Initial Case Quality Control Form
Breast (BRCA)

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.

#	Question	Entry Alternatives	Working Instructions
Tumor Information: The following sections are to be provided by a Pathologist			
1*	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. 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.
2*	Histologic Subtype of Tumor Submitted for TCGA	☐ Infiltrating Ductal Carcinoma ☐ Infiltrating Lobular Carcinoma ☐ Mucinous Carcinoma ☐ Medullary Carcinoma ☐ Metaplastic Ductal Carcinoma ☐ Infiltrating Carcinoma, NOS ☐ Mixed Histology, specify ☐ Other, specify	Indicate the confirmed diagnosis of the tumor submitted for TCGA. 3081934
3†	Other Diagnosis or Mixed Histology	_____	If the diagnosis of tumor submitted for TCGA is not included in the provided list, specify the diagnosis. 3124492
4*	Tumor Type	☐ Primary *(primary untreated malignant biospecimen)*	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.
5*	Anatomic Organ Sub-Division of Frozen Biospecimen	☐ Right ☐ Left	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. 2008006
6*	Date of Cancer Sample Procurement	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	Provide the date of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008197 (Month), 3008195 (Day), 3008199 (Year)
7	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
8*	Method of Cancer Sample Procurement	☐ Lumpectomy ☐ Simple mastectomy ☐ Modified radical mastectomy ☐ Other method (please specify)	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514
9†	Other Method of Cancer Sample Procurement	_____	If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure. 2006730

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#	Question	Entry Alternatives	Working Instructions
10*	Country Where Cancer Sample was Procured	_____	Provide the country where the tissue submitted for TCGA was procured. 3203072
11*	Race	☐ 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 Middle East, or North Africa.* ☐ Black or African American *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."* ☐ 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: *Not provided or available.* ☐ Unknown: *Could not be determined or unsure.*	Provide the patient's race using the defined categories. 2192199
12	Ethnicity	☐ 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 *Not provided or available.* ☐ Unknown *Could not be determined or unsure.*	Provide the patient's ethnicity using the defined categories. 2192217
13*	Vessel Used	☐ Cryovial ☐ Cassette ☐ Other, specify ☐ Biospecimen Storage Bag ☐ Cryomold	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. 3081940
14†	Other Vessel Used	_____	If the vessel used to ship the tissue to the BCR is not included in the provided list, specify the vessel used. 3288137
15*	Is tumor sample being submitted for macrodissection?	☐ Yes ☐ No	Indicate whether the tumor sample submitted to the BCR is intended to undergo macrodissection after the BCR receives the sample. 3288488
16*	Was sample prescreened at site?	☐ Yes ☐ No	Indicate whether the sample submitted to the BCR was prescreened at the TSS. 3081942
Tumor Slides Submitted			
17*	Types of Slides Submitted	☐ Physical Top Slide ☐ Digital Top Slide Image ☐ Physical FFPE Slide ☐ Digital FFPE Slide Image	Indicate the type(s) of slide(s) submitted to the BCR. TBD Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface

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#	Question	Entry Alternatives	Working Instructions
18*	Slide/Digital Image ID #	_____	Provide the slide ID for each slide (physical and digital image) submitted to the BCR. 2321277
Tumor 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.			
19*	Tumor Identifier	_____	Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. 3288096
20*	Weight of Frozen Tumor	_____(mg) *(0.2cm³ (0.6cm * 0.6cm * 0.6cm) = ~200mg*	Provide the weight of the tumor sample submitted for TCGA. 3081946 Weight can be estimated based on the size of the tumor submitted.
21*	Tumor Nuclei %	_____ (%)	Provide the percent of tumor nuclei for the sample submitted for TCGA. 2841225 Check with the BCR to confirm the current acceptable TCGA metrics.
22*	Necrosis %	_____ (%)	Provide the percent of necrosis for the sample submitted for TCGA. 2841237 Check with the BCR to confirm the current acceptable TCGA metrics.
Normal Information A normal control must be present to qualify.			
23*	Type(s) of Normal Control *Check all that apply*	☐ Whole Blood ☐ Buffy Coat ☐ Lymphocytes ☐ Extracted DNA from Blood ☐ Non-Neoplastic Control Tissue*	Indicate the type of normal control submitted for this case. 3081936 *Non-neoplastic Control Tissue may only be submitted with NCI approval.
Normal Control: Whole Blood			
24†	Method of Normal Sample Procurement	☐ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
25†	Date of Normal Sample Procurement	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	Indicate the date of the procedure performed to obtain the normal control sample submitted for TCGA. 3288195 (Month), 3288196 (Day), 3288197 (Year)
26	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
27†	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			
28†	Normal Control Type	☐ Buffy Coat ☐ Lymphocytes	Indicate the type of normal control submitted for TCGA. 3081936

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#	Question	Entry Alternatives	Working Instructions
29†	Method of Normal Sample Procurement	☐ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
30†	Date of Normal Sample Procurement	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	Indicate the date of the procedure performed to obtain the normal control sample submitted for TCGA. 3288195 (Month), 3288196 (Day), 3288197 (Year)
31	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
32†	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			
33†	Method of Normal Sample Procurement	☐ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
34†	Date of Normal Sample Procurement	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	Indicate the date of the procedure performed to obtain the normal control sample submitted for TCGA. 3288195 (Month), 3288196 (Day), 3288197 (Year)
35	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
36†	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
37†	Extracted DNA Quantity	_____(µg)	Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. 3288185
38†	Extracted DNA Quantification Method	_____	Provide the quantification method of the normal control sample sent to the BCR for TCGA. 3288186
39†	Extracted DNA Concentration	_____(µg/µL)	Provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA. 3288187
40†	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			
41†	Method of Normal Sample Procurement	☐ Surgical Resection ☐ Other Method (please specify)	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147

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#	Question	Entry Alternatives	Working Instructions
42	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
43†	Date of Normal Sample Procurement	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	Indicate the date of the procedure performed to obtain the normal control sample submitted for TCGA. 3288195 (Month), 3288196 (Day), 3288197 (Year)
44	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
45†	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
46†	Anatomic Site of Non-Neoplastic Control Tissue	☐Right Breast ☐Left Breast ☐Lymph Nodes ☐ Other (please specify)	If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. 3081938
47	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
48†	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. 3088708 **Adjacent (≤ 2cm) Normal Tissue** is not accepted for this tissue type. **Unknown Normal Tissue** is not acceptable for this tissue type.
49†	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.

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.

50*	Name of Pathologist	_____	Provide the name of the Pathologist that provided the information for all previous sections. 3288225

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#	Question	Entry Alternatives	Working Instructions
51*	Date of Pathologist Review	_____	Provide the date of the pathology review performed by the TSS pathologist above. 3288224
52	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
Principal Investigator/Authorized Designee Confirmation			
53*	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. 3288520 Check with the BCR to confirm the current acceptable TCGA metrics.
54*	Percent Necrosis meets TCGA metrics?	☐ Yes ☐ No	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. 3288524 Check with the BCR to confirm the current acceptable TCGA metrics.
55*	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. 3288292
56*	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	Confirm that the diagnosis provided on this CQCF for the tumor sample being submitted to TCGA is consistent with the diagnosis found on the patient's pathology report for the tumor being sent to the BCR. 3288300 If "yes," skip related question below. The diagnosis is considered to be consistent if at least one of the following criteria are met: 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
57†	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	☐ Macrodissection performed at TSS to select for a region containing an acceptable TCGA diagnosis *(see note at right)* ☐ Pathology analysis at TSS determined a specific histological subtype different from original pathology report *(see note at right)* ☐ Pathology review of frozen section for TCGA determined histological subtype different from the pathology report *(see note at right)*	If the diagnosis provided on this form is not consistent with the diagnosis found on the pathology report provided, specify a reason for this inconsistency. 3288315 If a TSS pathology review of the TCGA committed sample resulted in a different histological subtype than what is documented on the original pathology report, an amendment to the pathology report should be submitted when the sample is shipped to the BCR; or in the absence of an amended pathology report, the TSS must complete and submit an electronic copy of the "TCGA Pathologic Diagnosis Discrepancy Form". In the case of diagnosis modifications, institution protocol should be followed for proper quality assurance.
58*	History of Other Malignancy	☐ 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. 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 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.
59*	History of Neoadjuvant Treatment ***for Tumor Submitted for TCGA***	☐ None ☐ Radiation prior to sample procurement* ☐ Pharmaceutical treatment prior to sample procurement* ☐ Both pharmaceutical treatment and radiation prior to sample procurement*	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 *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.
60*	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			
61†	Date of Consent	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	If the patient was formally consented, provide the date of consent. 3081955 (Month), 3081957 (Day), 3081959 (Year)
62	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
Date of Death Do not complete date of death, if patient formally consented.			
63†	Date of Death	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	If the patient consented by death, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)

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#	Question	Entry Alternatives	Working Instructions
64	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

_____ _____ ___ ___/ ___ ___/ ___ ___ ___ ___

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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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.