Enrollment: Stomach

V4.7

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	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	Primary Site of Disease*	☐ Stomach	2735776 Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA.
3	Anatomic Organ Sub-Division (check all that apply)	☐ Gastroesophageal Junction ☐ Cardia / Proximal ☐ Fundus / Body ☐ Antrum / Distal ☐ Stomach, NOS ☐ Other *(please specify)*	3212021 Using the patient's pathology/laboratory report, select the anatomic organ sub-division of the tumor used for TCGA. Include all areas of tumor involvement.
4	Other Anatomic Organ Sub-Division	_____	3407703 If the anatomic organ sub-division is not included in the provided list, specify the other anatomic organ sub-division of the tumor used for TCGA
5	Histological Subtype*	☐ Stomach, Intestinal Adenocarcinoma Tubular Type ☐ Stomach, Intestinal Adenocarcinoma Papillary Type ☐ Stomach, Intestinal Adenocarcinoma Mucinous Type ☐ Stomach, Intestinal Adenocarcinoma, Not Otherwise Specified (NOS) ☐ Stomach, Adenocarcinoma, Signet Ring Type ☐ Stomach, Adenocarcinoma, Diffuse Type ☐ Stomach Adenocarcinoma, Not Otherwise Specified	3081934 Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. ***Note 1: All other subtypes not listed are excluded from this study.*** ***Note 2: Mixed Tumor Types Are Excluded***
6	Tumor Grade *	☐ G1 Well Differentiated ☐ G2 Moderately Differentiated ☐ G3 Poorly Differentiated ☐ GX Unknown	2785839 Using the patient's pathology/laboratory report, select the tumor grade of the tumor submitted for TCGA. ***Note: Grade 4 (G4) tumors are excluded from this study.***
7	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.
8	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.

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9	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			
10	Month of Birth	☐☐ (MM)	2896950 Provide the month the patient was born.
11	Day of Birth	☐☐ (DD)	2896952 Provide the day the patient was born
12	Year of Birth	☐☐☐☐ (YYYY)	2896954 Provide the year the patient was born
13	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 described on this form to the patient's date of the 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***
14	Race	☐ American Indian or Alaska Native (A person having origins in any original peoples of North and South America, and 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, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam) ☐ White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa) ☐ Black or African American (A person having origins in any black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or 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.
15	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.
16	State/Province of Sample Procurement	_____	3203072 Provide the name of the state or province in which the sample was procured.
17	City of Sample Procurement	_____	3203075 Provide the name of a city in which the sample was procured.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
18	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 orbilateral 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.***
19	History of Neo-adjuvant Treatment for 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)			
20	Month of Initial Pathologic Diagnosis*	☐☐ (MM)	2896956 Provide the month the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
21	Day of Initial Pathologic Diagnosis*	☐☐ (DD)	2896958 Provide the day the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
22	Year of Initial Pathologic Diagnosis*	☐☐☐☐ (YYYY)	2896960 Provide the year the patient was initially pathologically diagnosed with the malignancy submitted for TCGA.
23	Were Lymph Nodes Examined at the Time of Primary Resection?	☐ Yes ☐ No ☐ Unknown	2200396 Indicate whether any lymph nodes were pathologically examined at the time of the primary resection.
24	Number of Lymph Nodes Examined	☐☐	3 Provide the number of lymph nodes pathologically assessed, if one or more lymph nodes were removed.
25	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.
26	Residual Tumor (at time of initial surgery)	☐ RX ☐ R0 ☐ R1 ☐ R2 ☐ Not Evaluated	2608702 Using the patient's pathology/laboratory report, select the tissue margin status at time of surgical resection.
27	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.
28	Pathologic Spread: Primary Tumor **(pT)** (AJCC)*	☐ TX ☐ T1a ☐ T2a ☐ T3 ☐ T4a ☐ T0 ☐ T1b ☐ T2b ☐ T4 ☐ T4b ☐ T1 ☐ T2	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).
29	Pathologic Spread: Lymph Nodes **(pN)** (AJCC)*	☐ NX ☐ N1 ☐ N3 ☐ N3b ☐ N0 ☐ N2 ☐ N3a	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).

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

Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
30	Pathologic Spread: Distant Metastases **(M)** (Clinical or Pathological) (AJCC)*	☐ MX ☐ M0 ☐ M1	3045439 Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the code for the clinical or pathological M (metastasis) as defined by the American Joint Committee on Cancer (AJCC).
31	Tumor Stage (Pathological and/or Clinical)(AJCC) *	☐ Stage I ☐ Stage IIA ☐ Stage IIIB ☐ Stage IA ☐ Stage IIB ☐ Stage IIIC ☐ Stage IB ☐ Stage III ☐ Stage IV ☐ Stage II ☐ Stage IIIA	3065862 Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the clinical or pathological stage as defined by the American Joint Committee on Cancer (AJCC).
32	Vital Status*	☐ Living ☐ Deceased	5 Indicate whether the patient was living or deceased at the date of last contact.
Date of Last Contact		☐ Not Applicable (Patient is Deceased)	
33	Month of Last Contact	☐☐ (MM)	2897020 If the patient is living, 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.***
34	Day of Last Contact	☐☐ (DD)	2897022 If the patient is living, 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.***
35	Year of Last Contact	☐☐☐☐ (YYYY)	2897024 If the patient is living, 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.***
36	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	3008273 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 last contact. ***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		☐ Not Applicable (Patient is Alive)	
37	Month of Death	☐☐ (MM)	2897026 If the patient is deceased, provide the month of death.
38	Day of Death	☐☐ (DD)	2897028 If the patient is deceased, provide the day of death.
39	Year of Death	☐☐☐☐ (YYYY)	2897030 If the patient is deceased, provide the year of death.
40	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	3165475 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 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.***
41	Tumor Status (at time of last contact or at time of death)	☐ Tumor Free ☐ With Tumor ☐ Unknown Tumor Status	2759550 Indicate whether the patient was tumor/disease free at the date of last contact or death.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
42	Cause of Death	☐ Stomach Cancer ☐ Other Malignancy (not stomach cancer related) ☐ Other Non-Malignant Disease ☐ Unknown Cause of Death	2554674 If the patient is deceased, indicate the cause of death for the patient.
43	Patient History of Reflux Disease	☐ Yes ☐ No ☐ Unknown	3203079 Indicate whether the patient has a prior history of reflux disease.
44	Was Patient Receiving Anti-Reflux Treatment at Time of Sample Procurement	☐ Yes ☐ No ☐ Unknown	3203107 Indicate whether the patient was receiving anti-reflux medication at the time of sample procurement.
45	If Patient Was Receiving Anti-Reflux Treatment at time of Sample Procurement, What Type of Treatment was Being Given?	☐ Proton Pump Inhibitors (e.g., Prilosec, Nexium, etc; drug class nomenclature often ends in -prazole) ☐ H2 Blockers (e.g., Zantac, Tagamet, etc; drug class nomenclature often ends in -tidine) ☐ Antacids (e.g., Tums, Ca2+, Gaviscon, bismuth, etc. typically metal hydroxides) ☐ Unknown	3203127 If applicable, indicate the type of anti-reflux treatment that the patient was receiving at the time of sample procurement. ***Note: Check all that apply.***
46	Previous or Current Diagnosis of Barrett's Esophagus	☐ Yes ☐ No ☐ Unknown	3203140 Indicate whether the subject was previously or is currently diagnosed with Barrett's Esophagus.
47	Previous or Current Diagnosis of H. *pylori* Infection?	☐ Yes ☐ No ☐ Unknown	3203146 Indicate whether the subject was previously or is currently diagnosed with H. Pylori.
48	Family History of Stomach Cancer in a First Degree Relative (parents, siblings, or children)	☐ Yes ☐ No ☐ Unknown	3203179 Indicate whether the subject has a first degree relative (parents, siblings, children) with a history of stomach cancer.
49	Number of First degree relatives: parents, siblings, or children who have been diagnosed with stomach cancer	___ ___	3203277 Indicate the number of first degree relatives (parents, siblings, children) who have been diagnosed with stomach cancer.
50	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.***
51	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***
52	Measure of Success of Outcome at the Completion of Initial First Course Treatment	☐ Progressive Disease ☐ Complete Response ☐ Stable Disease ☐ Not Applicable ☐ Partial Response ☐ Unknown	2786727 Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies).
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.			
53	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.***

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

Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date of New Tumor Event After Initial Treatment		☐ Not Applicable	
54	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.
55	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.
56	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.
57	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	3392464 Provide the number of days from the date the patient was initially pathologically diagnosed with the disease described on this form to the date of new tumor event. ***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.***
58	Type of New Tumor Event (check all that apply)	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	3119721 Indicate whether the patient's new tumor event was a locoregional recurrence or a distant metastasis of the tissue submitted for TCGA; or a new primary tumor. ***Note: If the patient has had multiple new tumor events prior to the submission of the Enrollment Form, the Follow-up Form should be used to report information relative to the second or subsequent tumor events.***
59	Diagnostic Evidence of Recurrence / Relapse (check all that apply)	☐ Biopsy w/Histologic Confirmation ☐ Convincing Imaging (i.e. CT, PET, MRI) ☐ Positive Biomarker(s)	2786205 Indicate the procedure or testing method used to diagnose tumor recurrence or relapse.
60	Additional Surgery for New Tumor Event Loco-regional Procedure	☐ Yes ☐ Unknown ☐ No	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**		☐ Not Applicable (No Loco-regional Procedure for New Tumor Event)	
61	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.
62	Day of Additional Surgery for New Tumor Event Loco-regional	☐☐ (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.
63	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.
64	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event - Locoregional	_____	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 (locoregional). ***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.***
65	Residual Tumor after Surgery for New Tumor Event Loco-regional	☐ RX ☐ R1 ☐ R0 ☐ R2 ☐ Not Evaluated	3104061 If the patient had surgery for the new loco-regional tumor event, provide the status of any residual tumor after this surgery.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
66	Site of New Tumor Event (Metastasis)	☐ Liver ☐ Other (please specify) ☐ Lung ☐ Peritoneal Surfaces ☐ Non-Regional / Distant Lymph Nodes	3108271 Indicate the site of this new metastatic tumor event, as it relates to the tissue submitted for TCGA.
67	Other Site of New Tumor Event – (Metastasis) (please specify)	_____	3128033 If the metastatic site is not included in the list for the question above, designate the site of this new metastatic tumor event.
68	Additional Surgery for New Tumor Event Metastasis Procedure	☐ Yes ☐ Unknown ☐ No	3008757 Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question.
Date of Additional Surgery for New Tumor Event Metastasis		☐ Not Applicable (No Surgical Procedure for Metastatic Tumor Recurrence / Progression)	
69	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.
70	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.
71	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.
72	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.***
73	Residual Tumor after Surgery for New Tumor Event Metastatic	☐ Not Evaluated ☐ R1 ☐ RX ☐ R2 ☐ R0	3104081 If the patient had surgery for the new metastatic tumor event, provide the status of any residual tumor after this surgery.
74	Additional Treatment of New Tumor Event Radiation Therapy	☐ Yes ☐ Unknown ☐ No	3008761 Indicate whether the patient received radiation treatment for this new tumor event.
75	Additional Treatment of New Tumor Event Pharmaceutical Therapy)	☐ Yes ☐ Unknown ☐ No	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): _____