Enrollment Form

Adrenocortical 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 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 cannot answer the question because the answer is not known at the TSS. 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 be selected by the TSS if it is known that the information being requested cannot be obtained. If for example, a test was not performed the results of that test cannot be provided because it was "Not Evaluated."

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

Completed By *(Interviewer Name in OpenClinica)*: _____Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1	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
2	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

Patient Information

#	Data Element	Entry Alternatives	Working Instructions
3*	Date of Birth	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
4*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604

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#	Data Element	Entry Alternatives	Working Instructions
5*	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 *Not provided or available.* ☐ Unknown *Could not be determined or unsure.*	Provide the patient's race using the defined categories. 2192199
6	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
7*	History of Other Malignancy	☐ Yes ☐ No	Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. 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, the case will be excluded from TCGA. 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.
8*	History of Neo-adjuvant Therapy for Sample Submitted for TCGA	☐ Yes ☐ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737 Mitotane prior to surgery is an exclusionary criterion for this study. 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.
9	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
10*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5

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#	Data Element	Entry Alternatives	Working Instructions
11	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)
12	Date of Death	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
Adjuvant Treatment Information			
13*	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy *for the tumor submitted for TCGA*. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
14*	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy *for the tumor submitted for TCGA*. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
15	Did the Patient Receive Mitotane Therapy at any time?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient has at any time received mitotane treatment. 3646372
16	Did the patient receive mitotane therapy in an adjuvant setting (following complete surgical resection)?	☐ Yes ☐ No ☐ Unknown ☐ Not Applicable *(patient had macroscopic disease and/or non-resectable disease)*	Indicate whether the patient received mitotane treatment after the submitted tumor was removed. 3646377 *Adjuvant mitotane is defined as the use of mitotane after the presumed surgical cure with the intent of delaying or preventing recurrence.
17	Were therapeutic mitotane levels (>14 mg/L) achieved in the adjuvant setting?	☐ Yes ☐ No ☐ Unknown	Indicate whether therapeutic levels were achieved in the adjuvant setting. 3646378
18	If therapeutic mitotane levels (>14 mg/L) were achieved in the adjuvant setting, were levels therapeutic at the time of recurrence?	☐ Yes ☐ No ☐ Unknown ☐ No Recurrence	If therapeutic levels were achieved in the adjuvant setting, indicate whether levels were therapeutic at the time of recurrence. 3646379
19	Did the patient receive mitotane therapy for macroscopic residual disease and/or non-resectable disease?	☐ Yes ☐ No ☐ Not Applicable	Indicate whether the patient received mitotane treatment for macroscopic residual disease and/or non-resectable disease. 3646385
20	Were therapeutic mitotane levels (>14 mg/L) achieved when used for macroscopic residual disease and/or non-resectable disease?	☐ Yes ☐ No ☐ Unknown	Indicate whether therapeutic levels were achieved in the adjuvant setting. 3646380
21	If therapeutic mitotane levels (>14 mg/L) were achieved in the setting of macroscopic residual disease and/or non-resectable disease, were levels therapeutic at time of progression?	☐ Yes ☐ No ☐ Unknown ☐ No Progression	If therapeutic levels were achieved in the setting of treating macroscopic residual disease and/or non-resectable disease, indicate whether they were achieved at the time of progression. 3646382

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#	Data Element	Entry Alternatives	Working Instructions
22	Clinical Status Within Three (3) Months of Surgery	☐ No Imaging Evidence of Disease ☐ Persistent Locoregional Disease ☐ Persistent Distant Metastatic Disease ☐ Biochemical Evidence of Disease	Indicate the patient's clinical status within three months of the surgery related to the tumor submitted for TCGA. 3186684
23	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 (Treatment Ongoing) ☐ Unknown	Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies). 2786727

Pathologic/Prognostic Information

#	Data Element	Entry Alternatives	Working Instructions
24*	Primary Site of Disease	☐ Adrenal Gland	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
25*	Laterality	☐ Right ☐ Left ☐ Bilateral	Using the patient's pathology/laboratory report, select the laterality of the disease. Include all areas of invasion. 827
26*	Histological Subtype	☐ Adrenocortical Carcinoma – Usual Type ☐ Adrenocortical Carcinoma – Oncocytic ☐ Adrenocortical Carcinoma – Myxoid	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. 3081934
27*	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)
28	Was a pre-operative CT performed?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received a pre-operative x-ray computed tomography (CT) scan. 3534857
29	Findings of Pre-Operative CT Scan	☐ Normal ☐ Lung Involvement ☐ Liver Involvement ☐ Vena Cava Involvement/thrombus ☐ Retroperitoneal Lymph Node Involvement ☐ Kidney Involvement ☐ Carcinomatosis	If the patient did receive a pre-operative x-ray computed tomography (CT) scan, provide the findings of the scan. 3151439
30	Were Lymph Nodes Examined at the Time of Primary Resection?	☐ Yes ☐ No ☐ Unknown	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
31	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3
32	Number of Lymph Nodes Positive by H&E light microscopy	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3086388

Weiss Assessment: Report the findings for each category and then provide an overall score.

#	Data Element	Weiss Category	Present	Absent	Working Instructions
33	Weiss Assessment	Nuclear Grade III or IV	☐	☐	Using the Weiss histopathologic criteria, indicate the absence or presence of each of the categories provided. 3648743
		Mitotic Rate > 5/50 HPF	☐	☐	
		Atypical Mitotic Figures	☐	☐	
		Cytoplasm presence <= to 25%	☐	☐	
		Diffuse Architecture	☐	☐	
		Necrosis	☐	☐	
		Venous Invasion	☐	☐	
		Sinusoid Invasion	☐	☐	

#	Data Element	Entry Alternatives	Working Instructions
		Invasion of Tumor Capsule ☐ ☐	
34	Overall Weiss Assessment Score	☐ 0 ☐ 4 ☐ 8 ☐ 1 ☐ 5 ☐ 9 ☐ 2 ☐ 6 ☐ 3 ☐ 7	For each Weiss criterion evaluated in the prior question, score 0 for absent and 1 for present and add the individual scores to determine the overall Weiss score. 3648744
35	Mitoses per 50 High Powered Fields (HPF)	_____	Provide the number of mitoses per 50 high powered fields (HPF) at the time of diagnosis. 3646391
36	Pathologic ENSAT Staging: Primary Tumor (T) (7th Edition, 2009)	☐ T1 (T1 = Tumor ≤ 5.0 cm in size and has not invaded tissues outside the adrenal gland) ☐ T2 (T2 = Tumor > 5.0 cm in size and has not invaded tissues outside the adrenal gland) ☐ T3 (T3 = Tumor of any size that has invaded the fat that surrounds the adrenal gland) ☐ T4 (T4 = Tumor of any size that has invaded nearby organs such as the kidney, pancreas, spleen or liver)	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3648746
37	Pathologic ENSAT Staging: Lymph Nodes (N) (7th Edition, 2009)	☐ N0 (N0 = No involvement of regional lymph nodes) ☐ N1 (N1 = Involvement of regional lymph nodes)	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3648747 Please Note: If the lymph nodes were not removed, the TCGA study will consider no lymph node involvement, and "N0" should be selected.
38	Clinical ENSAT Staging: Distant Metastasis (M) (7th Edition, 2009)	☐ M0 (M0 = No involvement of distant organs or tissues) ☐ M1 (M1 = Involvement of distant organs or tissues such as liver, bone or brain)	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3648748
39	Overall ENSAT Staging: Tumor Stage (7th Edition, 2009)	☐ Stage I (T1, N0, M0) (Stage I = The tumor is ≤ 5.0cm and has not invaded surrounding tissues or organs and has not spread to lymph nodes or distant organs or tissues.) ☐ Stage II (T2, N0, M0) (Stage II = The tumor is > 5.0cm and has not invaded surrounding tissues or organs and has not spread to lymph nodes or distant organs or tissues.) ☐ Stage III (T3/T4, N0/N1, M0) (Stage III = Tumor of any size that has spread to the fat outside the adrenal gland or into nearby organs or tissues and/or has spread to the regional lymph nodes.) ☐ Stage IV (Any T, Any N, M1) (Stage IV = Tumor of any size that involves distant organs such as liver, bone or brain. The tumor may or may not involve nearby organs, tissues or lymph nodes.)	Using the patient's pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3203222
40	Residual Tumor	☐ RX (Presence of residual tumor cannot be assessed) ☐ R0 (No residual tumor) ☐ R1 (Microscopic residual tumor) ☐ R2 (Macroscopic residual tumor)	If the patient had a non-nodal metastasis associated with the diagnosis of the tumor submitted for TCGA, provide the site of the first non-nodal metastasis. Only select more than one site if there were synchronous metastasis where the first non-nodal met was found at multiple sites. 2608702

#	Data Element	Entry Alternatives	Working Instructions
41	Method used to Confirm Metastatic Disease at time of Initial Diagnosis *(check all that apply)*	☐ Biopsy Proven ☐ Imaging Suspected ☐ Other (please specify) ☐ Unknown	If the patient had a metastatic tumor at the time of diagnosis, provide the method used to confirm the metastatic disease. 3178364
42	Other Method used to Confirm Metastatic Disease	_____	If the patient had a metastatic tumor at the time of diagnosis and the method used to confirm the metastatic disease is not included in the provided list, indicate the method used. 3178376
43	Site of Metastatic Tumor at Initial Diagnosis *(check all that apply)*	☐ Bone ☐ Lung ☐ Liver ☐ Peritoneum ☐ Other (please specify)	If the patient had a metastatic tumor at the time of diagnosis, provide the site of metastatic disease. 2967298
44	Other Site of Metastatic Tumor at Initial Diagnosis	_____	If the patient had a metastatic tumor at the time of diagnosis and the site of disease is not included in the provided list, indicate the site of metastatic disease. 2961431
45	History of Adrenal Hormone Excess *(check all that apply)*	☐ None ☐ Androgen ☐ Mineralcorticoids ☐ Cortisol ☐ Estrogen ☐ Unknown	If patient has a history of adrenal hormone excess, please provide all hormones affected. 3646386
46	Basis for Hormone Excess Diagnosis	☐ Clinical Assessment ☐ Biochemical Assessment ☐ Both Clinical and Biochemical Assessments ☐ Unknown	If the patient has a history of adrenal hormone excess, provide the basis for the diagnosis of the excess. 3646387
47	Germline Genotype Testing Performed	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had germline genotyping performed. 3121565
48	Type of Germline Genotype Testing Performed	**Test** / **Present** / **Absent** / **Not Performed** P53 MEN1 NFI FAP DNA Mismatch Repair RET Other	If the patient had germline genotyping performed, provide the results. 3121628
49	Other Type of Germline Genotype Testing Performed	_____	If the type of germline genotype testing performed is not included on the provided list, indicate the type of testing performed 4500214

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.*

Please Note: The New Tumor Event section on OpenClinica can be completed multiple times, if the patient had multiple New Tumor Events.

#	Data Element	Entry Alternatives	Working Instructions
50*	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. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.

#	Data Element	Entry Alternatives	Working Instructions
51	Type of New Tumor Event	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ Biochemical Evidence of Disease ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology as the tumor submitted to TCGA. 3119721
52	Site of New Tumor Event	☐ Bone ☐ Peritoneum/Tumor Bed ☐ Lung ☐ Retroperitoneum ☐ Liver ☐ Lymph Node(s) ☐ Soft Tissue ☐ Other, specify	Indicate the site of this new tumor event. 3108271
53	Other Site of New Tumor Event	_____	If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033
54	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)
55	How was this New Tumor Event confirmed?	☐ Imaging ☐ Pathology ☐ Unknown	If the patient had a new tumor event, provide the method used to confirm the diagnosis. 3186701
56	Evidence of Histologic Progression	☐ Yes ☐ No ☐ Unknown	Indicate whether the new tumor event had evidence of histologic progression (i.e. transition from low grade to high grade). 3181376
57	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
58	Date of Additional Surgery for New Tumor Event	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (Month), 3427613 (Day), 3427614 (Year)
59	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
60	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 | Date