## 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.								
report	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.								
	issue Source Site (TSS):TSS ID:TSS Unique Patient ID: Interviewer Name:Interview Date/ //								
		pm the NCI to provide time intervals as a substitute for requested dates on this form? $\Box$ Y							
		gin with the date of initial pathologic diagnosis.							
Tumo	<b>r Information:</b> The followin	g sections are to be provided by a Pathologist							
#	Question	Entry Alternatives	Working Instructions						
1	Histologic Subtype of Tumor Submitted for TCGA	<ul> <li>Esophagus Adenocarcinoma, NOS</li> <li>Esophagus Squamous Cell Carcinoma</li> </ul>	Indicate the confirmed diagnosis of the tumor submitted for TCGA. <u>3081934</u>						
2	Tumor Type	Primary (primary untreated malignant biospecimen)	Indicate the type of tumor submitted for TCGA. <u>3288124</u> This is a biospecimen that <b>has not</b> been treated with chemotherapy or radiation prior to resection.						
tumor	rs but to organize our collection	ollection of ALL tumors originating across the stomach and esophagus. We recognize that it is often we are asking for the best possible assessment of the classification of the tumor. <b>If the tumor appe</b> <b>ubmit the tumor to TCGA with the Gastric Adenocarcinoma Form, which can be provided by</b> t	ears to be centered in the stomach or Gastric/						
		nors which appear to originate in the esophagus (or are centered in the esophagus), complet	e the following questions.						
3	In which third of the esophagus is the tumor <u>centered</u> ? <i>Check only one</i>	<ul> <li>Proximal</li> <li>Mid</li> <li>Distal</li> </ul>							
4	In which third(s) of the esophagus is the tumor <u>involved</u> ? Check all that apply	<ul> <li>Proximal</li> <li>Mid</li> <li>Distal</li> </ul>	Using the list provided, indicate the involved locations of the tumor submitted for TCGA. 3295806						
5	Does the tumor cross the Indicate whether the tumor submitted for TCGA crossed the								
6	Procurement		Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3008197</u>						
7	Day of Cancer Sample	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31	Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3008195</u>						
8	Year of Cancer Sample Procurement		Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3008199</u>						
9	Method of Cancer Sample Procurement	<ul> <li>Endoscopic Biopsy</li> <li>Endoscopic Mucosal Resection</li> </ul>	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514						

#### Initial Case Quality Control Form Esophageal (ESCA)

#	Question	Entry Alternatives	Working Instructions
		□ Surgical Resection	
10	Country Where Cancer Sample was Procured		Provide the country where the tissue submitted for TCGA was procured. 3203072
11	Race	<ul> <li>American Indian or Alaska Native         <ul> <li>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.</li> </ul> </li> <li>Asian         <ul> <li>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.</li> </ul> </li> <li>White         <ul> <li>A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.</li> </ul> </li> <li>Black or African American         <ul> <li>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."</li> </ul> </li> <li>Native Hawaiian or other Pacific Islander:         <ul> <li>A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</li> <li>Not Reported: Not provided or available.</li> <li>Unknown: Could not be determined or unsure.</li> </ul></li></ul>	Provide the patient's race using the defined categories. 2192199
12	Ethnicity	<ul> <li>Not Hispanic or Latino         <ul> <li>A person not meeting the definition of Hispanic or Latino.</li> </ul> </li> <li>Hispanic or Latino         <ul> <li>A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.</li> </ul> </li> <li>Not Evaluated         <ul> <li>Not provided or available.</li> <li>Unknown</li></ul></li></ul>	Provide the patient's ethnicity using the defined categories. 2192217
13	Vessel Used	CryovialCassetteOther, specifyBiospecimen Storage BagCryomold	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. <u>3081940</u>
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. <u>3288137</u>
15	Is tumor sample being submitted for Laser Cryo- Enrichment (LCE)?	□ Yes □ No	Indicate whether the tumor sample submitted to the BCR is intended to undergo Laser Cryo-Enrichment (LCE) after the BCR receives the sample. <u>3288488</u>
16	Was sample prescreened at site?	□ Yes □ No	Indicate whether the sample submitted to the BCR was prescreened at the TSS. <u>3081942</u>
17	If the sample submitted was not prescreened at the TSS, how was the sample reviewed?	<ul> <li>FFPE* Slide Reviewed,One of several biopsies reviewed</li> <li>Section adjacent to submitted tissue reviewed</li> </ul>	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
Tum	or Slides Submitted		

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## Initial Case Quality Control Form Esophageal (ESCA)

#	Question	Entry Alternatives	Working Instructions						
<u>18</u>	Types of Slides Submitted	<ul> <li>Physical Top Slide</li> <li>Digital Top Slide Image</li> <li>Physical FFPE Slide</li> <li>Digital FFPE Slide Image</li> </ul>	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						
<u>19</u>	Slide/Digital Image ID #		Provide the slide ID for each slide (physical and digital image) submitted to the BCR. <u>2321277</u>						
Tumo	Fumor 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.								
<u>20</u>	Tumor Identifier		Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. <u>3288096</u>						
<u>21</u>	Weight of Frozen Tumor	(mg) (0.2cm <sup>3</sup> (0.6cm * 0.6cm * 0.6cm) = ~200mg	Provide the weight of the tumor sample submitted for TCGA. <u>3081946</u>						
<u>22</u>	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.						
<u>23</u>	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.						
Norm	al Information A normal co	ntrol must be present to qualify.							
24	Type(s) of Normal Control <i>Check all that apply</i>	<ul> <li>Whole Blood</li> <li>Extracted DNA from Blood</li> <li>Buffy Coat</li> <li>Non-Neoplastic Control Tissue*</li> <li>Lymphocytes</li> <li>Secondary Normal Tissue – Barrett's Esophagus*</li> </ul>	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 <i>is not permitted</i> as the only normal control. These tissues should be submitted as Double Normal cases only.						
Norn	nal Control: Whole Blood								
25	Method of Normal Sample Procurement	Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>						
26	Month of Normal Sample Procurement		Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>						
27	Day of Norman Sample	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       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									
Norn	Normal Control: Buffy Coat/ Lymphocytes										
30	Normal Control Type	<ul> <li>Buffy Coat</li> <li>Lymphocytes</li> </ul>	Indicate the type of normal control submitted for TCGA. <u>3081936</u>								
31	Method of Normal Sample Procurement	Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>								
32	Month of Normal Sample Procurement		Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>								
33	Day of Normal Sample Procurement	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>								
34	Year of Normal Sample Procurement		Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>								
<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								
Norn	nal Control: Extracted DNA	from Blood									
36	Method of Normal Sample Procurement	Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>								
37	Month of Normal Sample Procurement		Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>								
38	Day of Normal Sample Procurement	□ 01       □ 02       □ 03       □ 04       □ 05       □ 06       □ 07       □ 08       □ 09       □ 10       □ 11       □ 12         □ 13       □ 14       □ 15       □ 16       □ 17       □ 18       □ 19       □ 20       □ 21       □ 22       □ 23       □ 24         □ 25       □ 26       □ 27       □ 28       □ 29       □ 30       □ 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>								
39	Year of Normal Sample Procurement		Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>								
<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. <u>3288138</u>								
<u>41</u>	Extracted DNA Quantity	(µg)	Provide the quantity (μg) of the normal control sample sent to the BCR for TCGA. <u>3288185</u>								
<u>42</u>	Extracted DNA Quantification Method		Provide the quantification method of the normal control sample sent to the BCR for TCGA. <u>3288186</u>								

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#	Question	Entry Alternatives	Working Instructions						
<u>43</u>	Extracted DNA Concentration	(μg/μL)	Provide the concentration ( $\mu$ g/ $\mu$ L) of the normal control sample sent to the BCR for TCGA. 3288187						
<u>44</u>	Extracted DNA Volume	(μL)	Provide the volume ( $\mu$ L) of the normal control sample sent to the BCR for TCGA. <u>3288188</u>						
Norn	nal Control: Non-Neoplastic	c Control Tissue							
45	Method of Normal Sample Procurement	Image: Surgical ResectionImage: Excisional BiopsyIncisional BiopsyOther Method (please specify)	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>						
46	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. <u>3288151</u>						
47	Month of Normal Sample Procurement		Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>						
48	Day of Normal Sample	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>						
49	Year of Normal Sample Procurement		Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>						
<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. <u>3288138</u>						
<u>51</u>	Anatomic Site of Non- Neoplastic Control Tissue	<ul> <li>Proximal</li> <li>Mid</li> <li>Distal</li> <li>Other, specify</li> </ul>	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	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. <u>3088708</u> 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.

Pag	Page 6 Initial Case Quality Control Form Esophageal (ESCA) V4.03 091112										
#	Question	Entry Alternatives	Working Instructions								
Tissı repo	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.										
55	Name of Pathologist		Provide the name of the Pathologist that provided the information for all previous sections. <u>3288225</u>								
56	Date of Pathologist Review		Provide the date of the pathology review performed by the TSS pathologist above. 3288224								
Prin	cipal Investigator/Authoriz	zed Designee Confirmation									
57	Percent Tumor Nuclei meets TCGA metrics?	□ Yes □ No	Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics for TCGA. <u>3288520</u> Check with the BCR to confirm the current acceptable TCGA metrics.								
58	Percent Necrosis meets TCGA metrics?	□ Yes □ No	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. <u>3288524</u> Check with the BCR to confirm the current acceptable TCGA metrics.								
59	De-Identified Pathology Report Submitted?	□ Yes □ No	Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples. <u>3288292</u>								
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?	□Yes □No	<ul> <li>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.</li> <li><u>3288300</u></li> <li>If "yes," skip related question below.</li> <li>The diagnosis is considered to be consistent if at least one of the following criteria are met: <ol> <li>Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR.</li> <li>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.</li> <li>Diagnosis on the CQCF is 'histology, NOS'' (i.e., Adenocarcinoma, NOS) and the pathology report lists a specific subtype within the same histologic group</li> <li>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.</li> </ol> </li> </ul>								

## Initial Case Quality Control Form Esophageal (ESCA)

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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.	<ul> <li>Macrodissection performed at TSS to select for a region containing an acceptable TCGA diagnosis <i>(see note at right)</i></li> <li>Pathology analysis at TSS determined a specific histological subtype different from original pathology report <i>(see note at right)</i></li> <li>Pathology review of frozen section for TCGA determined histological subtype different from the pathology report <i>(see note at right)</i></li> </ul>	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. <u>3288315</u> 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.
62	History of Other Malignancy	<ul> <li>None</li> <li>History of Prior Malignancy</li> <li>History of Synchronous/ Bilateral Malignancy</li> <li>Both History of Synchronous/ Bilateral and Prior Malignancy</li> </ul>	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. <u>3382736</u> 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.
63	History of Neoadjuvant Treatment <i>for Tumor</i> <i>Submitted for TCGA</i>	<ul> <li>None</li> <li>Radiation prior to sample procurement*</li> <li>Pharmaceutical treatment prior to sample procurement*</li> <li>Both pharmaceutical treatment and radiation prior to sample procurement*</li> </ul>	Indicate whether the patient received therapy for this cancer prior to the sample procurement of <b>the tumor submitted for</b> <b>TCGA</b> . If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instruction. <u>3382737</u> *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.
64	Consent Status	□ Consented □ Exemption 4* □ Deceased □ Waiver*	Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. 3288361 *Exemptions and waivers for consent must be approved by NCI.
Date	of Consent		
65	Month of Consent		If the patient was formally consented, provide the month of consent. <u>3081955</u>
66	Day of Consent	01       02       03       04       05       06       07       08       09       10       11       12         13       14       15       16       17       18       19       20       21       22       23       24         25       26       27       28       29       30       31       21       22       23       24	If the patient was formally consented, provide the day of consent. 3081957
67	Year of Consent		If the patient was formally consented, provide the year of consent. <u>3081959</u>

#### Initial Case Quality Control Form

Esophageal (ESCA)

#	Question	Entry Alternatives									Working Instructions			
Date	Date of Death Do not complete date of death, if patient formally consented.													
68	Month of Death	• 01	02	• 03	□ 04	• 05	<b>D</b> 06	• 07	08	□ 09	□ 10	<b>□</b> 11	<b>1</b> 2	If the patient consented by death, provide the month of death. 2897026
69	Day of Death	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	□ 03 □ 15 □ 27	□ 04 □ 16 □ 28	□ 05 □ 17 □ 29	□ 06 □ 18 □ 30	□ 07 □ 19 □ 31	□ 08 □ 20	□ 09 □ 21	□ 10 □ 22	□ 11 □ 23	□ 12 □ 24	If the patient consented by death, provide the day of death. <u>2897028</u>
70	Year of Death													If the patient consented by death, provide the year of death. <u>2897030</u>

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.

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<b>Fime</b>	'ime 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. <u>3288496</u>						
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. <u>3288499</u> Do not complete days to death, if patient formally consented.						