# Sample Submission Form

Colon Adenocarcinoma



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

*Tissue Source Site (TSS) acknowledges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen biospecimen is consistent with the primary diagnosis reported by the TSS through histopathology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, the TSS authorizes the BCR to report these patient results to the TSS by means of a formal report in confidential email format for the quality assurance program of the TSS to address.*

Tissue Source Site (TSS): _____TSS ID: _____ TSS Unique Patient ID: _____ Interviewer Name: _____Interview Date ___ ___/___ ___ /___ ___ ___ ___

| # | Question | Entry Alternatives | Working Instructions |
|---|---|---|---|
| | **Verification of Requirements**<br>Prior to the shipment of samples to the BCR, the TSS must answer the following questions to verify that all requirements are met. | | |
| 1 | Type of Biospecimen Submission<br>*(check all that apply)* | ☐ Tumor Sample<br>☐ Normal Sample | Please provide the type of biospecimen(s) being submitted at the time of completion of this form. |
| **Consent Information** | | | |
| 2* | Consent Status | ☐ Formally Consented<br>☐ Consented by Death<br>☐ Exemption 4 *(see note at right)*<br>☐ Waiver *(see note at right)* | Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent.<br>Exemptions and waivers for consent must be approved by NCI.<br>3288361 |
| 3† | Date of Formal Consent | _____ _____ _____ _____ _____ _____ _____ _____<br>*Month* *Day* *Year* | If the patient was formally consented, provide the month of consent.<br>Do not complete if the patient consented by death.<br>3081955 (month), 3081957 (day), 3081959 (year) |
| 4† | Date of Death | _____ _____ _____ _____ _____ _____ _____ _____<br>*Month* *Day* *Year* | If the patient consented by death (i.e. they did not formally consent), provide the month of death.<br>Do not complete if the patient formally consented.<br>2897026 (month), 2897028 (day), 2897030 (year) |
| **History of Malignancies** | | | |
| 5* | History of Other Malignancy<br>*(Including ALL Prior and Synchronous Malignancies)* | ☐ None<br>☐ Prior Malignancy<br>☐ Synchronous Malignancy<br>☐ Both Synchronous and Prior Malignancy | Indicate whether the patient has a history of malignancies, including synchronous or bilateral malignancies. Please complete an Other Malignancy Form (OMF) for each malignancy diagnosed prior to or at the time the submitted tissue was procured.<br>If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, only complete an OMF for the initial diagnosis of each of these types.<br>3382736 |
| **Neoadjuvant Treatment** | | | |
| 6* | History of Neoadjuvant Treatment (prior to procurement) of Tumor Submitted | ☐ None<br>☐ Radiation prior to sample procurement*<br>☐ Pharmaceutical treatment prior to sample procurement*<br>☐ Both pharmaceutical and radiation treatment prior to sample procurement* | Indicate whether the patient received therapy for the tumor submitted prior to the sample procurement. If the patient did receive treatment prior to procurement, the TSS should contact the BCR for further instruction.<br>*Systemic therapy and certain localized therapies (those administered to the same site as the submitted tissue) given prior to the procurement of the sample submitted are exclusionary.<br>3382737 |
| **Pathology Prescreen at the TSS** | | | |
| 7* | Was the submitted sample prescreened at the TSS? | ☐ Yes<br>☐ No | Indicate whether the sample submitted to the BCR was prescreened at the TSS.<br>3081942 |
| 8* | Name of Pathologist<br>*(person who performed the review of the submitted slide)* | _____ | Provide the name of the pathologist who performed the review of the submitted sample.<br>3288225 |

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|---|---|---|---|
| 9* | Date of Pathology Prescreen | _____ _____ _____ _____ _____ _____ _____ _____<br>*Month* *Day* *Year* | Provide the date the pathologist performed the prescreen review.<br>3288224 |
| 10* | Does the percent of tumor nuclei meet current project metrics? | ☐ Yes | Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics.<br>3288520 |
| 11* | Does the percent necrosis meet the current project metrics? | ☐ Yes | Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics.<br>3288524 |
| **Initial Pathology Report** | | | |
| 12* | Will an original diagnostic de-identified pathology report be submitted? | ☐ Yes<br>☐ No | Confirm that a de-identified pathology report is being sent to BCR prior to or with the shipment of the physical samples.<br>Cases without a pathology report at the time of sample submission will be excluded.<br>3288292 |
| 13* | Is the histologic diagnosis on the CQCF (as determined by the TSS pathology review of the submitted slide) consistent with the histology listed on the submitted pathology report? | ☐ Yes<br>☐ No | Confirm that the diagnosis provided on this CQCF for the tumor sample being submitted is consistent with the diagnosis found on the patient's pathology report for the tumor being sent to the BCR. If "yes," skip related question below.<br>The diagnosis is considered to be consistent if at least one of the following criteria are met:<br>1) Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR.<br>2) Diagnosis on the CQCF includes at least one of the subtypes listed on the pathology report and all subtypes on the pathology report are acceptable.<br>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.<br>4) Diagnosis on the CQCF indicates "Mixed Subtype" and the pathology report lists two or more acceptable subtypes, provided that percent subtype(s) meet applicable disease-specific requirements.<br>3288300 |
| 14† | If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency. | ☐ Macrodissection Performed *(see definition at right)*<br>☐ Other Pathology Review *(see definition at right)*<br>☐ Pathology Review for this Project *(see definition at right)* | If the diagnosis provided on this form is not consistent with the final diagnosis found on the pathology report provided, specify a reason for this inconsistency.<br>1.) Macrodissection that was performed at the TSS to select a region containing an acceptable diagnosis determined a specific histological subtype that is different from the original pathology report<br>2.) The pathology analysis performed at the TSS determined a specific histological subtype that is different from the original pathology report<br>3.) The pathology review of the frozen section for this project determined that the histologic subtype is different from the pathology report<br>If a TSS pathology review of the submitted sample resulted in a different histologic subtype than what is documented on the original pathology report, an amendment to the pathology report should be submitted when the sample is shipped to the BCR; in the absence of an amended pathology report, the TSS must complete and submit an electronic copy of the "Pathologic Diagnosis Discrepancy Form". In the case of diagnosis modifications, institution protocol should be followed for proper quality assurance.<br>3288315 |
| **Demographic Information** | | | |
| 15* | Date of Birth | _____ _____ _____ _____ _____ _____ _____ _____<br>*Month* *Day* *Year* | Provide the date the patient was born.<br>2896950(month), 2896952(day), 2896954 (year) |

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| # | Question | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 16* | Race | ☐ American Indian or Alaska Native<br>☐ Asian<br>☐ Black or African American<br>☐ Native Hawaiian or other Pacific Islander<br>☐ White<br>☐ Unknown | Provide the patient's race using the provided categories, as defined below.<br>**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.<br>**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.<br>**White:** A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.<br>**Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."<br>**Native Hawaiian or other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.<br>**Unknown**<br>2192199 |
| 17 | Ethnicity | ☐ Not Hispanic or Latino<br>☐ Hispanic or Latino<br>☐ Unknown | Provide the patient's ethnicity using the provided categories, defined below:<br>**Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.<br>**Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.<br>**Unknown**<br>2192217 |
| | **Tumor Information**<br>The following information must be completed for the tumor sample submitted and should be answered specifically about the submitted sample(s). If multiple vials of the tumor sample are submitted, the "Tumor Sample Information" must be completed for each vial submitted to the BCR. | | |
| **Pathologic/Anatomic Information** | | | |
| 18* | Tumor Category | ☐ Primary<br>☐ Metastatic<br>☐ Recurrent | Indicate whether a primary tumor is being submitted to the BCR.<br>3288124 |
| 19* | Histological Subtype | ☐ Colon Adenocarcinoma<br>☐ Colon Mucinous Adenocarcinoma | Indicate the histologic subtype of the malignant sample submitted.<br>3081934 |
| 20* | Anatomic Site of Submitted Sample<br>(*For tumors that overlap regions, check all that apply)* | ☐ Colon<br>☐ Other (For Metastatic or Recurrent Tumors only; Please Specify) | Indicate the anatomic site of the tumor biospecimen submitted.<br>4132154 |
| 21† | Other Anatomic Site<br>*(For Metastatic or Recurrent Tumors only)* | _____ | If the anatomic site of the metastatic tumor is not listed in the previous question, provide the specific site of the metastatic tumor.<br>2584114 |
| 22* | Region of Submitted Sample<br>*(Check all that apply)* | ☐ Colon, NOS<br>☐ Cecum<br>☐ Sigmoid Colon<br>☐ Splenic Flexure<br>☐ Ascending Colon<br>☐ Hepatic Flexure<br>☐ Descending Colon<br>☐ Transverse Colon<br>☐ Not Applicable (Metastatic/Recurrent Only) | Indicate the region of the anatomic site of the tumor biospecimen submitted.<br>3081961 |
| **Diagnosis Information** | | | |
| 23* | Date of Initial Pathologic Diagnosis | _____ _____ _____ _____ _____ _____ _____ _____<br>*Month* *Day* *Year* | Provide the date the patient was initially pathologically diagnosed with the malignancy submitted.<br>2896956 (month), 2896958(day), 2896960 (year) |

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| # | Question | Entry Alternatives | Working Instructions |
|---|---|---|---|
| **Tumor Procurement Information** | | | |
| 24* | Date of Tumor Sample Procurement | _____ _____ _____ _____ _____ _____ _____ _____<br>*Month* *Day* *Year* | Provide the procurement date of the malignancy that yielded the submitted tumor.<br>3008197 (month), 3008195(day), 3008199 (year) |
| 25* | Method of Tumor Sample Procurement | ☐ Right Hemicolectomy<br>☐ Left Hemicolectomy<br>☐ Transverse Colectomy<br>☐ Sigmoid Colectomy<br>☐ Total Colectomy<br>☐ Pan-Procto Colectomy<br>☐ Low Anterior Colon Resection<br>☐ Other Surgical Resection | Indicate the procedure or surgery performed to obtain the malignant tissue that yielded the submitted sample.<br>3103514 |
| 26* | Country where Tumor Sample was Procured | _____ | Provide the country where the malignant tissue that yielded the submitted sample was procured.<br>3152016 |
| **Tumor Sample Information** If multiple vials of the tumor sample are submitted, this section must be completed for each vial submitted to the BCR. | | | |
| 27* | Tumor Identifier | _____ | Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor sample needs a unique ID.<br>3288096 |
| 28* | What type of tumor sample is being submitted? | ☐ Portion<br>☐ Block<br>☐ Scroll | Indicate the text term to describe the kind of tumor sample that is being submitted.<br>3812626 |
| 29* | Preservation Method | ☐ FFPE<br>☐ Frozen | Indicate whether the sample being submitted is a frozen sample or a formalin fixed paraffin embedded (FFPE) sample.<br>2231144 |
| 30* | Weight of Submitted Sample | _____ (mg)<br>(0.2 $cm^3$ (0.6cm * 0.6cm *0.6cm) ≈ 200mg | Provide the weight of the tumor sample submitted.<br>Weight can be estimated based on the size of the tumor submitted.<br>3081946 |
| 31* | Tumor Nuclei Percent (%) | _____ (%) | Provide the percent of tumor nuclei for the sample submitted.<br>Check with the BCR to confirm the current acceptable metrics.<br>2841225 |
| 32* | Necrosis Percent (%) | _____ (%) | Provide the percent of necrosis for the sample submitted.<br>Check with the BCR to confirm the current acceptable metrics.<br>2841237 |
| **Shipment/Slide Information** | | | |
| 33* | Type(s) of Slides Submitted | **Physical Slide**<br>☐ Frozen Top Slide<br>☐ FFPE Top Slide<br>☐ FFPE Diagnostic Slide<br>**Digital Slide Image**<br>☐ Frozen Top Slide<br>☐ FFPE Top Slide<br>☐ FFPE Diagnostic Slide | Indicate the type(s) of slide(s) submitted to the BCR.<br>**Top Slide Definition**: Slide cut directly from frozen biospecimen = mirror image of inked surface<br>3521909 |
| 34* | Slide/Digital Image ID | _____ | Provide the slide ID for each slide (physical and digital image) submitted to the BCR.<br>2321277 |
| 35* | Shipment Vessel Used | ☐ Cryovial<br>☐ Biospecimen Storage Bag<br>☐ Cassette<br>☐ Cryomold<br>☐ Other | Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR).<br>Check with the BCR to confirm that your shipment container is approved.<br>3081940 |

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| # | Question | Entry Alternatives | Working Instructions |
|---|---|---|---|
| | **Normal Control Information**<br>The following information must be completed for the normal control sample submitted and should be answered specifically about the submitted control(s). If multiple normal control types are submitted, **ALL QUESTIONS** should be completed for each sample. If multiple vials of the same normal control are submitted, the "Normal Control Sample Information" must be completed for each vial submitted to the BCR. | | |
| 36* | Will a normal control be submitted? | ☐ Yes<br>☐ A germline control has previously been submitted for this case | Indicate whether a primary tumor is being submitted to the BCR. |
| 37* | Type(s) of Normal Control(s)<br>*Check all that apply* | ☐ Whole Blood<br>☐ Buffy Coat<br>☐ Lymphocytes<br>☐ Extracted DNA from Blood<br>☐ Frozen Non-Neoplastic Tissue<br>☐ FFPE Non-Neoplastic Tissue | Indicate the type(s) of normal control(s) submitted for this case.<br>3081936 |
| **Normal Sample Procurement Information** | | | |
| 38† | Method of Normal Control Procurement | ☐ Blood Draw<br>☐ Surgical Resection | Indicate the procedure performed to obtain the normal control sample submitted.<br>3288147 |
| 39† | Date of Normal Control Procurement | _____ _____ _____ _____ _____ _____ _____ _____<br>*Month* *Day* *Year* | Provide the date of the procedure performed to obtain the normal control submitted.<br>3288195 (month), 3288196 (day), 3288197 (year) |
| **Normal Control Sample Information** | | | |
| 40† | Normal Control ID | _____ | Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID.<br>3288138 |
| *Extracted DNA from Blood or Saliva:* Only complete this section if submitting Extracted DNA from Blood. | | | |
| 41† | Extracted DNA Quantity of Normal Control | _____ (µg) | Provide the quantity (µg) of the normal control sample sent to the BCR.<br>3288185 |
| 42† | Extracted DNA Quantification Method of Normal Control | _____ | Provide the quantification method of the normal control sample sent to the BCR.<br>3288186 |
| 43† | Extracted DNA Concentration of Normal Control | _____ (µg/µL) | Provide the concentration (µg/ µL) of the normal control sample sent to the BCR.<br>3288187 |
| 44† | Extracted DNA Volume of Normal Control | _____ (µL) | Provide the volume (µL) of the normal control sample sent to the BCR.<br>3288188 |
| *Normal Germline Control Tissue:* (Uninvolved organ only) Only complete this section if submitting germline control tissue. | | | |
| 45† | Anatomic Site of Normal Germline Control Tissue<br>(Uninvolved organ only) | ☐ Spleen<br>☐ Other (please specify) | If the normal germline control type is non-neoplastic tissue, indicate the anatomic site of the tissue submitted.<br>4132152 |

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| # | Question | Entry Alternatives | Working Instructions |
|---|---|---|---|
| 46† | Other Anatomic Site of Normal Germline Control Tissue | _____ | If the anatomic site of the normal germline control is not listed in the previous question, provide the specific site of the normal control. 3288189 |
| 47† | Normal Slide Identifier | _____ | If the normal germline control type is non-neoplastic tissue and a slide for this tissue is being submitted, indicate the slide identifier here. 3288217 |
| *Peritumoral Tissue:* Only complete this section if submitting peritumoral tissue in addition to a germline control. | | | |
| 48* | Is a Peritumoral Tissue being submitted in addition to a normal germline control tissue? | ☐ Yes ☐ No | A peritumoral sample may only be submitted if a normal germline control sample is also submitted. |
| 49† | Method of Peritumoral Procurement | ☐ Surgical Resection | Indicate the procedure performed to obtain the normal control sample submitted. 3288147 |
| 50† | Date of Peritumoral Tissue Procurement | _____ _____ _____ _____ _____ _____ _____ _____ *Month* *Day* *Year* | Provide the date of the procedure performed to obtain the normal control submitted. 3288195 (month), 3288196 (day), 3288197 (year) |
| 51† | Normal Control ID | _____ | Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138 |
| 52† | What type of peritumoral sample is being submitted? | ☐ FFPE Sample ☐ Frozen Sample | Indicate whether the type of peritumoral sample being submitted is a frozen sample or a formalin fixed paraffin embedded (FFPE) sample. 4634873 |
| 53† | Anatomic Site of Peritumoral Tissue | ☐ Colon | If peritumoral tissue is submitted, indicate the anatomic site of the tissue submitted. 4633535 |
| 54† | Peritumoral Tissue Slide or Digital Image Identifier | _____ | If peritumoral tissue is submitted and a slide for this tissue is also being submitted, indicate the slide identifier here. 3462772 |
| **Time Intervals** The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form. Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection) Please Note: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form. | | | |
| i* | Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form? | ☐ Yes ☐ No | Indicate whether the TSS has permission to provide time intervals in lieu of dates. |
| ii | Number of Days from Date of Initial Pathological Diagnosis to Date of Pathological Review | _____ days | Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the pathological review performed as part of the submission process 3288189 |
| iii | Number of Days from Date of Initial Pathological Diagnosis to Date of Consent | _____ days | If the patient formally consented, provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the patient's formal consent. 3288498 |
| iv | Number of Days from Date of Initial Pathological Diagnosis to Date of Death | _____ days | If the patient consented by death, provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the patient's death. Note: If the patient formally consented prior to death, do not answer this question only answer the question above that asks for the number of days between the date of diagnosis and the date of the patient consent. 3288499 |

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| # | Question | Entry Alternatives | Working Instructions |
|---|---|---|---|
| v | Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth | _____ days | Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth<br>3008233 |
| vi | 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<br>3288495 |
| vii | 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<br>3288496 |
| viii | 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<br>3288496 |
| ix | 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<br>3288496 |
| x | Number of Days from Date of Initial Pathological Diagnosis to Date of Normal Sample Procurement (Uninvolved Non-Neoplastic Tissue–Frozen or FFPE) | _____ 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<br>3288496 |
| xi | Number of Days from Date of Initial Pathological Diagnosis to Date of Normal Sample Procurement (Peritumoral 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<br>3288496 |

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

Principal Investigator or Designee Signature | Print Name | Date

***I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.***