V4.40

Tissue Source Site (TSS) Name:TSS Identifier:TSS Unique Patient #:							
Form Notes:	Completed By: Completion Date (MM/DD/YYYY):  Form Notes: An Enrollment Form should be completed for each TCGA qualified case upon qualification notice from the BCR. All information provided on this form should include activity from the Date of Initial Pathologic Diagnosis to the most recent Date of Last Contact with the patient. Questions regarding this form should be						
		orimary Clinical Outreach Contact at the BCR. nknown" and "Not Evaluated" on this form are as fo	ollows:				
Unknown: 1	This answer option should on	ly be selected if the TSS cannot answer the questio	on because the answer is				
	•	TCGA required data set, the TSS must complete a or d be selected by the TSS if it is known that the info		-			
Question	Data Floment Label	Data Entry Alternatives		CDE ID With Working Instructions			
Question  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.				
Patient Info	rmation						
2	Primary Site of Disease	☐ Colon ☐ Rectum		2735776 Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA.			
3	Histological Subtype	Colon Adenocarcinoma Colon Mucinous Adenocarcinoma Rectal Adenocarcinoma Rectal Mucinous Adenocarcinoma	3081934 Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA.  Note: All other subtypes not listed are excluded from this study.				
4	Anatomic Organ Sub- division	Colon Subsites  Cecum  Ascending Colon Hepatic Flexure Transverse Colon  Colon Subsites  Splenic Flexure Descending Colon Sigmoid Colon	2716417 Using the patient's pathology/laboratory report, select the anatomic organ subdivision of the tumor submitted for TCGA.				
5	Is this a Prospective Tissue Collection?	☐ Yes ☐ No	3088492 Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively.				
6	Is this a Retrospective Tissue Collection?	Yes No		3088528 Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively.			
7	Gender	☐ Male ☐ Female	2200604 Provide the patient's gender using the defined categories. Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.				
Date of Birth							
8	Month of Birth	□□ (MM) ==		2896950 Provide the month the patient was born			
9	Day of Birth	DD) 2896952 Provide the day the patient was born					
10	Year of Birth			2896954 Provide the year the patient was born			

V4.40

Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
11	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth		3008233 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Birth.  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.
12	Race	American Indian or Alaska Native (A person having origins in any original peoples of North and South America (including Central America), and who maintains tribal affiliation/ community attachment)  Asian (A person having origins in any of the original peoples of the Far East, Southeast Asia, or Indian subcontinent including Cambodia, China, India, Japan, Pakistan, the Philippines, Thailand, Vietnam)  White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa)  Black or African American (having origins in any black racial groups of Africa. "Haitian" or "Negro" can be used in addition to "Black/African American")  Native Hawaiian or other Pacific Islander (A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands)  Not Evaluated (Not provided or available)  Unknown (Could not be determined or unsure)	2192199 Provide the patient's race using the defined categories.
13	Ethnicity	Not Hispanic or Latino (A person not meeting the definition for Hispanic or Latino)  Hispanic or Latino (A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race)  Not Evaluated (Not provided or available)  Unknown (Could not be determined or unsure)	2192217 Provide the patient's ethnicity using the defined categories
14	Has the Patient Had Any Prior Cancer Diagnosed?	□ No □ History of Prior Malignancy □ History of Synchronous / Bilateral Malignancy	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.  Note 2: If the patient has any history of prior malignancies, including synchronous or bilateral malignancies, please complete an "Other Malignancy Form" for each malignancy diagnosed prior to the procurement of the tissue submitted for TCGA. 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.

Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
15	History of Neo-Adjuvant Treatment to Tumor Specimen Submitted for TCGA	□ No □ Radiation Prior to Sample Procurement □ Pharmaceutical Treatment Prior to Sample Procurement □ Both Pharmaceutical and Radiation Treatment Prior to Sample Procurement	Indicate whether the patient received therapy for this cancer prior to sample procurement of the tumor submitted for TCGA. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instructions.  Note: Systemic treatment and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to procurement of the sample submitted for TCGA are exclusionary.
Date of Initi	al Pathologic Diagnosis (of Tu	mor Associated with Tissue Procurement for TCGA of this colorectal tumor)	
16	Month of Initial Pathologic Diagnosis	□□ (MM)	2896956 Provide the month the patient was initially diagnosed with the malignancy submitted for TCGA
17	Day of Initial Pathologic Diagnosis	□□ (DD)	2896958 Provide the day the patient was initially diagnosed with the malignancy submitted for TCGA
18	Year of Initial Pathologic Diagnosis		2896960 Provide the year the patient was initially diagnosed with the malignancy submitted for TCGA
19	AJCC Cancer Staging Handbook Edition	First Edition (1978-1983)  Second Edition (1984-1988)  Third Edition (1989-1992)  Fourth Edition (1993-1997)  Fifth Edition (1998-2002)  Sixth Edition (2003-2009)  Seventh Edition (2010-Current)	2722309 Indicate the AJCC Cancer Staging Edition that was used to answer the following staging questions.
20	Pathologic Spread: Primary Tumor <b>(pT)</b>	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	3045435 Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC).
21	Pathologic Spread: Lymph Nodes <b>(pN)</b>	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	3065858 Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC).
22	Pathologic Spread: Distant Metastases (M) (clinical and/or pathological)	<ul><li>MX</li><li>M1</li><li>M1b</li><li>M1a</li><li>M1b</li></ul>	3045439 Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
23	Tumor Stage (Pathological)	Stage II Stage IIA Stage IIIA Stage IIIA Stage IV  Stage IB Stage IIC Stage IIIB Stage IVA  Stage II Stage III Stage IVA  Stage II Stage III Stage IVB	3065862 Using the patient's pathology/laboratory report, in conjunction with the patient's medical record, select the stage as defined by the American Joint Committee on Cancer (AJCC).
24	Residual Tumor	RX RO R1 R2	2608702 Using the pathology/laboratory report, select the tissue margin status at the time of surgical resection for the tumor submitted for TCGA.
25	Were Lymph Nodes Examined at the time of Primary Presentation	☐ Yes ☐ No	2200396 Indicate whether any lymph nodes were examined at the time of the primary resection for the tumor submitted to TCGA
26	Number of Lymph Nodes Examined		3 Provide the number of lymph nodes pathologically assessed if one or more lymph nodes were removed.

V4.40

Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
	Number of Lymph Nodes		3086388
27	Positive by H&E Light		Provide the number of lymph nodes identified as
27	Microscopy		positive through hematoxylin and eosin (H&E)
	Wilcioscopy		staining and light microscopy.
	Number of Lymph Nodes		3086383
	Positive for		Provide the number of lymph nodes identified as
28	micrometastasis by IHC Keratin Staining ONLY		positive through keratin immunohistochemistry
			(IHC) staining.
	iteration starring sites		2939553
29	Vital Status	Living Deceased	Indicate whether the patient was living or
29	Vitai Status	Living Deceased	deceased at the date of last contact.
Date of Last	Contact		deceased at the date of last contact.
Date of Last	Contact		2007020
			2897020
			Provide the month of last contact with the patient
30	Month of Last Contact	□ □ (MM)	(as reported by the patient, medical provider,
		(IVIIVI)	family member, or caregiver).
			Note: Do not answer this question if the patient
			is deceased.
			2897022
			Provide the day of last contact with the patient (as
24	5 (1 . 6		reported by the patient, medical provider, family
31	Day of Last Contact	□□ (DD)	member, or caregiver).
			Note: Do not answer this question if the patient
			is deceased.
			2897024
			Provide the year of last contact with the patient
32	Year of Last Contact		(as reported by the patient, medical provider,
		()	family member, or caregiver).
			Note: Do not answer this question if the patient
			is deceased.
	Number of Days from Date of Diagnosis to Date of Last Contact		3008273
			Provide the number of days from the date the
			patient was initially diagnosed pathologically with
			the disease to the date of Last Contact.
22			Note 1: Do not answer this question if the patient
33			is deceased.
			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.
			tilis jorin.
Date of Dea	th	Not Applicable (Patient is Alive)	
			2897026
34	Month of Death	□ □ (MM)	If the patient is deceased, provide the month of
٥.	Day of Death	(IVIIVI)	death.
			2897028
35		□□ (DD)	If the patient is deceased, provide the day of
33		□□ (DD)	
			death.
	Year of Death		2897030
36			If the patient is deceased, provide the year of
			death.
			3165475
			Provide the number of days from the date the
	Number of Days from Date of Diagnosis to Date of Death		patient was initially diagnosed pathologically with
37			the disease to the date of Death.
			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.
			2759550
38	Tumor Status	П П	
	Tumor Status	☐ Tumor Free ☐ With Tumor ☐ Unknown Tumor Status	Indicate whether the patient was tumor/disease
			free at the date of last contact or death.

Question	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions		
Prognostic/Predictive/Lifestyle Features (Used for Tumor Prognosis or Responsiveness to Treatment)						
39	Preoperative/ Pretreatment CEA Level	Not Applicable Unknown			2716510 Provide the carcinoembryonic antigen or CEA level (ng/ml) prior to the resection of tumor submitted to TCGA.	
40	Non-nodal Tumor Deposits (TD) in Resected Specimen	Yes No Unknown			3107051 Indicate the pathologic presence of tumor deposits in the pericolic or perirectal fat or in adjacent mesentery away from the leading edge of the tumor submitted to TCGA.	
41	Circumferential Resection Margin (CRM) (also known as radial surgical clearance)	(mm)			64202 Indicate the measured length (mm) between a malignant lesion of the colon or rectum and the nearest radial (or circumferential) border of tissue removed during surgery for the tumor submitted to TCGA.	
42	Is There Vascular Invasion?	Yes	No	Unknown	64358 Indicate if large vessel or venous invasion was pathologically present in the tumor specimen submitted to TCGA	
43	Lymphatic Invasion Present	☐ Yes ☐	No	Unknown	64171 Indicate if malignant cells are pathologically present in small or thin walled vessels suggesting lymphatic involvement in the tumor submitted to TCGA.	
44	Perineural Invasion Present	Yes	No	Unknown	64181 Indicate if perineural invasion or infiltration of tumor or cancer is pathologically present in tumor submitted to TCGA.	
45	Microsatellite Instability (Abnormal @ >33% loci tested)	Yes	No	Unknown	3123142 Indicate whether microsatellite instability was present in more than 33% of loci tested in the tumor submitted to TCGA.	
46	Number of Loci Tested				3107127 If microsatellite instability was identified, indicate the number of loci tested to detect recessive mutations in the tumor submitted to TCGA.	
47	Number of Abnormal Loci				3107129 Indicate the number of loci found to be abnormal during testing to detect microsatellite instability in the tumor submitted to TCGA.	
48	Was Loss of Expression of Mismatch Repair Proteins Tested (by IHC)?	☐ Yes ☐	No	Unknown	3123153 Indicate if testing was performed to identify any loss of expression in mismatch repair proteins tested by immunohistochemistry (IHC). Note: If not performed, skip to Question 50 'KRAS Gene Analysis Performed'	
Loss of Expr	ession of Mismatch Repair Pr	oteins by IHC				
	MLH1	Expressed Not expressed		3105496		
49	MSH2	Expressed Not expressed		Indicate if any loss of expression of mismatch		
	PMS2	☐ Expressed	☐ Expressed ☐ Not expressed		repair proteins by immunohistochemistry (IHC) is or is not expressed for each of the listed genes.	
	MSH6	Expressed	☐ Not expre	essed	or is not expressed for each of the listed genes.	
50	KRAS Gene Analysis Performed?		No	Unknown	3123147 Indicate if KRAS gene analysis was performed on tumor submitted for TCGA.  Note: If not performed, skip to Question 53 'BRAF Gene Analysis Performed'	
51	Mutation Found (KRAS)	Yes	□ No		2932340 If KRAS gene analysis was performed indicate if KRAS Mutation was found.	

V4.40

TSS Unique Patient #: Tissue Source Site (TSS) Name: \_\_\_\_\_\_ TSS Identifier: \_ **Data Entry Alternatives CDE ID With Working Instructions** Question **Data Element Label** 3124509 If KRAS Mutation is YES, □ 12 □ 13 Other 52 If KRAS mutation was identified indicate the What Codon? specific codon. 3123151 Yes Indicate if BRAF gene analysis was performed on tumor submitted for TCGA. **BRAF Gene Analysis** 53 No Note: If not performed, skip to Question 55 Performed? 'Synchronous Colon/Rectal Tumor(s) at Time of Unknown Tissue Collection'. 3107189 Normal **BRAF Gene Analysis** 54 If BRAF gene analysis was performed indicate the Results Abnormal result. History of Synchronous 2185953 Colon / Rectal Tumor(s) Yes Indicate whether the patient had a synchronous 55 at Time of Tissue colon or rectal cancer present at the time tissue No was procured for TCGA. Collection 3107197 History of Prior Colon Indicate if the patient had a previous history of 56 ☐ Yes □ No □ Unknown **Polyps** colon polyps as noted in the history/physical or previous endoscopic report(s). 64184 Were Colon Polyps Indicate if polyps were present in the colon, Yes □ No 57 Present (at Time of Tissue surgically and/or pathologically, at the time of Collection) tissue collection for the tumor submitted to TCGA. Patient Weight (at time of biospecimen 58 Provide the weight of the patient measured in procurement) (In kilograms. kilograms) Patient Height (at time of biospecimen 649 59 (cm) Provide the height of the patient in centimeters. procurement) (In centimeters) 3107205 Number of First Degree  $\Box$  0  $\square_2$  $\square$  3  $\square > 3$ Indicate the number of first degree relatives 60 Relatives with history of (parent, sibling and/or child) associated with a Colon/Rectal Cancer Unknown diagnosis of colon or rectal cancer. **Primary Treatment** 2005312 Yes Indicate whether the patient had adjuvant/ post-Adjuvant Post-Operative operative radiation therapy. 61 Radiation Therapy Note: If the patient did have adjuvant radiation. the Radiation Supplemental Form should be ☐ Unknown completed. 2785850 Yes Indicate whether the patient had adjuvant/ post-Adjuvant Post-Operative operative pharmaceutical therapy. 62 Nο **Pharmaceutical Therapy** Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Unknown Supplemental Form should be completed. New Tumor Event Information: Complete this section if the patient had a new tumor event after tissue procurement and prior to submission of the Enrollment Form. If the patient did not have a new tumor event, or if the TSS does not know, indicate this in the first question below; and then skip the remainder of this form. 3121376 Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary New Tumor Event After tumor) after their initial treatment for the tumor 63 **Initial Treatment** submitted to TCGA. Note: If the patient had multiple new tumor ☐ Unknown events, a follow-up form should be completed for

each new tumor event.

Question	Data Floment Label	Data Entry Alternatives	CDE ID With Working Instructions
Question Date of New	Data Element Label  Tumor Event	Data Entry Alternatives	CDE ID With Working Instructions
Date of New			2104044
64	Month of New Tumor Event After Initial	□□ (MM)	3104044
04		<b>□ □</b> (MM)	If the patient had a new tumor event, provide the
	Treatment		month of diagnosis for this new tumor event.
C.F.	Day of New Tumor Event		3104042
65	After Initial Treatment	□□ (DD)	If the patient had a new tumor event, provide the
			day of diagnosis for this new tumor event.
	Year of New Tumor Event		3104046
66	After Initial Treatment		If the patient had a new tumor event, provide the
			year of diagnosis for this new tumor event.
			3392464
			Provide the number of days from the date the
	Number of Days from		patient was initially diagnosed pathologically with
67	Date of Diagnosis to Date		the disease to the date of new tumor event after
67	of New Tumor Event		initial treatment.
	After Initial Treatment		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.
	Additional Surgery for		3008755
68	New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate
	Loco-Regional		whether the patient had surgery for the new loco-
5 . (4.11			regional tumor event in question.
Date of Add	itional Surgery for New Tumo	or Event Loco-Regional	T
	Month of Additional		2897032
69	Surgery for New Tumor	□ □ (MM)	If the patient had surgery for the new loco-
	Event	(\\\\\\\)	regional tumor event, provide the month of
	Loco-Regional		surgery for this new loco-regional tumor event.
	Day of Additional Surgery for New Tumor Event Loco Regional Procedure		2897034
70		$\square$ $\square$ $\square$ $\square$	If the patient had surgery for the new loco-
			regional tumor event, provide the day of surgery
	Vanuaf Additional		for this new loco-regional tumor event.
	Year of Additional		2897036
71	Surgery for New Tumor Event		If the patient had surgery for the new loco-
	Loco-Regional		regional tumor event, provide the year of surgery for this new loco-regional tumor event.
	LOCO-Regional		3408572
	Number of Days from		Provide the number of days from the date the patient was initially diagnosed pathologically with
	Date of Initial Pathologic		the disease described on this form to the date of
	Diagnosis to Date of Additional Surgery for		additional surgery for new tumor event (loco-
72			regional).
	New Tumor Event		Note: Only provide Interval data if you have
	Loco-Regional		received permission from the NCI to provide time
	Loco Regional		intervals as a substitute for requested dates on
			this form.
	Residual Tumor after		3104061
	surgery for New Tumor		If the patient had surgery for the new loco-
73	Event	$\square$ RX $\square$ RO $\square$ R1 $\square$ R2	regional tumor event, provide the status of any
	Loco-Regional		residual tumor after this surgery.
74	Additional Surgery for	☐ Yes	3008757
	New Tumor Event  Metastasis	□ No	Using the patient's medical records, indicate
			whether the patient had surgery for the new
		Unknown	metastatic tumor event in question.
75		Liver	1611
	City of Ashiri	Live	1611
	Site of Additional Surgery for New Tumor Event <b>Metastasis</b>	Lung	Indicate the location of additional surgery for the
		Lumph Nodes	new metastatic tumor event which has spread
		Lymph Nodes	from original tumor located in the large intestine
		Other	or rectum.

V4.40

Question	Data Element Label	Data Entry Altern	atives			CDE ID With Working Instructions
Date of Additional Surgery for New Tumor Event - Metastasis						
76	Month of Additional Surgery for New Tumor Event <b>Metastasis</b>		(MM)			2897038  If the patient had surgery for the new metastatic tumor event, provide the month of surgery for this new metastatic tumor event.
77	Day of Additional Surgery for New Tumor Event <b>Metastasis</b>		(DD)			2897040 If the patient had surgery for the new metastatic tumor event, provide the day of surgery for this new metastatic tumor event.
78	Year of Additional Surgery for New Tumor Event <b>Metastasis</b>		(YYYY)			2897042 If the patient had surgery for the new metastatic tumor event, provide the year of surgery for this new metastatic tumor event.
79	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event <b>Metastasis</b>					3408682 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 additional surgery for new tumor event (metastasis)  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.
80	Residual Tumor after surgery for New Tumor Event Metastatic (AJCC 7th Edition)	☐ RX	□ RO	☐ R1	☐ R2	3104081 If the patient had surgery for the new metastatic tumor event, provide the status of any residual tumor after this surgery.
Additional T	reatment					
81	Additional Treatment of New Tumor Event Radiation Therapy	☐ Yes	□ No		☐ Unknown	3008761 Indicate whether the patient received radiation treatment for this new tumor event.
82	Additional Treatment of New Tumor Event Pharmaceutical Therapy	Yes	□ No		☐ Unknown	2650646 Indicate whether the patient received pharmaceutical treatment for this new tumor event.
Comments:						
Principal Investigator Name: Principal Investigator Signature:						
	Date Signed (MM/DD/YYYY):					