

Initial Case Quality Control Form

Stomach (STAD)

Instructions: This form should be completed for all submitted cases, prior to the shipment of samples to the BCR. **Questions regarding this form should be directed to the Tissue Source Site's Clinical Outreach Contact at the BCR.**

Form Notes: 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
Verification of Requirements Prior to the shipment of samples to the BCR, the TSS must answer the following questions to verify that all requirements are met. For a complete list of requirements, please reference the Study Requirements Checklist document.			
Pathology Prescreen at the TSS			
1*	Was the submitted sample prescreened at the TSS?	<input type="checkbox"/> Yes	Indicate whether the sample submitted to the BCR was prescreened at the TSS. 3081942
2*	Name of Pathologist (person who performed the review of the submitted slide)	_____	Provide the name of the pathologist who performed the review of the submitted sample. 3288225
3*	Date of Pathology Prescreen	____/____/____ Month Day Year	Provide the date the reviewing pathologist performed the prescreen. 3288224
4*	Does the percent of tumor nuclei meet current project metrics?	<input type="checkbox"/> Yes	Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics. If submitting for macrodissection, please contact the BCR prior to shipment. 3288520
5*	Does the percent necrosis meet the current project metrics?	<input type="checkbox"/> Yes	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics. If submitting for macrodissection, please contact the BCR prior to shipment. 3288524
Initial Pathology Report			
6*	Will a De-Identified Pathology Report Be Submitted?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Confirm that the diagnosis provided on this CQCF for the tumor sample being submitted is consistent with the diagnosis found on the patient's pathology report for the tumor being sent to the BCR. Cases without a pathology report at the time of sample submission will be excluded. 3288292
7*	Is the histologic diagnosis determined by the prescreening consistent with the histology listed as the final diagnosis on the initial pathology report?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Confirm that the diagnosis provided on this form for the tumor sample being submitted is consistent with the final diagnosis found on the patient's pathology report for the tumor being sent to the BCR. If "yes," skip related question below. The diagnosis is considered to be consistent if at least one of the following criteria are met: 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 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 disease-specific requirements. 3288300

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8	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 (<i>see definition at right</i>) <input type="checkbox"/> Other Pathology Review (<i>see definition at right</i>) <input type="checkbox"/> Pathology Review for this Project (<i>see definition at right</i>)	<p>If the diagnosis provided on this form is not consistent with the final diagnosis found on the pathology report provided, specify a reason for this inconsistency.</p> <p>1.) Macrodissection that was performed at the TSS to select a region containing an acceptable diagnosis determined a specific histological subtype that is different from the original pathology report</p> <p>2.) The pathology analysis performed at the TSS determined a specific histological subtype that is different from the original pathology report</p> <p>3.) The pathology review of the frozen section for this project determined that the histologic subtype is different from the pathology report</p> <p style="color: red;">If a TSS pathology review of the submitted sample resulted in a different histologic 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; in the absence of an amended pathology report, the TSS must complete and submit an electronic copy of the "Pathologic Diagnosis Discrepancy Form". In the case of diagnosis modifications, institution protocol should be followed for proper quality assurance.</p> <p>3288315</p>
Patient Information			
9*	History of Other Malignancy (Including ALL Prior and Synchronous Malignancies)	<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, including synchronous or bilateral malignancies. Please complete an Other Malignancy Form (OMF) for each malignancy diagnosed prior to or at the time the submitted tissue was procured.</p> <p style="color: red;">If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, only complete an OMF for the initial diagnosis of each of these types.</p> <p>3382736</p>
10*	History of Neoadjuvant Treatment (prior to procurement) of Tumor Submitted	<input type="checkbox"/> Yes (<i>see note at right</i>) <input type="checkbox"/> No	<p>Indicate whether the patient received therapy for the tumor submitted prior to the sample procurement. If the patient did receive treatment prior to procurement, the TSS should contact the BCR for further instruction.</p> <p style="color: red;">Systemic therapy and certain localized therapies (those administered to the same site as the submitted tissue) given prior to the procurement of the sample submitted are exclusionary.</p> <p>3382737</p>
Consent Information			
11*	Consent Status	<input type="checkbox"/> Formally Consented <input type="checkbox"/> Consented by Death <input type="checkbox"/> Exemption (<i>see note at right</i>) <input type="checkbox"/> Waiver (<i>see note at right</i>)	<p>Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent.</p> <p style="color: red;">Exemptions and waivers for consent must be approved by NCI.</p> <p>3288361</p>
12	Date of Formal Consent	<div style="display: flex; justify-content: space-between; width: 100%;"> <div>_____</div> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; width: 100%; font-style: italic;"> <div>Month</div> <div>Day</div> <div>Year</div> </div>	<p>If the patient was formally consented, provide the month of consent.</p> <p>3081955 (month), 3081957 (day), 3081959 (year)</p>
13	Date of Death	<div style="display: flex; justify-content: space-between; width: 100%;"> <div>_____</div> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; width: 100%; font-style: italic;"> <div>Month</div> <div>Day</div> <div>Year</div> </div>	<p>If the patient consented by death (i.e. they did not formally consent), provide the month of death.</p> <p style="color: red;">Do not complete if the patient formally consented.</p> <p>2897026 (month), 2897028 (day), 2897030 (year)</p>
Demographic Information			
14*	Race	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> White <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	<p>Provide the patient's race using the provided categories, as defined below.</p> <p style="color: red;">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.</p> <p style="color: red;">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.</p> <p style="color: red;">White: A person having origins in any of the original peoples of the far Europe, the</p>

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			<p>Middle East, or North Africa.</p> <p><u>Black or African American:</u> A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black or African American.”</p> <p><u>Native Hawaiian or other Pacific Islander:</u> A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</p> <p><u>Not Evaluated</u></p> <p><u>Unknown</u></p> <p>2192199</p>
15	Ethnicity	<input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	<p>Provide the patient’s ethnicity using the provided categories, defined below:</p> <p><u>Not Hispanic or Latino:</u> A person not meeting the definition of Hispanic or Latino.</p> <p><u>Hispanic or Latino:</u> A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.</p> <p><u>Not Evaluated</u></p> <p><u>Unknown</u></p> <p>2192217</p>

Pathologic/Anatomic Information

The following information must be completed for the tumor sample submitted and should be answered specifically about the submitted sample(s). If multiple vials of the tumor sample are submitted, the “Tumor Sample Information” must be completed for each vial submitted to the BCR.

Pathologic/Anatomic Information

16*	Tumor Category	<input type="checkbox"/> Primary	<p>Indicate the tumor category of the tumor submitted.</p> <p>3288124</p>
17*	Histologic Diagnosis of Tumor Submitted for TCGA	<input type="checkbox"/> Stomach Intestinal Adenocarcinoma – Tubular Type <input type="checkbox"/> Stomach Intestinal Adenocarcinoma – Papillary Type <input type="checkbox"/> Stomach Intestinal Adenocarcinoma – Mucinous Type <input type="checkbox"/> Stomach Intestinal Adenocarcinoma – Type NOS <input type="checkbox"/> Stomach Adenocarcinoma – Signet Ring Type <input type="checkbox"/> Stomach Adenocarcinoma – Diffuse Type <input type="checkbox"/> Stomach Adenocarcinoma – NOS	<p>Indicate the histologic subtype of the malignant sample submitted.</p> <p>3081934</p>
18	Anatomic Organ Sub-Division of Frozen Biospecimen	<input type="checkbox"/> Gastroesophageal Junction <input type="checkbox"/> Cardia/Proximal <input type="checkbox"/> Fundus/Body <input type="checkbox"/> Antrum/Distal <input type="checkbox"/> Stomach (NOS) <input type="checkbox"/> Other (please specify)	<p>Indicate the sub-division of the anatomic site of the frozen tumor biospecimen submitted for TCGA.</p> <p>4132152</p>
19	Other Anatomic Site of Frozen Biospecimen	_____	<p>Indicate the other anatomic site of the frozen tumor submitted for TCGA.</p> <p>3320289</p>

Tumor Procurement Information

20*	Date of Tumor Sample Procurement	<div> <div>_____</div> <div>_____</div> <div>_____</div> </div> <div> <div>Month</div> <div>Day</div> <div>Year</div> </div>	<p>Provide the procurement date of the malignancy that yielded the submitted tumor.</p> <p>3008197 (month), 3008195(day), 3008199 (year)</p>
21*	Shipment Vessel Used	<input type="checkbox"/> Cryovial <input type="checkbox"/> Biospecimen Storage Bag <input type="checkbox"/> Cassette <input type="checkbox"/> Cryomold <input type="checkbox"/> Other Liquid Nitrogen Resistant Container	<p>Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR).</p> <p>3081940</p>

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22	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
23*	Method of Tumor Sample Procurement	<input type="checkbox"/> Surgical Resection <input type="checkbox"/> Endoscopic Biopsy <input type="checkbox"/> Excisional Biopsy <input type="checkbox"/> Other (please specify)	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514
24	Other Method of Tumor Sample Procurement	_____	If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure. 2006730
25*	Country where Tumor Sample was Procured	_____	Provide the country where the malignant tissue that yielded the submitted sample was procured. 3152016
26*	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
Tumor Sample Information If multiple vials of the tumor sample are submitted, this section must be completed for each vial submitted to the BCR.			
27*	Tumor ID	_____	Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor sample needs a unique ID. 3288096
28*	Weight of Frozen Tumor Sample	_____ (mg) (0.2 cm ³ (0.6cm * 0.6cm * 0.6cm) ≈ 200mg)	Provide the weight of the tumor sample submitted. Weight can be estimated based on the size of the tumor submitted. 3081946
29*	Tumor Nuclei Percent (%)	_____ (%)	Provide the percent of tumor nuclei for the sample submitted. Check with the BCR to confirm the current acceptable metrics. 2841225
30*	Necrosis Percent (%)	_____ (%)	Provide the percent of necrosis for the sample submitted. Check with the BCR to confirm the current acceptable metrics. 2841237
Shipment/Slide Information			
31*	Type(s) of Slides Submitted	<input type="checkbox"/> Physical Frozen Top Slide <input type="checkbox"/> Digital Frozen 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. Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface 3521909
32*	Slide/Digital Image ID	_____	Provide the slide ID for each slide (physical and digital image) submitted to the BCR. 2321277
Normal Control Information			
The following information must be completed for the normal control sample submitted and should be answered specifically about the submitted control(s). If multiple normal control types are submitted, ALL QUESTIONS should be completed for each sample. If multiple vials of the same normal control are submitted, the "Normal Control Sample Information" must be completed for each vial submitted to the BCR.			
33	Type(s) of Normal Control(s) <i>Check all that apply</i>	<input type="checkbox"/> Whole Blood <input type="checkbox"/> Extracted DNA from Blood or Saliva <input type="checkbox"/> Buffy Coat <input type="checkbox"/> Non-Neoplastic Control Tissue <input type="checkbox"/> Lymphocytes	Indicate the type(s) of normal control(s) submitted for this case. Non-neoplastic control tissue may only be submitted with NCI approval. 3081936
Normal Sample Procurement Information			
34	Date of Normal Control Procurement	_____ <i>Month Day Year</i>	Provide the date of the procedure performed to obtain the normal control submitted. 3288195 (month), 3288196 (day), 3288197 (year)

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#	Question	Entry Alternatives	Working Instructions
35	Method of Normal Control Procurement	<input type="checkbox"/> Blood Draw <input type="checkbox"/> Buccal Swab <input type="checkbox"/> Mouthwash <input type="checkbox"/> Skin Punch <input type="checkbox"/> Surgical Resection <input type="checkbox"/> Other Method (please specify)	Indicate the procedure performed to obtain the normal control sample submitted. 3288147
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 procedure. 3288151
Normal Control Sample Information			
37	Normal Control ID		Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
<i>Extracted DNA from Blood or Saliva: Only complete this section if submitting Extracted DNA from Blood.</i>			
38	Extracted DNA Quantity of Normal Control	_____ (µg)	Provide the quantity (µg) of the normal control sample sent to the BCR. 3288185
39	Extracted DNA Quantification Method of Normal Control	_____	Provide the quantification method of the normal control sample sent to the BCR. 3288186
40	Extracted DNA Concentration of Normal Control	_____ (µg/µL)	Provide the concentration (µg/ µL) of the normal control sample sent to the BCR. 3288187
41	Extracted DNA Volume of Normal Control	_____ (µL)	Provide the volume (µL) of the normal control sample sent to the BCR. 3288188
<i>Non-Neoplastic Control Tissue: Only complete this section if submitting Non-Neoplastic Control Tissue.</i>			
42	Anatomic Site of Non-Neoplastic Control Tissue	<input type="checkbox"/> Gastroesophageal Junction <input type="checkbox"/> Cardia/Proximal <input type="checkbox"/> Fundus/Body <input type="checkbox"/> Antrum/Distal <input type="checkbox"/> Skin <input type="checkbox"/> Other (please specify)	If the normal control type is non-neoplastic tissue, indicate the anatomic site of the non-neoplastic control tissue submitted. 3081938
43	Other Site of Non-Neoplastic Control Tissue	_____	If the normal control type is non-neoplastic tissue, and it is not available in the dropdown list above, provide the site of the tissue submitted. 3288189
44	Is the proximity of the non-neoplastic control tissue > 2cm from the tumor submitted?	<input type="checkbox"/> Distal (>2cm) from the primary tumor	If the normal control type is non-neoplastic tissue, confirm that the submitted tissue was at least 2cm away from the primary tumor. Adjacent (≤ 2cm) tissue is not accepted. If the proximity of the non-neoplastic control tissue from the submitted tumor is unknown, the tissue will be excluded. 3088708
45	Normal Slide or Digital Image Identifier	_____	If the normal control type is non-neoplastic tissue, provide the ID of the slide or digital image of the normal sample submitted.
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. Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection) <i>Please Note: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>			
i*	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the TSS has permission to provide time intervals in lieu of dates.

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#	Question	Entry Alternatives	Working Instructions
ii	Number of Days from Date of Initial Pathological Diagnosis to Date of Pathological Review	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the pathological review performed as part of the submission process 3288497
iii	Number of Days from Date of Initial Pathological Diagnosis to Date of Consent	_____ days	If the patient formally consented, provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the patient's formal consent. 3288498
iv	Number of Days from Date of Initial Pathological Diagnosis to Date of Death	_____ days	If the patient consented by death, provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the patient's death. Note: If the patient formally consented prior to death, do not answer this question only answer the question above that asks for the number of days between the date of diagnosis and the date of the patient consent. 3288499
v	Number of Days from Date of Initial Pathological Diagnosis to Date of Cancer Sample Procurement	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the procedure that produced the malignant sample submitted 3288495
vi	Number of Days from Date of Initial Pathological Diagnosis to Date of Normal Sample Procurement (Whole Blood)	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the procedure that produced the normal control sample submitted 3288496
vii	Number of Days from Date of Initial Pathological Diagnosis to Date of Normal Sample Procurement (Buffy Coat/Lymphocytes)	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the procedure that produced the normal control sample submitted 3288496
viii	Number of Days from Date of Initial Pathological Diagnosis to Date of Normal Sample Procurement (Extracted DNA)	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the procedure that produced the normal control sample submitted 3288496
ix	Number of Days from Date of Initial Pathological Diagnosis to Date of Normal Sample Procurement (Non-Neoplastic Tissue)	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the procedure that produced the normal control sample submitted 3288496

_____/_____/_____
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.