

# Sample Submission Form

## Breast Carcinoma (BRCA)

The Sample Submission Form (SSF) should be completed for every case sent to the Biospecimen Core Resource (BCR). This form covers the submission of a single tumor sample and a normal germline sample for the same patient. If additional samples are submitted to the BCR (including metastatic or recurrent tumor samples), a subsequent copy of this form is required for each additional sample.

*Note: This form also includes a section for peritumoral samples that may be submitted in addition to the tumor and germline samples. Peritumoral samples are not required, but are allowable if a normal germline control is also submitted to the BCR.*

### Spreadsheet Submissions

If a BCR-created spreadsheet is being completed in lieu of the electronic form(s) in OpenClinica, please reference this document to accurately map the information from the Tissue Source Site's (TSS) database to the spreadsheet. A BCR-formatted spreadsheet must be submitted if OpenClinica is not used; the BCR will not be able to accept a generic Excel file of the data. The BCR-created spreadsheet is in Excel, and includes allowable (registered) answers for your reference. Each question is registered with the Cancer Data Standards Registry and Repository (caDSR) and is assigned a Common Data Element (CDE) number (listed in column "R" on the Sample Submission Spreadsheet).

Please note that each column in the spreadsheet represents a single SSF and should be completed for each tumor sample submitted to the BCR. If multiple tumor samples are submitted for the same patient, additional columns should be completed for subsequent tumors. If multiple aliquots of the same sample are submitted, additional rows can be added for each aliquot by clicking on the "+" symbol in the far left margin of the spreadsheet. All indicated questions must be completed for each aliquot in order to track the aliquots separately.

*Disclaimer: Submitting TSSs acknowledge that the BCR may confirm that the diagnosis of the 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 pathology findings to the TSS by means of a formal report in confidential email format for the quality assurance program of the TSS to address.*

### Verification Requirements

The following questions should be answered to confirm the submitted cases meet basic requirements for this project.

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
1	N/A	TSS Patient Identifier		A unique patient identifier assigned by the TSS submitting the sample. This ID should be used to link the case identifier(s) for this project to something the TSS can use to locate information for the patient. This ID will not be released to external institutions.
2	2660030	Sex of Patient	<input type="checkbox"/> Male <input type="checkbox"/> Female	The biological sex of the patient.
3	3288361	Consent Status	<input type="checkbox"/> Formally Consented <input type="checkbox"/> Consented by Death <input type="checkbox"/> Exemption <input type="checkbox"/> Waiver <input type="checkbox"/> Unknown	Indicates whether the patient was formally consented or if the submitting institution did not receive consent due to a waiver, exemption, or the patient's death.
4*	3081955 3081957 3081959	Date of Formal Consent	Month: ____ ____ Day: ____ ____ Year: ____ ____ ____	The date the patient was formally consented to participate in a research study.

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
5*	2897026 2897028 2897030	Date of Death	Month: ____ ____ Day: ____ ____ Year: ____ ____ ____	The date the patient died. This should only be provided if the patient was not formally consented, but was instead consented by death.
6	3382736	History of Prior or Synchronous Malignancies	<input type="checkbox"/> None <input type="checkbox"/> Prior Malignancy <input type="checkbox"/> Synchronous Malignancy <input type="checkbox"/> Prior and Synchronous Malignancies	Indicates whether the patient had a malignancy diagnosed prior to or at the same time as the tumor submitted to the BCR. <b>TSSs must complete the Other Malignancy section for patients with prior or synchronous malignancies to determine whether the case is eligible for this project.</b>
7	3382737	Pre-Operative Treatment for Submitted Sample (Prior to Sample Procurement) <i>Pharmaceutical therapy includes chemotherapy, immunotherapy, targeted therapy, and hormone therapy.</i>	<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	Indicates whether the patient had prior treatment (radiation or pharmaceutical therapy), given to treat the tumor that yielded the sample submitted to the BCR. This treatment would have been administered prior to the procurement of the tumor. <b>TSSs will be contacted regarding any patient with a history of prior treatment to ensure the prior treatment is not exclusionary.</b>
8	3288225	Name of Pathologist who Performed the Prescreen Review of Submitted Slide		The name of the TSS pathologist who performed the pathologic pre-screen review to determine whether the case was eligible for this project.
9*	3462941 3462917 3462960	Date of Pathologist Prescreen Review	Month: ____ ____ Day: ____ ____ Year: ____ ____ ____	The date the TSS pathologist performed the pathologic prescreen review.
<b>Please submit a de-identified copy of the patient's diagnostic pathology report.</b>				
10	3288300	Is the histologic diagnosis on the Sample Submission Form (as determined by the TSS pathology prescreen review of the submitted slide) consistent with the histology listed on the submitted original diagnostic pathology report?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicates whether the histologic diagnosis included on the submitted pathology report is consistent with the histologic diagnosis selected on this form. <b>If the diagnosis determined during the TSS prescreen review is inconsistent with the diagnosis on the pathology report, the submitting site should submit a Pathologic Diagnosis Discrepancy Form, which is provided by the BCR.</b>
11	3288315	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 <input type="checkbox"/> Other Pathology Review <input type="checkbox"/> Pathology Review for this Project	Provides a reason for inconsistency if there is a discrepancy between the histologic diagnosis on the submitted pathology report and the diagnosis selected on this form. The allowable reasons are listed below: <b>Macrodissection Performed:</b> The inconsistency was caused because macrodissection was performed at the TSS to select a region containing an acceptable diagnosis, and the sample histological subtype of the resulting sample was different from the original pathology report. <b>Other Pathology Review:</b> Pathology analysis not related to the pathologic prescreen review determined a specific histological subtype that is different from the original pathology report. <b>Pathology Review for this Project:</b> The pathologic prescreen review for this project determined that the histologic subtype is different from the pathology report.

### Tumor Information

The following questions regarding the submitted tumor sample(s) should be completed for each of the submitted tumor samples. If multiple aliquots of the same tumor are submitted, the specified questions should be answered for each aliquot. This section also includes information regarding the digital or physical slides submitted to the BCR. If multiple slides or images are selected, these questions should be completed for each submitted slide or image.

**Requirements for Submissions of Multiple Tumor Samples for a Single Patient:** If more than one tumor sample is submitted, this form should be completed for each subsequent sample. If a spreadsheet is being completed, an additional column should be added for each subsequent sample.

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
12	3288124	Tumor Category	<input type="checkbox"/> Primary <input type="checkbox"/> Metastatic <input type="checkbox"/> Recurrent <input type="checkbox"/> Additional Primary	The type of tumor being submitted. All cases must include a primary tumor for this project. A subsequent SSF in OpenClinica or an additional column in the BCR-created spreadsheet should be completed for each sample sent in addition to the primary tumor.
13	3081934	Histological Subtype	<input type="checkbox"/> Infiltrating Ductal Carcinoma <input type="checkbox"/> Infiltrating Lobular Carcinoma <input type="checkbox"/> Infiltrating Carcinoma NOS <input type="checkbox"/> Mucinous Carcinoma <input type="checkbox"/> Medullary Carcinoma <input type="checkbox"/> Metaplastic Carcinoma <input type="checkbox"/> Mixed Histology (Please Specify) <input type="checkbox"/> Other Histology (Please Specify)	The histologic type of the submitted tumor that was determined by the TSS pathologic prescreen review.
14	3124492	Other or Mixed Histologic Subtype		The specific histologic diagnosis not included in the provided list.
15	4742851	Anatomic Site of Submitted Sample	<input type="checkbox"/> Breast <input type="checkbox"/> Other (Please Specify)	The site of the specific sample submitted to the BCR. If the tumor that yielded the sample sent to the BCR included multiple sites of disease, indicate only the site of the specific sample sent to the BCR for this project.
16	4742871	Other Anatomic Site of Submitted Sample		The site of the submitted sample if it was not included in the list provided.
17	4742918	Region of the Submitted Sample (select all that apply)	<input type="checkbox"/> Upper Inner Quadrant <input type="checkbox"/> Upper Outer Quadrant <input type="checkbox"/> Lower Inner Quadrant <input type="checkbox"/> Lower Outer Quadrant	The specific region of the submitted sample.
18	4742852	Laterality (If applicable)	<input type="checkbox"/> Left <input type="checkbox"/> Right	If applicable, indicate the laterality of the submitted sample.
19*	2896956 2896958 2896960	Date of Initial Pathologic Diagnosis of Primary Tumor	Month: ____ Day: ____ Year: ____	The date the tumor that yielded the submitted sample was initially diagnosed pathologically.
20	2757941	Method of Initial Pathologic Diagnosis	<input type="checkbox"/> Lumpectomy <input type="checkbox"/> Simple Mastectomy <input type="checkbox"/> Modified Radical Mastectomy <input type="checkbox"/> Biopsy (all types) <input type="checkbox"/> Other Surgical Resection (Please Specify)	The procedure performed to procure the sample used for the initial pathologic diagnosis.

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
21	2757948	Other Method of Initial Pathologic Diagnosis		The procedure performed to procure the sample used for initial pathologic diagnosis not included in the provided list.
22*	3008197 3008195 3008199	Date of Cancer Sample Procurement	Month: ____ Day: ____ Year: _____	The date the submitted sample was removed from the patient.
23	3103514	Method of Cancer Sample Procurement	<input type="checkbox"/> Lumpectomy <input type="checkbox"/> Simple Mastectomy <input type="checkbox"/> Modified Radical Mastectomy <input type="checkbox"/> Biopsy (all types) <input type="checkbox"/> Other Surgical Resection	The type of procedure that yielded the sample submitted to the BCR.
24	3152016	Country Where Cancer Sample was Procured	<i>See the BCR spreadsheet or OpenClinica for a complete list of allowable values.</i>	The country where the procedure that yielded the sample submitted to the BCR was performed.

**Tumor Sample Information**

The following questions should be completed for each aliquot submitted. If a spreadsheet is being completed, additional rows can be added for each aliquot by clicking on the “+” symbol in the far left margin of the spreadsheet.

**Requirements for Tumor Pathology Metrics:** A minimum of 60% tumor nuclei and maximum of 20% necrosis are allowed. At this time, Formalin Fixed Paraffin Embedded (FFPE) or Frozen Tissue is required.

25	26	27	28	29	30	31
3288096	3812626	5120693	3081946	2841225	2841237	3081940
Tumor Identifier	Tumor Sample Type	Preservation Method	Sample Weight (mg)	Tumor Nuclei %	Tumor Necrosis %	Shipment Vessel Used
The ID on the physical tumor sample submitted to the BCR. Each individual aliquot should have a unique ID.	Indicates whether the physical tumor sample submitted was provided as a portion cut from a larger piece of tumor, a FFPE block, scrolls cut from a FFPE block, or an unstained slide.	The method used to preserve the sample.	The weight of the submitted tumor. The weight can be estimated based on the measurement of the tumor. (Example: 0.2cm <sup>3</sup> (0.6cm * 0.6cm * 0.6cm) = ~200mg).	The percent nuclei as determined by the TSS pre-screen pathology review.	The percent necrosis as determined by the TSS pre-screen pathology review.	The vessel used for the shipment of the submitted sample to the BCR.
	<input type="checkbox"/> Portion <input type="checkbox"/> Block <input type="checkbox"/> Scroll <input type="checkbox"/> Unstained Slide	<input type="checkbox"/> FFPE <input type="checkbox"/> Frozen				<input type="checkbox"/> Cryovial <input type="checkbox"/> Biospecimen Storage Bag <input type="checkbox"/> Cassette <input type="checkbox"/> Cryomold <input type="checkbox"/> Other
	<input type="checkbox"/> Portion <input type="checkbox"/> Block <input type="checkbox"/> Scroll <input type="checkbox"/> Unstained Slide	<input type="checkbox"/> FFPE <input type="checkbox"/> Frozen				<input type="checkbox"/> Cryovial <input type="checkbox"/> Biospecimen Storage Bag <input type="checkbox"/> Cassette <input type="checkbox"/> Cryomold <input type="checkbox"/> Other

\*If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the “Time Interval” section of the addendum on page 12.

**Slide Information**

The following questions should be completed for each slide submitted. If multiple slides are submitted, every slide should have its own identifier.

If a spreadsheet is being completed, additional rows can be added for each slide by clicking on the “+” symbol in the far left margin of the spreadsheet.

32	33
3521909	2321277
Type(s) of Slides Submitted (select only one for each ID)	Slide or Digital Image ID
The type of slide submitted, which includes both the preservation method and format of the slide. This question should be answered for each tumor slide submitted.	The identifier for the slide or digital image provided to the BCR.
<input type="checkbox"/> Physical Slide - Frozen Top Slide <input type="checkbox"/> Digital Slide Image - Frozen Top Slide <input type="checkbox"/> Physical Slide - FFPE Top Slide <input type="checkbox"/> Digital Slide Image - FFPE Top Slide <input type="checkbox"/> Physical Slide - FFPE Diagnostic Slide <input type="checkbox"/> Digital Slide Image - FFPE Diagnostic Slide	
<input type="checkbox"/> Physical Slide - Frozen Top Slide <input type="checkbox"/> Digital Slide Image - Frozen Top Slide <input type="checkbox"/> Physical Slide - FFPE Top Slide <input type="checkbox"/> Digital Slide Image - FFPE Top Slide <input type="checkbox"/> Physical Slide - FFPE Diagnostic Slide <input type="checkbox"/> Digital Slide Image - FFPE Diagnostic Slide	
<input type="checkbox"/> Physical Slide - Frozen Top Slide <input type="checkbox"/> Digital Slide Image - Frozen Top Slide <input type="checkbox"/> Physical Slide - FFPE Top Slid <input type="checkbox"/> Digital Slide Image - FFPE Top Slide <input type="checkbox"/> Physical Slide - FFPE Diagnostic Slide <input type="checkbox"/> Digital Slide Image - FFPE Diagnostic Slide	

**Germline Control Information**

The following questions regarding the submitted germline control sample(s) should be completed for each individual sample submitted.

**Requirements for Germline Control Submissions:** At this time a blood derived normal is required.

**Germline Control Sample Information – Whole Blood, Buffy Coat or Lymphocytes**

The following questions should be completed for each submitted germline control that contains whole blood, buffy coat, or lymphocytes.

**Requirements for Whole Blood Submissions:** A minimum of 5-10mL of whole blood is required.

**Requirements for Lymphocyte Submissions:** A minimum of 10<sup>6</sup> lymphocytes are required.

If multiple aliquots are submitted, each aliquot should have a unique identifier and the appropriate questions should be answered for each of the aliquots. If a spreadsheet is being completed, additional rows can be added for each aliquot by clicking on the “+” symbol in the far left margin of the spreadsheet.

33	34	35*	36
3081936	3288147	3288195, 3288196, 3288197	3288138
Normal Control Type	Method of Normal Sample Procurement	Date of Normal Sample Procurement	Normal Identifier
Indicate the type of normal control submitted.	The type of procedure that yielded the germline control sample submitted to the BCR.	The date the submitted germline control sample was removed from the patient.	An identifier assigned by the TSS to indicate a unique aliquot of a germline control sample.
<input type="checkbox"/> Whole Blood <input type="checkbox"/> Buffy Coat <input type="checkbox"/> Lymphocytes	<input type="checkbox"/> Blood Draw	Month: ____ Day: ____ Year: ____	
<input type="checkbox"/> Whole Blood <input type="checkbox"/> Buffy Coat <input type="checkbox"/> Lymphocytes	<input type="checkbox"/> Blood Draw	Month: ____ Day: ____ Year: ____	

\*If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the “Time Interval” section of the addendum on page 12.

**Germline Control Sample Information – Extracted DNA from Whole Blood or Buccal Cells**

The following questions should be completed for each submitted germline control that contains extracted DNA.

If multiple aliquots are submitted, each aliquot should have a unique identifier and the appropriate questions should be answered for each of the aliquots. If a spreadsheet is being completed, additional rows can be added for each aliquot by clicking on the “+” symbol in the far left margin of the spreadsheet.

**Requirements for Extracted DNA:** A minimum of 6-10 µg of DNA is required.

37	38	39*	40	41	42	43	44
3081936	3288147	3288195, 3288196, 3288197	3288138	3288185	3288186	3288187	3288188
Normal Control Type	Method of Normal Sample Procurement	Date of Normal Sample Procurement	Normal Identifier	Extracted DNA Quantity (µg)	Extracted DNA Quantification Method	Extracted DNA Concentration (µg/µL)	Extracted DNA Volume (µL)
Indicate the type of normal control submitted.	The type of procedure that yielded the germline control sample submitted to the BCR.	The date the submitted germline control sample was removed from the patient.	An identifier assigned by the TSS to indicate a unique aliquot of a germline control sample.	The quantity of DNA submitted to the BCR.	The quantification method of DNA submitted to the BCR.	The concentration of DNA submitted to the BCR.	The volume of DNA submitted to the BCR.
<input type="checkbox"/> Extracted DNA from Blood <input type="checkbox"/> Extracted DNA from Buccal Cells	<input type="checkbox"/> Blood Draw <input type="checkbox"/> Buccal Swab <input type="checkbox"/> Mouthwash	Month: ____ Day: ____ Year: _____					
<input type="checkbox"/> Extracted DNA from Blood <input type="checkbox"/> Extracted DNA from Buccal Cells	<input type="checkbox"/> Blood Draw <input type="checkbox"/> Buccal Swab <input type="checkbox"/> Mouthwash	Month: ____ Day: ____ Year: _____					
<input type="checkbox"/> Extracted DNA from Blood <input type="checkbox"/> Extracted DNA from Buccal Cells	<input type="checkbox"/> Blood Draw <input type="checkbox"/> Buccal Swab <input type="checkbox"/> Mouthwash <input type="checkbox"/>	Month: ____ Day: ____ Year: _____					

**Germline Control Sample Information – Non-Neoplastic Tissue**

The following questions should be completed for each submitted germline control.

If multiple aliquots are submitted, each aliquot should have a unique identifier and the appropriate questions should be answered for each of the aliquots. If a spreadsheet is being completed, additional rows can be added for each aliquot by clicking on the “+” symbol in the far left margin of the spreadsheet.

**Requirements for Non-Neoplastic Tissue:** Anatomic site of uninvolved normal tissue should be distal (greater than 2cm) from the primary tumor. Currently, non-neoplastic tissue can only be submitted with prior permission from the CCG Program Office.

\*If time intervals are being provided in lieu of dates (month and year at a minimum), these questions can be found in the “Time Interval” section of the addendum on page 12.

45	46	47*	48	49	50	51	52	53
3081936	3288147	3288195 3288196 3288197	5119191	3288138	3288217	4132152	3288189	5118539
Normal Control Type	Method of Normal Sample Procurement	Date of Normal Sample Procurement	Preservation Method	Normal Identifier	Slide or Digital Image ID	Anatomic Site	Other Anatomic Site	Laterality (if applicable)
Indicate the type of normal control submitted.	The type of procedure that yielded the germline control sample submitted to the BCR.	The date the submitted germline control sample was removed from the patient.	The method used to preserve the sample.	An identifier assigned by the TSS to indicate a unique aliquot of a germline control.	The unique identifier assigned to each normal slide/image by the TSS.	The anatomic site of the submitted germline control sample.	The site of the submitted germline control sample if it was not included in the list provided.	The laterality of the submitted germline control sample, if applicable.
<input type="checkbox"/> Non-Neoplastic Tissue	<input type="checkbox"/> Lumpectomy <input type="checkbox"/> Simple Mastectomy <input type="checkbox"/> Modified Radical Mastectomy <input type="checkbox"/> Biopsy (all types) <input type="checkbox"/> Other Surgical Resection	Month: ____ Day: ____ Year: _____	<input type="checkbox"/> FFPE <input type="checkbox"/> Frozen			<input type="checkbox"/> Breast <input type="checkbox"/> Spleen <input type="checkbox"/> Lymph Node(s) <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Left <input type="checkbox"/> Right
<input type="checkbox"/> Non-Neoplastic Tissue	<input type="checkbox"/> Lumpectomy <input type="checkbox"/> Simple Mastectomy <input type="checkbox"/> Modified Radical Mastectomy <input type="checkbox"/> Biopsy (all types) <input type="checkbox"/> Other Surgical Resection	Month: ____ Day: ____ Year: _____	<input type="checkbox"/> FFPE <input type="checkbox"/> Frozen			<input type="checkbox"/> Breast <input type="checkbox"/> Spleen <input type="checkbox"/> Lymph Node(s) <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Left <input type="checkbox"/> Right
<input type="checkbox"/> Non-Neoplastic Tissue	<input type="checkbox"/> Lumpectomy <input type="checkbox"/> Simple Mastectomy <input type="checkbox"/> Modified Radical Mastectomy <input type="checkbox"/> Biopsy (all types) <input type="checkbox"/> Other Surgical Resection	Month: ____ Day: ____ Year: _____	<input type="checkbox"/> FFPE <input type="checkbox"/> Frozen			<input type="checkbox"/> Kidney <input type="checkbox"/> Spleen <input type="checkbox"/> Lymph Node(s) <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Left <input type="checkbox"/> Right

**Peritumoral Tissue Information**

The following questions regarding the submitted peritumoral tissue sample(s) should be completed for each of the submitted peritumoral samples. If more than one peritumoral sample is submitted, this form should be completed for each of the samples.

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
51	5085114	Method of Peritumoral Sample Procurement	<input type="checkbox"/> Lumpectomy <input type="checkbox"/> Simple Mastectomy <input type="checkbox"/> Modified Radical Mastectomy <input type="checkbox"/> Biopsy (all types) <input type="checkbox"/> Other Surgical Resection	The type of procedure that yielded the peritumoral tissue sample submitted to the BCR.
52*	5085116 5085115 5085117	Date of Peritumoral Sample Procurement	Month: ____ Day: ____ Year: _____	The date the submitted peritumoral tissue sample was removed from the patient.

**Peritumoral Tissue Sample Information**

The following questions should be completed for each aliquot submitted. If multiple aliquots are submitted, each aliquot should have a unique identifier and the appropriate questions should be answered for each of the aliquots. This should only be completed if peritumoral tissue is submitted to the BCR in addition to a germline control.

If a spreadsheet is being completed, additional rows can be added for each aliquot by clicking on the “+” symbol in the far left margin of the spreadsheet.

53	54	55	56	57	58	59
5085118	5085119	4634873	5118535	4633535	5118531	4633536
Peritumoral ID	Peritumoral Slide or Digital Image ID	Peritumoral Sample Type	Preservation Method	Anatomic Site of Peritumoral Tissue	Other Anatomic Site of Peritumoral Tissue	Laterality of the Peritumoral Tissue
The ID on the peritumoral sample submitted to the BCR. Each individual aliquot should have a unique ID.	The unique identifier assigned to each peritumoral slide by the TSS.	The type of peritumoral sample submitted.	The method used to preserve the sample.	The anatomic site of the submitted peritumoral sample.	The site of the submitted peritumoral sample if it was not included in the list provided.	If applicable, indicate the laterality of the submitted peritumoral tissue sample.
		<input type="checkbox"/> Portion <input type="checkbox"/> Block <input type="checkbox"/> Scroll <input type="checkbox"/> Unstained Slide	<input type="checkbox"/> FFPE <input type="checkbox"/> Frozen	<input type="checkbox"/> Breast <input type="checkbox"/> Other (Please Specify)		<input type="checkbox"/> Left <input type="checkbox"/> Right

**Other Malignancies (Including Prior or Synchronous Malignancies)**

The following questions are relevant only for cases where the patient had a history of malignancies diagnosed prior to or at the same time the submitted primary tumor was diagnosed. If multiple other prior or synchronous diagnoses occurred, the questions below should be completed for each malignancy. However, if the patient had multiple diagnoses of basal or squamous cell skin cancer, the following questions are only required for the initial diagnosis of each of these types of skin cancer.

If question number 6 on this form was answered “yes”, this section should be completed for each of the patient’s prior or synchronous malignancies.

If a spreadsheet is being completed, additional rows can be added for each malignancy by clicking on the “+” symbol in the far left margin of the spreadsheet.

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions	
60	3182890	Type of Other Malignancy	<input type="checkbox"/> Prior <input type="checkbox"/> Synchronous	Indicates whether the patient had a malignancy diagnosed prior to or at the same time as the malignancy that yielded the tumor sample submitted to the BCR.	
61	2735776	Primary Site of Other Malignancy	<i>See the BCR spreadsheet or OpenClinica for a complete list of sites.</i>	The primary site of the other malignancy. <b>If a prior malignancy occurred in the same location as the tumor that yielded the sample submitted, the case will be excluded from the project.</b>	
62	2584114	Other Primary Site of Other Malignancy		The site of the other malignancy if it was not included in the list provided.	
63	4122391	Laterality of the Other Malignancy	<input type="checkbox"/> Left <input type="checkbox"/> Right <input type="checkbox"/> Bilateral	<input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown	The laterality of the other malignancy.
64	4122411	Histological Type of the Other Malignancy	<i>See the BCR spreadsheet or OpenClinica for a complete list of histologies.</i>	The histology of the other malignancy.	
65	3124492	Other Histological Type of the Other Malignancy		The histology of the other malignancy if it was not included in the list provided.	

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
66*	3462297 3462298 3462299	Date of Initial Diagnosis of the Other Malignancy	Month: ____ ____ Day: ____ ____ Year: ____ ____ ____	The date the other malignancy was pathologically diagnosed.
67	3186538	Did the patient have surgery for the other malignancy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether the patient had surgery for the other malignancy.
68	3462300	Type of Surgery for the Other Malignancy		The type of surgery performed to treat or diagnose the other malignancy.
69*	2896963 2896965 2896985	Date of Surgical Resection for the Other Malignancy	Month: ____ ____ Day: ____ ____ Year: ____ ____ ____	The date of the surgery was performed to treat or diagnose the other malignancy.
70	3178327	Did the patient have pharmaceutical therapy for the other malignancy? <i>If the answer is "yes" or "unknown", the case will be excluded from the project.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether the patient received pharmaceutical therapy (including chemotherapy, hormone therapy, immunotherapy, targeted therapy and any other type of pharmaceutical treatment) to treat the other malignancy.
71	3178365	Extent of Pharmaceutical Therapy for the Other Malignancy	<input type="checkbox"/> Locoregional <input type="checkbox"/> Systemic <input type="checkbox"/> Unknown	Describes the extent of therapy, which can be locoregional (specific to the region of the other malignancy) or systemic.
72	2975232	Drug Names		The type of pharmaceutical drug(s) the patient received to treat the other malignancy.
73*	3103072 3103070 3103074	Date Pharmaceutical Therapy Started for the Other Malignancy	Month: ____ ____ Day: ____ ____ Year: ____ ____ ____	The date the patient started receiving pharmaceutical therapy for the other malignancy.
74	3178328	Did Patient Receive Radiation Therapy for the other Malignancy? <i>If the answer is "unknown", the case will be excluded from the project.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether the patient received radiation therapy for the other malignancy.
75	3178353	Extent of Radiation Therapy for the Other Malignancy <i>If the answer to this question is "systemic" or "unknown", the case will be excluded from the project.</i>	<input type="checkbox"/> Locoregional <input type="checkbox"/> Systemic <input type="checkbox"/> Unknown	Describes the extent of therapy, which can be locoregional (specific to the region of the other malignancy) or systemic.
76	2865132	If the patient received locoregional radiation, was the radiation therapy given to the same field as the tumor submitted for this project? <i>If the answer is "yes" or "unknown", the case will be excluded from the project.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicates whether the radiation for the other malignancy was given to the site of the tumor that yielded the sample submitted to the BCR.

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
77*	2897100 2897102 2897104	Date Radiation Therapy Started for the Other Malignancy	Month: ____ ____ Day: ____ ____ Year: ____ ____ ____	The date the radiation therapy for the other malignancy began.
78	3114049	FIGO Staging System (Gynecologic Tumors Only) for the Other Malignancy (if applicable)	<input type="checkbox"/> 1988 <input type="checkbox"/> 1995 (cervical only) <input type="checkbox"/> 2009	If applicable, the staging system used for gynecologic tumors staged using the FIGO system.
79	3225684	FIGO Stage for the Other Malignancy (if applicable)	<input type="checkbox"/> Stage I <input type="checkbox"/> Stage IA <input type="checkbox"/> Stage IA1 <input type="checkbox"/> Stage IA2 <input type="checkbox"/> Stage IB <input type="checkbox"/> Stage IB1 <input type="checkbox"/> Stage IB2 <input type="checkbox"/> Stage IC <input type="checkbox"/> Stage II <input type="checkbox"/> Stage IIA <input type="checkbox"/> Stage IIB <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IIIA <input type="checkbox"/> Stage IIIB <input type="checkbox"/> Stage IIIC <input type="checkbox"/> Stage IIIC1 <input type="checkbox"/> Stage IIIC2 <input type="checkbox"/> Stage IV <input type="checkbox"/> Stage IVA <input type="checkbox"/> Stage IVB	If applicable, the patient's stage using the FIGO system.
80	2722309	AJCC Cancer Staging Edition for the Other Malignancy	<input type="checkbox"/> 1 <sup>st</sup> Edition (1978-1983) <input type="checkbox"/> 2 <sup>nd</sup> Edition (1984-1988) <input type="checkbox"/> 3 <sup>rd</sup> Edition (1989-1992) <input type="checkbox"/> 4 <sup>th</sup> Edition (1993-1997) <input type="checkbox"/> 5 <sup>th</sup> Edition (1998-2002) <input type="checkbox"/> 6 <sup>th</sup> Edition (2003-2009) <input type="checkbox"/> 7 <sup>th</sup> Edition (2010-present)	If applicable, the staging edition used for tumors staged using the AJCC criteria. Edition should correspond to year of diagnosis.
81	3045435	Pathologic Spread: Primary Tumor (pT) for the Other Malignancy	<input type="checkbox"/> TX <input type="checkbox"/> T0 <input type="checkbox"/> Tis <input type="checkbox"/> Tis (DCIS) <input type="checkbox"/> Tis (LCIS) <input type="checkbox"/> Tis (Paget's) <input type="checkbox"/> Ta <input type="checkbox"/> T1 <input type="checkbox"/> T1mi <input type="checkbox"/> T1a <input type="checkbox"/> T1a1 <input type="checkbox"/> T1a2 <input type="checkbox"/> T1b <input type="checkbox"/> T1b1 <input type="checkbox"/> T1b2 <input type="checkbox"/> T1c <input type="checkbox"/> T2 <input type="checkbox"/> T2a <input type="checkbox"/> T2a1 <input type="checkbox"/> T2a2 <input type="checkbox"/> T2b <input type="checkbox"/> T3 <input type="checkbox"/> T3a <input type="checkbox"/> T3b <input type="checkbox"/> T4 <input type="checkbox"/> T4a <input type="checkbox"/> T4b <input type="checkbox"/> T4c <input type="checkbox"/> T4d	If applicable, the patient's pathologic tumor spread as defined by the AJCC primary tumor descriptions (pT).
82	3203106	Pathologic Spread: Lymph Nodes (pN) for the Other Malignancy	<input type="checkbox"/> NX <input type="checkbox"/> N0 <input type="checkbox"/> N0 (i-) <input type="checkbox"/> N0 (i+) <input type="checkbox"/> N0 (mol-) <input type="checkbox"/> N0 (mol+) <input type="checkbox"/> N1 <input type="checkbox"/> N1mi <input type="checkbox"/> N1a <input type="checkbox"/> N1b <input type="checkbox"/> N1bl <input type="checkbox"/> N1bII <input type="checkbox"/> N1bIII <input type="checkbox"/> N1bIV <input type="checkbox"/> N1c <input type="checkbox"/> N2 <input type="checkbox"/> N2a <input type="checkbox"/> N2b <input type="checkbox"/> N2c <input type="checkbox"/> N3 <input type="checkbox"/> N3a <input type="checkbox"/> N3b <input type="checkbox"/> N3c <input type="checkbox"/> N4	If applicable, the patient's pathologic lymph node spread as defined by the AJCC primary tumor descriptions (pN).

#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions	
83	3045439	Pathologic Spread: Distant Metastasis (M) for the Other Malignancy	<input type="checkbox"/> MX <input type="checkbox"/> M0 <input type="checkbox"/> cM0 (i+) <input type="checkbox"/> M1 <input type="checkbox"/> M1a <input type="checkbox"/> M1b	If applicable, the patient's pathologic metastasis spread as defined by the AJCC primary tumor descriptions (M).	
84	3203222	AJCC Tumor Stage for the Other Malignancy	<input type="checkbox"/> 0a <input type="checkbox"/> 0is <input type="checkbox"/> 0 <input type="checkbox"/> I <input type="checkbox"/> IA <input type="checkbox"/> IA1 <input type="checkbox"/> IA2 <input type="checkbox"/> IB <input type="checkbox"/> IB1 <input type="checkbox"/> IB2 <input type="checkbox"/> IC <input type="checkbox"/> II <input type="checkbox"/> IIA <input type="checkbox"/> IIA1 <input type="checkbox"/> IIA2 <input type="checkbox"/> IIB	<input type="checkbox"/> IIC <input type="checkbox"/> III <input type="checkbox"/> IIIA <input type="checkbox"/> IIIB <input type="checkbox"/> IIIC <input type="checkbox"/> IV <input type="checkbox"/> IVA <input type="checkbox"/> IVB	If applicable, the patient's stage using the AJCC criteria.

### Time Intervals

The following questions are not relevant for any TSS that has provided complete or partial (minimum of month and year) dates for any questions on this form asking for a date. If a TSS is not able to provide a full date or partial date, due to an Internal Review Board requirement, the following time intervals should be completed as defined. Please note that these intervals should begin and end with the exact time points described.

#	Element ID(s)	Question Text	Allowable Values	Instructions and Definitions
4-ALT	3288498	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Consent</b>		The number of days between the initial pathologic diagnosis and the date the patient was formally consented to participate in a research study.
5-ALT	3288499	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Death</b>		The number of days between the initial pathologic diagnosis and the date the patient died. This should be provided if the patient was not formally consented, but was instead consented by death.
9-ALT	3288497	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Pathologist Prescreen Review</b>		The number of days between the initial pathologic diagnosis and the date the TSS pathologist performed the pathologic prescreen review.
22-ALT	3288495	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Cancer Sample Procurement</b>		The number of days between the initial pathologic diagnosis and the date the submitted sample was removed from the patient.
36-ALT 38-ALT 45-ALT	3288496	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Germline Sample Procurement</b>		The number of days between the initial pathologic diagnosis and the date the submitted germline control sample was removed from the patient.
52-ALT	5085123	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Peritumoral Sample Procurement</b>		The number of days between the initial pathologic diagnosis and the date the submitted peritumoral tissue sample was removed from the patient.
66-ALT	3462301	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Initial Diagnosis of Other Malignancy</b>		The number of days between the initial pathologic diagnosis and the date the other malignancy was pathologically diagnosed.
69-ALT	3462302	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date of Surgical Resection for the Other Malignancy</b>		The number of days between the initial pathologic diagnosis and the date the surgery was performed to treat or diagnose the other malignancy.
73-ALT	3392465	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date Pharmaceutical Therapy Started for the Other Malignancy</b>		The number of days between the initial pathologic diagnosis and the date the patient started receiving pharmaceutical therapy for the other malignancy.
77-ALT	3008313	Number of days from Date of Initial Pathologic Diagnosis to the <b>Date Radiation Therapy Started for the Other Malignancy</b>		The number of days between the initial pathologic diagnosis and the date the radiation therapy for the other malignancy began.