<u>Instructions:</u> 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.

Tissu	e Source Site (TSS):	TSS Identifier:	TSS Unique Patient Identifier:	
Comp	oleted By (Interviewer Name	on OpenClinica):	Completed Date:	
Gene	ral 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.	
Pat	ient 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 Chromophobe Renal Cell Carcinom	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	Presence of Sarcomatoid Features	☐ Yes ☐ Unknown ☐ No ☐ Not Evaluated	Using the patient's pathology/laboratory report, indicate if sarcomatoid features were present in the kidney tumor. 2429787	
5	Percent of Tumor that is Sarcomatoid	(%)	If sarcomatoid features are present in the kidney tumor, indicate the percentage of sarcmoatoid features. 2429786	
6	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	
7	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	
8	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	
9*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604	

#	Data Element	Entry Alternatives	Working Instructions	
Date	e of Birth			
10*	Date of Birth	Month Day Year	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)	
11	Number of Days from Date of Initial Pathologic Diagnosis to		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	
	Date of Birth		the NCI to provide time intervals as a substitute for requested dates on this form.	
		 □ 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. 	Provide the patient's race using the defined categories. 2192199	
12*	Race	 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		
13	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	
14*	Has the Patient Had Any Prior Cancer Diagnosed?	□ No□ History of Prior Malignancy□ 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 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.	
15*	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)				
16	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)	

#	Data Element	Entry Alternatives		Working Instructions
Lyn	iph Node Status			
18	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
19	Number of Lymph Nodes Examined			Provide the number of lymph nodes examined, if one or more lymph nodes were removed. $\underline{3}$
20	Number of Lymph Nodes Positive			Provide the number of lymph nodes involved with disease as determined by pathologic examination. 89
AJC	C Staging			
21*	AJCC Cancer Staging Edition	☐ 1st Edition (1978-198 ☐ 2nd Edition (1984-198 ☐ 3rd Edition (1989-199 ☐ 4th Edition (1993-199 ☐ 5th Edition (1998-200) ☐ 6th Edition (2003-200) ☐ 7th Edition (2010-curn	98) 2) 7) 2) 9)	Indicate the AJCC Cancer Staging Edition that was used to answer the following staging questions. 2722309
22*	Primary Tumor (T)	□ TX □ T2 □ T0 □ T2a □ T1 □ T2b □ T1a □ T3 □ T1b □ 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). 3045435
23*	Regional Lymph Nodes (N)	□ 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). 3065858
24*	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)
25*	Tumor Stage (Pathological) (and/or Clinical)	☐ Stage I☐ Stage II☐ 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). 3203222
26*	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	e of Last Contact (If patient	is living)		
27*	Date of Last Contact	Month Day		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)
28	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				
29*	Date of Death			If the patient is deceased, provide the date of death. <u>2897026</u> (Month), <u>2897028</u> (Day), <u>2897030</u> (Year)
30	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.

#	Data Element	Entry Alternatives		Working Instructions		
	Tumor Status	☐ Tumor free		Indicate whether the patient was tumor/disease free at the date of last contact or death.		
31	(at time of last contact or	☐ With tumor		2759550		
	death)	☐ Unknown Tumor Sta				
Pro	ognostic/Predictive/Lifestyle Features Used for Tumor Prognosis or Responsiveness to Treatment					
		☐ Elevated	☐ Not Evaluated	Indicate the outcome of LDH test results.		
32	LDH	□ Normal	☐ Unknown	3113468		
		☐ Low	□ Ulikilowii	3113400		
		☐ Elevated	☐ Not Evaluated	Indicate the outcome of serum calcium test results.		
33	Serum Calcium	□ Normal	□ Unknown	3113470		
		□ Low	LI Ulikilowii	<u>0110170</u>		
	Hemoglobin	☐ Elevated	☐ Not Evaluated	Indicate the outcome of hemoglobin test results.		
34		□ Normal	☐ Unknown	3113466		
		Low	- Olikilowii	<u> </u>		
	Platelets	☐ Elevated	☐ Not Evaluated	Indicate the outcome of platelet test results.		
35		□ Normal	☐ Unknown	3104944		
		Low	- Olikilowii	3104744		
		☐ Elevated	☐ Not Evaluated	Indicate the outcome of white cell count test results.		
36	White Cell Count	■ Normal	☐ Unknown	3104948		
		Low	L chikhowh			
	Erythrocyte	☐ Elevated	☐ Not Evaluated	Indicate the outcome of erythrocyte sedimentation rate (ESR)		
37	Sedimentation Rate	□ Normal	☐ Unknown	test results. 3104952		
		Low		· 		
		☐ Lifelong Non-smoker		Indicate the patient's current smoking status or smoking history as self-reported by the patient.		
		O .	21014E0			
		☐ Current smoker (incl				
		and non-daily smoke	rs or occasional			
	m 1	smokers)	1 6 45			
38	Tobacco Smoking	☐ Current reformed smoker for > 15 years (greater than 15 years)				
	History Indicator					
		☐ Current reformed sm				
		(less than or equal to				
		☐ Current reformed sm specified	loker, duration not			
		Smoking History not	Documented			
		3 Silloking History Hot	Documented	If the patient is a current or reformed smoker, indicate the		
39	Year of Onset of			year in which the patient began smoking.		
	Tobacco Smoking			<u>2228604</u>		
	V			If the patient is a reformed smoker, indicate the year in which		
40	Year of Quitting			the patient quit smoking.		
	Tobacco Smoking			<u>2228610</u>		
				Indicate the lifetime tobacco exposure of the patient. Number		
41	Number Pack Years Smoked			of pack years is defined as the number of cigarettes smoked per day times (x) the number of years smoked divided (/) by		
41				20.		
L				<u>2955385</u>		
				Provide the patient's Karnofsky Score using the defined		
	Performance Status Score: Karnofsky Score (Pre-Operative)	□ 100		categories. This score represents the functional capabilities of the patient.		
		□ 90		2003853		
		□ 80		100: Normal, no complaints; no evidence of disease		
		1 70		90: Able to carry on normal activity; minor signs or symptoms of		
		□ 60 □ 50		disease 80: Normal activity with effort; some signs or symptoms of disease		
42		□ 50 □ 40		70: Cares for self; unable to carry on normal activity or to do active work		
42		□ 40 □ 20		work <u>60:</u> Requires occasional assistance; but is able to care for most of		
		□ 30 □ 20		his/her needs		
				50: Requires considerable assistance and frequent medical care 40: Disabled; requires special care		
		□ 10 □ 0		30: Severely disabled		
		□ Not Evaluated		20: Very sick; requiring hospitalization 10: Moribund; fatal processes progressing rapidly		
		☐ Unknown		<u>0:</u> Dead		
		LI UIIKIIUWII		Not Evaluated: Not provided or available. <u>Unknown:</u> Could not be determined or unsure.		
		1		Out of the out of the outer mines of unsure.		

ш	Data Florant	Enter Altomaticos	Working Instructions				
#	Data Element	Entry Alternatives	Working Instructions Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score				
43	Performance Status Score: Eastern Cooperative Oncology Group (ECOG) 1 2 3 4 Not Evaluated Unknown		represents the functional performance status of the patient. 88 @: 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.				
44	Performance Status Score: Timing	☐ Post Adjuvant Therapy ☐ At Recurrence/Progression of Disease ☐ Post Secondary Therapy ☐ Other ☐ Unknown	Unknown: Could not be determined or unsure. Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories. 2792763				
Prir	nary Treatment						
45*	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.				
46*	Adjuvant (Post- Operative) Pharmaceutical	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post- operative pharmaceutical therapy. 3397567 If the patient did have adjuvant pharmaceutical therapy, the				
	Therapy		Pharmaceutical Supplemental Form should be completed.				
47	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				
New	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.						
48*	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	e of New Tumor Event after	Initial Treatment					
49*	Date of New Tumor Event		If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)				
50	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.				
51	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							
52	Date of Additional Surgery for New Tumor		If the patient had surgery for the new loco-regional tumor event, provide the date of surgery for this new loco-regional tumor event.				
	Event Locoregional	Month Day Year	2897032 (Month) 2897034 (Day) 2897036 (Year)				

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#	Data Element		Entry Alternati	ves	Working Instructions
53	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.
54	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
Dat	e of Additional Surgery for I	New Tumor Eve	nt Metastatic		
55	Date of Additional Surgery for New Tumor Event Metastatic			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)
56	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.
Add	litional Treatment				
57	Additional treatment for New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown			Indicate whether the patient received radiation treatment for this new tumor event. 3427615
58	Additional treatment for New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown			Indicate whether the patient received pharmaceutical treatment for this new tumor event. $\underline{3427616}$
—— Prin	cipal Investigator or Desig	nee Signature		Print Name	//
	Time name Property Tour				