Enrollment: LGG

V4.2

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	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 Information			
2	Primary Site of Disease	☐ Central Nervous System	2735776 Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA.
3	Histological Subtype	☐ Astrocytoma ☐ Oligodendroglioma ☐ Oligoastrocytoma	3081934 Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. ***Note: All other subtypes not listed are excluded from this study.***
4	Histologic Classification	☐ Grade II ☐ Grade III	3121592 Using the patient's pathology/laboratory report, select the histologic grade for the tumor submitted to TCGA.
5	Laterality of Site	☐ Left ☐ Right ☐ Midline	3130361 Using the patient's pathology/laboratory report and/or medical record, designate the side of the body from which this tumor, submitted for TCGA, originated.
6	Tumor Site	☐ Supratentorial-Frontal Lobe ☐ Supratentorial-Temporal Lobe ☐ Supratentorial-Parietal Lobe ☐ Supratentorial-Occipital Lobe ☐ Posterior Fossa-Cerebellum ☐ Posterior Fossa-Brain Stem ☐ Supratentorial-Not Otherwise Specified	3139375 Using the patient's pathology/laboratory report in conjunction with the medical record, indicate the anatomic location of the tumor within the brain.
7	Supratentorial Localization	☐ Spinal Cord ☐ White Matter ☐ Deep Gray (e.g. basal ganglia or thalamus) ☐ Cerebral Cortex ☐ Not Listed on Medical Record	3133891 Using the patient's pathology/laboratory report in conjunction with the medical record, indicate the location of the supratentorial tumor.
8	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.
9	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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10	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			
11	Month of Birth	☐☐ (MM)	2896950 Provide the month the patient was born
12	Day of Birth	☐☐ (DD)	2896952 Provide the day the patient was born
13	Year of Birth	☐☐☐☐ (YYYY)	2896954 Provide the year the patient was born
14	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 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.***
15	Race	☐ American Indian or Alaska Native (A person having origins in any original peoples of North and South America (including Central America), and who 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, Pakistan, the Philippines, Thailand, Vietnam) ☐ White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa) ☐ Black or African American (having origins in any black racial groups of Africa. "Haitian" or "Negro" can be used in addition to "Black/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.
16	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
17	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 or bilateral 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.***

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18	History of Neo-Adjuvant Treatment to 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 of this colorectal tumor)			
19	Month of Initial Pathologic Diagnosis	☐☐ (MM)	2896956 Provide the month the patient was initially diagnosed with the malignancy submitted for TCGA
20	Day of Initial Pathologic Diagnosis	☐☐ (DD)	2896958 Provide the day the patient was initially diagnosed with the malignancy submitted for TCGA
21	Year of Initial Pathologic Diagnosis	☐☐☐☐ (YYYY)	2896960 Provide the year the patient was initially diagnosed with the malignancy submitted for TCGA
22	History of Therapeutic Ionizing Radiation to Head	☐ Yes ☐ No ☐ Unknown	3120926 Indicate if the patient has a history of therapeutic ionizing radiation to the head prior to the current tissue resection for TCGA. ***Note: If "Yes" the sample submitted to TCGA is excluded.***
23	Seizures	☐ Yes ☐ No ☐ Unknown	3121333 Indicate if the patient/participant presented with seizures prior to diagnosis of LGG.
24	Headaches	☐ Yes ☐ No ☐ Unknown	3121345 Indicate if the patient/participant presented with headaches prior to diagnosis of LGG.
25	Mental Status Changes	☐ Yes ☐ No ☐ Unknown	3121352 Indicate if the patient/participant presented with mental status changes prior to diagnosis of LGG.
26	Visual Changes	☐ Yes ☐ No ☐ Unknown	3121359 Indicate if the patient/participant presented with visual changes prior to diagnosis of LGG.
27	Sensory Changes	☐ Yes ☐ No ☐ Unknown	3121365 Indicate if the patient/participant presented with sensory changes prior to diagnosis of LGG.
28	Motor/Movement Changes	☐ Yes ☐ No ☐ Unknown	3120991 Indicate if the patient/participant presented with motor/movement changes prior to diagnosis of LGG.
29	Symptom Related to Disease that Presented First	☐ Seizures ☐ Visual Changes ☐ Headaches ☐ Sensory Changes ☐ Mental Status Changes ☐ Motor/Movement Changes	3133911 Indicate the first presenting symptom related to the diagnosis of the patient's/participant's LGG.
30	Longest Duration Of First Presenting Symptom	☐ 0-30 Days ☐ 31-90 Days ☐ 91-180 Days ☐ > 180 days	3121001 Indicate the longest duration or length of time in which the patient/participant experienced the first presenting symptom.
31	Personal History of Asthma	☐ Yes ☐ No ☐ Unknown	3133921 Indicate if the patient/participant had a personal history of asthma.
32	Personal History of Eczema	☐ Yes ☐ No ☐ Unknown	3133925 Indicate if the patient/participant had a personal history of eczema.

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Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
33	Personal History of Hay Fever (seasonal pollen allergies)	☐ Yes ☐ No ☐ Unknown	3133930 Indicate if the patient/participant had a personal history of hay fever (seasonal pollen allergies).
34	Personal History of Allergy to Dust or Mold	☐ Yes ☐ No ☐ Unknown	3133934 Indicate if the patient/participant had a personal history of allergy to dust or mold.
35	Age at First Diagnosis of Asthma, Eczema, Hay Fever, or Allergy to Dust or Mold	☐ < 12 Years ☐ 12-20 Years ☐ > 20 Years	3121273 Indicate the age grouping which describes the age of the patient/participant at the time of onset of the diagnosis of asthma, eczema, hay fever, or allergy to dust or mold.
36	History of Food Allergy	☐ Yes ☐ No ☐ Unknown	3121278 Indicate if the patient/participant had a personal history of food allergies. ***Note: If yes, please complete Type of Allergy and Age at Diagnosis questions***
37	Type(s) of Food Allergy/Allergies	_____	3121280 List the specific types of food allergies for the patient/participant.
38	Age at Diagnosis of First Food Allergy	☐ < 12 Years ☐ 12-20 Years ☐ > 20 Years	3121301 Indicate the age grouping which describes the age of the patient/participant at the time of onset of the diagnosis of the first food allergy.
39	History of Allergy to Animals or Insects	☐ Yes ☐ No ☐ Unknown	3121314 Indicate if the patient/participant had a personal history of allergies to animals or insects. ***Note: If yes, please complete Type of Allergy and Age at Diagnosis questions***
40	Type(s) of Allergy/ Allergies to Animal or Insect	_____	3121316 List the specific types of animal/ insect allergies for the patient/participant.
41	Age at Diagnosis of First Allergy to Animals or Insects	☐ < 12 Years ☐ 12-20 Years ☐ > 20 Years	3121318 Indicate the age grouping which describes the age of the patient/participant at the time of onset of the diagnosis of the first allergy to animals or insects.
42	Pre-operative Corticosteroids Administered	☐ Yes ☐ No ☐ Unknown	3121323 Indicate if pre-operative corticosteroids were administered to the patient/participant.
43	Pre-operative Anti-Seizure Medication Administered	☐ Yes ☐ No ☐ Unknown	3121328 Indicate if pre-operative anti-seizure medications were administered to the patient/participant.
44	Vital Status	☐ Living ☐ Deceased	2939553 Indicate whether the patient was living or deceased at the date of last contact.
Date of Last Contact			
45	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.***
46	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.***

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Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
47	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.***
48	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 to the date of last contact. ***Note 1: Do not answer this question if the patient is deceased.*** ***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.***
Date of Death			
49	Month of Death	☐☐ (MM)	2897026 If the patient is deceased, provide the month of death.
50	Day of Death	☐☐ (DD)	2897028 If the patient is deceased, provide the day of death.
51	Year of Death	☐☐☐☐ (YYYY)	2897030 If the patient is deceased, provide the year of death.
52	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 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.***
53	Tumor Status (at time of last contact or at time of death)	☐ Tumor Free ☐ Unknown Tumor Status ☐ With Tumor	2759550 Indicate whether the patient was tumor/disease free at the date of last contact or death.
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment			
54	Family History of Cancer (First degree relatives: parents, siblings, or children)	☐ Yes ☐ No ☐ Unknown	2436860 Indicate whether the patient/participant has a first degree relative (parents, siblings, children) with a history of cancer.
55	Family History of Primary Brain Tumor (First degree relatives: parents, siblings, or children)	☐ Yes ☐ No ☐ Unknown	3133957 Indicate whether the patient/participant has a first degree relative (parents, siblings, or children) with a history of a primary brain tumor.
56	Was IDH1 Mutation tested?	☐ Yes ☐ No ☐ Unknown	3133962 Indicate if testing was performed to identify the presence of IDH1 Mutation. ***Note: If yes, please complete Method Tested question***
57	If IDH1 Mutation Tested, What Method was Used?	☐ IHC ☐ Sequence Analysis	3133963 If IDH1 Mutation Testing was performed, indicate the testing method used.
58	Mutation found?	☐ Yes ☐ No ☐ Unknown	3133967 Indicate if mutation was identified during IDH1 mutation testing.

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59	Inherited Genetic Syndrome (e.g. NF1, NF2, tuberous sclerosis, etc.)	☐ Yes ☐ No ☐ Unknown	3133971 Indicate if the patient/participant had a personal history of an inherited genetic syndrome.
60	Specific Inherited Genetic Syndrome	_____	3133974 Specify the name(s) of the any inherited genetic syndromes identified.
61	Performance Status Score: Karnofsky Score	☐ 100 Normal, no complaints; no evidence of disease ☐ 90 Able to carry on normal activity; minor signs or symptoms of disease ☐ 80 Normal activity with effort; some signs or symptoms of disease ☐ 70 Cares for self; unable to carry on normal activity or to do active work ☐ 60 Requires occasional assistance; but is able to care for most of his/her needs ☐ 50 Requires considerable assistance and frequent medical care ☐ 40 Disabled; requires special care ☐ 30 Severely disabled ☐ 20 Very sick; requiring hospitalization ☐ 10 Moribund; fatal processes progressing rapidly ☐ 0 Dead ☐ Unknown ☐ Not Evaluated	2003853 Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient.
62	Performance Status Score: Eastern Cooperative Oncology Group	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Not Evaluated ☐ Unknown	88 Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient.
63	Performance Status Score: Timing	☐ Pre-Operative ☐ Post-Adjuvant ☐ Not Evaluated ☐ Pre-Adjuvant ☐ Other ☐ Unknown	2792763 Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories.
Date of Initial Score of Performance Status Scale			
64	Month of Initial Score of Performance Status Scale	☐☐ (MM)	3121343 Provide the month when the initial performance status scale (Karnofsky or ECOG) was obtained.
65	Day of Initial Score of Performance Status Scale	☐☐ (DD)	3121350 Provide the day when the initial performance status scale (Karnofsky or ECOG) was obtained.
66	Year of Initial Score of Performance Status Scale	☐☐☐☐ (YYYY)	3121354 Provide the year when the initial performance status scale (Karnofsky or ECOG) was obtained.
67	Number of Days from Date of Initial Pathologic Diagnosis to date of Initial Score of Performance Status Score	_____	3479270 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of initial score of Performance Status Score. ***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.***

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Primary Treatment			
68	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.***
69	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.***
70	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.
New Tumor Event - Complete this section below 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; and then skip the remainder of this form.			
71	New Tumor Event After Initial Treatment	☐ Yes ☐ No ☐ Unknown	3121376 Indicate whether the patient had a new tumor event (e.g. Remote Resection, 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			
72	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.
73	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.
74	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.
75	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.***
76	Additional Surgery for New Tumor Event **Loco-Regional Procedure**	☐ 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 Additional Surgery for New Tumor Event			
77	Month of Additional Surgery for New Tumor Event **Loco-Regional Procedure**	☐☐ (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.
78	Day of Additional Surgery for New Tumor Event **Loco-Regional Procedure**	☐☐ (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.
79	Year of Additional Surgery for New Tumor Event **Loco-Regional Procedure**	☐☐☐☐ (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.

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Question	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
80	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event **Loco-Regional Procedure**	_____	3408572 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of additional surgery for new tumor event (Local-Regional). ***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.***
81	Additional Surgery for New Tumor Event **Remote Resection**	☐ Yes ☐ No ☐ Unknown	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 Remote Resection			
82	Month of Additional Surgery for New Tumor Event **Remote Resection**	☐☐ (MM)	2897038 If the patient had surgery for the new metastatic tumor event, provide the month of surgery for this new metastatic tumor event.
83	Day of Additional Surgery for New Tumor Event **Remote Resection**	☐☐ (DD)	2897040 If the patient had surgery for the new metastatic tumor event, provide the day of surgery for this new metastatic tumor event.
84	Year of Additional Surgery for New Tumor Event **Remote Resection**	☐☐☐☐ (YYYY)	2897042 If the patient had surgery for the new metastatic tumor event, provide the year of surgery for this new metastatic tumor event.
85	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event **Remote Resection**	_____	3408682 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease 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.***
Additional Treatment			
86	New Tumor Event **Radiation Therapy**	☐ Yes ☐ No ☐ Unknown	3427615 Indicate whether the patient received radiation treatment for this new tumor event.
87	New Tumor Event **Pharmaceutical Therapy**	☐ Yes ☐ No ☐ Unknown	3427616 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): _____