Initial Case Quality Control Form

Lower Grade Glioma (LGG)

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 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 ___ ___/___ ___ /___ ___ ___ ___

#	Question	Entry Alternatives	Working Instructions
STOP	**Verification of TCGA Requirements** Prior to the shipment of samples to the BCR, the TSS must answer the following questions to verify that TCGA requirements are met. For a complete list of requirements, please reference the TCGA Study Requirements Checklist document. ☐ **If your TSS is submitting time intervals in lieu of partial (month/year) or full dates check here and work with the BCR to ensure all data are captured appropriately.**		
TCGA Prescreen at the TSS			
1*	Was the submitted sample prescreened prior to TCGA submission?	☐ Yes, the submitted sample was prescreened.	Indicate whether the sample submitted to the BCR was prescreened at the TSS. 3081942
2*	TCGA Prescreen Reviewing Pathologist Name	_____	Provide the name of the pathologist that performed the prescreen of the sample submitted for TCGA. 3288225
3*	Date of TCGA Pathology Prescreen	_____ _____ _____ _____ _____ _____ _____ _____ *Month* *Day* *Year*	Provide the date the reviewing pathologist performed the TCGA prescreen. 3288224
4*	Does the percent tumor nuclei meet current TCGA metrics?	☐ Yes, the tumor nuclei meets the current metrics. ☐ No, the tumor is being submitted for macrodissection.	Confirm that the malignant sample submitted to the BCR meets the current tumor nuclei metrics for TCGA. If submitting for macrodissection, please contact the BCR prior to shipment. 3288520
5*	Does the percent necrosis meet the current TCGA metrics?	☐ Yes, the necrosis meets the current metrics. ☐ No, the tumor is being submitted for macrodissection.	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. If submitting for macrodissection, please contact the BCR prior to shipment. 3288524
Initial Pathology Report			
6*	De-Identified Pathology Report Submitted to the BCR	☐ Yes, a de-identified pathology report was submitted or will be submitted with the shipment to the BCR.	Confirm that a de-identified pathology report is being sent to BCR prior to or with the shipment of the physical samples. Cases without a pathology report at the time of sample submission will be excluded. 3288292
7*	Is the histologic diagnosis determined by the TCGA prescreening consistent with the histology listed as the final diagnosis on the initial pathology report?	☐ Yes ☐ No	Confirm that the diagnosis provided on this form for the tumor sample being submitted to TCGA is consistent with the final diagnosis found on the patient's pathology report for the tumor being sent to the BCR. If "yes," skip related question below. 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 as 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 histologic 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. 3288300

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8†	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)* ☐ TCGA prescreen determined a specific histological subtype different from original pathology report *(see note at right)*	If the diagnosis provided on this form is not consistent with the final diagnosis found on the pathology report provided, specify a reason for this inconsistency. If a TSS pathology review of the TCGA submitted sample resulted in a different histologic 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; 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. 3288315
Patient Information			
9*	History of Other Malignancy *(Including ALL Prior and Synchronous Malignancies)*	☐ Yes ☐ No	Indicate whether the patient has a history of malignancies, including synchronous or bilateral malignancies. Please complete an Other Malignancy Form (OMF) for each malignancy diagnosed prior to or at the time the TCGA submitted tissue was procured. If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, only complete an OMF for the initial diagnosis of each of these types. 3382736
10*	History of Neoadjuvant Treatment (prior to procurement) of Tumor Submitted for TCGA	☐ Yes *(see note at right)* ☐ No	Indicate whether the patient received therapy for the tumor submitted for TCGA prior to the sample procurement. If the patient did receive treatment prior to procurement, the TSS should contact the BCR for further instruction. 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. 3382737
11*	Consent Status	☐ Formally Consented ☐ Consented by Death ☐ Exemption *(see note at right)* ☐ Waiver *(see note at right)*	Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. Exemptions and waivers for consent must be approved by NCI. 3288361
12†	Date of Formal Consent	____ ____ ____ ____ ____ ____ ____ ____ *Month* *Day* *Year*	If the patient was formally consented, provide the month of consent. 3081955 (month), 3081957 (day), 3081959 (year)
13†	Date of Death	____ ____ ____ ____ ____ ____ ____ ____ *Month* *Day* *Year*	If the patient consented by death (i.e. they did not formally consent), provide the month of death. Do not complete if the patient formally consented. 2897026 (month), 2897028 (day), 2897030 (year)
14*	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown	Provide the patient's race using the provided categories, as defined below. **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 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. **Unknown** 2192199

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15	Ethnicity	☐ Not Hispanic or Latino ☐ Hispanic or Latino ☐ Unknown	Provide the patient's ethnicity using the provided categories, defined below: **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. **Unknown** 2192217
History of Surgical Treatment for Lower Grade Glioma (LGG)			
16*	Was the submitted tumor biopsied or surgically resected prior to the operation that yielded the submitted sample?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received a biopsy or surgical resection of the submitted tumor, prior to the operation that yielded the submitted tumor. 3857794
17†	If the submitted tumor was previously biopsied or resected, what type of procedure was performed?	☐ Sterotactic Biopsy ☐ Craniotomy ☐ Unknown	If the patient had a biopsy or resection for the submitted tumor prior to the procedure that yielded the submitted tumor, indicate the type of procedure that was initially performed. 3857971
19†	If the patient had a prior surgical resection, what was the extent of the resection based on post-operative imaging?	_____	If the patient had a biopsy or resection for the submitted tumor prior to the procedure that yielded the submitted tumor, indicate the extent of the resection based on post-operative imaging. 3857896
18†	Date of Prior Biopsy or Resection	____ ____ *Month* / ____ ____ *Day* / ____ ____ ____ ____ *Year*	If the patient had a biopsy or resection for the submitted tumor prior to the procedure that yielded the submitted tumor, provide the date of the procedure. 3857887
20†	Did the patient receive chemotherapy or radiation between the original biopsy/resection and the operation that yielded the submitted sample?	☐ Yes ☐ No ☐ Unknown	If the patient had a biopsy or resection for the submitted tumor prior to the procedure that yielded the submitted tumor, indicate whether the patient received chemotherapy or radiation treatment between the time of the original biopsy/resection and the operation that yielded the sample submitted for TCGA. 3857887

Tumor Information

The following information must be completed for the tumor sample submitted for TCGA and should be answered specifically about the submitted sample(s). If multiple vials of the tumor sample are submitted, the "Tumor Sample Information" must be completed for each vial submitted to the BCR.

Pathologic/Anatomic Information			
21*	Tumor Category	☐ Primary Untreated Malignant Biospecimen	Indicate the tumor category of the tumor submitted for TCGA. 3288124
22*	Histologic Diagnosis of Tumor Submitted for TCGA	☐ Astrocytoma Grade II ☐ Astrocytoma Grade III ☐ Oligoastrocytoma Grade II ☐ Oligoastrocytoma Grade III ☐ Oligodendroglioma Grade II ☐ Oligodendroglioma Grade III	Indicate the confirmed pathologic diagnosis (based on the TCGA prescreen) of the tumor submitted for TCGA. 3081934
23*	Anatomic Site of Frozen Biospecimen	☐ Brain ☐ Spinal Cord ☐ Unknown	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. 2735776
24†	Anatomic Organ Sub-Division of Frozen Biospecimen	☐ Supratentorial ☐ Posterior Fossa	Indicate the sub-division of the anatomic site of the frozen tumor biospecimen submitted for TCGA. 2008006
Tumor Sample Procurement Information			

Comment [LT1]: New CDE

Comment [LT2]: New CDE and Working Instructions

Comment [LT3]: New CDE and Working Instructions

Comment [LT4]: New CDE and Working Instructions

Comment [LT5]: New CDE and Working Instructions

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#	Question	Entry Alternatives	Working Instructions
25*	Date of Tumor Sample Procurement	_____ _____ _____ _____ _____ _____ _____ _____ *Month* *Day* *Year*	Provide the date of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008197 (month), 3008195(day), 3008199 (year)
26*	Method of Tumor Sample Procurement	☐ Biopsy Only ☐ Subtotal Resection ☐ Gross Total Resection	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514
27*	Country where Tumor Sample was Procured	_____	Provide the country where the tissue submitted for TCGA was procured. 3152016
Tumor Sample Information If multiple vials of the tumor sample are submitted, this section must be completed for each vial submitted to the BCR.			
28*	Tumor Sample ID	_____	Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor sample needs a unique ID. 3288096
29*	Weight of Frozen Tumor Sample	_____ (mg) (0.2 cm^3 (0.6cm * 0.6cm *0.6cm) ≈ 200mg	Provide the weight of the tumor sample submitted for TCGA. Weight can be estimated based on the size of the tumor submitted. 3081946
30*	Tumor Nuclei Percent (%) of Frozen Tumor Sample	_____ (%)	Provide the percent of tumor nuclei for the sample submitted for TCGA. Check with the BCR to confirm the current acceptable TCGA metrics. 2841225
31*	Necrosis Percent (%) of Frozen Tumor Sample	_____ (%)	Provide the percent of necrosis for the sample submitted for TCGA. Check with the BCR to confirm the current acceptable TCGA metrics. 2841237
Shipment/Slide Information			
32*	Shipment Vessel Used	☐ Cryovial ☐ Biospecimen Storage Bag ☐ Cassette ☐ Cryomold ☐ Other (Please Specify)	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. 3081940
33†	Other Shipment 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
34*	Type(s) of Slides Submitted	☐ Physical Frozen Top Slide ☐ Digital Frozen Top Slide Image ☐ Physical FFPE Slide ☐ Digital FFPE Slide Image	Indicate the type(s) of slide(s) submitted to the BCR. **Top Slide Definition**: Slide cut directly from frozen biospecimen = mirror image of inked surface 3521909
35*	Slide/Digital Image ID	_____	Provide the slide ID for each slide (physical and digital image) submitted to the BCR. 2321277
Normal Control Information The following information must be completed for the normal control sample submitted for TCGA and should be answered specifically about the submitted control(s). If multiple normal control types are submitted, **ALL QUESTIONS** should be completed for each sample. If multiple vials of the same normal control are submitted, the "Normal Control Sample Information" must be completed for each vial submitted to the BCR.			
36*	Type(s) of Normal Control(s) *Check all that apply*	☐ Whole Blood ☐ Buffy Coat ☐ Lymphocytes ☐ Extracted DNA from Blood ☐ Extracted DNA from Saliva ☐ Non-Neoplastic Control Tissue	Indicate the type(s) of normal control(s) submitted for this case. Non-neoplastic control tissue may only be submitted with NCI approval. 3081936
Normal Sample Procurement Information			

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#	Question	Entry Alternatives	Working Instructions
37*	Date of Normal Control Procurement	_____ _____ _____ _____ _____ _____ _____ _____ *Month* *Day* *Year*	Provide the date of the procedure performed to obtain the normal control submitted for TCGA. 3288195 (month), 3288196 (day), 3288197 (year)
38*	Method of Normal Control Procurement	☐ Blood Draw ☐ Surgical Resection ☐ Skin Punch ☐ Buccal Swab ☐ Mouthwash ☐ Other (Please Specify)	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
39†	Other Method of Normal Control Procurement	_____	If the method of normal sample procurement is not included in the provided list, specify the method of procurement. 3288151
Normal Control Sample Information			
40*	Normal Control ID	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
Extracted DNA: Only complete this section if submitting Extracted DNA from Blood or Saliva			
41†	Extracted DNA Quantity of Normal Control	_____ (µg)	Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. 3288185
42†	Extracted DNA Quantification Method of Normal Control	_____	Provide the quantification method of the normal control sample sent to the BCR for TCGA. 3288186
43†	Extracted DNA Concentration of Normal Control	_____ (µg/µL)	Provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA. 3288187
44†	Extracted DNA Volume of Normal Control	_____ (µL)	Provide the volume (µL) of the normal control sample sent to the BCR for TCGA. 3288188
Non-Neoplastic Control Tissue: Only complete this section if submitting Non-Neoplastic Control Tissue.			
45†	Anatomic Site of Non-Neoplastic Control Tissue	☐ Skin ☐ Other (Please Specify)	If the normal control type is non-neoplastic tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. 3081938
46†	Other Anatomic Site of Non-Neoplastic Control Tissue	_____	
47†	Is the proximity of the non-neoplastic control tissue > 2cm from the tumor submitted for TCGA?	☐ Yes, the submitted non-neoplastic control tissue is > 2cm from submitted tumor.	If the normal control type is non-neoplastic tissue, confirm that the submitted tissue was at least 2cm away from the primary tumor. Adjacent (≤ 2cm) tissue is not accepted. If the proximity of the non-neoplastic control tissue from the submitted tumor is unknown, the tissue will be excluded. 3088708

_____ _____ ___ ___/ ___ ___/ ___ ___ ___ ___

Principal Investigator 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.