Enrollment Form

Kidney Papillary Renal Cell 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?	☐ Yes ☐ 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	☐ Kidney	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
3*	Histological Subtype	☐ Kidney Papillary Renal Cell 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 Type	☐ Type 1 ☐ Type 2 ☐ Type Unknown	Using the patient's pathology/laboratory report, select the morphologic subtype of papillary renal cell carcinoma for the tumor submitted for TCGA. 3104937
5	Tumor Laterality	☐ Right (Kidney) ☐ Left (Kidney) ☐ 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?	☐ Yes ☐ 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?	☐ Yes ☐ 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	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604

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#	Data Element	Entry Alternatives	Working Instructions
Date of Birth			
9	Date of Birth	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	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	_____	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	☐ 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 Evaluated ☐ Unknown	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 ☐ Unknown	Provide the patient's ethnicity using the defined categories. 2192217
13	Height *(at time of diagnosis)*	_____(cm)	Provide the patient's height (centimeters) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 649
14	Weight *(at time of diagnosis)*	_____(kg)	Provide the patient's weight (kilograms) at the time the patient was diagnosed with the malignancy being submitted for TCGA. 651
15*	Has the Patient Had Any Prior Cancer Diagnosed?	☐ No ☐ History of Prior Malignancy ☐ History of Synchronous / Bilateral Malignancy ☐ Both History of Synchronous/ Bilateral and Prior 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 *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.*

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#	Data Element	Entry Alternatives	Working Instructions
16*	History of neo-adjuvant Treatment for Tumor Specimen Submitted for TCGA	☐ No ☐ Radiation Prior to Sample Procurement ☐ Pharmaceutical Treatment Prior to Sample Procurement ☐ 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 *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.*
Date of Initial Pathological Diagnosis (of this renal tumor associated with tissue procurement for TCGA)			
17	Date of Initial Pathologic Diagnosis	___ ___ *Month* ___ ___ *Day* ___ ___ ___ ___ *Year*	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (Month), 2896958 (Day), 2896960 (Year)
18	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			
19	Were Lymph Nodes Examined at the Time of Primary Resection?	☐ Yes ☐ No	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
20	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3
21	Number of Lymph Nodes Positive	_____	Provide the number of lymph nodes involved with disease as determined by pathologic examination. 89
AJCC Staging			
22*	AJCC Cancer Staging Edition	☐ 1st Edition *(1978-1983)* ☐ 2nd Edition *(1984-1988)* ☐ 3rd Edition *(1989-1992)* ☐ 4th Edition *(1993-1997)* ☐ 5th Edition *(1998-2002)* ☐ 6th Edition *(2003-2009)* ☐ 7th Edition *(2010-current)*	Indicate the AJCC Cancer Staging Edition that was used to answer the following staging questions. 2722309
23*	Primary Tumor (T)	**Clinical** ☐ TX ☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T3c ☐ T4 ☐ T4a ☐ T4b **Pathologic** ☐ TX ☐ T0 ☐ T1 ☐ T1a ☐ T1b ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T3c ☐ T4 ☐ T4a ☐ 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). 3440328 (Clinical) 3045435 (Pathologic)
24*	Regional Lymph Nodes (N)	**Clinical** ☐ NX ☐ N0 ☐ N1 ☐ N2 ☐ N3 ☐ N4 **Pathologic** ☐ NX ☐ N0 ☐ N1 ☐ N2 ☐ N3 ☐ 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). 3440330 (Clinical) 3203106 (Pathologic)
25*	Distant Metastasis (M)	**Clinical** ☐ MX ☐ M0 ☐ M1 **Pathologic** ☐ MX ☐ M0 ☐ M1	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)
26*	Tumor Stage	**Clinical** ☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV **Pathologic** ☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV	Using the patient's medical records, or pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3440332 (Clinical) 3203222 (Pathologic)

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#	Data Element	Entry Alternatives	Working Instructions
27*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
Date of Last Contact (If patient is living)			
28*	Date of Last Contact	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	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)
29	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.
Date of Death			
30*	Date of Death	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
31	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.
32	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ 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			
33	LDH	☐ Elevated ☐ Normal ☐ Low ☐ Not Evaluated ☐ Unknown	Indicate the outcome of LDH test results. 3113468
34	Serum Calcium	☐ Elevated ☐ Normal ☐ Low ☐ Not Evaluated ☐ Unknown	Indicate the outcome of serum calcium test results. 3113470
35	Hemoglobin	☐ Elevated ☐ Normal ☐ Low ☐ Not Evaluated ☐ Unknown	Indicate the outcome of hemoglobin test results. 3113466
36	Platelets	☐ Elevated ☐ Normal ☐ Low ☐ Not Evaluated ☐ Unknown	Indicate the outcome of platelet test results. 3104944
37	White Cell Count	☐ Elevated ☐ Normal ☐ Low ☐ Not Evaluated ☐ Unknown	Indicate the outcome of white cell count test results. 3104948
38	Erythrocyte Sedimentation Rate	☐ Elevated ☐ Normal ☐ Low ☐ Not Evaluated ☐ Unknown	Indicate the outcome of erythrocyte sedimentation rate (ESR) test results. 3104952
39	Tobacco Smoking History Indicator	☐ Lifelong Non-smoker (less than 100 cigarettes smoked in Lifetime) ☐ Current smoker (includes daily smokers and non-daily smokers or occasional smokers) ☐ Current reformed smoker for > 15 years (greater than 15 years) ☐ Current reformed smoker for ≤15 years (less than or equal to 15 years) ☐ Current reformed smoker, duration not specified ☐ Smoking History not Documented	Indicate the patient's current smoking status or smoking history as self-reported by the patient. 2181650

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40	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
41	Year of Quitting Tobacco Smoking	_____ _____ _____ _____	If the patient is a reformed smoker, indicate the year in which the patient quit smoking. 2228610
42	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
43	Performance Status Score: Karnofsky Score (Pre-Operative)	☐ 100 ☐ 90 ☐ 80 ☐ 70 ☐ 60 ☐ 50 ☐ 40 ☐ 30 ☐ 20 ☐ 10 ☐ 0 ☐ Not Evaluated ☐ 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.*
44	Performance Status Score: Eastern Cooperative Oncology Group (ECOG)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Not Evaluated ☐ 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.*
45	Performance Status Score: Timing	☐ Post Adjuvant Therapy ☐ At Recurrence/Progression of Disease ☐ Post Secondary Therapy ☐ Other ☐ Unknown ☐ Not Evaluated	Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories. 2792763
Primary Treatment			
46*	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
47*	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
48	Measure of Success of Outcome at the Completion of Initial First Course Treatment *(surgery and adjuvant therapies)*	☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Not Applicable ☐ Unknown	Provide the patient's response to their initial first course treatment. 2786727

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#	Data Element	Entry Alternatives	Working Instructions
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.*			
49*	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ 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 *If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.*
Date of New Tumor Event after Initial Treatment			
50	Date of New Tumor Event	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)
51	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.
52	Additional Surgery for New Tumor Event Loco-regional Procedure	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new loco-regional tumor event in question. 3008755
Date of Additional Surgery for New Tumor Event Loco-Regional			
53	Date of Additional Surgery for New Tumor Event Locoregional	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	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)
54	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.
55	Additional Surgery for New Tumor Event Metastasis Procedure	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question. 3008757
Date of Additional Surgery for New Tumor Event Metastatic			
56	Date of Additional Surgery for New Tumor Event Metastatic	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	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)
57	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event Metastasic	_____	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			
58	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615

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#	Data Element	Entry Alternatives	Working Instructions
59	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

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

Principal Investigator or Designee Signature | Print Name | Month/Day/Year