Enrollment: Colon / Rectum

V4.40

Tissue Source Site (TSS) Name: _____ TSS Identifier: _____ TSS Unique Patient #: _____
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 directed to the Tissue Source Site's (TSS) primary Clinical Outreach Contact at the BCR.

The following definitions for the use of "Unknown" and "Not Evaluated" on this form are as follows:

Unknown: This answer option should only be selected if the TSS cannot answer the question because the answer is not known at the TSS. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing the reason why the answer is unknown.

Not Evaluated: This answer option should be selected by the TSS if it is known that the information being requested cannot be obtained due to the test not being performed.

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.***
Patient Information			
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 ☐ Splenic Flexure ☐ Descending Colon ☐ Sigmoid Colon **Rectal Subsites** ☐ Sigmoid Colon ☐ Rectum ☐ Rectosigmoid Junction	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	☐☐☐☐ (YYYY)	2896954 Provide the year the patient was born

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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	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.*** ***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.***

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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	3382737 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 Initial Pathologic Diagnosis (of Tumor 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	☐☐☐☐ (YYYY)	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 **(pT)**	☐ TX ☐ Tis ☐ T2 ☐ T2b ☐ T4 ☐ T4b ☐ T0 ☐ T1 ☐ T2a ☐ T3 ☐ T4a	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 **(pN)**	☐ NX ☐ N1 ☐ N1b ☐ N2 ☐ N2b ☐ N0 ☐ N1a ☐ N1c ☐ N2a ☐ N3	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)**	☐ MX ☐ M1 ☐ M1b ☐ M0 ☐ M1a	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 I ☐ Stage IIA ☐ Stage IIIA ☐ Stage IV ☐ Stage IA ☐ Stage IIB ☐ Stage IIIB ☐ Stage IVA ☐ Stage IB ☐ Stage IIC ☐ Stage IIIC ☐ Stage IVB ☐ Stage II ☐ Stage III	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 ☐ R0 ☐ 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.

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

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

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	_____ (ng/ml) ☐ 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) ☐ Unknown	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 Expression of Mismatch Repair Proteins by IHC			
49	MLH1	☐ Expressed ☐ Not expressed	3105496 Indicate if any loss of expression of mismatch repair proteins by immunohistochemistry (IHC) is or is not expressed for each of the listed genes.
	MSH2	☐ Expressed ☐ Not expressed	
	PMS2	☐ Expressed ☐ Not expressed	
	MSH6	☐ Expressed ☐ Not expressed	
50	KRAS Gene Analysis Performed?	☐ Yes ☐ 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.

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Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
52	If KRAS Mutation is YES, What Codon?	☐ 12 ☐ 61 ☐ 13 ☐ Other	3124509 If KRAS mutation was identified indicate the specific codon.
53	BRAF Gene Analysis Performed?	☐ Yes ☐ No ☐ Unknown	3123151 Indicate if BRAF gene analysis was performed on tumor submitted for TCGA. ***Note: If not performed, skip to Question 55 'Synchronous Colon/Rectal Tumor(s) at Time of Tissue Collection'.***
54	BRAF Gene Analysis Results	☐ Normal ☐ Abnormal	3107189 If BRAF gene analysis was performed indicate the result.
55	History of Synchronous Colon / Rectal Tumor(s) at Time of Tissue Collection	☐ Yes ☐ No	2185953 Indicate whether the patient had a synchronous colon or rectal cancer present at the time tissue was procured for TCGA.
56	History of Prior Colon Polyps	☐ Yes ☐ No ☐ Unknown	3107197 Indicate if the patient had a previous history of colon polyps as noted in the history/physical or previous endoscopic report(s).
57	Were Colon Polyps Present (at Time of Tissue Collection)	☐ Yes ☐ No	64184 Indicate if polyps were present in the colon, surgically and/or pathologically, at the time of tissue collection for the tumor submitted to TCGA.
58	Patient Weight (at time of biospecimen procurement) (In kilograms)	____ ____ ____. ____ (kg)	651 Provide the weight of the patient measured in kilograms.
59	Patient Height (at time of biospecimen procurement) (In centimeters)	____ ____ ____. ____ (cm)	649 Provide the height of the patient in centimeters.
60	Number of First Degree Relatives with history of Colon/Rectal Cancer	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ >3 ☐ Unknown	3107205 Indicate the number of first degree relatives (parent, sibling and/or child) associated with a diagnosis of colon or rectal cancer.
Primary Treatment			
61	Adjuvant Post-Operative Radiation Therapy	☐ Yes ☐ No ☐ Unknown	2005312 Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***Note: If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.***
62	Adjuvant Post-Operative Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	2785850 Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical 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.			
63	New Tumor Event After Initial Treatment	☐ Yes ☐ No ☐ Unknown	3121376 Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after their initial treatment for the tumor submitted to TCGA. ***Note: If the patient had multiple new tumor events, a follow-up form should be completed for each new tumor event.***

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Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date of New Tumor Event			
64	Month of New Tumor Event After Initial Treatment	☐☐ (MM)	3104044 If the patient had a new tumor event, provide the month of diagnosis for this new tumor event.
65	Day of New Tumor Event After Initial Treatment	☐☐ (DD)	3104042 If the patient had a new tumor event, provide the day of diagnosis for this new tumor event.
66	Year of New Tumor Event After Initial Treatment	☐☐☐☐ (YYYY)	3104046 If the patient had a new tumor event, provide the year of diagnosis for this new tumor event.
67	Number of Days from Date of Diagnosis to Date of New Tumor Event After Initial Treatment	_____	3392464 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event 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.***
68	Additional Surgery for New Tumor Event **Loco-Regional**	☐ Yes ☐ No ☐ Unknown	3008755 Using the patient's medical records, indicate whether the patient had surgery for the new loco-regional tumor event in question.
Date of Additional Surgery for New Tumor Event Loco-Regional			
69	Month of Additional Surgery for New Tumor Event **Loco-Regional**	☐☐ (MM)	2897032 If the patient had surgery for the new loco-regional tumor event, provide the month of surgery for this new loco-regional tumor event.
70	Day of Additional Surgery for New Tumor Event Loco Regional Procedure	☐☐ (DD)	2897034 If the patient had surgery for the new loco-regional tumor event, provide the day of surgery for this new loco-regional tumor event.
71	Year of Additional Surgery for New Tumor Event **Loco-Regional**	☐☐☐☐ (YYYY)	2897036 If the patient had surgery for the new loco-regional tumor event, provide the year of surgery for this new loco-regional tumor event.
72	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event **Loco-Regional**	_____	3408572 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 (loco-regional). ***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.***
73	Residual Tumor after surgery for New Tumor Event **Loco-Regional**	☐ RX ☐ R0 ☐ R1 ☐ R2	3104061 If the patient had surgery for the new loco-regional tumor event, provide the status of any residual tumor after this surgery.
74	Additional Surgery for New Tumor Event **Metastasis**	☐ Yes ☐ No ☐ Unknown	3008757 Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question.
75	Site of Additional Surgery for New Tumor Event **Metastasis**	☐ Liver ☐ Lung ☐ Lymph Nodes ☐ Other	1611 Indicate the location of additional surgery for the new metastatic tumor event which has spread from original tumor located in the large intestine or rectum.

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Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date of Additional Surgery for New Tumor Event - Metastasis			
76	Month of Additional Surgery for New Tumor Event **Metastasis**	☐☐ (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 **Metastasis**	☐☐ (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 **Metastasis**	☐☐☐☐ (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 **Metastasis**	_____	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 ☐ R0 ☐ 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 Treatment			
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:

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_____

Principal Investigator Name: _____ Principal Investigator Signature: _____

Date Signed (MM/DD/YYYY): _____