Tissue Source Site (TSS) Name:		TSS Identifier: T	SS Unique Patient #:		
Completed	Ву:	Completion Date	(MM/DD/YYYY):		
should includ directed to the The following Unknown: The selected for a Not Evaluate	orm Notes: An Enrollment Form should be completed for each TCGA qualified case upon qualification notice from the BCR. All information provided on this form hould 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 lirected 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 elected 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.1 and 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		
Date of Form		Data Liftly Atternatives	CDE ID WITH WORKING HISTIACTIONS		
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 Infor	mation				
2	Primary Site of Disease*	Pancreas	2735776 Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA.		
3	Invasive Adenocarcinoma	☐ Yes ☐ No	3027106 Confirm that the pancreas tumor sample being submitted to TCGA is an invasive adenocarcinoma.		
4	Histological Subtype*	Pancreas, Adenocarcinoma Ductal Type Pancreas, Colloid (mucinous non-cystic) Carcinoma Pancreas, Hepatoid Carcinoma Pancreas, Medullary Carcinoma Pancreas, Signet Ring Cell Carcinoma Pancreas, Undifferentiated Carcinoma Pancreas, Carcinoma w/Osteoclast-like Giant Cells Pancreas, Adenocarcinoma, Other Subtype (please specify below)	3081934 Indicate the histologic subtype, if available, for the pancreas adenocarcinoma tumor sample being submitted to TCGA. Note1: Mixed Histologic Subtypes Are Excluded For This Tumor Type Note2: Cholangiocarcinoma is excluded.		
5	Other Histological Subtype		3124492 If the histological subtype is not included in the provided list, specify the histological subtype of the pancreas adenocarcinoma tumor that is being submitted to TCGA.		
6	Tumor Type*	Primary	3288124 Confirm that the tumor being submitted to TCGA is a primary untreated malignant biospecimen.		
7	Anatomic Organ Sub- division	Head of Pancreas Body of Pancreas Other (please specify)	2008006 Using the patient's pathology/laboratory report, select the anatomic organ subdivision of the tumor submitted for TCGA.		
8	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.		

Tissue Source Site (TSS) I	Name: TSS Identi	ier: TSS Uniqu	ue Patient #:

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
9	Is this a Prospective Tissue Collection?	Yes No	3088492 Indicate whether the TSS providing tissue is contracted for prospective tissue collection. Note: If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively.
10	Is this a Retrospective Tissue Collection?	☐ Yes ☐ No	3088528 Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. Note: If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively.
11	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			
12	Month of Birth	□□ (MM)	2896950 Provide the month the patient was born.
13	Day of Birth	DD)	2896952 Provide the day the patient was born.
14	Year of Birth	CYYYY)	2896954 Provide the year the patient was born.
15	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 patient's 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.
16	Race	American Indian or Alaska Native (A person having origins in any original peoples of North and South America, and maintains tribal affiliation/community) 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 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 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.
17	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

Tissue Source Site (TSS) Na	e: TSS Identifier:	TSS Unique Patient #:	

Question #	Data Flement Lahel	Data Entry Alternatives	CDF ID With Working Instructions
Question #	Has the Patient Had Any Prior Cancer Diagnosed? *	No History of Prior Malignancy	CDE ID With Working Instructions 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
		☐ History of Synchronous / Bilateral 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 	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 Tum	or Associated with Tissue Procurement for TCGA)	
20	Month of Initial Pathologic Diagnosis*	□□ (MM)	2896956 Provide the month the patient was initially diagnosed with the malignancy submitted for TCGA.
21	Day of Initial Pathologic Diagnosis	□□ (DD)	2896958 Provide the day the patient was initially diagnosed with the malignancy submitted for TCGA.
22	Year of Initial Pathologic Diagnosis*	□□□□ (YYYYY)	2896960 Provide the year the patient was initially diagnosed with the malignancy submitted for TCGA.
23	Method of Initial Pathologic Diagnosis	Cytology	2757941 Provide the procedure used to initially diagnose the patient.
24	Other Method of Initial Pathologic Diagnosis		2757948 If the procedure used to pathologically diagnose the patient was not included in the list provided, please describe the method used.
25	Type of Surgery Performed	☐ Whipple ☐ Distal Pancreatectomy ☐ Other Method (please specify)	3121809 Indicate the type of surgical procedure performed.
26	Other Specified Type of Surgery Performed	·	3121814 Indicate the other type of surgical procedure performed.

		Enrollmen	t Form: Pancreas	V4.6
Tissue Source Site (TSS) Name:		TSS Identifier:TSS Identifier:		SS Unique Patient #:
Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions
27	Were Lymph Nodes Examined at the time of Primary Resection?	Yes	□ No	2200396 Indicate whether any lymph nodes were pathologically examined at the time of the primary resection.
28	Number of Lymph Nodes Pathologically Examined			3 Provide the number of lymph nodes pathologically assessed, if one or more lymph nodes were removed.
29	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.
30	Number of Lymph Nodes Positive by IHC Keratin Staining ONLY			3086383 Provide the number of lymph nodes positive through keratin immunohistochemistry (IHC) staining.
31	Tumor Grade*	G1 Well differentiated G2 Moderately differentiated G3 Poorly differentiated	G4 Undifferentiated GX Grade cannot be assessed	2785839 Using the patient's pathology/laboratory report, select the tumor grade of the entire tumor from which the TCGA sample was procured.
32	Grade Tier System	Four Tier	☐ Three Tier	3385981 Using the patient's pathology report, indicate the level (tier) of the system used to describe the cellular histologic grade designated in the question above.
33	Maximum Tumor Dimension (cm)			64215 Provide the length of the largest dimension/diameter of the original tumor as stated on the pathology report.
34	Residual Tumor (at time of initial surgery)	R0 (No residual tumor) R1 (Microscopic residual tumor) R2 (Macroscopic residual tumor) RX (Presence of residual tumor)	r)	2608702 Using the patient's pathology/laboratory report, select the tissue margin status at time of surgical resection.
35	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 Based on the date the patient was staged select the American Joint Committee on Cancer (AJCC) edition used to stage the patient.
36	Pathologic Spread: Primary Tumor (pT) *	□ TX □ T1 □ T0 □ T1a	□ T1b □ T3 □ T4	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).
37	Pathologic Spread: Lymph Nodes (pN) *	NX N1 N1 N1 N1a	□ N1b □ N3 □ N4	3065858 Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC).
	Pathologic Spread: Distant			3045439 Using the patient's pathology/laboratory report in

□ мо

☐Stage II

Stage IIA

Stage IIB

Metastases (M)(Clinical or

Tumor Stage (Clinical or

Pathological)*

Pathological) *

Vital Status*

38

39

40

□ мх

Stage I

Stage IA

Stage IB

Living

☐Stage III

Stage IV

Deceased

☐Stage IVA

Stage IVB

conjunction with the patient's medical record, select

the stage for the clinical or pathological M (metastasis)

as defined by the American Joint Committee on Cancer

Using the patient's pathology/laboratory report in

the clinical or pathological stage as defined by the

American Joint Committee on Cancer (AJCC).

the date of last contact.

conjunction with the patient's medical record, select

Indicate whether the patient was living or deceased at

(AJCC). 3065862

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Tissue Source Site (TSS) Name: TSS Identifier: T			SS Unique Patient #:
Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date of Last C	Contact (or date of death, if de	ceased)	
41	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.
42	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.
43	Year of Last Contact		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.
44	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)	
			2897026
45	Month of Death		If the patient is deceased, provide the month of death.
46	Day of Death	[DD]	2897028 If the patient is deceased, provide the day of death.
47	Year of Death		2897030 If the patient is deceased, provide the year of death.
48	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.
49	Tumor Status (at Date of Last Contact)	Tumor Free Unknown Tumor Status With Tumor	2759550 Indicate whether the patient was tumor/disease free at the date of last contact or death.
50	Cause of Death	Pancreatic Cancer Surgical Complications Other Malignancy (not pancreatic cancer related) Other Non-Malignant Disease Other Cause of Death (i.e. accident related) Unknown Cause of Death	2554674 If the patient is deceased, indicate the cause of death for the patient.
51	Source of Death Information	Death Certificate Medical Record Autopsy	2390921 Indicate the source used to identify the patient's cause of death.

Tissue Sour	ce Site (TSS) Name:	TSS Identifier:	TSS Unique Patient #:
Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Prognostic / F	Predictive / Lifestyle Features	Used for Tumor Prognosis or Responsiveness to Treatment	
52	Tobacco Smoking History Indicator*	 Lifelong Non-smoker (<100 cigarettes smoked in Lifetime) Current smoker (includes daily smokers and non-daily smokers (or occasional smokers) Current reformed smoker for > 15 years Current reformed smoker for ≤ 15 years Current Reformed Smoker, Duration Not Specified Smoking history not documented 	2181650 Indicate the patient's current smoking status or smoking history as self-reported by the patient.
53	Year of Onset of Tobacco Smoking		2228604 If the patient is a current or reformed smoker, indicate the year in which the patient began smoking.
54	Year of Quitting Tobacco Smoking		2228610 If the patient is a reformed smoker, indicate the year in which the patient quit smoking.
55	Number Pack Years Smoked	Number Pack Years	2955385 Indicate the lifetime tobacco exposure of the patient. Number of pack years is defined as the number of cigarettes smoked per day times (x) the number of years smoked divided (/) by 20.
56	Alcohol History Documented?	Yes No	2201918 Indicate if the patient's alcohol history is documented. A response to a question that asks whether the patient has consumed at least 12 drinks of any kind of alcoholic beverage in their lifetime.
57	Alcohol Exposure Intensity	Not Evaluated None Daily Drinker Unknown Occasional Drinker (< once a month) Social Drinker (> once a month, and < once week) Weekly Drinker (> or = to 1 time per week)	3457767 Indicate the patient's current level of exposure to alcohol.
58	Frequency of Alcohol Consumption	Days Per Week	3114013 Indicate the average number of days each week that the patient consumes an alcoholic beverage.
59	Amount of Alcohol Consumption Per Day	☐ ☐ Drinks Per Day	3124961 Indicate the average number of alcoholic beverages that a person consumes per day.
60	History of Diabetes	☐ Yes ☐ No ☐ Unknown	3197322 Indicate if the patient has been previously diagnosed with diabetes.
If History of D	iabetes, Date of Onset		
61	Month of diabetes onset	□□ (MM)	3457737 If the patient has a history of diabetes, provide the month of onset.
62	Day of diabetes onset	□□ (DD)	3457738 If the patient has a history of diabetes, provide the day of onset.
63	Year of diabetes onset		3457739 If the patient has a history of diabetes, provide the year of onset.
64	Number of Days from Date of Initial Pathologic Diagnosis to date of Diabetes Onset		3457768 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 onset of diabetes. 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.

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

Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions
65	History of Clinical Chronic Pancreatitis	☐ Yes ☐ No	Unknown	3457760 Indicate if chronic pancreatitis was diagnosed (documented) clinically > 1 year prior to surgery.
If History of C	linical Chronic Pancreatitis, Da	ate of Onset		, , , , , , , , , , , , , , , , , , , ,
66	Month of pancreatitis onset	ПП (ММ)		3457761 If the patient has a history of chronic pancreatitis, provide the month of onset.
67	Day of pancreatitis onset	□□ (DD)		3457762 If the patient has a history of chronic pancreatitis, provide the day of onset.
68	Year of pancreatitis onset	(YYYY)		3457763 If the patient has a history of chronic pancreatitis, provide the year of onset.
69	Number of Days from Date of Initial Pathologic Diagnosis to date of Clinical Chronic Pancreatitis Onset			3457771 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 Clinical Chronic Pancreatitis Onset 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.
70	History of Cancer in a First Degree Relative	Yes No	Unknown	2436860 Indicate if a first degree relative (parents, siblings, or children) of the patient has a history of a cancer diagnosis.
71	Type of Cancer in First Degree Relative (check all that apply)	Pancreas Melanoma	□ Breast □ Other	3457764 Indicate the type of cancer diagnoses identified in the patient's first degree relatives (parents, siblings, or children).
Primary Treat	tment			·
72	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.
73	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.
74	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies)	Progressive Disease Stable Disease Partial Response	Complete Response Not Applicable Unknown	2786727 Provide the patient's response to their initial first course treatment
				and prior to submission of the Enrollment Form. If the
75	New Tumor Event After Initial Treatment	if the TSS does not know, indicate t Yes No Unknown	uns in the first question; and then	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.
Date of New Tumor Event After Initial Treatment Not Applicable				
76	Month of New Tumor Event After Initial Treatment	Not Applicable		3104044 If the patient had a new tumor event, provide the month of diagnosis for this new tumor event.
77	Day of New Tumor Event After Initial Treatment			3104042 If the patient had a new tumor event, provide the day of diagnosis for this new tumor event.
78	Year of New Tumor Event After Initial Treatment			3104046 If the patient had a new tumor event, provide the year of diagnosis for this 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
79	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 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.
80	Type of New Tumor Event	Locoregional Recurrence Distant Metastasis New Primary Tumor	3119721 Indicate whether the patient's new tumor event was a loco-regional recurrence or a distant metastasis of the tissue submitted for TCGA; or a new primary tumor. Note: If the patient had multiple new tumor events a follow-up form should be completed for each new tumor event.
81	Site of New Tumor Event	Lung Peritoneal Surfaces Liver Tumor Bed Non-Regional Lymph Nodes/Distant Lymph Nodes Other (please specify)	3108271 Indicate the site of this new tumor event, as it relates to the tissue submitted for TCGA.
82	Other site of New Tumor Event (please specify)		3128033 If the tumor site is not included in the list for the question above, designate the site of this new tumor event.
83	Diagnostic Evidence of Recurrence/ Relapse (Check all that apply)	Biopsy with 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.
84	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	3008755 Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question.
Date of Addit	ional Surgery for New Tumor	Event Not Applicable	
85	Month of Additional Surgery for New Tumor Event	ПП (ММ)	3427612 If the patient had surgery for the new tumor event, provide the month this surgery was performed.
86	Day of Additional Surgery for New Tumor Event	□□ (DD)	3427613 If the patient had surgery for the new tumor event, provide the day this surgery was performed.
87	Year of Additional Surgery for New Tumor Event	□□□□ (YYYY)	3427614 If the patient had surgery for the new tumor event, provide the year this surgery was performed.
88	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event		3008335 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. 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.
89	Residual Tumor after Surgery for New Tumor Event	RX R0 R1 R2 Not Evaluated	3008753 If the patient had surgery for the new tumor event, provide the status of any residual tumor after this surgery.

Enrollment Form: Pancreas

V4.6

Tissue Source Site (TSS) Name:		TSS Identifie	TSS Identifier: TSS Unique Patient #:		
Question #	Data Element Label	Data Entry Alternatives		CDE ID With Working Instructions	
Additional Tr	reatment				
90	Additional treatment of New Tumor Event Radiation Therapy	☐ Yes ☐ No	Unknown	3008761 Indicate whether the patient received radiation treatment for this new tumor event.	
91	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 Ir	nvestigator Name:	Principal	Investigator Signatu	re:	
	Date Signed (MM/DD/YYYY):				