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?	☐ 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?	☐ 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?	☐ 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?	☐ Yes ☐ 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?	☐ Yes ☐ 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.	☐ Macrodissection Performed *(see definition at right)* ☐ Other Pathology Review *(see definition at right)* ☐ Pathology Review for this Project *(see definition at right)*	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. 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 2.) The pathology analysis performed at the TSS determined a specific histological subtype that is different from the original pathology report 3.) The pathology review of the frozen section for this project determined that the histologic subtype is different from the pathology report 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. 3288315
Patient Information			
9*	History of Other Malignancy *(Including ALL Prior and Synchronous Malignancies)*	☐ None ☐ History of Prior Malignancy ☐ History of Synchronous/ Bilateral Malignancy ☐ Both History of Synchronous/ Bilateral and Prior Malignancy	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. 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. 3382736
10*	History of Neoadjuvant Treatment (prior to procurement) of Tumor Submitted	☐ Yes *(see note at right)* ☐ No	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. 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. 3382737
Consent Information			
11*	Consent Status	☐ Formally Consented ☐ Consented by Death ☐ Exemption *(see note at right)* ☐ Waiver *(see note at right)*	Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. Exemptions and waivers for consent must be approved by NCI. 3288361
12	Date of Formal Consent	_____ _____ _____ _____ _____ _____ _____ _____ *Month* *Day* *Year*	If the patient was formally consented, provide the month of consent. 3081955 (month), 3081957 (day), 3081959 (year)
13	Date of Death	_____ _____ _____ _____ _____ _____ _____ _____ *Month* *Day* *Year*	If the patient consented by death (i.e. they did not formally consent), provide the month of death. Do not complete if the patient formally consented. 2897026 (month), 2897028 (day), 2897030 (year)
Demographic Information			
14*	Race	☐ American Indian or Alaska Native ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ Not Evaluated ☐ Unknown	Provide the patient's race using the provided categories, as defined below. **American Indian or Alaska Native:** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. **Asian:** A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. **White:** A person having origins in any of the original peoples of the far Europe, the

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			Middle East, or North Africa. **Black or African American:** 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." **Native Hawaiian or other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. **Not Evaluated** **Unknown** 2192199
15	Ethnicity	☐ Not Hispanic or Latino ☐ Hispanic or Latino ☐ Not Evaluated ☐ Unknown	Provide the patient's ethnicity using the provided categories, defined below: **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Evaluated** **Unknown** 2192217
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	☐ Primary	Indicate the tumor category of the tumor submitted. 3288124
17*	Histologic Diagnosis of Tumor Submitted for TCGA	☐ Stomach Intestinal Adenocarcinoma – Tubular Type ☐ Stomach Intestinal Adenocarcinoma – Papillary Type ☐ Stomach Intestinal Adenocarcinoma – Mucinous Type ☐ Stomach Intestinal Adenocarcinoma – Type NOS ☐ Stomach Adenocarcinoma – Signet Ring Type ☐ Stomach Adenocarcinoma – Diffuse Type ☐ Stomach Adenocarcinoma – NOS	Indicate the histologic subtype of the malignant sample submitted. 3081934
18	Anatomic Organ Sub-Division of Frozen Biospecimen	☐ Gastroesophageal Junction ☐ Cardia/Proximal ☐ Fundus/Body ☐ Antrum/Distal ☐ Stomach (NOS) ☐ Other (please specify)	Indicate the sub-division of the anatomic site of the frozen tumor biospecimen submitted for TCGA. 4132152
19	Other Anatomic Site of Frozen Biospecimen	_____	Indicate the other anatomic site of the frozen tumor submitted for TCGA. 3320289
Tumor Procurement Information			
20*	Date of Tumor Sample Procurement	_____ _____ _____ _____ _____ _____ _____ _____ *Month* *Day* *Year*	Provide the procurement date of the malignancy that yielded the submitted tumor. 3008197 (month), 3008195(day), 3008199 (year)
21*	Shipment Vessel Used	☐ Cryovial ☐ Biospecimen Storage Bag ☐ Cassette ☐ Cryomold ☐ Other Liquid Nitrogen Resistant Container	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR). 3081940

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#	Question	Entry Alternatives	Working Instructions
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	☐ Surgical Resection ☐ Endoscopic Biospy ☐ Excisional Biopsy ☐ 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?	☐ Yes ☐ 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	☐ Physical Frozen Top Slide ☐ Digital Frozen Top Slide Image ☐ Physical FFPE Slide ☐ 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) *Check all that apply*	☐ Whole Blood ☐ Extracted DNA from Blood or Saliva ☐ Buffy Coat ☐ Non-Neoplastic Control Tissue ☐ 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	____ ____ ____ ____ ____ ____ ____ ____ *Month* *Day* *Year*	Provide the date of the procedure performed to obtain the normal control submitted. 3288195 (month), 3288196 (day), 3288197 (year)

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35	Method of Normal Control Procurement	☐ Blood Draw ☐ Buccal Swab ☐ Mouthwash ☐ Skin Punch ☐ Surgical Resection ☐ 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
Extracted DNA from Blood or Saliva: Only complete this section if submitting Extracted DNA from Blood.			
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
Non-Neoplastic Control Tissue: Only complete this section if submitting Non-Neoplastic Control Tissue.			
42	Anatomic Site of Non-Neoplastic Control Tissue	☐ Gastroesophageal Junction ☐ Cardia/Proximal ☐ Fundus/Body ☐ Antrum/Distal ☐ Skin ☐ 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?	☐ 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) 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*	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ 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.