### **Initial Case Quality Control Form**

Bladder (BLCA)

**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

repor	ted by the TSS through histop		boratory. If the BCR identi	fies a possible discrepancy, th	e TSS authorizes the BCR to report these patient ress.
Tissue	Source Site (TSS):	TSS ID: TSS Unique Pa	tient ID: Intervi	ewer Name:	Interview Date/ /
	*	m the NCI to provide time interva gin with the date of initial pathologic		ested dates on this form? $\Box$	Yes □ No
Tumo	or Information: The following	g sections are to be provided by a	Pathologist		
#	Question		<b>Entry Alternatives</b>		Working Instructions
1	Diagnosis	☐ Muscle invasive urothelial carcino	oma (pT2 or above)		Indicate the confirmed diagnosis of the tumor submitted for TCGA. 2549638
					Indicate the type of tumor submitted for TCGA.  3288124
2	Tumor Type	☐ Tumor specimen from de novo un	treated malignancy of the bla	adder* (pT2 or above)	* This is a biospecimen that <b>has not</b> been treated with chemotherap (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 Check all that apply	□ Ta □ T1 □ Tis □ No <i>known</i> histor	ory 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. 3288513
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. $\underline{3436248}$		
Date	e of Last BCG Treatment Onl	complete this section if the patient	t has a history of non-musc	le invasive bladder cancer and	received BCG treatment.
6	Month of Last BCG Treatment		□ 06 □ 07 □ 08 I	<b>1</b> 09 <b>1</b> 10 <b>1</b> 11 <b>1</b> 12	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.  3288242
7	Day of Last BCG Treatment	01       02       03       04       05         13       14       15       16       17         25       26       27       28       29		□ 09 □ 10 □ 11 □ 12 □ 21 □ 22 □ 23 □ 24	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	□ Dome □ U	Trigone Jreteric orifice Wall, NOS	☐ Wall, anterior☐ Wall, lateral☐ Wall, posterior	Indicate the anatomic site of the frozen tumor biospecimen submitted for TCGA. $\underline{2008006}$

#	Question	Entry Alternatives Working Instructions					
Date	of Cancer Sample Procure	·	· ·				
10	Month of Cancer Sample Procurement		Provide the month of the procedure performed to obtain the malignant tissue submitted for TCGA.  3008197				
11	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				
12	Year of Cancer Sample Procurement		Provide the year of the procedure performed to obtain the malignant tissue submitted for TCGA.  3008199				
13	Method of Cancer Sample Procurement	☐ Transurethral resection (TURBT) ☐ Excisional biopsy ☐ Other Method (please specify)	Indicate the procedure performed to obtain the malignant tissue submitted for TCGA. $\underline{3103514}$				
14	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. $\underline{2006730}$				
15	Country Where Cancer Sample was Procured		Provide the country where the tissue submitted for TCGA was procured.  3203072				
16	Race	<ul> <li>American Indian or Alaska Native         <ul> <li>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.</li> </ul> </li> <li>Asian         <ul> <li>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.</li> <li>White</li></ul></li></ul>	Provide the patient's race using the defined categories.  2192199				
17	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				
18	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				

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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.  3288488
21	Was sample prescreened at site?	□ Yes □ No	Indicate whether the sample submitted to the BCR was prescreened at the TSS.  3081942
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.  3081944  Top Slide Definition: Slide cut directly from frozen biospecimen = mirror image of inked surface
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.  3081948  Physical top-slides are preferred
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.  3295810
Tume	or Information If the TSS is s	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. 3288096
27	Weight of Frozen Tumor	(mg)	Provide the weight of the tumor sample submitted for TCGA. 3081946
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. Check with the BCR to confirm the current acceptable TCGA metrics.  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	Entry Alternatives	Working Instructions			
Norm	al Information A normal co	ntrol must be present to qualify.				
31	Type(s) of Normal Control Check all that apply	☐ Whole Blood ☐ Extracted DNA from Blood ☐ Buffy Coat ☐ 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.			
Norn	nal Control: Whole Blood					
<u>32</u>	Method of Normal Sample Procurement	□ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA.  3288147			
<u>33</u>	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			
<u>34</u>	Day of Normal Sample	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			
<u>35</u>	Year of Normal Sample Procurement		Provide the year of the procedure performed to obtain the normal control submitted for TCGA.  3288197			
<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. 3288138			
Norn	nal Control: Buffy Coat/ Lyn	phocytes				
<u>37</u>	Normal Control Type	☐ Buffy Coat ☐ Lymphocytes	Indicate the type of normal control submitted for TCGA. 3081936			
<u>38</u>	Method of Normal Sample Procurement	□ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA.  3288147			
<u>39</u>	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			
<u>40</u>	Day of Normal Sample	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			
<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.  3288138				
Norn	nal Control: Extracted DNA j	rom Blood				
43	Method of Normal	□ Blood Draw	Indicate the procedure performed to obtain the normal control sample submitted for TCGA.			

#	Question		Entry Alternatives									Working Instructions		
	Sample Procurement													<u>3288147</u>
44	Month of Normal Sample Procurement	<b>1</b> 01	<b>1</b> 02	<b>1</b> 03	<b>1</b> 04	<b>0</b> 5	<b>1</b> 06	<b>1</b> 07	□ 08	□ 09	<b>1</b> 0	<b>1</b> 11	<b>1</b> 2	Provide the month of the procedure performed to obtain the normal control submitted for TCGA.  3288195
<u>45</u>	Dragument Sample	□ 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.  3288196
<u>46</u>	Year of Normal Sample Procurement													Provide the year of the procedure performed to obtain the normal control submitted for TCGA.  3288197
<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. 3288138
<u>48</u>	Extracted DNA Quantity								(μg)					Provide the quantity (µg) of the normal control sample sent to the BCR for TCGA. $\underline{3288185}$
<u>49</u>	Extracted DNA Quantification Method		Provide the quantification method of t sent to the BCR for TCGA.					Provide the quantification method of the normal control sample sent to the BCR for TCGA. $\underline{3288186}$						
<u>50</u>	Extracted DNA Concentration		Provide the				Provide the concentration ( $\mu g/\mu L$ ) of the normal control sample sent to the BCR for TCGA. 3288187							
<u>51</u>	Extracted DNA Volume		(μL)				Provide the volume ( $\mu L$ ) of the normal control sample sent to the BCR for TCGA. 3288188							
Norn	nal Control: Non-Neoplastic	Contro	ol Tissu	e										
<u>52</u>	Method of Normal Sample Procurement													
<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. 3288151								
<u>54</u>	Month of Normal Sample Procurement	<b>1</b> 01	<b>1</b> 02	<b>1</b> 03	<b>1</b> 04	<b>1</b> 05	<b>1</b> 06	<b>1</b> 07	□ 08	<b>1</b> 09	<b>1</b> 0	<b>1</b> 11	<b>1</b> 2	Provide the month of the procedure performed to obtain the normal control submitted for TCGA.  3288195
<u>55</u>	Drogument	□ 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		□ 11 □ 23		Provide the day of the procedure performed to obtain the normal control submitted for TCGA.  3288196
<u>56</u>	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				
<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. 3288138				
<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.  3081938 Site matched is preferred.				
<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.  3288189				
<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.  3088708  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						
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.							
Tissu	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.

62	Name of Pathologist	<del></del>	Provide the name of the Pathologist that provided the information for all previous sections.  3288225
63	Date of Pathologist Review		Provide the date of the pathology review performed by the TSS pathologist above. 3288224
Prin	cipal Investigator/Authoriz	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.  3288520 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.  3288524

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.  3288292	
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.  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.	
68	If the diagnosis on this form is not consistent with the provided pathology report, indicate the reason for the inconsistency.	<ul> <li>□ Macrodissection performed at TSS to select for a region containing an acceptable TCGA diagnosis (see note at right)</li> <li>□ Pathology analysis at TSS determined a specific histological subtype different from original pathology report (see note at right)</li> <li>□ Pathology review of frozen section for TCGA determined histological subtype different from the pathology report (see note at right)</li> </ul>	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.	

#	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.  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.  A history of non-muscle invasive bladder cancer is allowable.
70	History of Neoadjuvant Treatment <b>for Tumor</b> <b>Submitted for TCGA</b>	□ 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 <i>the tumor submitted for TCGA</i> . 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.  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	01         02         03         04         05         06         07         08         09         10         11         01	If the patient was formally consented, provide the month of consent.  3081955
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	If the patient was formally consented, provide the day of consent.  3081957
74	Year of Consent		If the patient was formally consented, provide the year of consent.  3081959
Date	of Death If the patient form	ally consented, only supply the date the patient consented.	

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$\Box$		

#	Question	Entry Alternatives											Working Instructions	
75	Month of Death	<b>1</b> 01	<b>1</b> 02	<b>1</b> 03	<b>1</b> 04	<b>1</b> 05	<b>1</b> 06	<b>1</b> 07	□ 08	<b>1</b> 09	<b>1</b> 0	<b>1</b> 1	<b>1</b> 2	If the patient consented by death, provide the month of death. 2897026
76	Day of Death	<b>□</b> 13	□ 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	If the patient consented by death, provide the day of death. 2897028
77	Year of Death													If the patient consented by death, provide the year of death. 2897030

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.

Print Name

Date

Principal Investigator or Designee Signature

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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.

	Time intervals: The following questions are only to be answered if the rissue 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.  3288496								
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.  3288498								
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.  3288499  If the patient formally consented, only supply the date the patient consented.								