Initial Case Quality Control Form

Bladder (BLCA)

V4.06 091112

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? \Box Yes \Box 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	□ Muscle invasive urothelial carcinoma (pT2 or above)	Indicate the confirmed diagnosis of the tumor submitted for TCGA. 2549638
2	Tumor Type	□ Tumor specimen from de novo untreated malignancy of the bladder* (<i>pT2 or above</i>)	Indicate the type of tumor submitted for TCGA. 3288124 * This is a biospecimen that has not been treated with chemotherapy (including intravesical treatment) or radiation prior to resection. BCG treatment must not be given within 90 days from the date the tumor was resected.
3	Diagnosis subtype	 Papillary Non-papillary 	Using the patient's pathology/laboratory report, indicate whether the disease was papillary or non-papillary. 2783887
4	If Patient has History of Non-Muscle Invasive Bladder Cancer <i>Check all that apply</i>	 □ Ta □ T1 □ Tis □ No <i>known</i> history of non-muscle invasive bladder cancer 	If the patient has a history of non-muscle invasive bladder cancer, indicate the AJCC Primary Tumor (T) classification for this patient. <u>3288513</u>
5	Was BCG treatment given for the non-muscle invasive bladder cancer?	□ Yes □ No □Unknown	If the patient has a history of non-muscle invasive bladder cancer, indicate whether they received BCG treatment for that tumor. <u>3436248</u>
Date	of Last BCG Treatment Onl	y complete this section if the patient has a history of non-muscle invasive bladder cancer and	received BCG treatment.
6	Month of Last BCG Treatment		If the patient had a history of prior non-muscle invasive bladder cancer and received BCG treatment, provide the month of the last BCG treatment. <u>3288242</u>
7	Day of Last BCG	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 31	If the patient had a history of prior non-muscle invasive bladder cancer and received BCG treatment, provide the day of the last BCG treatment. 3288248
8	Year of Last BCG Treatment		If the patient had a history of prior non-muscle invasive bladder cancer and received BCG treatment, provide the year of the last BCG treatment. 3288249
9	Anatomic Organ Sub- Division of Frozen Biospecimen	Bladder, NOSTrigoneWall, anteriorDomeUreteric orificeWall, lateralNeckWall, NOSWall, posterior	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. <u>2008006</u>

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Ouestion Entry Alternatives Working Instructions **Date of Cancer Sample Procurement** Provide the month of the procedure performed to obtain the Month of Cancer Sample malignant tissue submitted for TCGA. $\square01$ **□**10 **□**11 **□**12 10 **D** 02 **D** 03 **D** 04 **D** 05 **D** 06 **D** 07 08 09 Procurement 3008197 Provide the day of the procedure performed to obtain the malignant **D** 01 **D** 02 **D** 03 **D** 04 **D** 05 **D** 06 **D** 07 **D** 08 **D** 09 **□**10 **□** 11 **1**2 Day of Cancer Sample tissue submitted for TCGA. **1**13 **□**14 **□**15 **□**16 **D**17 **□**18 **□** 19 **2**0 $\Box 21 \quad \Box 22$ **2**3 **D** 24 11 3008195 Procurement $\square 25$ **D** 28 $\Box 26$ **2**7 **2**9 **□** 30 **D** 31 Provide the year of the procedure performed to obtain the Year of Cancer Sample malignant tissue submitted for TCGA. 12 Procurement 3008199 Indicate the procedure performed to obtain the malignant tissue □ Transurethral resection (TURBT) □ Cystectomy Method of Cancer Sample submitted for TCGA. 13 □ Other Method (please specify) □ Excisional biopsv Procurement 3103514 If the procedure performed to obtain the malignant tissue is not Other Method of Cancer included in the provided list, specify the procedure. 14 Sample Procurement 2006730 Provide the country where the tissue submitted for TCGA was **Country Where Cancer** procured. 15 Sample was Procured 3203072 Provide the patient's race using the defined categories. American Indian or Alaska Native 2192199 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 16 Race 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. □ Not Hispanic or Latino Provide the patient's ethnicity using the defined categories. 2192217 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 17 Ethnicity race □ Not Evaluated Not provided or available. Unknown Could not be determined or unsure. Cryovial Cassette □ Other, specify Indicate the type of vessel used to ship the tissue to the Biospecimen Core Resource (BCR) for TCGA. 18 Vessel Used Biospecimen Storage Bag Cryomold 3081940

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#	Question	Entry Alternatives	Working Instructions
19	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
20	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. <u>3288488</u>
21	Was sample prescreened at site?	□ Yes □ No	Indicate whether the sample submitted to the BCR was prescreened at the TSS. <u>3081942</u>
22	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. <u>3081944</u> <i>Top Slide Definition: Slide cut directly from frozen biospecimen =</i> <i>mirror image of inked surface</i>
23	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. <u>3081948</u> <i>Physical top-slides are preferred</i>
24	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.
25	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. <u>3295810</u>
Tumo	or Information If the TSS is a	submitting multiple pieces of the same primary tumor for this case; complete the following	ng information for each piece of tumor sent to the BCR.
26	Tumor Identifier		Provide the TSS unique tumor ID. If multiple pieces of tumor are submitted, each tumor needs a unique ID. <u>3288096</u>
27	Weight of Frozen Tumor	(mg) (0.2cm ³ (0.6cm * 0.6cm * 0.6cm) = ~200mg	Provide the weight of the tumor sample submitted for TCGA. <u>3081946</u>
28	Tumor Nuclei %	(%)	Provide the percent of tumor nuclei for the sample submitted for TCGA. <i>Check with the BCR to confirm the current acceptable TCGA metrics.</i> 2841225
29	Necrosis %	(%)	Provide the percent of necrosis for the sample submitted for TCGA. <i>Check with the BCR to confirm the current acceptable TCGA metrics.</i> 2841237
30	Slide/Digital Image ID #		Provide the slide ID for the physical top slide OR the digital slide image being sent to the BCR. 2321277

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#	Question		Working Instructions											
Norm	Normal Information A normal control must be present to qualify.													
31	Type(s) of Normal Control <i>Check all that apply</i>	🗖 Bu	Whole BloodExtracted DNA from BloodBuffy CoatNon-Neoplastic Control Tissue*									Indicate the type of normal control submitted for this case. <u>3081936</u> *Non-neoplastic Control Tissue may only be submitted with NCI approval.		
Norr	nal Control: Whole Blood													
<u>32</u>	Method of Normal Sample Procurement	🗖 Blo	ood Drav	N										Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>
<u>33</u>	Month of Normal Sample Procurement	□ 01	02	D 03	□ 04	D 05	D 06	D 07	08	09	1 10	□ 11	1 2	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>
<u>34</u>	Day of Normal Sample Procurement	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	□ 03 □ 15 □ 27	□ 04 □ 16 □ 28	□ 05 □ 17 □ 29	□ 06 □ 18 □ 30	□ 07 □ 19 □ 31	□ 08 □ 20	□ 09 □ 21	□ 10 □ 22	□ 11 □ 23	□ 12 □ 24	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>
<u>35</u>	Year of Normal Sample Procurement													Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>
<u>36</u>	Normal Identifier													Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
Norr	nal Control: Buffy Coat/ Lyr	nphocy	rtes											
<u>37</u>	Normal Control Type		ffy Coat mphocy											Indicate the type of normal control submitted for TCGA. <u>3081936</u>
<u>38</u>	Method of Normal Sample Procurement	🗖 Blo	ood Drav	v										Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>
<u>39</u>	Month of Normal Sample Procurement	D 01	02	• 03	□ 04	□ 05	D 06	• 07	□ 08	D 09	□ 10	□ 11	1 2	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>
<u>40</u>	Day of Normal Sample Procurement	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	□ 03 □ 15 □ 27		D 17	□ 06 □ 18 □ 30		□ 08 □ 20	□ 09 □ 21	□ 10 □ 22	□ 11 □ 23	□ 12 □ 24	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>
<u>41</u>	Year of Normal Sample Procurement													Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>
<u>42</u>	Normal Identifier													Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
Norr	nal Control: Extracted DNA	from B	lood											
<u>43</u>	Method of Normal	🗖 Blo	ood Drav	V										Indicate the procedure performed to obtain the normal control sample submitted for TCGA.

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	<u> </u>					_								
#	Question					E	ntry Alt	ernative	es					Working Instructions
	Sample Procurement													3288147
<u>44</u>	Month of Normal Sample Procurement	D 01	D 02	D 03	D 04	□ 05	D 06	D 07	□ 08	D 09	□ 10	□ 11	□ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>
<u>45</u>	Day of Normal Sample Procurement	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	031527	□ 04 □ 16 □ 28	□ 05 □ 17 □ 29	□ 06 □ 18 □ 30	□ 07 □ 19 □ 31	□ 08 □ 20	□ 09 □ 21	□ 10 □ 22	□ 11 □ 23	□ 12 □ 24	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>
<u>46</u>	Year of Normal Sample Procurement													Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>
<u>47</u>	Normal Identifier													Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
<u>48</u>	Extracted DNA Quantity								(µg)					Provide the quantity (μ g) of the normal control sample sent to the BCR for TCGA. 3288185
<u>49</u>	Extracted DNA Quantification Method													Provide the quantification method of the normal control sample sent to the BCR for TCGA. <u>3288186</u>
<u>50</u>	Extracted DNA Concentration								_(µg/µ	L)				Provide the concentration (μ g/ μ L) of the normal control sample sent to the BCR for TCGA. 3288187
<u>51</u>	Extracted DNA Volume								(µL)					Provide the volume (μ L) of the normal control sample sent to the BCR for TCGA. <u>3288188</u>
Norn	nal Control: Non-Neoplastic	c Contr	ol Tissu	е										
<u>52</u>	Method of Normal Sample Procurement		rgical ex her Metl											Indicate the procedure performed to obtain the normal control sample submitted for TCGA. <u>3288147</u>
<u>53</u>	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. <u>3288151</u>
<u>54</u>	Month of Normal Sample Procurement	• 01	□ 02	□ 03	□ 04	D 05	D 06	D 07	□ 08	□ 09	□ 10	□ 11	□ 12	Provide the month of the procedure performed to obtain the normal control submitted for TCGA. <u>3288195</u>
<u>55</u>	Day of Normal Sample Procurement	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	□ 03 □ 15 □ 27	□ 04 □ 16 □ 28	□ 05 □ 17 □ 29	□ 06 □ 18 □ 30	□ 07 □ 19 □ 31	□ 08 □ 20	□ 09 □ 21	□ 10 □ 22	□ 11 □ 23	□ 12 □ 24	Provide the day of the procedure performed to obtain the normal control submitted for TCGA. <u>3288196</u>
<u>56</u>	Year of Normal Sample Procurement													Provide the year of the procedure performed to obtain the normal control submitted for TCGA. <u>3288197</u>

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#	Question	Entry Alternatives	Working Instructions
<u>57</u>	Normal Identifier		Provide the TSS unique normal ID. If multiple normal control samples are submitted, each normal control needs a unique ID. <u>3288138</u>
<u>58</u>	Anatomic Site of Non- Neoplastic Control Tissue	 Smooth muscle normal Macroscopic urothelial normal 	If the normal control type is normal tissue, indicate the anatomic site of the non-neoplastic control tissue submitted for TCGA. <u>3081938</u> <u>Site matched is preferred.</u>
<u>59</u>	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. <u>3288189</u>
<u>60</u>	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. <u>3088708</u> Adjacent (< 2cm) Normal Tissue is not accepted for this tissue type. Unknown Normal Tissue is not acceptable for this tissue type.
<u>61</u>	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
	cation: By providing the bel y controlled.	ow information, the Principal Investigator acknowledges that the information provided b	y the institution is true and correct and has been
Tissu repoi	rted by the TSS through histor	dges that the Biospecimen Core Resource (BCR) may confirm that the diagnosis of the frozen pathology examination in the BCR laboratory. If the BCR identifies a possible discrepancy, th rmal report in confidential email format for the quality assurance program of the TSS to ad	ne TSS authorizes the BCR to report these patient dress.
62	Name of Pathologist		Provide the name of the Pathologist that provided the information for all previous sections. <u>3288225</u>
63	Date of Pathologist Review		Provide the date of the pathology review performed by the TSS pathologist above. <u>3288224</u>
Prin	cipal Investigator/Authori	zed Designee Confirmation	
64	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. <u>3288520</u> Check with the BCR to confirm the current acceptable TCGA metrics.
65	Percent Necrosis meets TCGA metrics?	□ Yes □ No	Confirm that the malignant sample submitted to the BCR meets the current necrosis metrics for TCGA. <u>3288524</u> Check with the BCR to confirm the current acceptable TCGA

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#	Question	Entry Alternatives	Working Instructions
66	De-Identified Pathology Report Submitted?	□ Yes □ No	metrics. Confirm that a de-identified pathology report will be sent to BCR prior to or with the shipment of the physical samples. <u>3288292</u>
67	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. <u>3288300</u> If "yes," skip related question below. The diagnosis is considered to be consistent if at least one of the following criteria are met: Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR. Diagnosis on the CQCF is identical to the pathology report for the tumor being sent to the BCR. 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. 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.
68	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 <i>(see note at right)</i> Pathology analysis at TSS determined a specific histological subtype different from original pathology report <i>(see note at right)</i> Pathology review of frozen section for TCGA determined histological subtype different from different from the pathology report <i>(see note at right)</i> 	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. <u>3288315</u> 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.

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#	Question	Entry Alternatives	Working Instructions							
69	History of Other Malignancy	 None History of Prior Malignancy History of Synchronous/ Bilateral Malignancy 	Indicate whether the patient has a history of 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. <u>3382736</u> 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. A history of non-muscle invasive bladder cancer is allowable.							
70	History of Neoadjuvant Treatment <i>for Tumor</i> <i>Submitted for TCGA</i>	 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. <u>3382737</u> *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. BCG treatment must not be given within 90 days from the date the tumor was resected.							
71	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									
72	Month of Consent		If the patient was formally consented, provide the month of consent. <u>3081955</u>							
73	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 31	If the patient was formally consented, provide the day of consent. <u>3081957</u>							
74	Year of Consent		If the patient was formally consented, provide the year of consent. <u>3081959</u>							
Date	te of Death If the patient formally consented, only supply the date the patient consented.									

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#	Question					E	Working Instructions							
75	Month of Death	• 01	02	D 03	□04	□ 05	D 06	D 07	□ 08	□ 09	□ 10	□ 11	□ 12	If the patient consented by death, provide the month of death. 2897026
76	Day of Death	□ 01 □ 13 □ 25	□ 02 □ 14 □ 26	□ 03 □ 15 □ 27	□ 04 □ 16 □ 28	□ 05 □ 17 □ 29	□ 06 □ 18 □ 30	□ 07 □ 19 □ 31	□ 08 □ 20	□ 09 □ 21	□ 10 □ 22		□ 12 □ 24	If the patient consented by death, provide the day of death. <u>2897028</u>
77	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	Fime 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 Last BCG Treatment	days	If the patient received BCG treatment for non-muscle invasive cancer, provide the number of days from the date the patient was diagnosed with the disease described on this form to the LAST date the patient received BCG treatment. 3440606								
ii	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								
iii	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. <u>3288496</u>								
iv	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								
v	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. <u>3288498</u>								
vi	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. <u>3288499</u> If the patient formally consented, only supply the date the patient consented.								