Enrollment: Glioblastoma

Tissue Source Site (TSS) Name: _____ HCMI Identifier (ID3): _____

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

Form Notes: An Enrollment Form should be completed for each HCMI case upon qualification notice from Leidos. 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.

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
1	ID2	_____	2003301	Provide the patient's ID2 (this ID will only be used by IMS for internal quality control).
2	ID3	_____	5845012	Provide the HCMI-specific anonymized ID (ID3).
3	Index date	☐ Initial pathologic diagnosis ☐ Sample procurement ☐ First patient visit	6154722	Select the reference date used to calculate time intervals (e.g. days to treatment). Date of initial pathologic diagnosis is the HCMI standard and should be used unless it is unavailable. If an alternative index date is used, indicate it here and use it for all interval calculations.
Normal Control Information				
4	Type of normal control	☐ Whole blood ☐ Buccal cells ☐ Buffy coat ☐ Lymphocytes ☐ Extracted DNA from blood ☐ Extracted DNA from saliva ☐ Extracted DNA from buccal cells ☐ Extracted DNA from normal tissue ☐ FFPE non-neoplastic tissue ☐ Non-neoplastic tissue	3081936	Indicate the type of normal control submitted for this case.
Tumor Tissue Collected for Molecular Characterization, Sample Information				
5	Tumor tissue sample preservation method	☐ FFPE ☐ Fresh ☐ OCT ☐ Snap frozen	5432521	Provide the method used to preserve the tumor tissue sample collected to be used for molecular characterization.
Cancer Model Information				
6	Anatomic site of tumor from which model was derived	☐ Brain ☐ Other (specify) ☐ Unknown	6033148	Indicate the anatomic site of the tumor tissue used to generate the model for the HCMI. ***Note: If the anatomic site of tumor tissue is not listed, proceed to Question 6a, otherwise, skip to Question 7.***
6a	Other anatomic site	_____	5946219	If the anatomic site for the tumor submitted to HCMI is not included on the provided list, specify the anatomic site.
7	Method of cancer sample procurement	☐ Biopsy ☐ Gross total resection ☐ Subtotal resection ☐ Other (specify)	3103514	Indicate the procedure performed to obtain the tumor tissue used to generate the model for HCMI. ***Note: If the method of sample procurement is not listed, proceed to Question 7a, otherwise, skip to Question 8.***
7a	Other method of sample procurement	_____	2006730	If the procedure performed to obtain the tumor tissue is not included in the provided list, specify the procedure.
8	Number of days from index date to date of cancer sample procurement	_____	3288495	Provide the number of days from the index date to the date of the procedure that produced the tumor tissue submitted for HCMI.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
9	ICD-10 code for model tumor	☐ C71.0 ☐ C71.1 ☐ C71.2 ☐ C71.3 ☐ C71.4 ☐ C71.5 ☐ C71.9 ☐ C72.9 ☐ Other (specify)	3226287	Provide the ICD-10 code for the tumor used to generate the model submitted to HCMI. ***Note: If the ICD-10 code is not listed, proceed to Question 9a, otherwise, skip to Question 10.***
9a	Other ICD-10 code	_____	3226287	If the ICD-10 code for the tumor used to generate the model submitted to HCMI is not included on the provided list, specify the ICD-10 code.
10	Tumor tissue type	☐ Premalignant ☐ Primary ☐ Recurrent ☐ Metastatic ☐ Additional primary ☐ NOS	3288124	Provide the tumor tissue type for the biospecimen used to produce the model for the HCMI.
Patient Information				
11	Gender	☐ Male ☐ Female ☐ Unspecified	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.
12	Height	_____	649	Provide the patient's height, in centimeters.
13	Weight	_____	651	Provide the patient's weight, in kilograms.
14	Body mass index (BMI)	_____	2006410	If the patient's height and weight are not collected, provide the patient's body mass index (BMI).
15	Race	☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ Unknown ☐ Not allowed to collect	2192199	Provide the patient's race using the defined categories. **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 peoples of the Far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Phillippine Islands, Thailand, and Vietnam. **Black or African American:** A person having origins in any of the black racial groups of Africa. **Native Hawaiian or other Pacific Islander:** A person having origins on any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Island. **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
16	Ethnicity	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown ☐ Not allowed to collect	2192217	Provide the patient's ethnicity using the defined categories. **Hispanic or Latino:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. **Not Hispanic or Latino:** A person not meeting the definition of Hispanic or Latino.
17	Year of birth	_____	2896954	Provide the year of the patient's birth. If the patient was born prior to 1928, insert the date 1928.
18	Family history of cancer	☐ Same ☐ Different ☐ None ☐ Unknown	5832923	Has a first-degree relative of the patient been diagnosed with a cancer of the same or a different type?

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
19	Tobacco smoking history	☐ Lifelong non-smoker (<100 cigarettes smoked in a lifetime) ☐ Current smoker (includes daily and non-daily smokers) ☐ Current reformed smoker (duration not specified) ☐ Current reformed smoker for >15 years ☐ Current reformed smoker for ≤15 years	2181650	Indicate the patient's history of tobacco smoking as well as their current smoking status using the defined categories.
Primary Tumor Diagnosis Information				
20	Number of days from index date to date of last contact	_____	3008273	Provide the number of days from the index date to the date of last contact.
21	Patient age on index date	_____	6379572	Provide the age (in days) of the patient on the index date. If the patient's age is greater than 32,507 days (89 years), please enter 32,507.
22	Morphology	☐ 9440/3 ☐ 9441/3 ☐ 9442/3 ☐ Other (specify)	3226275	Using the patient's pathology/laboratory report, provide the ICD-O-3 histology code of the primary tumor. ***Note: If the morphology is not listed, proceed to Question 22a, otherwise, skip to Question 23.***
22a	Other morphology	_____	3226275	If the ICD-O-3 histology code describing the morphology of the patient's primary tumor is not included on the previous list, provide the ICD-O-3 histology code.
23	Tissue or organ of origin	☐ Brain ☐ Other (specify)	3427536	Using the patient's pathology/laboratory report, select the primary site of the disease. ***Note: If the tissue or organ of origin is not listed, proceed to Question 23a, otherwise, skip to Question 24.***

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23a	Other tissue or organ of origin	☐ Abdomen ☐ Accessory sinus ☐ Adrenal gland ☐ Anus ☐ Appendix ☐ Bladder ☐ Bone ☐ Breast ☐ Connective, subcutaneous and other soft tissues ☐ Esophagus ☐ Eye ☐ Gallbladder ☐ Gum ☐ Head, face or neck ☐ Heart ☐ Kidney ☐ Larynx ☐ Lip ☐ Liver ☐ Lung ☐ Lymph node ☐ Male genital organs ☐ Mediastinum ☐ Meninges ☐ Mouth ☐ Nasal cavity ☐ Nasopharynx ☐ Nervous system ☐ Oropharynx ☐ Other ill-defined sites ☐ Ovary ☐ Palate ☐ Pancreas ☐ Penis ☐ Peripheral nerves and autonomic nervous system of trunk ☐ Peritoneum ☐ Pharynx ☐ Pituitary gland ☐ Prostate gland ☐ Rectosigmoid junction ☐ Rectum ☐ Renal pelvis ☐ Retroperitoneum ☐ Skin ☐ Small intestine ☐ Spinal cord ☐ Spleen ☐ Stomach ☐ Testis ☐ Thymus ☐ Thyroid gland ☐ Tongue ☐ Tonsil ☐ Trachea ☐ Unknown primary site ☐ Urinary system ☐ Uterus ☐ Vagina ☐ Vulva	3427536	If the primary site of the disease is not included on the previous list, select the primary site of the disease.
24	Histological type	☐ Brain cancer ☐ Other (specify)	3081932	Provide the traditional surgical pathology text description of the histological tumor type. ***Note: If the histological type is not listed, proceed to Question 24a, otherwise, skip to Question 25.***
24a	Other histological type	_____	3294805	If the traditional surgical pathology text description of the histological tumor type is not included on the previous list, please specify the histological type.
25	Histological subtype	☐ Giant cell glioblastoma ☐ Gliosarcoma ☐ NOS ☐ Other (specify)	3081934	Using the patient's pathology/laboratory report, select the histological subtype of the primary tumor. ***Note: If the histological subtype is not listed, proceed to Question 25a, otherwise, skip to Question 26.***
25a	Other histological subtype	_____	3124492	If the histological subtype for the primary tumor is not included in the provided list, specify the histological subtype.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
26	Prior malignancy (of the same cancer type)	☐ Yes ☐ No ☐ Unknown	5832924	Indicate whether the patient has a history of prior malignancy of the same cancer type.
27	Prior malignancy (other cancer type)	☐ Yes ☐ No ☐ Unknown	5878828	Indicate whether the patient has a history of prior malignancy of a different cancer type.
28	WHO histologic grade	☐ Grade 1 ☐ Grade 2 ☐ Grade 3 ☐ Grade 4 ☐ Unknown	2181858	Provide the WHO histologic grade of the primary tumor.
29	Is necrosis present?	☐ Yes ☐ No ☐ Unknown	64740	Indicate if there is evidence of localized death of cells associated with the presence of the tumor.
30	Metastasis at diagnosis assessment status	☐ Metastatic ☐ Non-metastatic (confirmed) ☐ Non-metastatic (unconfirmed)	3438571	Indicate whether there was evidence of metastasis at the time of diagnosis of the primary tumor.
31	Site of relapse	☐ Local ☐ Regional ☐ Distant ☐ Not applicable	2002506	If the primary tumor relapsed, select all sites of relapse. ***Note: If the primary tumor did not relapse, select 'Not applicable'.***
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment				
32	Performance status score: Karnofsky score	☐ 100: Normal; no complaints ☐ 90: Able to carry out 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 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; requires hospitalization ☐ 10: Moribund; fatal processes progressing rapidly ☐ 0: Dead ☐ Unknown ☐ Not evaluated	2003853	Indicate the score from the Karnofsky Performance status scale, representing the functional capabilities of a person.
33	Number of days from index date to the date initial score obtained for the Karnofsky performance status scale	_____	3479270	Provide the number of days from the index date to the date that the Karnofsky performance status assessment was performed.
34	Performance status score: Eastern Cooperative Oncology Group	☐ 0: Asymptomatic ☐ 1: Symptomatic but fully ambulatory ☐ 2: Symptomatic; in bed less than 50% of the day ☐ 3: Symptomatic; in bed more than 50% of the day but not bed-ridden ☐ 4: Bed-ridden ☐ 5: Dead ☐ Unknown ☐ Not evaluated	88	Indicate the ECOG functional performance status of the patient/participant.

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

Question	Question Text	Data Entry Options	CDE ID	Instruction Text
35	Number of days from index date to the date initial score obtained for the ECOG performance status scale	_____	3479270	Provide the number of days from the index date to the date that the ECOG performance status assessment was performed.
36	Was IDH1/2 mutation analysis performed?	☐ Yes ☐ No ☐ Unknown	6062597	Indicate whether mutation analysis of IDH1 or IDH2 was performed. ***Note: If not performed, skip to Question 40.***
37	Was a mutation in IDH1/2 identified?	☐ Yes ☐ No	6002200	Indicate whether an IDH1 or IDH2 mutation was identified at testing. ***Note: If mutation was not identified, skip to Question 40.***
38	What method was used to identify the mutation?	☐ Cancer hotspot panel ☐ Next generation targeted sequencing ☐ Whole exome sequencing ☐ Other (specify)	6003729	Specify the method used to identify the mutation(s). ***Note: If the mutation identification method is not listed, proceed to Question 38a, otherwise, skip to Question 39.***
38a	Other mutation identification method	_____	6002204	If the mutation identification method is not included in the provided list, specify the method used to identify mutation(s).
39	If IDH1/2 mutation identified, which one?	☐ IDH1 R132H ☐ IDH1 R132C ☐ IDH1 R132S ☐ IDH1 R132G ☐ IDH1 R132L ☐ IDH2 R172W ☐ IDH2 R172K ☐ IDH2 R172M ☐ Other (specify)	6002206	Select the mutation identified in IDH1/2. ***Note: If the IDH1/2 mutation is not listed, proceed to Question 39a, otherwise, skip to Question 40.***
39a	Other IDH1/2 mutation	_____	6002207	If the mutation in IDH1/2 is not included in the provided list, specify the mutation in IDH1/2.
40	Was IDH1 R132H IHC performed?	☐ Yes ☐ No ☐ Unknown	6062408	Indicate whether immunohistochemistry for IDH1 R132H was performed. ***Note: If not performed, skip to Question 42.***
41	IDH1 R132H expression by IHC	☐ Positive ☐ Negative ☐ Equivocal	6063674	Indicate the expression of IDH1 R132H as determined by immunohistochemistry (IHC).
42	MGMT promoter methylation status	☐ Methylated ☐ Partially methylated ☐ Unmethylated ☐ Indeterminate ☐ Not available	2799251	Indicate the methylation status of the MGMT promoter per testing results.
43	Hereditary cancer predisposition syndrome	☐ Fanconi anemia ☐ Gorlin syndrome ☐ Li-Fraumeni syndrome ☐ Lynch syndrome ☐ Rubinstein-Taybi syndrome ☐ Turcot syndrome ☐ Unknown ☐ Not applicable	6002201	Indicate all hereditary cancer predisposition syndromes identified in the patient.
44	MMR status	☐ Evidence of MMR mutation by sequencing ☐ Evidence of MMR protein loss by IHC ☐ MMR loss evidence hypermutation phenotype (>10 mutations/Mb) ☐ No evidence of MMR alteration ☐ Not performed	6002208	Indicate the patient's Mismatch Repair (MMR) gene mutation status.

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Question	Question Text	Data Entry Options	CDE ID	Instruction Text
Treatment Information				
45	History of neoadjuvant treatment	☐ No ☐ Yes; radiation prior to resection ☐ Yes; pharmaceutical treatment prior to resection ☐ Yes; both radiation and pharmaceutical treatment prior to resection ☐ Unknown	3382737	Indicate whether the patient received neoadjuvant radiation or pharmaceutical treatment. ***Note: Radiation therapy is addressed in Questions 53-54. Pharmaceutical therapy is addressed in Questions 46-52.***
46	Neoadjuvant chemotherapy type	☐ Cytotoxic chemotherapy ☐ Hormonal ☐ Immunotherapy (cellular and immune checkpoint) ☐ Targeted therapy (small molecule inhibitors and targeted antibodies) ☐ Not applicable	5832928	Select all neoadjuvant chemotherapy types that were administered to the patient. ***Note: Cytotoxic chemotherapy is addressed in Questions 47-48. Immunotherapy is addressed in Questions 49-50. Targeted therapy is addressed in Questions 51-52.***
47	Neoadjuvant chemotherapeutic regimen	☐ Bevacizumab ☐ Carboplatin ☐ Irinotecan ☐ Lomustine ☐ Temozolomide ☐ Vincristine ☐ Vorinostat ☐ Other (specify) ☐ Chemotherapy not given	2853313	Select all chemotherapeutics used for neoadjuvant therapy. ***Note: If the neoadjuvant chemotherapeutic regimen is not listed, proceed to Question 47a, otherwise, skip to Question 48.***
47a	Other neoadjuvant chemotherapeutic regimen	_____	62694	If the neoadjuvant therapy is not included in the provided list, specify neoadjuvant therapy.
48	Days to neoadjuvant chemotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with neoadjuvant chemotherapy.
49	Immunotherapy	_____	2185614	Specify the name of the immunotherapy administered. ***Note: If immunotherapy was not administered, skip to Question 51.***
50	Days to immunotherapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with immunotherapy.
51	Targeted therapy	_____	2842797	Select the targeted therapy administered to the patient. ***Note: If targeted therapy was not administered, skip to Question 53.***
52	Days to targeted therapy treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with targeted therapy.

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53	Radiation therapy administered type	☐ 2D conventional ☐ 3D conformal ☐ Brachytherapy HDR ☐ Brachytherapy LDR ☐ IMRT ☐ Proton Beam ☐ Stereotactic Body RT ☐ Stereotactic Radiosurgery ☐ WBRT ☐ Other (specify) ☐ Unspecified ☐ Not applicable	3028890	Provide the type of radiation therapy that was administered to the patient. ***Note: If radiation therapy was not administered, skip the remaining questions. If the radiation therapy is not listed, proceed to Question 53a, otherwise, skip to Question 54.***
53a	Other radiation therapy	_____	2195477	If the radiation therapy type is not included in the provided list, specify the type.
54	Days to radiation treatment from index date	_____	5102411	Provide the number of days from the index date to the date of treatment with radiation therapy.