checkbox"/> Whole Blood <input type="checkbox"/> Buffy Coat <input type="checkbox"/> Lymphocytes <input type="checkbox"/> Extracted DNA from Blood <input type="checkbox"/> Extracted DNA from Saliva or Oral mucosa	Indicate the type of normal control submitted for this case. 3081936
Normal Control: Whole Blood			
24	Method of Normal Sample Procurement	<input type="checkbox"/> Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
25	Date of Normal Sample Procurement	____ ____ <i>Month Day</i> ____ ____ ____ <i>Year</i>	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. 3288195 (Month), 3288196 (Day), 3288197 (Year)
28	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
Normal Control: Buffy Coat/ Lymphocytes			
29	Method of Normal Sample Procurement	<input type="checkbox"/> Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
30	Date of Normal Sample Procurement	____ ____ <i>Month Day</i> ____ ____ ____ <i>Year</i>	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. 3288195 (Month), 3288196 (Day), 3288197 (Year)
33	Normal Control Type	<input type="checkbox"/> Buffy Coat <input type="checkbox"/> Lymphocytes	Indicate the type of normal control submitted for TCGA. 3081936
34	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
Normal Control: Extracted DNA from Blood			
35	Method of Normal Sample Procurement	<input type="checkbox"/> Blood Draw <input type="checkbox"/> Oragene <input type="checkbox"/> Other, specify _____	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147

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#	Question	Entry Alternatives	Working Instructions
36	Other Method of Normal Sample Procurement	_____	If the procedure performed to obtain the normal sample is not included in the provided list, specify the method used. 3288151
37	Date of Normal Sample Procurement	<div style="display: flex; justify-content: space-around; align-items: center;"> <div>_____ <i>Month</i></div> <div>_____ <i>Day</i></div> <div>_____ <i>Year</i></div> </div>	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. 3288195 (Month), 3288196 (Day), 3288197 (Year)
40	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
41	Extracted DNA Quantity	_____ (µg)	Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. 3288185
42	Extracted DNA Quantification Method	_____	Provide the quantification method of the normal control sample sent to the BCR for TCGA. 3288186
43	Extracted DNA Concentration	_____ (µg/µL)	Provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA. 3288187
44	Extracted DNA Volume	_____ (µL)	Provide the volume (µL) of the normal control sample sent to the BCR for TCGA. 3288188

Verification: By providing the below information, the Principal Investigator acknowledges that the information provided by the institution is true and correct and has been quality controlled.

Pathology Review

Tissue Source Site (TSS) acknowledges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen biospecimen is consistent with the primary diagnosis reported by the TSS through histopathology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, the TSS authorizes the BCR to report these patient results to the TSS by means of a formal report in confidential email format for the quality assurance program of the TSS to address.

45	Name of Pathologist	_____	Provide the name of the Pathologist that provided the information for all previous sections. 3288225
46	Date of Pathologist Review	_____	Provide the date of the pathology review performed by the TSS pathologist above. 3462941 (Month), 3462917 (Day), 3462960 (Year)

Principal Investigator/Authorized Designee Confirmation

47	Percent Tumor Nuclei meets TCGA metrics?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics for TCGA. 3288520 Check with the BCR to confirm the current acceptable TCGA metrics. If submitting for macrodissection, please contact the BCR prior to shipment.
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#	Question	Entry Alternatives	Working Instructions
48	Percent Necrosis meets TCGA metrics?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. 3288524 Check with the BCR to confirm the current acceptable TCGA metrics. If submitting for macrodissection, please contact the BCR prior to shipment.
49	De-Identified Pathology Report Submitted?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples. 3288292
50	Is the histologic diagnosis on the CQCF (as determined by the TSS pathology review of the TCGA frozen section top slide) consistent with the histology listed in the final diagnosis on the pathology report?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Confirm that the diagnosis provided on this CQCF for the tumor sample being submitted to TCGA is consistent with the diagnosis found on the patient's pathology report for the tumor being sent to the BCR. 3288300 If "yes," skip related question below. The diagnosis is considered to be consistent if at least one of the following criteria are met: <ol style="list-style-type: none"> 1) Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR. 2) Diagnosis on the CQCF includes as least one of the subtypes listed on the pathology report and all subtypes on the pathology report are acceptable for TCGA. 3) Diagnosis on the CQCF is "histology, NOS" (i.e., Adenocarcinoma, NOS) and the pathology report lists a specific subtype within the same histologic group 4) Diagnosis on the CQCF indicates "Mixed Subtype" and the pathology report lists two or more acceptable subtypes, provided that percent subtype(s) meet applicable TCGA disease-specific requirements.
51	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	<input type="checkbox"/> Macrodissection performed at TSS to select for a region containing an acceptable TCGA diagnosis (<i>see note at right</i>) <input type="checkbox"/> Pathology analysis at TSS determined a specific histological subtype different from original pathology report (<i>see note at right</i>) <input type="checkbox"/> Pathology review of frozen section for TCGA determined histological subtype different from the pathology report (<i>see note at right</i>)	If the diagnosis provided on this form is not consistent with the diagnosis found on the pathology report provided, specify a reason for this inconsistency. 3288315 If a TSS pathology review of the TCGA committed sample resulted in a different histological subtype than what is documented on the original pathology report, an amendment to the pathology report should be submitted when the sample is shipped to the BCR; or in the absence of an amended pathology report, the TSS must complete and submit an electronic copy of the "TCGA Pathologic Diagnosis Discrepancy Form". In the case of diagnosis modifications, institution protocol should be followed for proper quality assurance.

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#	Question	Entry Alternatives	Working Instructions
52	History of Other Malignancy	<input type="checkbox"/> None <input type="checkbox"/> History of Prior Malignancy <input type="checkbox"/> History of Synchronous/ Bilateral Malignancy <input type="checkbox"/> Both History of Synchronous/ Bilateral and Prior Malignancy	<p>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. 3382736</p> <p>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.</p>
53	History of Neoadjuvant Treatment for Tumor Submitted for TCGA	<input type="checkbox"/> None <input type="checkbox"/> Radiation prior to sample procurement* <input type="checkbox"/> Pharmaceutical treatment prior to sample procurement* <input type="checkbox"/> Both pharmaceutical treatment and radiation prior to sample procurement*	<p>Indicate whether the patient received therapy for this cancer prior to the sample procurement of the tumor submitted for TCGA. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instruction. 3382737</p> <p>*Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the procurement of the sample submitted for TCGA are exclusionary. However, for the melanoma study, patients treated with interferon at least 90 days prior to procurement are accepted into TCGA.</p>
54	Consent Status	<input type="checkbox"/> Formally Consented <input type="checkbox"/> Consented by Death	<input type="checkbox"/> Exemption 4* <input type="checkbox"/> Waiver*
Date of Consent			
55	Date of Consent	<div> <div>____</div> <div>____</div> <div>____</div> <div>____</div> </div> <div> <div>Month</div> <div>Day</div> <div>Year</div> </div>	<p>If the patient was formally consented, provide the date of consent. 3081955 (Month), 3081957 (Day), 3081959 (Year)</p>
Date of Death (Note: If the patient formally consented, only supply the date the patient consented.)			
58	Date of Death	<div> <div>____</div> <div>____</div> <div>____</div> <div>____</div> </div> <div> <div>Month</div> <div>Day</div> <div>Year</div> </div>	<p>If the patient consented by death, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)</p>

Principal Investigator or Designee Signature

Print Name

____/____/_____
Date

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