Case Quality Control Form (CQCF): Pancreas

V4.50

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

Completed By: _____ Completion Date (MM/DD/YYYY): _____

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

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
1	Has this TSS received permission from 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 pathological 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	Invasive Adenocarcinoma Diagnosis Indicator	☐ Yes ☐ No	3027106 Confirm that the pancreas tumor sample being submitted to TCGA is an invasive adenocarcinoma.
3	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 for the pancreas tumor sample being submitted to TCGA. ***Note 1: Cholangiocarcinoma and Mixed Histologic Subtypes Are Excluded For This Tumor Type.*** ***Note 2: Tumors originating in the bile duct, ampulla and duodenum are excluded.***
4	Other Histological Subtype	_____	3124492 If the histological subtype is not included in the provided list, specify the histological subtype of the pancreatic adenocarcinoma that is being submitted to TCGA.
5	Tumor Type*	☐ Primary	3288124 Confirm that the tumor being submitted to TCGA is a primary untreated malignant biospecimen.
6	Anatomic Site of Frozen Biospecimen (check all that apply)*	☐ Pancreatic Head ☐ Pancreatic Tail ☐ Pancreatic Body ☐ Other (please specify)	3421413 Indicate the anatomic site of the frozen tumor submitted for TCGA. ***Note: Tumors originating in the bile duct, ampulla and duodenum are excluded.***
7	Other Anatomic Site of Frozen Biospecimen	_____	3320289 If the anatomic site of the frozen biospecimen is not included in the provided list, specify the other anatomic site of the frozen tumor submitted to TCGA.
8	Confirmed Intraductal Papillary Mucinous Neoplasm (IPMN) Diagnosis on Pathology Report	☐ Yes ☐ Unknown ☐ No	2483560 Indicate if the pathology report states that the pancreas tumor was associated with IPMN.
9	Confirmed Mucinous Cystic Neoplasm (MCN) Diagnosis on Pathology Report	☐ Yes ☐ Unknown ☐ No	3407712 Indicate if the pathology report states that the pancreas tumor was associated with MCN
Date of Sample Procurement			
10	Month of Sample Procurement	☐☐ (MM)	3008197 Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA.
11	Day of Sample Procurement	☐☐ (DD)	3008195 Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA.

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
12	Year of Sample Procurement	☐☐☐☐ (YYYY)	3008199 Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA.
13	Number of Days from Date of Diagnosis to Date of Cancer Sample Procurement	_____	3288495 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the procedure that produced the malignant sample submitted for TCGA. ***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	Method of Cancer Sample Procurement*	☐ Surgical Resection ☐ Other Method (*please specify below)* ☐ Excisional Biopsy	3103514 Indicate the procedure performed to obtain the malignant tissue submitted for TCGA.
15	Other Method of Cancer Sample Procurement	_____	2006730 If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure.
16	Country Where Cancer Sample Was Procured*	_____	3203072 Provide the country where the tissue submitted for TCGA was procured.
17	Race	☐ American Indian or Alaska Native *A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.* ☐ Asian *A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, 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 the far Europe, the Middle East, or North Africa.* ☐ Black or African American *A person having origins in any of any of the 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 Reported: *Not provided or available.* ☐ Unknown: *Could not be determined or unsure.*	2192199 Provide the patient's race using the defined categories.
18	Ethnicity	☐ Not Hispanic or Latino *A person not meeting the definition of 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.
19	Vessel Used*	☐ Cryovial ☐ Cassette ☐ Cryomold ☐ Biospecimen Storage Bag ☐ Other vessel (*please specify below*)	3081940 Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA.
20	Other Vessel Used	_____	3288137 If the vessel used to ship tissue to the Biospecimen Core Resource (BCR) is not included in the provided list, specify the other type of vessel used.

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
21	Is Tumor Sample being submitted for Laser Cryo Enrichment (LCE) processing?*	☐ Yes ☐ No	3288488 Indicate if the tumor sample being submitted is to be processed using Laser Cryo Enrichment (LCE). **Note: Most pancreatic adenocarcinoma cases are not expected to be suitable for this technology.**
22	Was sample prescreened at site?*	☐ Yes ☐ No	3081942 Indicate whether the sample submitted to the BCR was prescreened at the TSS.
23	Will Top Slide be submitted to the BCR?*	☐ Yes ☐ No	3081944 Indicate whether a physical top slide for the sample submitted to the BCR will be shipped with the tissue sample. **Note: Top slide definition-Slide cut directly from frozen biospecimen = mirror image of inked surface.**
24	Will Digital Slide Image be submitted to the BCR?*	☐ Yes ☐ No	3081948 Indicate whether a digital slide image for the sample submitted to the BCR will be shipped with the tissue sample. ***Note: Physical top slides are preferred.***
25	Tumor Identifier*	_____	3288096 Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID.
26	Weight of Frozen Tumor*	_____	3081946 Provide the weight of the tumor sample submitted for TCGA. ***Note: (0.2cm^3 (0.6cm * 0.6cm * 0.6cm) = ~200mg***
27	Tumor Nuclei %*	_____	2841225 Provide the percent of tumor nuclei for the sample submitted for TCGA. ***Note: Check with the BCR to confirm the current acceptable TCGA metrics.***
28	Tumor Necrosis %*	_____	2841237 Provide the percent of necrosis for the sample submitted for TCGA. ***Note: Check with the BCR to confirm the current acceptable TCGA metrics.***
29	Top Slide / Digital Slide Image ID #*	_____	2321277 Provide the slide ID for the physical top slide OR the digital slide image being sent to the BCR.
Normal Information: *A normal control must be present to qualify*			
30	Normal 1 Identifier	_____	3288138 Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID.
31	Type(s) of Normal Control*	☐ Whole Blood ☐ Buffy Coat ☐ Lymphocytes ☐ Extracted DNA from Blood ☐ Normal Tissue from Duodenum ☐ Normal Tissue from Other Anatomic Site *(specify below)*	3081936 Indicate the type of normal control submitted for this case. ***Note 1: Whole blood is the preferred normal.*** ***Note 2: Normal tissue is accepted from an adjacent organ if the normal tissue is > 2cm from the tumor. All normal tissue must be reviewed by a pathologist to ensure no evidence of tumor cells.*** ***Note 3: Normal tissue from pancreas is only allowed if a second source of germline material is provided (e.g. DNA from blood, tissue from other organ).***
32	Other Anatomic Site of Non-Neoplastic Control Tissue	_____	3288189 If the normal control type is normal tissue from an adjacent organ, specify the site of the non-neoplastic control.
33	Method of Normal Sample Procurement	☐ Blood Draw ☐ Excisional Biopsy ☐ Surgical Resection ☐ Other Method (*please specify below*)	3288147 Indicate the procedure performed to obtain the normal sample submitted for TCGA.
34	Other Method of Normal Sample Procurement	_____	3288151 If the procedure performed to obtain the normal sample is not included in the provided list, specify the procedure.
35	Proximity of Normal Tissue (from adjacent organ) to Tumor	☐ > 2 cm from the primary tumor	3088708 Confirm that the normal tissue being submitted from an adjacent organ is > 2cm from the primary tumor. ***Note 1: Adjacent normal tissue (>2 cm) from the pancreas is only accepted as part of the "double normal" study. In this situation, the blood normal and the pancreas normal may be***

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
			submitted with prior NCI approval. ***Note 2: Adjacent normal pancreas tissue (<2cm) and normal tissue of unknown proximity is not accepted for this tumor type.***
Date of Normal Sample Procurement			
36	Month of Normal Sample Procurement	☐☐ (MM)	3288195 Provide the month of the procedure performed to obtain the normal control sample submitted for TCGA.
37	Day of Normal Sample Procurement	☐☐ (DD)	3288196 Provide the day of the procedure performed to obtain the normal control sample submitted for TCGA.
38	Year of Normal Sample Procurement	☐☐☐☐ (YYYY)	3288197 Provide the year of the procedure performed to obtain the normal control sample submitted for TCGA.
39	Number of Days from Date of Diagnosis to Date of Normal Sample Procurement	_____	3288496 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the procedure that produced the normal control sample submitted for TCGA. ***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.***
40	Extracted DNA Quantity	_____	3288185 If the normal control type is extracted DNA from blood, provide the quantity (µg) of the normal control sample sent to the BCR for TCGA.
41	Extracted DNA Quantification Method	_____	3288186 If the normal control type is extracted DNA from blood, provide the quantification method of the normal control sample sent to the BCR for TCGA.
42	Extracted DNA Concentration	_____	3288187 If the normal control type is extracted DNA from blood, provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA.
43	Extracted DNA Volume	_____	3288188 If the normal control type is extracted DNA from blood, provide the volume (µL) of the normal control sample sent to the BCR for TCGA.
44	Normal Slide ID #	_____	3288217 If the normal control type is normal tissue, provide the slide ID for the physical top slide OR the digital slide image of the normal control being sent to the BCR.
45	Name of Pathologist	_____	3288225 Provide the name of the Pathologist that reviewed the top slide and provided the information for all previous sections.
46	Date of Pathologist Review	☐☐/☐☐/☐☐☐☐ (MM/DD/YYYY)	3288224 Provide the date of the pathology prescreening review performed by the TSS pathologist above.
47	Number of Days from Date of Diagnosis to Date of Pathological Review	_____	3288497 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of the pathological review performed as part of the submission process for TCGA. ***Note: Only provide Interval data if you have received***
48	Percent Tumor Nuclei meets TCGA metrics?*	☐ Yes ☐ No	3288520 Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics for TCGA. ***Note: Check with the BCR to confirm the current acceptable TCGA metrics.***
49	Percent Tumor Necrosis meets TCGA metrics?*	☐ Yes ☐ No	3288524 Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. ***Note: Check with the BCR to confirm the current acceptable TCGA metrics.***
50	De-Identified Pathology Report Submitted?*	☐ Yes ☐ No	3288292 Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples.

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
51	Is the histologic diagnosis on the CQCF (as determined by the TSS pathology review of the TCGA frozen section top slide) consistent with the histology listed in the final diagnosis on the pathology report?*	☐ Yes *(skip related question below.)* ☐ No *	3288300 Confirm that the diagnosis provided on this CQCF for the tumor sample being submitted to TCGA is consistent with the diagnosis found on the patient's pathology report for the tumor being sent to the BCR. ***Note: The diagnosis is considered to be consistent if at least one of the following criteria are met:*** ***1) Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR.*** ***2) Diagnosis on the CQCF includes at least one of the subtypes listed on the pathology report and all subtypes on the pathology report are acceptable for TCGA.*** ***3) Diagnosis on the CQCF is "histology, NOS" (i.e. Adenocarcinoma, NOS) and the pathology report lists a specific subtype within the same histological group.*** ***4) Diagnosis on the CQCF indicates "Mixed Subtype" and the pathology report lists two or more acceptable subtypes, provided that percent subtype(s) meet applicable TCGA disease-specific requirements.Note: If "yes," skip related question below. The TSS needs approval from the NCI if the diagnosis on this form does not match the provided pathology report.***
52	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	☐ Macrodissection performed at TSS to select for region containing an acceptable TCGA diagnosis ☐ Pathology analysis at TSS determined a specific histological subtype different from original pathology report (see note at right) ☐ Pathology review of frozen section for TCGA determined histological subtype different from the pathology report (see note at right)	3288315 If the diagnosis provided on this form is not consistent with the diagnosis found on the patient's pathology report for the tumor being submitted for TCGA, specify a reason for this inconsistency. ***Note: If a TSS pathology review of the TCGA committed sample resulted in a different histological subtype than what is documented on the pathology report, an amendment to the pathology report should be submitted when the sample is shipped to the BCR; or in the absence of an amended pathology report, the TSS must complete and submit an electronic copy of the "TCGA Pathologic Diagnosis Discrepancy Form."***
53	History of Neo-adjuvant Treatment for Tumor Specimen Submitted for TCGA*	☐ No ☐ Radiation Prior to Sample Procurement ☐ Pharmaceutical Treatment Prior to Sample Procurement ☐ Both Radiation and Pharmaceutical 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.***
54	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 malignancies. ***Note: 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.***
55	Consent Status*	☐ Consented ☐ Exemption 4 ☐ Deceased ☐ Waiver	3288361 Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. ***Note: Either the Date of Consent or the Date of Death must be provided to qualify.***
Date of Consent			
56	Month of Consent	☐☐ (MM)	3081955 If the patient was formally consented, provide the month of consent.
57	Day of Consent	☐☐ (DD)	3081957 If the patient was formally consented, provide the day of consent.
58	Year of Consent	☐☐☐☐ (YYYY)	3081959 If the patient was formally consented, provide the year of consent.

Question #	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
59	Number of Days from Date of Diagnosis to Date of Consent	_____	3288498 If the patient formally consented, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's formal consent.
Date of Death			
60	Month of Death	☐☐ (MM)	2897026 If the patient consented by death, provide the month of death. ***Note: If the patient formally consented prior to death, only supply the date the patient consent.***
61	Day of Death	☐☐ (DD)	2897028 If the patient consented by death, provide the day of death
62	Year of Death	☐☐☐☐ (YYYY)	2897030 If the patient consented by death, provide the year of death.
63	Number of Days from Date of Diagnosis to Date of Death	_____	3288499 If the patient consented by death, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's death. ***Note: If the patient formally consented prior to death, do not answer this question only answer the question above that asks for the number of days between the date of diagnosis and the date of the patient consent.***

Comments:

_____

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_____

Principal Investigator Name: _____

Principal Investigator Signature: _____

Date Signed (MM/DD/YYYY): _____