Initial Case Quality Control Form

V4.5 070513

Pheochromocytoma and Paraganglioma (PCPG)

Instructions: This form should be completed for all cases submitted for TCGA, prior to the shipment of samples to the BCR.

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

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.

Tissue Source Site (TSS): ______TSS ID: _____TSS Unique Patient ID: ______Interviewer Name: _____Interview Date ____/___ /_____/_____ Working Instructions # Ouestion **Entry Alternatives Tumor Information** Indicate the confirmed histologic diagnosis of the tumor □ Pheochromocytoma submitted for TCGA. Histologic Diagnosis of 1* □ Paraganglioma (Extra-adrenal Pheochromocytoma) 3081934 Tumor Submitted for TCGA Paraganglioma The listed histologies are the only histologic types being accepted for this TCGA study. Recurrent tumors are NOT accepted. Indicate the type of tumor submitted for TCGA. 3288124 This is a biospecimen that **has not** been treated with chemotherapy 2* □ Primary (primary untreated malignant biospecimen) **Tumor Presentation** or radiation prior to resection. If a metastatic tumor is being submitted for a triplet case, please complete the Metastatic CQCF.

3*	Did this patient have a known diagnosis of	□ Yes □ No	Indicate whether the patient was diagnosed with metastatic disease.
3	metastatic disease?		<u>65384</u>
4*	Anatomic Site of Malignant Specimen	 Adrenal Gland Extra-adrenal*, <i>i.e. Outside the Adrenal Gland</i> (please specify) 	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. <u>3081961</u> *Head & Neck paragangliomas are not accepted.
5	Anatomic Site of Extra- Adrenal Biospecimen		If the submitted tumor was located in an extra-adrenal site, please specify the site of disease. 2584114
6	Tumor Laterality	□ Right □ Left □ Bilateral	Indicate the laterality if the frozen tumor biospecimen submitted for TCGA was located in a paired site. <u>827</u>
7*	Date of Cancer Sample Procurement	Month Day Year	Provide the date of the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3008197 (month), 3008195(day), 3008199</u> (year)
8*	Method of Cancer Sample Procurement	 Surgical Resection Other Method (please specify) 	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. <u>3103514</u>
9	Other Method of Cancer Sample Procurement		If the procedure performed to obtain the malignant tissue is not included in the provided list, specify the procedure. <u>2006730</u>
10*	Country Where Cancer Sample was Procured		Provide the country where the tissue submitted for TCGA was procured. <u>3203072</u>
11*	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 	Provide the patient's race using the defined categories. 2192199

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		 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 Evaluated: Not provided or available. Unknown: Could not be determined or unsure. 				
12	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. 	Provide the patient's ethnicity using the defined categories. 2192217			
13*	Vessel Used	□ Cryovial □ Cassette □ Other, specify □ Other, specify	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. <u>3081940</u>			
14	Other Vessel Used		If the vessel used to ship the tissue to the BCR is not included in the provided list, specify the vessel used. 3288137			
15*	Is tumor sample being submitted for macrodissection?	□ Yes □ No	Indicate whether the tumor sample submitted to the BCR is intended to undergo macrodissection after the BCR receives the sample. <u>3288488</u>			
16*	Was sample prescreened at site?	□ Yes	Indicate whether the sample submitted to the BCR was prescreened at the TSS. 3081942			
Tumo	or Slides Submitted					
17*	Types of Slides Submitted Check all that apply	 Physical Top Slide Digital Top Slide Image Digital FFPE Slide Image 	Indicate the type(s) of slide(s) submitted to the BCR. <u>3521909</u> Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface			
18*	Slide/Digital Image ID #		Provide the slide ID for each slide (physical and digital image) submitted to the BCR. 2321277			
Tumo	Tumor Sample Information If the TSS is submitting multiple pieces of the same primary tumor for this case; complete the following information for each piece of tumor sent to the BCR.					
19*	Tumor Identifier		Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. 3288096			
20*	Weight of Frozen Tumor	(mg) (0.2cm ³ (0.6cm * 0.6cm) = ~200mg	Provide the weight of the tumor sample submitted for TCGA. <u>3081946</u> Weight can be estimated based on the size of the tumor submitted.			

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#	Question		Entry Alternat	ives		Working Instructions
21*	Tumor Nuclei %	(%)				Provide the percent of tumor nuclei for the sample submitted for TCGA. <u>2841225</u> Check with the BCR to confirm the current acceptable TCGA metrics.
22*	Necrosis %	(%)				Provide the percent of necrosis for the sample submitted for TCGA. <u>2841237</u> Check with the BCR to confirm the current acceptable TCGA metrics.
23*	Germline Genotype Testing Performed	□ Yes □ No □ Unknown				Indicate whether the patient had germline genotyping performed. 3121565
		Test	Present	Absent	Not Performed	If the patient had germline genotyping performed, provide the
24	Type of Germline Genotype Testing Performed	RET VHL NF1 NF1 Clinical Diagnosis SDHA SDHB SDHC SDHD SDHAF2 (SDH5) TMEM127 MAX				results. 3121628
25*	Biochemical Testing Performed	□ Yes □ No □ Unknown				Indicate whether biochemical testing was performed on this patient. 3641292
26	Biochemical Phenotype (Check all that apply)	Image: Norepinephrine-secretingImage: Metanephrine-secretingImage: Normetanephrine-secretingImage: Dopamine-secretingImage: Epinephrine-secretingImage: Methoxytyramine-secreting			If the patient had biochemical testing performed, provide the results. <u>3645883</u>	
Norm	Normal Information A normal control must be present to qualify.					
27*	Type(s) of Normal Control Check all that apply	 Whole Blood (preferred) Buffy Coat Lymphocytes Extracted DNA from Blood Extracted DNA from Saliva Non-Neoplastic Control Tissue – Kidney Non-Neoplastic Control Tissue – Not Kidney* 			Indicate the type of normal control submitted for this case. <u>3081936</u> *Non-neoplastic Control Tissue from an organ other than the kidneys may only be submitted with NCI approval.	
Norm	Normal Control: Whole Blood					
28	Method of Normal Sample Procurement	Blood Draw				Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>

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#	Question		Entry Alternatives		Working Instructions
29	Date of Normal Sample Procurement	Month	Day	Year	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195 (month), 3288196 (day), 3288197</u> (year)
30	Normal Identifier				Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
Norm	al Control: Buffy Coat/ Lymph	ocytes			
31	Method of Normal Sample Procurement	Blood Draw			Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>
32	Date of Normal Sample Procurement	Month	Day	Year	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195 (month)</u> , <u>3288196 (day)</u> , <u>3288197 (year)</u>
33	Normal Identifier		Duy		Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
Norm	al Control: Extracted DNA from	n Blood or Saliva			
34	Method of Normal Sample Procurement	 Blood Draw Oragene Other, specify 			Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>
35	Other Method of Normal Sample Procurement	· · · · · · · · · · · · · · · · · · ·			If the procedure performed to obtain the normal sample is not included in the provided list, specify the method used. <u>3288151</u>
36	Date of Normal Sample Procurement	Month	Day	Year	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195 (month), 3288196 (day), 3288197</u> (year)
37	Normal Identifier				Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
38	Extracted DNA Quantity		(µg)		Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. $\underline{3288185}$
39	Extracted DNA Quantification Method				Provide the quantification method of the normal control sample sent to the BCR for TCGA. <u>3288186</u>
40	Extracted DNA Concentration		(μg/μL)		Provide the concentration (μ g/ μ L) of the normal control sample sent to the BCR for TCGA. <u>3288187</u>
41	Extracted DNA Volume		(μL)		Provide the volume (μ L) of the normal control sample sent to the BCR for TCGA. <u>3288188</u>
Normal Control: Non-Neoplastic Control Tissue					
42	Method of Normal Sample Procurement	Surgical ResectionOther Method (please specify)			Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>

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#	Question	Entry Alternatives	Working Instructions				
43	Other Method of Normal Sample Procurement		If the procedure performed to obtain the normal sample is not included in the provided list, specify the method used. <u>3288151</u>				
44	Date of Normal Sample Procurement	Month Day Year	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195 (month), 3288196 (</u> day), <u>3288197</u> (year)				
45	Normal Identifier		Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>				
46	Anatomic Site of Non- Neoplastic Control Tissue	□ Kidney □ Other (please specify)	If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. <u>3081938</u>				
47	Other Site of Non-Neoplastic Control Tissue		If the normal control type is normal tissue and the anatomic site is not included in the provided list, specify the site of the non- neoplastic control. <u>3288189</u>				
48	Proximity of Normal Tissue to Tumor	Distal (> 2cm) from the primary tumor	If the normal control type is normal tissue, confirm that the submitted normal tissue was at least 2cm away from the primary tumor. <u>3088708</u> Adjacent (≤ 2cm) Normal Tissue is not accepted for this tissue type. Unknown Normal Tissue is not acceptable for this tissue type.				
49	Normal Slide ID#		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. 3288217				
Verif	Verification: By providing the below information, the Principal Investigator acknowledges that the information provided by the institution is true and correct and has been quality controlled.						
Tissue throu	Pathology Review 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.						
50*	Name of Pathologist		Provide the name of the Pathologist that provided the information for all previous sections. <u>3288225</u>				
51*	Date of Pathologist Review	Month Day Year	Provide the date of the pathology review performed by the TSS pathologist above. 3462941 (month), 3462917 (day), 3462960 (year)				
Princ	ipal Investigator/Authorized	Designee Confirmation					
52*	Percent Tumor Nuclei meets TCGA metrics?	□ Yes □ No	Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics for TCGA. <u>3288520</u> Check with the BCR to confirm the current acceptable TCGA metrics.				

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#	Question	Entry Alternatives	Working Instructions
53*	Percent Necrosis meets TCGA metrics?	□ Yes □ No	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. <u>3288524</u> Check with the BCR to confirm the current acceptable TCGA metrics.
54*	De-Identified Pathology Report Submitted?	□ Yes □ No	Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples. <u>3288292</u>
55*	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 □ No	 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. <u>3288300</u> If "yes," skip related question below. The diagnosis is considered to be consistent if at least one of the following criteria are met: Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR. Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR. Diagnosis on the CQCF includes as least one of the subtypes listed on the pathology report and all subtypes on the pathology report are acceptable for TCGA. Diagnosis on the CQCF is "histology, NOS" (i.e., Adenocarcinoma, NOS) and the pathology report lists a specific subtype within the same histologic group 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.
56	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 a region containing an acceptable TCGA diagnosis (see note at right) 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) 	If the diagnosis provided on this form is not consistent with the diagnosis found on the pathology report provided, specify a reason for this inconsistency. <u>3288315</u> If a TSS pathology review of the TCGA committed sample resulted in a different histological subtype than what is documented on the original 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". In the case of diagnosis modifications, institution protocol should be followed for proper quality assurance.
57*	History of Malignancies (Including History of Malignant Pheochromocytoma/ Paraganglioma)	 None History of Prior Malignancy History of Synchronous/ Bilateral Malignancy Both History of Synchronous/ Bilateral and Prior Malignancy 	Indicate whether the patient has a history of malignancies. If the patient has any history, 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. <u>3382736</u> If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.

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#	Question	E	Intry Alternative	s	Working Instructions	
58	Did the patient have a history of pheochromocytoma or paraganglioma (including benign)?	☐ Yes ☐ No ☐ Unknown			Indicate whether the patient has a history of pheochromocytoma or paraganglioma (either benign or malignant). <u>3641293</u>	
59*	History of Neoadjuvant Treatment <i>for Tumor</i> <i>Submitted for TCGA</i>	□ Yes □ No			Indicate whether the patient received therapy for this cancer prior to the 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 instruction. <u>3382737</u> *Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the procurement of the sample submitted for TCGA are exclusionary.	
60*	Consent Status	 Consented Deceased Exemption 4* Waiver* 			Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. If the submitting institution's IRB has approved consent for TCGA, consent requirements have been met. <u>3288361</u> *Exemptions and waivers for consent must be approved by NCI.	
Date	of Consent					
61	Date of Normal Sample Procurement	Month	Day	Year	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. <u>3081955 (month), 3081957 (day), 3081959</u> (year)	
Date	Date of Death Do not complete date of death, if patient formally consented.					
62	Date of Normal Sample Procurement	Month	Day	Year	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. <u>2897026 (month), 2897028 (day), 2897030 (year)</u>	
					//	
	Principal Ir	vestigator or Designee Signature		Print Name	Date	

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.