Initial Case Quality Control Form
Melanoma

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 ___ ___/___ ___ /___ ___ ___ ___

Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form? ☐ Yes ☐ No

Note: Provided time intervals must begin with the date of initial pathologic diagnosis.

Tumor Information: The following sections are to be provided by a Pathologist

#	Question	Entry Alternatives	Working Instructions
1	Diagnosis	☐ Melanoma of the Skin	Indicate the confirmed diagnosis of the tumor submitted for TCGA. 3284266 Glabrous skin (palms or soles), Nail apparatus and Mucosa are excluded.
2	Tumor Type	☐ Primary *(primary untreated malignant biospecimen)* ☐ Metastatic	Indicate the type of tumor submitted for TCGA. 3288124 All submitted biospecimens should NOT have systemic treatment prior to procurement. Interferon treatment prior to procurement is accepted, if administered at least 90 days prior to tumor procurement.
3	Anatomic Site of Frozen Biospecimen	☐ Skin surface/ cutaneous *(for primary tumors only)* ☐ Regional lymph node ☐ Regional cutaneous or subcutaneous tissue *(includes satellite & in-transit metastasis)* ☐ Distant metastasis, specify	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. 2008006
4	Other Site of Disease	_____	If the submitted tissue was a distant metastasis, indicate the location of the tumor. 2584114
5	Month of Cancer Sample Procurement	☐01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008197
6	Day of Cancer Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008195
7	Year of Cancer Sample Procurement	_____	Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA. 3008199
8	Method of Cancer Sample Procurement	☐ Surgical Resection ☐ Incisional Biopsy ☐ Excisional Biopsy ☐ Other Method, (please specify)	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. 3103514
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. 2006730

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#	Question	Entry Alternatives	Working Instructions
10	Country Where Cancer Sample was Procured	_____	Provide the country where the tissue submitted for TCGA was procured. 3203072
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 *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 Reported: *Not provided or available.* ☐ Unknown: *Could not be determined or unsure.*	Provide the patient's race using the defined categories. 2192199
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 ☐ Biospecimen Storage Bag ☐ Cryomold	Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. 3081940
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 Laser Cryo-Enrichment (LCE)?	☐ Yes ☐ No	Indicate whether the tumor sample submitted to the BCR is intended to undergo Laser Cryo-Enrichment (LCE) after the BCR receives the sample. 3288488
16	Was sample prescreened at site?	☐ Yes ☐ No	Indicate whether the sample submitted to the BCR was prescreened at the TSS. 3081942
17	Will top slide be submitted to the BCR?	☐ Yes ☐ No	Indicate whether a physical top slide for the sample submitted to the BCR will be shipped with the tissue sample. 3081944 *Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface*
18	Will digital top slide image be sent to the BCR?	☐ Yes ☐ No	Indicate whether a digital slide image for the sample submitted to the BCR will be shipped with the tissue sample. 3081948 *Physical top-slides are preferred*

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#	Question	Entry Alternatives	Working Instructions
19	Will FFPE slide or image be submitted to the BCR?	☐ Slide ☐ Image	Indicate whether a physical slide or digital slide image of the formalin-fixed paraffin-embedded (FFPE) diagnostic block will be shipped with the tissue sample to the BCR. 3295811 *If the FFPE slide(s) or image(s) are sent in a shipment subsequent to the initial submission of tumor and normal samples, these questions can be skipped.*
20	FFPE Slide/Digital Image ID#	_____	Provide the slide ID for the physical FFPE slide OR the FFPE digital slide image being sent to the BCR. 3295810
Tumor Information: If submitting multiple pieces of the same primary tumor for this case, complete the following information for each piece of tumor sent to the BCR.			
21	Tumor Identifier	_____	Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. 3288096
22	Weight of Frozen Tumor	_____(mg) *(0.2cm³ (0.6cm * 0.6cm * 0.6cm) = ~200mg*	Provide the weight of the tumor sample submitted for TCGA. 3081946
23	Tumor Nuclei %	_____ (%)	Provide the percent of tumor nuclei for the sample submitted for TCGA. *Check with the BCR to confirm the current acceptable TCGA metrics.* 2841225
24	Necrosis %	_____ (%)	Provide the percent of necrosis for the sample submitted for TCGA. *Check with the BCR to confirm the current acceptable TCGA metrics.* 2841237
25	Slide/Digital Image ID #	_____	Provide the slide ID for the physical top slide OR the digital slide image being sent to the BCR. 2321277
Normal Information: A normal control must be present to qualify.			
26	Type(s) of Normal Control *Check all that apply*	☐ Whole Blood ☐ Buffy Coat ☐ Lymphocytes ☐ Extracted DNA from Blood ☐ Non-Neoplastic Control Tissue*	Indicate the type of normal control submitted for this case. 3081936 **Non-neoplastic Control Tissue may only be submitted with NCI approval.*
Normal Control: Whole Blood			
27	Method of Normal Sample Procurement	☐ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
28	Month of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
29	Day of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
30	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197

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#	Question	Entry Alternatives	Working Instructions
31	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
Normal Control: Buffy Coat/ Lymphocytes			
32	Normal Control Type	☐ Buffy Coat ☐ Lymphocytes	Indicate the type of normal control submitted for TCGA. 3081936
33	Method of Normal Sample Procurement	☐ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
34	Month of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
35	Day of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
36	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
37	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
Normal Control: Extracted DNA from Blood			
38	Method of Normal Sample Procurement	☐ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
39	Month of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
40	Day of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
41	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
42	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
43	Extracted DNA Quantity	_____(µg)	Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. 3288185
44	Extracted DNA Quantification Method	_____	Provide the quantification method of the normal control sample sent to the BCR for TCGA. 3288186
45	Extracted DNA Concentration	_____(µg/µL)	Provide the concentration (µg/ µL) of the normal control sample sent to the BCR for TCGA. 3288187

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#	Question	Entry Alternatives	Working Instructions
46	Extracted DNA Volume	_____(µL)	Provide the volume (µL) of the normal control sample sent to the BCR for TCGA. 3288188
Normal Control: Non-Neoplastic Control Tissue			
47	Method of Normal Sample Procurement	☐ Surgical Resection ☐ Incisional Biopsy ☐ Excisional Biopsy ☐ Other Method (please specify)	Indicate the procedure performed to obtain the normal control sample submitted for TCGA. 3288147
48	Other Method of Normal Sample Procurement	_____	If the procedure performed to obtain the normal sample is not included in the provided list, specify the procedure. 3288151
49	Month of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. 3288195
50	Day of Normal Sample Procurement	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. 3288196
51	Year of Normal Sample Procurement	_____	Provide the year of the procedure performed to obtain the normal control submitted for TCGA. 3288197
52	Normal Identifier	_____	Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. 3288138
53	Anatomic Site of Non-Neoplastic Control Tissue	☐ Skin surface/ cutaneous ☐ Other (please specify)	If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. 3081938 *Site matched is preferred.*
54	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. 3288189
55	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. 3088708 ***Adjacent (≤ 2cm) Normal Tissue*** *is not accepted for this tissue type.* ***Unknown Normal Tissue*** *is not acceptable for this tissue type.*
56	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

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.

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#	Question	Entry Alternatives	Working Instructions
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.*			
57	Name of Pathologist	_____	Provide the name of the Pathologist that provided the information for all previous sections. 3288225
58	Date of Pathologist Review	_____	Provide the date of the pathology review performed by the TSS pathologist above. 3288224
Principal Investigator/Authorized Designee Confirmation			
59	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. 3288520 Check with the BCR to confirm the current acceptable TCGA metrics.
60	Percent Necrosis meets TCGA metrics?	☐ Yes ☐ No	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. 3288524 Check with the BCR to confirm the current acceptable TCGA metrics.
61	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. 3288292
62	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. 3288300 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.

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#	Question	Entry Alternatives	Working Instructions
63	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. 3288315 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.
64	History of Other Malignancy *(Non-melanoma malignancies only)*	☐ None ☐ History of Prior Malignancy ☐ History of Synchronous/ Bilateral Malignancy	Indicate whether the patient has a history of non-melanoma 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. 3382736 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.
65	History of Neoadjuvant Treatment ***for Tumor Submitted for TCGA***	☐ None ☐ Radiation prior to sample procurement* ☐ Pharmaceutical treatment prior to sample procurement* ☐ Both pharmaceutical treatment and radiation prior to sample procurement*	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. 3382737 *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. However, for the melanoma study, patients treated with interferon at least 90 days prior to procurement are accepted into TCGA.
66	Consent Status	☐ Consented ☐ Exemption 4* ☐ Deceased ☐ Waiver*	Indicate whether the patient was formally consented, consented by death, or if the case has an exemption or waiver for consent. 3288361 *Exemptions and waivers for consent must be approved by NCI.
Date of Consent			
67	Month of Consent	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient was formally consented, provide the month of consent. 3081955
68	Day of Consent	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient was formally consented, provide the day of consent. 3081957

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#	Question	Entry Alternatives	Working Instructions
69	Year of Consent	_____	If the patient was formally consented, provide the year of consent. 3081959
Date of Death *(Note: If the patient formally consented, only supply the date the patient consented.)*			
70	Month of Death	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient consented by death, provide the month of death. 2897026
71	Day of Death	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ 15 ☐ 16 ☐ 17 ☐ 18 ☐ 19 ☐ 20 ☐ 21 ☐ 22 ☐ 23 ☐ 24 ☐ 25 ☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient consented by death, provide the day of death. 2897028
72	Year of Death	_____	If the patient consented by death, provide the year of death. 2897030

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

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.

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Time Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form.

#	Question	Entry Alternatives	Working Instructions
i	Number of Days from Date of Diagnosis to Date of Cancer Sample Procurement	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the malignant sample submitted for TCGA. 3288495
ii	Number of Days from Date of Diagnosis to Normal Sample Procurement	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the procedure that produced the normal control sample submitted for TCGA. 3288496
iii	Number of Days from Date of Diagnosis to Date of Pathological Review	_____ days	Provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the pathological review performed as part of the submission process for TCGA. 3288497
iv	Number of Days from Date of Diagnosis to Date of Consent	_____ days	If the patient formally consented, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's formal consent. 3288498
v	Number of Days from Date of Diagnosis to Date of Death	_____ days	If the patient consented by death, provide the number of days from the date the patient was diagnosed with the disease described on this form to the date of the patient's death. 3288499 *Note: If the patient formally consented, only supply the date the patient consented.*