

Enrollment Form

Kidney Clear Cell Renal Carcinoma

Instructions: The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial melanoma diagnosis to the most recent date of contact with the patient (“Date of Initial Pathologic Diagnosis” and “Date of Last Contact” on this form).

Questions regarding this form should be directed to the Tissue Source Site’s primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the “Unknown” and “Not Evaluated” answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____ TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By (Interviewer Name on OpenClinica): _____ Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1*	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. Provided time intervals must begin with the date of initial pathologic diagnosis (i.e. biopsy or resection). Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
Patient Information			
2*	Primary Site of Disease	<input type="checkbox"/> Kidney	Using the patient’s pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
3*	Histological Subtype	<input type="checkbox"/> Kidney Clear Cell Renal Carcinoma	Using the patient’s pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. 3081934 All other subtypes not listed are excluded from this study.
4	Tumor Grade	<input type="checkbox"/> G1 Well Differentiated <input type="checkbox"/> G2 Moderately Differentiated <input type="checkbox"/> G3 Poorly Differentiated <input type="checkbox"/> G4 Undifferentiated <input type="checkbox"/> GX Grade Cannot be Assessed	Using the patient’s pathology/laboratory report, select the tumor grade of the tumor submitted for TCGA. 2785839
5	Tumor Laterality	<input type="checkbox"/> Right (Kidney) <input type="checkbox"/> Left (Kidney) <input type="checkbox"/> Bilateral	Using the patient’s pathology/laboratory report and medical record, designate the side of the body where the cancer is located. 827
6	Is this a prospective tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. 3088492
7	Is this a retrospective tissue collection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. 3088528
8*	Gender	<input type="checkbox"/> Female <input type="checkbox"/> Male	Provide the patient’s gender using the defined categories. 2200604

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#	Data Element	Entry Alternatives	Working Instructions
<i>Date of Birth</i>			
9*	Date of Birth	<p>_____</p> <p style="text-align: center;"><i>Month Day Year</i></p>	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
10	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	<p>_____</p>	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth. 3008233 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
11*	Race	<input type="checkbox"/> American Indian or Alaska Native <i>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.</i> <input type="checkbox"/> Asian <i>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.</i> <input type="checkbox"/> White <i>A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.</i> <input type="checkbox"/> Black or African American <i>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."</i> <input type="checkbox"/> Native Hawaiian or other Pacific Islander: <i>A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.</i> <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Provide the patient's race using the defined categories. 2192199
12	Ethnicity	<input type="checkbox"/> Not Hispanic or Latino <i>A person not meeting the definition of Hispanic or Latino.</i> <input type="checkbox"/> Hispanic or Latino <i>A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.</i> <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Provide the patient's ethnicity using the defined categories. 2192217
13*	Has the Patient Had Any Prior Cancer Diagnosed?	<input type="checkbox"/> No <input type="checkbox"/> History of Prior Malignancy <input type="checkbox"/> History of Synchronous / Bilateral Malignancy	Indicate whether the patient has a history of prior 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. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736 <i>If this question cannot be answered because the answer is unknown, please contact the BCR. 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.</i>
14*	History of neo-adjuvant Treatment for Tumor Specimen Submitted for TCGA	<input type="checkbox"/> No <input type="checkbox"/> Radiation Prior to Sample Procurement <input type="checkbox"/> Pharmaceutical Treatment Prior to Sample Procurement <input type="checkbox"/> Both Pharmaceutical and Radiation Treatment Prior to Sample Procurement	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the resection of the tumor that yielded the sample submitted for TCGA. 3382737 <i>Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the resection of the sample submitted for TCGA is exclusionary.</i>
<i>Date of Initial Pathological Diagnosis (of this renal tumor associated with tissue procurement for TCGA)</i>			
15	Date of Initial Pathologic Diagnosis	<p>_____</p> <p style="text-align: center;"><i>Month Day Year</i></p>	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (Month), 2896958 (Day), 2896960 (Year)

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16	Age at Initial Pathological Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
Lymph Node Status			
17	Were Lymph Nodes Examined at the Time of Primary Resection?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
18	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3
19	Number of Lymph Nodes Positive	_____	Provide the number of lymph nodes involved with disease as determined by pathologic examination. 89
AJCC Staging			
20*	AJCC Cancer Staging Edition	<input type="checkbox"/> 1 st Edition (1978-1983) <input type="checkbox"/> 2 nd Edition (1984-1988) <input type="checkbox"/> 3 rd Edition (1989-1992) <input type="checkbox"/> 4 th Edition (1993-1997) <input type="checkbox"/> 5 th Edition (1998-2002) <input type="checkbox"/> 6 th Edition (2003-2009) <input type="checkbox"/> 7 th Edition (2010-current)	Indicate the AJCC Cancer Staging Edition that was used to answer the following staging questions. 2722309
21*	Primary Tumor (T)	<input type="checkbox"/> TX <input type="checkbox"/> T2 <input type="checkbox"/> T3b <input type="checkbox"/> T0 <input type="checkbox"/> T2a <input type="checkbox"/> T3c <input type="checkbox"/> T1 <input type="checkbox"/> T2b <input type="checkbox"/> T4 <input type="checkbox"/> T1a <input type="checkbox"/> T3 <input type="checkbox"/> T4a <input type="checkbox"/> T1b <input type="checkbox"/> T3a <input type="checkbox"/> T4b	Using the patient's medical records, or pathology/laboratory report, select the code for the primary tumor (T) defined by the American Joint Committee on Cancer (AJCC). 3045435
22*	Regional Lymph Nodes (N)	<input type="checkbox"/> NX <input type="checkbox"/> N2 <input type="checkbox"/> N0 <input type="checkbox"/> N3 <input type="checkbox"/> N1 <input type="checkbox"/> N4	Using the patient's medical records, or pathology/laboratory report, select the code for the nodal (N) defined by the American Joint Committee on Cancer (AJCC). 3203106
23*	Distant Metastasis (M)	Clinical	Using the patient's medical records, or pathology/laboratory report, select the code for the metastasis (M) defined by the American Joint Committee on Cancer (AJCC). 3440331 (Clinical) 3045439 (Pathologic)
		<input type="checkbox"/> MX <input type="checkbox"/> M0 <input type="checkbox"/> M1	
		Pathologic	
		<input type="checkbox"/> MX <input type="checkbox"/> M0 <input type="checkbox"/> M1	
24*	Tumor Stage (Pathological) (and/or Clinical)	<input type="checkbox"/> Stage I <input type="checkbox"/> Stage II <input type="checkbox"/> Stage III <input type="checkbox"/> Stage IV	Using the patient's medical records, or pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3203222
25*	Vital Status (at date of last contact)	<input type="checkbox"/> Living <input type="checkbox"/> Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
Date of Last Contact (If patient is living)			
26*	Date of Last Contact	_____ / _____ / _____ <i>Month Day Year</i>	If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (Month), 2897022 (Day), 2897024 (Year)
27	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of last contact. 3008273 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.

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#	Data Element	Entry Alternatives	Working Instructions
<i>Date of Death</i>			
28*	Date of Death	<p style="text-align: center;">_____</p> <p style="text-align: center;"><i>Month Day Year</i></p>	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
29	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death. 3165475 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
30	Tumor Status (at time of last contact or death)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> Unknown Tumor Status	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
Prognostic/Predictive/Lifestyle Features Used for Tumor Prognosis or Responsiveness to Treatment			
31	LDH	<input type="checkbox"/> Elevated <input type="checkbox"/> Normal <input type="checkbox"/> Low <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Indicate the outcome of LDH test results. 3113468
32	Serum Calcium	<input type="checkbox"/> Elevated <input type="checkbox"/> Normal <input type="checkbox"/> Low <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Indicate the outcome of serum calcium test results. 3113470
33	Hemoglobin	<input type="checkbox"/> Elevated <input type="checkbox"/> Normal <input type="checkbox"/> Low <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Indicate the outcome of hemoglobin test results. 3113466
34	Platelets	<input type="checkbox"/> Elevated <input type="checkbox"/> Normal <input type="checkbox"/> Low <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Indicate the outcome of platelet test results. 3104944
35	White Cell Count	<input type="checkbox"/> Elevated <input type="checkbox"/> Normal <input type="checkbox"/> Low <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Indicate the outcome of white cell count test results. 3104948
36	Erythrocyte Sedimentation Rate	<input type="checkbox"/> Elevated <input type="checkbox"/> Normal <input type="checkbox"/> Low <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Indicate the outcome of erythrocyte sedimentation rate (ESR) test results. 3104952
37	Tobacco Smoking History Indicator	<input type="checkbox"/> Lifelong Non-smoker (less than 100 cigarettes smoked in Lifetime) <input type="checkbox"/> Current smoker (includes daily smokers and non-daily smokers or occasional smokers) <input type="checkbox"/> Current reformed smoker for > 15 years (greater than 15 years) <input type="checkbox"/> Current reformed smoker for ≤15 years (less than or equal to 15 years) <input type="checkbox"/> Current reformed smoker, duration not specified <input type="checkbox"/> Smoking History not Documented	Indicate the patient's current smoking status or smoking history as self-reported by the patient. 2181650
38	Year of Onset of Tobacco Smoking	_____	If the patient is a current or reformed smoker, indicate the year in which the patient began smoking. 2228604
39	Year of Quitting Tobacco Smoking	_____	If the patient is a reformed smoker, indicate the year in which the patient quit smoking. 2228610
40	Number Pack Years Smoked	_____	Indicate the lifetime tobacco exposure of the patient. Number of pack years is defined as the number of cigarettes smoked per day times (x) the number of years smoked divided (/) by 20. 2955385

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41	Performance Status Score: Karnofsky Score (Pre-Operative)	<input type="checkbox"/> 100 <input type="checkbox"/> 90 <input type="checkbox"/> 80 <input type="checkbox"/> 70 <input type="checkbox"/> 60 <input type="checkbox"/> 50 <input type="checkbox"/> 40 <input type="checkbox"/> 30 <input type="checkbox"/> 20 <input type="checkbox"/> 10 <input type="checkbox"/> 0 <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient. 2003853 100: Normal, no complaints; no evidence of disease 90: Able to carry on 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 to 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; requiring hospitalization 10: Moribund; fatal processes progressing rapidly 0: Dead Not Evaluated: Not provided or available. Unknown: Could not be determined or unsure.
42	Performance Status Score: Eastern Cooperative Oncology Group (ECOG)	<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient. 88 0: Asymptomatic 1: Symptomatic, but fully ambulatory 2: Symptomatic, in bed less than 50% of day 3: Symptomatic, in bed more than 50% of day, but not bed-ridden 4: Bed-ridden Not Evaluated: Not provided or available. Unknown: Could not be determined or unsure.
43	Performance Status Score: Timing	<input type="checkbox"/> Post Adjuvant Therapy <input type="checkbox"/> At Recurrence/Progression of Disease <input type="checkbox"/> Post Secondary Therapy <input type="checkbox"/> Other <input type="checkbox"/> Unknown <input type="checkbox"/> Not Evaluated	Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories. 2792763
Primary Treatment			
44*	Adjuvant (Post-Operative) Radiation Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. 2005312 <i>If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.</i>
45*	Adjuvant (Post-Operative) Pharmaceutical Therapy	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. 3397567 <i>If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i>
46	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies)	<input type="checkbox"/> Progressive Disease <input type="checkbox"/> Stable Disease <input type="checkbox"/> Partial Response <input type="checkbox"/> Complete Response <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown	Provide the patient's response to their initial first course treatment. 2786727
New Tumor Event Information Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.			
47*	New Tumor Event After Initial Treatment?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after initial treatment for the tumor submitted to TCGA. If the patient had multiple new tumor events, a follow-up form should be completed for each new tumor event. 3121376 <i>If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.</i>
<i>Date of New Tumor Event after Initial Treatment</i>			
48*	Date of New Tumor Event	_____ <i>Month Day Year</i>	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)

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49	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. 3392464 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
50	Additional Surgery for New Tumor Event Loco-regional Procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new loco-regional tumor event in question. 3008755
<i>Date of Additional Surgery for New Tumor Event Loco-Regional</i>			
51	Date of Additional Surgery for New Tumor Event Locoregional	_____ <i>Month Day Year</i>	If the patient had surgery for the new loco-regional tumor event, provide the date of surgery for this new loco-regional tumor event. 2897032 (Month), 2897034 (Day), 2897036 (Year)
52	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event Locoregional	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of additional surgery for new tumor event (Local-Regional). 3408572 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
53	Additional Surgery for New Tumor Event Metastasis Procedure	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question. 3008757
<i>Date of Additional Surgery for New Tumor Event Metastatic</i>			
54	Date of Additional Surgery for New Tumor Event Metastatic	_____ <i>Month Day Year</i>	If the patient had surgery for the new metastatic tumor event, provide the date of surgery for this new metastatic tumor event. 2897038 (Month), 2897040 (Day), 2897042 (Year)
55	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event Metastatic	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of additional surgery for new tumor event (metastasis). 3408682 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
Additional Treatment			
56	Additional treatment for New Tumor Event: <i>Radiation Therapy</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
57	Additional treatment for New Tumor Event: <i>Pharmaceutical Therapy</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

 Principal Investigator or Designee Signature

 Print Name

 _____/_____/_____
 Month/Day/Year