Tissue Source Site (TSS) Name: \_\_\_\_\_\_ TSS Identifier: \_\_\_\_\_ TSS Unique Patient #: \_\_\_\_\_

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Completed By: \_

\_\_ Completion Date (MM/DD/YYYY): \_\_

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

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Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions
1	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	□ Yes □ No		Please note that time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box to the left. Note 1: Provided time intervals must begin with the date of initial pathologic diagnosis. (i.e., biopsy or resection) Note 2: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
2	Histological Subtype	<ul> <li>Colon Adenocarcinoma</li> <li>Colon Mucinous Adenocarcinoma</li> <li>Rectal Adenocarcinoma</li> <li>Rectal Mucinous Adenocarcinoma</li> </ul>		3081934 Indicate the histologic subtype for the colon/rectum tumor sample being submitted to TCGA. Note: Mixed Subtypes Are Excluded For This Tumor Type. All other subtypes not listed are excluded from this study.
3	Tumor Type	Primary		3288124 Confirm that the tumor being submitted to TCGA is a primary untreated malignant biospecimen.
4	Anatomic Site of Frozen Biospecimen	Cecum     Hepatic Flexure       Sigmoid Colon     Descending       Splenic Flexure     Transverse	ctal Subsites Sigmoid Colon Rectum Rectosigmoid Junction	3081961 Indicate the anatomic site of the frozen tumor submitted for TCGA.
Date of Cance	r Sample Procurement		-	
5	Month of Cancer Sample Procurement	ПП (ММ)		3008197 Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA.
6	Day of Cancer Sample Procurement	(DD)		3008195 Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA.
7	Year of Cancer Sample Procurement			3008199 Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA.
8	Number of Days from Date of Initial Pathologic Diagnosis to Date of Cancer Sample Procurement			3288495 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of the procedure that produced the malignant sample submitted for TCGA. <i>Note: Only provide interval data if you have received</i> <i>permission from the NCI to provide time intervals as a</i> <i>substitute for requested dates on this form.</i>
9	Method of Cancer Sample Procurement	Right Hemicolectomy       Pan-Procto Cole         Transverse Colectomy       Anterior Resect         Left Hemicolectomy       Abdomino-Peri         Sigmoid Colectomy       Endo-Rectal Tul         Total Colectomy       Other (please specified)	tion of Rectum ineal Resection imor Resection	3103514 Indicate the procedure performed to obtain the malignant tissue submitted for TCGA.
10	Other Method of Cancer Sample Procurement			2006730 If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure.
11	Country Where Cancer Sample Was Procured			3203072 Provide the country where the tissue submitted for TCGA was procured.



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Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions
Question #	Data Element Laber	Data Entry Alternatives		3081944
22	Will Top Slide be submitted to the BCR?	Yes		Indicate whether a physical top slide for the sample submitted to the BCR will be shipped with the tissue sample.
				Note: Top slide definition: Slide cut directly from frozen
				biospecimen = mirror image of inked surface. 3081948
	Will Digital Slide Image			Indicate whether a digital slide image for the sample
23	be submitted to the	Yes		submitted to the BCR will be shipped with the tissue
	BCR?	No		sample.
				Note: Physical top slides are preferred.
24	Top Slide / Digital Slide			2321277
24	Image ID #		-	Provide the slide ID for the physical top slide OR the digital slide image being sent to the BCR.
Normal Inform	nation	Instructions: A normal control	must be present to qualify.	side indge being sent to the ben.
				3081936
25	Type of Normal	Whole Blood	Lymphocytes (Buffy Coat)	Indicate the type of normal control submitted for this case.
25	Control	Normal Tissue	Extracted DNA from Blood	Note: Whole blood is preferred. Normal tissue is only
				allowable with NCI approval.
				3288138 Provide the TSS unique normal ID. If multiple normal
26	Normal Identifier		_	control samples are submitted, each normal control needs
				a unique ID.
		Blood Draw		
		—	Pan-Procto Colectomy	
		Total Colectomy	Endo-Rectal Tumor Resection	
27	Method of Normal	Sigmoid Colectomy		3288147
27	Sample Procurement	Left Hemicolectomy	Anterior Resection of Rectum	Indicate the procedure performed to obtain the normal sample submitted for TCGA.
			Abdomino-Perineal Resection	
		Right Hemicolectomy	Other (please specify)	
		Transverse Colectomy		
	Other Method of			3288151
28	Normal Sample Procurement		-	If the procedure performed to obtain the normal sample is not included in the provided list, specify the procedure.
Date of Norm	al Sample Procurement			not included in the provided list, specify the procedure.
Dute of Hom	•			3288195
29	Month of Normal Sample Procurement	(MM)		Provide the month of the procedure performed to obtain
	Sample Procurement			the normal control sample for TCGA.
20	Day of Normal Sample			3288196
30	Procurement			Provide the day of the procedure performed to obtain the normal control sample for TCGA.
				3288197
31	Year of Normal Sample Procurement			Provide the year of the procedure performed to obtain the
	riocurement			normal control sample for TCGA.
				3288496 Provide the number of days from the date the patient was
	Number of Days from			initially diagnosed pathologically with the disease
22	Date of Initial			described on this form to the date of the procedure that
32	Pathologic diagnosis to Date of Normal		-	produced the normal control sample submitted for TCGA.
	Sample Procurement			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.
	Extracted DNA			3288185
33	Quantity		-	If the normal control type is extracted DNA from blood,
33				provide the quantity ( $\mu g$ ) of the normal control sample
	E Locale d D M			sent to the BCR for TCGA.
	Extracted DNA Quantification Method		_	3288186 If the normal control type is extracted DNA from blood,
34				provide the quantification method of the normal control
				sample sent to the BCR for TCGA.
	Extracted DNA			3288187
35	Concentration		-	If the normal control type is extracted DNA from blood,
				provide the concentration ( $\mu$ g/ $\mu$ L) of the normal control sample sent to the BCR for TCGA.
	Extracted DNA Volume			3288188
36	,		-	If the normal control type is extracted DNA from blood,

		Case Quality Control Form	(COCF): Colon	/Rectum	V4.20
			, , , , , , , , , , , , , , , , , , , ,		
Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions	
				provide the volume (μL) of the normal co to the BCR for TCGA.	ontrol sample sent
37	Anatomic Site of Normal Tissue	Colon Subsites         Cecum       Ascending Colon         Sigmoid Colon       Transverse         Splenic Flexure       Colon         Hepatic       Descending         Flexure       Colon         Other (please specify)	Rectal Subsites          Sigmoid Colon         Rectum         Rectosigmoid         Junction         Other         (please specify)	3081938 If the normal control type is normal tissu anatomic site of the non-neoplastic cont submitted for TCGA. Note: Site matched	rol tissue
38	Other Anatomic Site of Normal Tissue			3288189 If the normal control type is normal tissu anatomic site is not included in the provi the site of the non-neoplastic control.	
39	Proximity of Normal Tissue to Tumor	☐ Distal (≥ 2 cm) from the primary tumor		3088708 If normal tissue is being submitted, confi normal tissue is ≥ 2.0cm from the primar Note: Adjacent and/or tissue of unknow not accepted for this tissue type.	y tumor.
40	Normal Slide ID #			3288217 If the normal control type is normal tissu slide ID for the physical top slide OR the of the normal control being sent to the B	digital slide image CR.
Verification: quality control		on below, the Principal Investigator acknowlea	lges that the informatio	n provided by the institution is true and cor	rect and has been
41	Name of Pathologist			3288225 Provide the name of the Pathologist that prescreened the top slide and provided t for all previous sections.	
42	Date of Pathologist Review			3288224 Provide the date of the pathology prescr performed by the TSS pathologist above.	
43	Number of Days from Date of Initial Pathologic Diagnosis to Date of Pathological Review			3288497 Provide the number of days from the dat initially diagnosed pathologically with the described on this form to the date of the review performed as part of the submiss TCGA. Note: Only provide interval data if you h permission from the NCI to provide time substitute for requested dates on this for	te the patient was e disease pathological ion process for <b>nave received</b> intervals as a
44	Percent Tumor Nuclei meets TCGA metrics?	Yes No		3288520 Confirm that the malignant sample subm meets the current tumor nuclei metrics f Note: Check with the BCR to confirm the acceptable TCGA metrics.	itted to the BCR or TCGA.
45	Percent Tumor Necrosis meets TCGA metrics?	Yes No		3288524 Confirm that the malignant sample subm meets the current necrosis metrics for TC Note: Check with the BCR to confirm the acceptable TCGA metrics.	CGA.
46	De-Identified Pathology Report Submitted?	Yes No		3288292 Confirm that a de-identified pathology re to BCR prior to or with the shipment of th samples.	
47	Is the histologic diagnosis on the CQCF (as determined by the TSS pathology review of the TCGA frozen section top slide) consistent with the histology listed in the final diagnosis on the	Yes (skip related question below).		3288300 Confirm that the diagnosis provided on t tumor sample being submitted to TCGA i the diagnosis found on the patient's path the tumor being sent to the BCR. Note: The diagnosis is considered to be least one of the following criteria are m 1) Diagnosis on the CQCF is identical to report for the tumor being sent to the B	s consistent with hology report for consistent if at et: the pathology

<b>a</b>			CDE ID With We direct and the	
Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions	
	pathology report?		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 for TCGA.	
			3) Diagnosis on the CQCF is "histology, NOS" (i.e.	
			Adenocarcinoma, NOS) and the pathology report lists a	
			specific subtype within the same histological group.	
			4) Diagnosis on the CQCF indicates "Mixed Subtype" and	
			the pathology report lists two or more acceptable	
			subtypes, provided that percent subtype(s) meet	
			applicable TCGA disease-specific requirements.	
			3288315	
			If the diagnosis provided on this form is not consistent	
			with the diagnosis found on the patient's pathology report	
		Macrodissection performed at TSS to select for region	for the tumor being submitted for TCGA, specify a reason	
		containing an acceptable TCGA diagnosis	for this inconsistency.	
	If the diagnosis on this		Note: If a TSS pathology review of the TCGA committed	
	form is not consistent	Pathology analysis at TSS determined a specific histological	sample resulted in a different histological subtype than	
48	with the provided	subtype different from original pathology report (see note at	what is documented on the pathology report, an	
40	pathology report,	right)	amendment to the pathology report should be submitted	
	indicate the reason for			
	the inconsistency.	Pathology review of frozen section for TCGA determined	when the sample is shipped to the BCR; or in the absence	
	- 1	histological subtype different from the pathology report (see	of an amended pathology report, the TSS must complete	
		note at right)	and submit an electronic copy of the "TCGA Pathologic	
			Diagnosis Discrepancy Form." In the case of diagnosis	
			modifications, institution protocol should be followed for	
			proper quality assurance	
			3382737	
			Indicate whether the patient received therapy for this	
	History of Neo- Adjuvant Treatment to		cancer prior to sample procurement of the tumor	
		Radiation Prior to Sample Procurement	submitted for TCGA. If the patient did receive treatment	
49			for this cancer prior to procurement, the TSS should	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Tumor Specimen	Pharmaceutical Treatment Prior to Sample Procurement	contact the BCR for further instructions.	
	Submitted for TCGA		Note: Systemic treatment and certain localized therapies	
		Both Pharmaceutical and Radiation Treatment Prior to	(those administered to the same site as the TCGA	
		Sample Procurement	submitted tissue) given prior to procurement of the	
			sample submitted for TCGA are exclusionary.	
			3382736	
			Indicate whether the patient has a history of prior	
			malignancies.	
			Note 1: If this question cannot be answered because the	
			answer is unknown, the case will be excluded from TCGA.	
	Has the Patient Had Any Prior Cancer Diagnosed?	No	Note 2: If the patient has any history of prior	
			malignancies, including synchronous or bilateral	
50		History of Prior Malignancy	malignancies, please complete an "Other Malignancy	
			Form" for each malignancy diagnosed prior to the	
		History of Synchronous / Bilateral Malignancy		
			procurement of the tissue submitted for TCGA. If the	
			patient has a history of multiple diagnoses of basal	
			and/or squamous cell skin cancers, complete an "Other	
			Malignancy Form" for the first diagnosis for each of these	
			types.	
			3288361	
		L Consented	Indicate whether the patient was formally consented,	
	Consent Status	Deceased		
51			consented by death, or if the case has an exemption or	
		Exemption 4	waiver for consent	
			Note: Either the Date of Consent or the Date of Death	
		L Waiver	must be provided to qualify.	
Date of Consent				
			3081955	
			If the patient was formally consented, provide the month	
52	Month of Consent		of consent.	
52	Month of Consent			
			Note: Do not answer this question if the patient	
			consented by death only.	
			3081957	
		<u></u>	If the patient was formally consented, provide the day of	
53	Day of Consent		consent.	
		x/	Note: Do not answer this question if the patient	
			consented by death only.	
	N 60			
54	Year of Consent		3081959	

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Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
			If the patient was formally consented, provide the year of
			consent.
			Note: Do not answer this question if the patient
			consented by death only.
			3288498
			If the patient formally consented, provide the number of
	Number of Days from Date of Initial Pathologic diagnosis		days from the date the patient was initially diagnosed
			pathologically with the disease described on this form to
55			the date of the patient's formal consent.
	to Date of Consent		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.
Date of Death	1		
			2897026
			If the patient consented by death, provide the month of
56	Month of Death		death.
	Wonth of Death		Note: If the patient formally consented, only supply the
			date the patient consent.
			2897028
			If the patient consented by death, provide the day of
57	Day of Death		death
57			Note: If the patient formally consented, only supply the
			date the patient consent.
			2897030
	Year of Death		
50			If the patient consented by death, provide the year of
58			death.
			Note: If the patient formally consented, only supply the
			date the patient consent.
59	Number of Days from Date of Initial Pathologic diagnosis to Date of Death		3288499
			If the patient consented by death, provide the number of
			days from the date the patient was initially diagnosed
			pathologically with the disease described on this form to
			the date of the patient's death.
			Note 1: 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.
			Note 2: 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.

#### Comments:

Principal Investigator Name: \_\_\_\_\_\_ Principal Investigator Signature: \_\_\_\_\_

Date Signed (MM/DD/YYYY): \_\_\_\_\_

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