

Initial Case Quality Control Form Esophageal (ESCA)

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 ____/____/____

Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form? Yes No

Note: Provided time intervals must begin with the date of initial pathologic diagnosis.

Tumor Information: The following sections are to be provided by a Pathologist

#	Question	Entry Alternatives	Working Instructions
1	Histologic Subtype of Tumor Submitted for TCGA	<input type="checkbox"/> Esophagus Adenocarcinoma, NOS <input type="checkbox"/> Esophagus Squamous Cell Carcinoma	Indicate the confirmed diagnosis of the tumor submitted for TCGA. 3081934
2	Tumor Type	<input type="checkbox"/> Primary (<i>primary untreated malignant biospecimen</i>)	Indicate the type of tumor submitted for TCGA. 3288124 This is a biospecimen that has not been treated with chemotherapy or radiation prior to resection.
TCGA is committed to the study and collection of ALL tumors originating across the stomach and esophagus. We recognize that it is often difficult to determine the exact origin of some of these tumors but to organize our collection we are asking for the best possible assessment of the classification of the tumor. If the tumor appears to be centered in the stomach or Gastric/ Esophageal Junction (GEJ), please submit the tumor to TCGA with the Gastric Adenocarcinoma Form, which can be provided by the BCR.			
For tumors which appear to originate in the esophagus (or are centered in the esophagus), complete the following questions.			
3	In which third of the esophagus is the tumor centered ? <i>Check only one</i>	<input type="checkbox"/> Proximal <input type="checkbox"/> Mid <input type="checkbox"/> Distal	
4	In which third(s) of the esophagus is the tumor involved ? <i>Check all that apply</i>	<input type="checkbox"/> Proximal <input type="checkbox"/> Mid <input type="checkbox"/> Distal	Using the list provided, indicate the involved locations of the tumor submitted for TCGA. 3295806
5	Does the tumor cross the Gastric/ Esophageal Junction (GEJ)?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the tumor submitted for TCGA crossed the Gastric/ Esophageal Junction (GEJ). 3295807
6	Month of Cancer Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008197
7	Day of Cancer Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30 <input type="checkbox"/> 31	Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008195
8	Year of Cancer Sample Procurement	_____	Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008199
9	Method of Cancer Sample Procurement	<input type="checkbox"/> Endoscopic Biopsy <input type="checkbox"/> Endoscopic Mucosal Resection	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514

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#	Question	Entry Alternatives	Working Instructions
		<input type="checkbox"/> Surgical Resection	
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 Reported: <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 Laser Cryo-Enrichment (LCE)?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the tumor sample submitted to the BCR is intended to undergo Laser Cryo-Enrichment (LCE) after the BCR receives the sample. 3288488
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
17	If the sample submitted was not prescreened at the TSS, how was the sample reviewed?	<input type="checkbox"/> FFPE* Slide Reviewed, One of several biopsies reviewed <input type="checkbox"/> Section adjacent to submitted tissue reviewed	If the sample submitted to the BCR was not prescreened, indicated the method used to review the sample. Please Note: *FFPE = Formalin-fixed Paraffin-embedded 3295808

Tumor Slides Submitted

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#	Question	Entry Alternatives	Working Instructions
18	Types of Slides Submitted	<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. <u>TBD</u> Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface
19	Slide/Digital Image ID #	_____	Provide the slide ID for each slide (physical and digital image) submitted to the BCR. <u>2321277</u>

Tumor Information 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.

20	Tumor Identifier	_____	Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. <u>3288096</u>
21	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. <u>3081946</u>
22	Tumor Nuclei %	_____ (%)	Provide the percent of tumor nuclei for the sample submitted for TCGA. <u>2841225</u> Check with the BCR to confirm the current acceptable TCGA metrics.
23	Necrosis %	_____ (%)	Provide the percent of necrosis for the sample submitted for TCGA. <u>2841237</u> Check with the BCR to confirm the current acceptable TCGA metrics.

Normal Information A normal control must be present to qualify.

24	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"/> Non-Neoplastic Control Tissue* <input type="checkbox"/> Secondary Normal Tissue – Barrett’s Esophagus*	Indicate the type of normal control submitted for this case. <u>3081936</u> Non-neoplastic Control Tissue may only be submitted with NCI approval. Normal tissue from a patient with a known diagnosis of Barrett’s Esophagus is <i>not permitted</i> as the only normal control. These tissues should be submitted as Double Normal cases only.
Normal Control: Whole Blood			
25	Method of Normal Sample Procurement	<input type="checkbox"/> Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>
26	Month of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>
27	Day of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30 <input type="checkbox"/> 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>
28	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>

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#	Question	Entry Alternatives	Working Instructions
<u>29</u>	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			
30	Normal Control Type	<input type="checkbox"/> Buffy Coat <input type="checkbox"/> Lymphocytes	Indicate the type of normal control submitted for TCGA. 3081936
31	Method of Normal Sample Procurement	<input type="checkbox"/> Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
32	Month of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
33	Day of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30 <input type="checkbox"/> 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
34	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
<u>35</u>	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			
36	Method of Normal Sample Procurement	<input type="checkbox"/> Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
37	Month of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
38	Day of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30 <input type="checkbox"/> 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
39	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
<u>40</u>	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
<u>41</u>	Extracted DNA Quantity	_____ (µg)	Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. 3288185
<u>42</u>	Extracted DNA Quantification Method	_____	Provide the quantification method of the normal control sample sent to the BCR for TCGA. 3288186

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#	Question	Entry Alternatives	Working Instructions
<u>43</u>	Extracted DNA Concentration	_____ (µg/µL)	Provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA. 3288187
<u>44</u>	Extracted DNA Volume	_____ (µL)	Provide the volume (µL) of the normal control sample sent to the BCR for TCGA. 3288188
Normal Control: Non-Neoplastic Control Tissue			
<u>45</u>	Method of Normal Sample Procurement	<input type="checkbox"/> Surgical Resection <input type="checkbox"/> Incisional Biopsy <input type="checkbox"/> Excisional Biopsy <input type="checkbox"/> Other Method (please specify)	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
<u>46</u>	Other Method of Normal Sample Procurement	_____	If the procedure performed to obtain the normal sample is not included in the provided list, specify the procedure. 3288151
<u>47</u>	Month of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
<u>48</u>	Day of Normal Sample Procurement	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30 <input type="checkbox"/> 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
<u>49</u>	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
<u>50</u>	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
<u>51</u>	Anatomic Site of Non-Neoplastic Control Tissue	<input type="checkbox"/> Proximal <input type="checkbox"/> Mid <input type="checkbox"/> Distal <input type="checkbox"/> Other, specify	If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. 3295809 Site matched is preferred.
<u>52</u>	Other Site of Non-Neoplastic Control Tissue	_____	If the normal control type is normal tissue and the anatomic site is not included in the provided list, specify the site of the non-neoplastic control. 3288189
<u>53</u>	Proximity of Normal Tissue to Tumor	<input type="checkbox"/> Distal (> 2cm) from the primary tumor	If the normal control type is normal tissue, confirm that the submitted normal tissue was at least 2cm away from the primary tumor. 3088708 Adjacent (≤ 2cm) Normal Tissue is not accepted for this tissue type. Unknown Normal Tissue is not acceptable for this tissue type.
<u>54</u>	Normal Slide ID#	_____	If the normal control type is normal tissue, provide the slide ID for the physical top slide OR the digital slide image of the normal control being sent to the BCR. 3288217

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.

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#	Question	Entry Alternatives	Working Instructions
<p>Pathology Review <i>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.</i></p>			
55	Name of Pathologist	_____	Provide the name of the Pathologist that provided the information for all previous sections. 3288225
56	Date of Pathologist Review	_____	Provide the date of the pathology review performed by the TSS pathologist above. 3288224
<p>Principal Investigator/Authorized Designee Confirmation</p>			
57	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 <i>Check with the BCR to confirm the current acceptable TCGA metrics.</i>
58	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 <i>Check with the BCR to confirm the current acceptable TCGA metrics.</i>
59	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
60	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 <i>If "yes," skip related question below.</i> <i>The diagnosis is considered to be consistent if at least one of the following criteria are met:</i> <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.

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#	Question	Entry Alternatives	Working Instructions
61	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>)	<p>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</p> <p>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.</p>
62	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 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>
63	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.</p>
64	Consent Status	<input type="checkbox"/> Consented <input type="checkbox"/> Exemption 4* <input type="checkbox"/> Deceased <input type="checkbox"/> Waiver*	<p>Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. 3288361</p> <p>*Exemptions and waivers for consent must be approved by NCI.</p>
Date of Consent			
65	Month of Consent	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12	<p>If the patient was formally consented, provide the month of consent. 3081955</p>
66	Day of Consent	<input type="checkbox"/> 01 <input type="checkbox"/> 02 <input type="checkbox"/> 03 <input type="checkbox"/> 04 <input type="checkbox"/> 05 <input type="checkbox"/> 06 <input type="checkbox"/> 07 <input type="checkbox"/> 08 <input type="checkbox"/> 09 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 <input type="checkbox"/> 24 <input type="checkbox"/> 25 <input type="checkbox"/> 26 <input type="checkbox"/> 27 <input type="checkbox"/> 28 <input type="checkbox"/> 29 <input type="checkbox"/> 30 <input type="checkbox"/> 31	<p>If the patient was formally consented, provide the day of consent. 3081957</p>
67	Year of Consent	_____	<p>If the patient was formally consented, provide the year of consent. 3081959</p>

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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.

#	Question	Entry Alternatives	Working Instructions
ii	Number of Days from Date of Diagnosis to Date of Cancer Sample Procurement	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the malignant sample submitted for TCGA. 3288495
iii	Number of Days from Date of Diagnosis to Normal Sample Procurement	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the normal control sample submitted for TCGA. 3288496
iv	Number of Days from Date of Diagnosis to Date of Pathological Review	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the pathological review performed as part of the submission process for TCGA. 3288497
v	Number of Days from Date of Diagnosis to Date of Consent	_____ days	If the patient formally consented, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's formal consent. 3288498
vi	Number of Days from Date of Diagnosis to Date of Death	_____ days	If the patient consented by death, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's death. 3288499 Do not complete days to death, if patient formally consented.