Sample Submission Form

Kidney Carcinoma

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	☐ Male ☐ Female	The biological sex of the patient.
3	3288361	Consent Status	☐ Formally Consented ☐ Consented by Death ☐ Exemption ☐ Waiver ☐ 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.
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.

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#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
6	3382736	History of Prior or Synchronous Malignancies	☐ None ☐ Prior Malignancy ☐ Synchronous Malignancy ☐ 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. TSSs must complete the Other Malignancy section for patients with prior or synchronous malignancies to determine whether the case is eligible for this project.
7	3382737	Pre-Operative Treatment for Submitted Sample (Prior to Sample Procurement) *Pharmaceutical therapy includes chemotherapy, immunotherapy, targeted therapy, and hormone therapy.*	☐ None ☐ Radiation prior to sample procurement ☐ Pharmaceutical treatment prior to sample procurement ☐ 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. TSSs will be contacted regarding any patient with a history of prior treatment to ensure the prior treatment is not exclusionary.
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.
Please submit a de-identified copy of the patient's **diagnostic pathology report**.				
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?	☐ Yes ☐ No	Indicates whether the histologic diagnosis included on the submitted pathology report is consistent with the histologic diagnosis selected on this form. 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.
11	3288315	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	☐ Macrodissection Performed ☐ Other Pathology Review ☐ 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: **Macrodissection Performed**: 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. **Other Pathology Review**: Pathology analysis not related to the pathologic prescreen review determined a specific histological subtype that is different from the original pathology report. **Pathology Review for this Project**: 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.

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#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
12	3288124	Tumor Category	☐ Primary ☐ Metastatic ☐ Recurrent ☐ 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	☐ Chromophobe Renal Cell Carcinoma ☐ Clear Cell Renal Carcinoma ☐ Papillary Renal Cell Carcinoma ☐ Collecting Duct Renal Cell Carcinoma ☐ Unclassified (Renal Cell Carcinoma NOS)	The histologic type of the submitted tumor that was determined by the TSS pathologic prescreen review.
14	4742851	Anatomic Site of Submitted Sample	☐ Kidney ☐ 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.
15	4742871	Other Anatomic Site of Submitted Sample		The site of the submitted sample if it was not included in the list provided.
16	4742852	Laterality *(If applicable)*	☐ Left ☐ Right	If applicable, indicate the laterality of the submitted sample.
17*	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.
18	2757941	Method of Initial Pathologic Diagnosis	☐ Open Radical Nephrectomy ☐ Laparoscopic Radical Nephrectomy ☐ Laparoscopic Partial Nephrectomy ☐ Hand-Assisted Laparoscopic Radical Nephrectomy ☐ Open Partial Nephrectomy ☐ Other; Please Specify	The procedure performed to procure the sample used for the initial pathologic diagnosis.
19	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.
20*	3008197 3008195 3008199	Date of Cancer Sample Procurement	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	The date the submitted sample was removed from the patient.
21	3103514	Method of Cancer Sample Procurement	☐ Open Radical Nephrectomy ☐ Laparoscopic Radical Nephrectomy ☐ Laparoscopic Partial Nephrectomy ☐ Hand-Assisted Laparoscopic Radical Nephrectomy ☐ Open Partial Nephrectomy ☐ Other; Please Specify	The type of procedure that yielded the sample submitted to the BCR.
22	2006730	Other Method of Cancer Sample Procurement		The type of procedure that yielded the sample submitted to the BCR, if it was not included in the list provided.
23	3152016	Country Where Cancer Sample was Procured	*See the BCR spreadsheet or OpenClinica for a complete list of allowable values.*	The country where the procedure was performed that yielded the sample submitted to the BCR.

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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.

24	25	26	27	28	29	30
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^3 (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.
	☐ Portion ☐ Block ☐ Scroll ☐ Unstained Slide	☐ FFPE ☐ Frozen				☐ Cryovial ☐ Biospecimen Storage Bag ☐ Cassette ☐ Cryomold ☐ Other
	☐ Portion ☐ Block ☐ Scroll ☐ Unstained Slide	☐ FFPE ☐ Frozen				☐ Cryovial ☐ Biospecimen Storage Bag ☐ Cassette ☐ Cryomold ☐ Other

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.

31		32
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.
☐ Physical Slide - Frozen Top Slide ☐ Physical Slide - FFPE Top Slide ☐ Physical Slide - FFPE Diagnostic Slide	☐ Digital Slide Image - Frozen Top Slide ☐ Digital Slide Image - FFPE Top Slide ☐ Digital Slide Image - FFPE Diagnostic Slide	
☐ Physical Slide - Frozen Top Slide ☐ Physical Slide - FFPE Top Slide ☐ Physical Slide - FFPE Diagnostic Slide	☐ Digital Slide Image - Frozen Top Slide ☐ Digital Slide Image - FFPE Top Slide ☐ 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.

**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 11.*

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 10^6 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.
☐ Whole Blood ☐ Buffy Coat ☐ Lymphocytes	☐ Blood Draw	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	
☐ Whole Blood ☐ Buffy Coat ☐ Lymphocytes	☐ Blood Draw	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	

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.
☐ Extracted DNA from Blood ☐ Extracted DNA from Buccal Cells	☐ Blood Draw ☐ Buccal Swab ☐ Mouthwash	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___					
☐ Extracted DNA from Blood ☐ Extracted DNA from Buccal Cells	☐ Blood Draw ☐ Buccal Swab ☐ Mouthwash	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___					

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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.

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.
☐ Non-Neoplastic Tissue	☐ Open Radical Nephrectomy ☐ Laparoscopic Radical Nephrectomy ☐ Laparoscopic Partial Nephrectomy ☐ Hand-Assisted Laparoscopic Radical Nephrectomy ☐ Open Partial Nephrectomy ☐ Biopsy (all types) ☐ Other Surgical Resection	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	☐ FFPE ☐ Frozen			☐ Kidney ☐ Spleen ☐ Lymph Node(s) ☐ Other (Please Specify)		☐ Left ☐ Right
☐ Non-Neoplastic Tissue	☐ Open Radical Nephrectomy ☐ Laparoscopic Radical Nephrectomy ☐ Laparoscopic Partial Nephrectomy ☐ Hand-Assisted Laparoscopic Radical Nephrectomy ☐ Open Partial Nephrectomy ☐ Biopsy (all types) ☐ Other Surgical Resection	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	☐ FFPE ☐ Frozen			☐ Kidney ☐ Spleen ☐ Lymph Node(s) ☐ Other (Please Specify)		☐ Left ☐ 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.

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#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
54	5085114	Method of Peritumoral Sample Procurement	☐ Open Radical Nephrectomy ☐ Laparoscopic Radical Nephrectomy ☐ Laparoscopic Partial Nephrectomy ☐ Hand-Assisted Laparoscopic Radical Nephrectomy ☐ Open Partial Nephrectomy ☐ Biopsy (all types) ☐ Other Surgical Resection	The type of procedure that yielded the peritumoral tissue sample submitted to the BCR.
55*	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.

56	57	58	59	60	61	62
5085118	5085119	4634873	5118535	4633535	5118531	4633536
Peritumoral ID	Peritumoral Slide or Digital Image ID	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.
		☐ Portion ☐ Block ☐ Scroll ☐ Unstained Slide	☐ FFPE ☐ Frozen	☐ Kidney ☐ Other (Please Specify)		☐ Left ☐ 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
63	3182890	Type of Other Malignancy	☐ Prior ☐ 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.
64	2735776	Primary Site of Other Malignancy	*See the BCR spreadsheet or OpenClinica for a complete list of sites.*	The primary site of the other malignancy. 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.

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#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
65	2584114	Other Primary Site of Other Malignancy		The site of the other malignancy if it was not included in the list provided.
66	4122391	Laterality of the Other Malignancy	☐ Left ☐ Not Applicable ☐ Right ☐ Unknown ☐ Bilateral	The laterality of the other malignancy.
67	4122411	Histological Type of the Other Malignancy	*See the BCR spreadsheet or OpenClinica for a complete list of histologies.*	The histology of the other malignancy.
68	3124492	Other Histological Type of the Other Malignancy		The histology of the other malignancy if it was not included in the list provided.
69*	3462297 3462298 3462299	Date of Initial Diagnosis of the Other Malignancy	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	The date the other malignancy was pathologically diagnosed.
70	3186538	Did the patient have surgery for the other malignancy?	☐ Yes ☐ No ☐ Unknown	Indicates whether the patient had surgery for the other malignancy.
71	3462300	Type of Surgery for the Other Malignancy		The type of surgery performed to treat or diagnose the other malignancy.
72*	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.
73	3178327	Did the patient have pharmaceutical therapy for the other malignancy? *If the answer is "yes" or "unknown", the case will be excluded from the project.*	☐ Yes ☐ No ☐ 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.
74	3178365	Extent of Pharmaceutical Therapy for the Other Malignancy	☐ Locoregional ☐ Systemic ☐ Unknown	Describes the extent of therapy, which can be locoregional (specific to the region of the other malignancy) or systemic.
75	2975232	Drug Names		The type of pharmaceutical drug(s) the patient received to treat the other malignancy.
76*	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.
77	3178328	Did Patient Receive Radiation Therapy for the other Malignancy? *If the answer is "unknown", the case will be excluded from the project.*	☐ Yes ☐ No ☐ Unknown	Indicates whether the patient received radiation therapy for the other malignancy.
78	3178353	Extent of Radiation Therapy for the Other Malignancy *If the answer to this question is "systemic" or "unknown", the case will be excluded from the project.*	☐ Locoregional ☐ Systemic ☐ Unknown	Describes the extent of therapy, which can be locoregional (specific to the region of the other malignancy) or systemic.

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#	CDE #(s)	Question Text	Allowable Values	Instructions and Definitions
79	2865132	If the patient received locoregional radiation, was the radiation therapy given to the same field as the tumor submitted for this project? *If the answer is "yes" or "unknown", the case will be excluded from the project.*	☐ Yes ☐ No ☐ 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.
80*	2897100 2897102 2897104	Date Radiation Therapy Started for the Other Malignancy	Month: ___ ___ Day: ___ ___ Year: ___ ___ ___ ___	The date the radiation therapy for the other malignancy began.
81	3114049	FIGO Staging System (Gynecologic Tumors Only) for the Other Malignancy (if applicable)	☐ 1988 ☐ 1995 (cervical only) ☐ 2009	If applicable, the staging system used for gynecologic tumors staged using the FIGO system.
82	3225684	FIGO Stage for the Other Malignancy (if applicable)	☐ Stage I ☐ Stage IB1 ☐ Stage IIB ☐ Stage IIIC1 ☐ Stage IA ☐ Stage IB2 ☐ Stage III ☐ Stage IIIC2 ☐ Stage IA1 ☐ Stage IC ☐ Stage IIIA ☐ Stage IV ☐ Stage IA2 ☐ Stage II ☐ Stage IIIB ☐ Stage IVA ☐ Stage IB ☐ Stage IIA ☐ Stage IIIC ☐ Stage IVB	If applicable, the patient's stage using the FIGO system.
83	2722309	AJCC Cancer Staging Edition for the Other Malignancy	☐ 1st Edition (1978-1983) ☐ 2nd Edition (1984-1988) ☐ 3rd Edition (1989-1992) ☐ 4th Edition (1993-1997) ☐ 5th Edition (1998-2002) ☐ 6th Edition (2003-2009) ☐ 7th Edition (2010-present)	If applicable, the staging edition used for tumors staged using the AJCC criteria. Edition should correspond to year of diagnosis.
84	3045435	Pathologic Spread: Primary Tumor (pT) for the Other Malignancy	☐ TX ☐ T0 ☐ Tis ☐ Tis (DCIS) ☐ Tis (LCIS) ☐ Tis (Paget's) ☐ Ta ☐ T1 ☐ T1mi ☐ T1a ☐ T1a1 ☐ T1a2 ☐ T1b ☐ T1b1 ☐ T1b2 ☐ T1c ☐ T2 ☐ T2a ☐ T2a1 ☐ T2a2 ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4 ☐ T4a ☐ T4b ☐ T4c ☐ T4d	If applicable, the patient's pathologic tumor spread as defined by the AJCC primary tumor descriptions (pT).
85	3203106	Pathologic Spread: Lymph Nodes (pN) for the Other Malignancy	☐ NX ☐ N0 ☐ N0 (i-) ☐ N0 (i+) ☐ N0 (mol-) ☐ N0 (mol+) ☐ N1 ☐ N1mi ☐ N1a ☐ N1b ☐ N1bI ☐ N1bII ☐ N1bIII ☐ N1bIV ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N2c ☐ N3 ☐ N3a ☐ N3b ☐ N3c ☐ N4	If applicable, the patient's pathologic lymph node spread as defined by the AJCC primary tumor descriptions (pN).
86	3045439	Pathologic Spread: Distant Metastasis (M) for the Other Malignancy	☐ MX ☐ M0 ☐ cM0 (i+) ☐ M1 ☐ M1a ☐ M1b ☐ M1c	If applicable, the patient's pathologic metastasis spread as defined by the AJCC primary tumor descriptions (M).

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#	CDE #(s)	Question Text	Allowable Values			Instructions and Definitions
87	3203222	AJCC Tumor Stage for the Other Malignancy	☐ 0a ☐ 0is ☐ 0 ☐ I ☐ IA ☐ IA1 ☐ IA2 ☐ IB	☐ IB1 ☐ IB2 ☐ IC ☐ II ☐ IIA ☐ IIA1 ☐ IIA2 ☐ IIB	☐ IIC ☐ III ☐ IIIA ☐ IIIB ☐ IIIC ☐ IV ☐ IVA ☐ IVB	If applicable, the patient's stage using the AJCC criteria.

**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 11.*

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 **Date of Consent**		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 **Date of Death**		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 **Date of Pathologist Prescreen Review**		The number of days between the initial pathologic diagnosis and the date the TSS pathologist performed the pathologic prescreen review.
20-ALT	3288495	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Cancer Sample Procurement**		The number of days between the initial pathologic diagnosis and the date the submitted sample was removed from the patient.
35-ALT 39-ALT 47-ALT	3288496	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Germline Sample Procurement**		The number of days between the initial pathologic diagnosis and the date the submitted germline control sample was removed from the patient.
55-ALT	5085123	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Peritumoral Sample Procurement**		The number of days between the initial pathologic diagnosis and the date the submitted peritumoral tissue sample was removed from the patient.
69-ALT	3462301	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Initial Diagnosis of Other Malignancy**		The number of days between the initial pathologic diagnosis and the date the other malignancy was pathologically diagnosed.
72-ALT	3462302	Number of days from Date of Initial Pathologic Diagnosis to the **Date of Surgical Resection for the Other Malignancy**		The number of days between the initial pathologic diagnosis and the date the surgery was performed to treat or diagnose the other malignancy.
76-ALT	3392465	Number of days from Date of Initial Pathologic Diagnosis to the **Date Pharmaceutical Therapy Started for the Other Malignancy**		The number of days between the initial pathologic diagnosis and the date the patient started receiving pharmaceutical therapy for the other malignancy.
80-ALT	3008313	Number of days from Date of Initial Pathologic Diagnosis to the **Date Radiation Therapy Started for the Other Malignancy**		The number of days between the initial pathologic diagnosis and the date the radiation therapy for the other malignancy began.

**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 11.*