

The Cancer Genome Atlas (TCGA) Clinical Data Reporting Form - GBM		Barcode Internal Use Only	
Tissue Source Site (TSS) Name: _____  TSS Identifier #: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		1. Completed By: _____  Date: <input type="checkbox"/> <input type="checkbox"/> M M   D D   Y Y	
<b>Tier 1 Clinical Data Definition:</b> All of these elements (1-22) are required to “qualify” the tumor specimen for TCGA project.		2. Completed By: _____  Date: <input type="checkbox"/> <input type="checkbox"/> M M   D D   Y Y	
Tier 1 Clinical Data (Page 1 of 3)			
Tier #	Data Element Label	Entry Alternatives	caBIG Definition
1: 01	TSS Unique Patient #		
1: 02	Organ of Origin – GBM	<input type="checkbox"/> Brain <input type="checkbox"/> Lung <input type="checkbox"/> Ovary	Text term for originating or primary anatomic site of the disease/condition under investigation or review. (2735776)
1: 03	Histological Type: a. <i>Untreated primary (De Nova) GBM</i> b. <i>Prior brain tissue diagnosis of lower grade Glioma</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No	Text term to indicate whether or not a brain tumor is the first occurrence of Glioblastoma Multiforme, which forms from glial (supportive) tissue of the brain and grows quickly. (2753300)  Text term to signify if a person had an earlier diagnosis of glioma with a lower histologic grade than the current glioma grade. (2786111)
1:04	Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis on their social roles. [ Explanatory Comment 1: Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc. (2200604)
1: 05	Date of Birth	<input type="checkbox"/> <input type="checkbox"/> M M   D D   Y Y	Person's Birth date (2201154)
1: 06	Reserved for Future Use		
1: 07	Tobacco smoking history indicator (Ovary-GBM: N/A)	N/A	Text indicator to represent a person's tobacco smoking, the act of puffing and/or inhaling smoke from a lit tobacco cigarette, cigar, or pipe. (2436233)
1: 08	Date of initial pathologic diagnosis	<input type="checkbox"/> <input type="checkbox"/> M M   D D   Y Y	The date this disease was first diagnosed. (58204)
1: 09	Neo-adjuvant (pre-operative) therapy (If yes, this is an exclusion criterion)	<input type="checkbox"/> Yes <input type="checkbox"/> No	The yes/no indicator to ask whether any treatment was given to the patient prior to surgery. (64176)
1: 10	Date of Surgical Resection	<input type="checkbox"/> <input type="checkbox"/> M M   D D   Y Y	The date of a surgical procedure. (2003986)

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<b>Tier 1 Clinical Data (Page 2 of 3)</b>			
Tier #	Data Element Label	Entry Alternatives	caBIG Definition
1: 11	Tumor Stage (pathological) GBM	N/A	Text term to represent the name of the histologic category or classification of a brain tumor. (2467507)
1: 12	Tumor Grade: GBM	N/A	Numeric value to express the degree of abnormality of cancer cells, a measure of differentiation and aggressiveness. (2785839)
1: 13	Complete Excision (RO)	<input type="checkbox"/> Yes (RO) <input type="checkbox"/> No (R1) <input type="checkbox"/> Unknown	Term to signify the complete removal or excision by surgical means of the primary tumor, so that surgical margins are free of gross and microscopic tumor. (2785845)
1: 14	Adjuvant (Post-Operative) <b>Irradiation therapy</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Yes/no indicator to ask if therapeutic application if radiation was initiated to treat disease following surgery to remove tumor and associated malignant tissue. (2005312)
1: 15	Adjuvant (Post-Operative) <b>Chemotherapy</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Text term to indicate whether a patient has received adjuvant postoperative chemotherapy. (2756823)
1: 16	Adjuvant (Post-Operative) <b>Immunotherapy</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Text term to indicate whether a patient has received adjuvant postoperative Immunotherapy. (2756814)
1: 17	Adjuvant (Post-Operative) <b>Hormonal Therapy</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Yes/no/unknown indicator whether adjuvant hormone therapy was administered following surgery. (2199669)
1: 18	Adjuvant (Post-Operative) <b>"Targeted" Molecular Therapy</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Text term to signify postoperative adjuvant cancer therapies which use drugs to act upon specific molecules, metabolic pathways or processes involved in carcinogenesis, tumor growth, or tumor spread. (2785850)
1: 19	Date of first Recurrence after therapy	<input type="checkbox"/> N/A <input type="checkbox"/> Unknown  <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M M D D Y Y	N/A =Tumor has not recurred at time of last clinical evaluation. (See 1:20)  The date related to the diagnosis or recognition of the presence and nature of the return of signs and symptoms of cancer after a period of improvement. (2663381)
1: 20	Date of Last Contact (clinical evaluation)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> M M D D Y Y	The date of the last successful contact with the patient, family member, or caregiver to establish responses for 1:21 and 1:22 below. (2004147)

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	TSS Unique Patient # _____		

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1: 21	Vital Status (date of last contact)	<input type="checkbox"/> Living <input type="checkbox"/> Deceased <input type="checkbox"/> Unknown	Test summary level description of patient / participant survival status. (2190384)
1: 22	Date of Death	<input type="checkbox"/> N/A  <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> M M    D D    Y Y	The actual date of a patients/participants death. (2004152)

Comments: \_\_\_\_\_  
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 Principal Investigator Signature

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 Print Name

/   /    
 M M    D D    Y Y

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Tissue Source Site (TSS) Name: _____ TSS Identifier #: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> TSS Unique Patient # _____ <b>Tier 2 Clinical Data Definition:</b> Desirable, but not mandatory clinical information for clinical correlation analyses.		1. Completed By: _____ Date: <input type="checkbox"/> <input type="checkbox"/> M M D D Y Y 2. Completed By: _____ Date: <input type="checkbox"/> <input type="checkbox"/> M M D D Y Y	
Tier 2 Clinical Data (Page 1 of 4)			
Tier #	Data Element Label	Entry Alternatives	caBIG Definition
2: 02	Anatomic Organ Sub-Division a. Brain b. Lung c. Ovary	<input type="checkbox"/> Brain <input type="checkbox"/> N/A <input type="checkbox"/> Lung <input type="checkbox"/> R <input type="checkbox"/> Upper <input type="checkbox"/> Middle <input type="checkbox"/> Lower <input type="checkbox"/> L <input type="checkbox"/> Upper <input type="checkbox"/> Lower <input type="checkbox"/> Ovary <input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Bilateral <input type="checkbox"/> Unknown	<b>Anatomic organ:</b> Text term for originating of primary anatomic site of the disease/condition under investigation or review. (2735776) <b>Detailed spatial description</b> to provide the exact location of an anatomic site or location. (2008006)
2: 08	Method of initial pathologic diagnosis (check all that apply)	<input type="checkbox"/> Cytology (e.g. peritoneal or pleural fluid) <input type="checkbox"/> Fine needle aspiration biopsy <input type="checkbox"/> Incision biopsy <input type="checkbox"/> Excisional biopsy <input type="checkbox"/> Tumor resection <input type="checkbox"/> Other method, specify: <input type="checkbox"/> Unknown	<b>Method:</b> Text name of the procedure to secure the tissue used for the original pathologic diagnosis. (2757941) <b>Other method:</b> Text to describe a method used to secure tissue for an original pathologic diagnosis that is different from other identified methods. (2757948)
2: 14	Adjuvant (Post-operative) <b>Irradiation therapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Radiation)	Yes/no indicator to ask if therapeutic application of radiation was initiated to treat disease following surgery to remove tumor and associated malignant tissue. (2005312)
2:15	Adjuvant (Post-operative) <b>Chemotherapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	Text term to indicate whether a patient has received adjuvant postoperative chemotherapy. (2756823)
2: 16	Adjuvant (Post-operative) <b>Immunotherapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	Text term to indicate whether a patient has received adjuvant postoperative Immunotherapy. (2756814)

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<b>Tier 2 Clinical Data (Page 2 of 4)</b>			
Tier #	Data Element Label	Entry Alternatives	caBIG Definition
2: 17	Adjuvant (Post-operative) <b>Hormone therapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	Yes/no/unknown indicator whether adjuvant hormone therapy was administered following surgery. (2199669)
2: 18	Adjuvant (Post-operative) <b>Targeted Molecular Therapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	Text term to signify postoperative adjuvant cancer therapies which use drugs to act upon specific molecules, metabolic pathways or processes involved in carcinogenesis, tumor growth, or tumor spread. (2785850)
2: 00A	Race	<input type="checkbox"/> 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) <input type="checkbox"/> Asian (A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam) <input type="checkbox"/> White (A person having origins in any of the original peoples of Europe, the Middle East, or North Africa) <input type="checkbox"/> 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.") <input type="checkbox"/> Native Hawaiian or other Pacific Islander (A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands) <input type="checkbox"/> Not Reported (Not provided or available) <input type="checkbox"/> Unknown (Could not be determined or unsure)	The text for reporting information about race based on the Office of Management and Budget (OMB) categories. (2192199)
	Ethnicity	<input type="checkbox"/> Not Hispanic or Latino (A person not meeting the definition for Hispanic or Latino) <input type="checkbox"/> Hispanic or Latino (A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race) <input type="checkbox"/> Not reported (Not provided or available) <input type="checkbox"/> Unknown (Could not be determined or unsure)	The text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories. (2192217)

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Tier #	Data Element Label	Entry Alternatives	caBIG Definition
2: 21	Vital Status A. Living B. Deceased	<input type="checkbox"/> Living (cancer status) <input type="checkbox"/> Tumor Free <input type="checkbox"/> With Tumor <input type="checkbox"/> Unknown Tumor Status <input type="checkbox"/> Deceased (cancer status) <input type="checkbox"/> Tumor Free <input type="checkbox"/> With Tumor <input type="checkbox"/> Unknown Tumor Status	The state or condition of an individual's neoplasm at a particular point in time. (2759550)  The state or condition of an individual's neoplasm at a particular point in time. (2759550)
2: 00B	Performance Status Scale  (complete Karnofsky Score Or Eastern Cancer Oncology Group)	<input type="checkbox"/> Not Recorded <b>Karnofsky Score</b> <input type="checkbox"/> 100 asymptomatic <input type="checkbox"/> 80-90 symptomatic but fully ambulatory <input type="checkbox"/> 60-70 symptomatic but in bed less than 50% of day <input type="checkbox"/> 40-50 symptomatic, in bed more than 50% of the day, but not bed ridden <input type="checkbox"/> 20-30 bed ridden <b>Eastern Cancer Oncology Group (ECOG)</b> <input type="checkbox"/> 0 asymptomatic <input type="checkbox"/> 1 symptomatic but fully ambulatory <input type="checkbox"/> 2 symptomatic but in bed less than 50% of day <input type="checkbox"/> 3 symptomatic, in bed more than 50% of the day, but not bed ridden <input type="checkbox"/> 4 bed ridden  <b>Timing of score:</b> <input type="checkbox"/> Preoperative <input type="checkbox"/> Pre-adjuvant therapy <input type="checkbox"/> Post-adjuvant therapy <input type="checkbox"/> Other <input type="checkbox"/> Unknown	<b>Score from the Karnofsky</b> Performance status scale, representing the functional capabilities of a person. (2003853)  <b>The ECOG functional</b> performance status of the patient/participant. (88)
2: 00C	Secondary Surgery for tumor recurrence or progression	<input type="checkbox"/> None  Loco-regional procedure: <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> Yes <div style="text-align: center;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>            M M D D Y Y         </div> Metastasis procedure: <input type="checkbox"/> Unknown <input type="checkbox"/> No <input type="checkbox"/> Yes <div style="text-align: center;"> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>            M M D D Y Y         </div>	<b>Indicator:</b> The yes/no/unknown indicator that asks whether the recurrence was treated by surgery. (2199761)  <b>Procedure:</b> Name of the secondary surgical procedure performed for recurrent or progressive disease. (2759612)  <b>Date:</b> Date of the secondary surgical procedure performed for recurrent or progressive disease. (2759616)

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**Tier 2 Clinical Data (Page 4 of 4)**

Tier #	Data Element Label	Entry Alternatives	caBIG Definition
2: 00D	Additional treatment of tumor recurrence/progression <b>Irradiation therapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Radiation)	<b>Indicator:</b> the yes/no indicator related to the additional administration of the use of high-energy radiation from x-rays, gamma rays, neutrons, and other sources to kill cancer cells and shrink tumors after the return of a disease. (2650648)
2: 00E	Additional treatment of tumor recurrence/progression <b>Chemotherapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	<b>Indicator:</b> The yes/no indicator related to the additional administration of chemotherapy after the return of a disease after a period of remission. (2650626)
2: 00F	Additional treatment of tumor recurrence/progression <b>Immunotherapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	<b>Indicator:</b> The yes/No indicator for the administration of additional immunotherapy to an individual after the recurrence or progression of disease. (2759828)
2: 00G	Additional treatment of tumor recurrence/progression <b>Hormone Therapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	<b>Indicator:</b> The yes/no indicator related to the additional administration of various treatment modalities that produce the desired therapeutic effect by means of change of hormone/hormones level after the return of a disease after a period of remission or new disease. (2650646)
2: 00H	Additional treatment of tumor recurrence/progression <b>Targeted molecular therapy</b>	<input type="checkbox"/> No <input type="checkbox"/> Yes  (If yes, complete Disease Treatment Regimen Supplemental form for: Pharmaceutical Therapy)	Text term to signify the treatment of an individual with recurrent or progressive disease with additional targeted therapy (2786150)

Comments:

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Principal Investigator Signature

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Print Name

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