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 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

	ot be obtained. This counformation requested w			-	uestion v	was never	performed on the patient or the TSS knows that
Γissu	Fissue Source Site (TSS):TSS Identifier:				:	TSS Unique Patient Identifier:	
Comp	leted By (Interviewer Name	e in OpenCl	inica):				Completed Date:
Gene	ral Information						
#	Data Element		Entr	y Alterna	atives		Working Instructions
1	Is this a prospective tissue collection?	□ Yes					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	
Patie	nt Information						
#	Data Element		Entr	y Alterna	atives		Working Instructions
3	Month of Birth	□ 01 □ 02 □ 03	□ 04 □ 05 □ 06		07 08 09	□ 10 □ 11 □ 12	Provide the month the patient was born. 2896950
4	Day of Birth	□ 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 the patient was born. 2896952
_	Year of Birth					_	Provide the year the patient was born. 2896954
5	rear or birtii						
6	Gender	☐ Fema					Provide the patient's gender using the defined categories. 2200604

#	Data Element	Entry Alternatives	Working Instructions
7	Race	 □ American Indian or Alaska Native	Provide the patient's race using the defined categories. 2192199
8	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
9	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.
10	History of Neo-adjuvant Treatment 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.
11	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
12	Vital Status (at date of last contact)	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553

#	Data Element	Entr	y Alternatives		Working Instructions
13	Month of Last Contact	□ 01 □ 04 □ 02 □ 05 □ 03 □ 06	□ 07 □ 08 □ 09	□ 10 □ 11 □ 12	If the patient is living, provide the month of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 Do not answer if patient is deceased.
14	Day of Last Contact	□ 01 □ 08 □ 02 □ 09 □ 03 □ 10 □ 04 □ 11 □ 05 □ 12 □ 06 □ 13 □ 07	□ 14 □ 20 □ 15 □ 21 □ 16 □ 22 □ 17 □ 23 □ 18 □ 24 □ 19 □ 25	☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient is living, provide the day of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897022 Do not answer if patient is deceased.
15	Year of Last Contact			-	If the patient is living, provide the year of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897024 Do not answer if patient is deceased.
16	Month of Death	□ 01 □ 04 □ 02 □ 05 □ 03 □ 06	□ 07 □ 08 □ 09	□ 10 □ 11 □ 12	If the patient is deceased, provide the month of death. 2897026
17	Day of Death	□ 01 □ 08 □ 02 □ 09 □ 03 □ 10 □ 04 □ 11 □ 05 □ 12 □ 06 □ 13 □ 07	14 20 15 21 16 22 17 23 18 24 19 25	☐ 26 ☐ 27 ☐ 28 ☐ 29 ☐ 30 ☐ 31	If the patient is deceased, provide the day of death. 2897028
18	Year of Death			_	If the patient is deceased, provide the year of death. 2897030
Adjı	ıvant Treatment Informatio	on			
19	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.
20	Adjuvant (Post- Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown			Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy <u>for the tumor submitted for TCGA</u> 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
21	Did the Patient Receive Mitotane Therapy at any time?	☐ Yes (skip to Quest ☐ No (skip to Quest ☐ Unknown			Indicate whether the patient has at any time received mitotane treatment. $\underline{3646372}$
22	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)		scopic	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.
23	Were therapeutic mitotane levels (>14 mg/L) achieved in the adjuvant setting?	☐ Yes ☐ No (skip to Quest ☐ Unknown	□ No (skip to Question #25)		Indicate whether therapeutic levels were achieved in the adjuvant setting. 3646378
24	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	☐ Yes ☐ No ☐ Unknown		If therapeutic levels were achieved in the adjuvant setting, indicate whether levels were therapeutic at the time of recurrence. 3646379

#	Data Element	Entry Alternatives	Working Instructions
25	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
26	Were therapeutic mitotane levels (>14 mg/L) achieved when used for macroscopic residual disease and/or non-resectable disease?	☐ Yes ☐ No (skip to Question #28) ☐ Unknown	Indicate whether therapeutic levels were achieved in the adjuvant setting. 3646380
27	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
28	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
29	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

	authorogic/11 ognostic mormation						
#	Data Element	Entry Alternatives	Working Instructions				
30	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				
31	Anatomic Organ Sub- Division	☐ Right Adrenal Gland☐ Left Adrenal Gland	Using the patient's pathology/laboratory report, select the anatomic organ sub-division of the tumor used for TCGA. Include all areas of tumor invasion. 2008006				
32	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. 2549638				
33	Month of Initial Pathologic Diagnosis	$\begin{array}{c ccccc} \square \ 01 & \square \ 04 & \square \ 07 & \square \ 10 \\ \square \ 02 & \square \ 05 & \square \ 08 & \square \ 11 \\ \square \ 03 & \square \ 06 & \square \ 09 & \square \ 12 \\ \end{array}$	Provide the month the patient was initially diagnosed with the malignancy submitted for TCGA. 2896956				
34	Day of Initial Pathologic Diagnosis	01 08 14 20 26 02 09 15 21 27 03 10 16 22 28 04 11 17 23 29 05 12 18 24 30 06 13 19 25 31 07	Provide the day the patient was initially diagnosed with the malignancy submitted for TCGA. 2896958				
35	Year of Initial Pathologic Diagnosis		Provide the year the patient was initially diagnosed with the malignancy submitted for TCGA. 2896960				
36	Was a pre-operative CT performed?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received a pre-operative x-ray computed tomography (CT) scan. 3534857				

#	Data Element	Entry Alternatives			Working Instructions
37	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
38	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
39	Number of Lymph Nodes Examined				Provide the number of lymph nodes examined, if one or more lymph nodes were removed. $\underline{3}$
40	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
Wei	ss Assessment: Report th	e findings for each category ar	nd then pro	ovide an	overall score.
	•	Weiss Category Nuclear Grade III or IV	Present	Absent	Using the Weiss histopathologic criteria, indicate the absence or presence of each of the categories provided. 3648743
	Weiss Assessment	Mitotic Rate > 5/50 HPF Atypical Mitotic Figures			
		Cytoplasm presence <= to 25%			
41		Diffuse Architecture			
		Necrosis			
		Venous Invasion			
		Sinusoid Invasion			
		Invasion of Tumor Capsule			
42	Overall Weiss Assessment Score	□ 0 □ 4 □ 1 □ 5 □ 2 □ 6 □ 3 □ 7	□ 8 □ 9		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
43	Mitoses per 50 High Powered Fields (HPF)				Provide the number of mitoses per 50 high powered fields (HPF) at the time of diagnosis. 3646391
44	Pathologic ENSAT Staging: Primary Tumor (T) (7 th 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
45	Pathologic ENSAT Staging: Lymph Nodes (N) (7 th Edition, 2009)	□ N0 (NO = No involvement of reg □ N1 (N1 = Involvement of region			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 "NO" should be selected.

#	Data Element	Entry Alternatives	Working Instructions
46	Clinical ENSAT Staging: Distant Metastasis (M) (7 th Edition, 2009)	 M0 (MO = No involvement of distant organs or tissues) M1 (NO = 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
47	Overall ENSAT Staging: Tumor Stage (7 th 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
48	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. 3124499
49	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
50	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
51	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
52	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
53	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

#	Data Element	Entry Alte	rnatives		Working Instructions
54	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
55	Germline Genotype Testing Performed	☐ Yes ☐ No ☐ Unknown			Indicate whether the patient had germline genotyping performed. 3121565
	Type of Germline	Test	Present	Absent	If the patient had germline genotyping performed, provide the
		P53			results. 3121628
		MEN1			3121020
56	Genotype Testing	NFI			
	Performed	FAP			
		DNA Mismatch Repair			
		Other			

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.

#	Data Element	Entry Alternatives	Working Instructions
57	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.
<u>58</u>	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
<u>59</u>	Anatomic 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
<u>60</u>	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
<u>61</u>	Month of New Tumor Event	□ 01 □ 04 □ 07 □ 10 □ 02 □ 05 □ 08 □ 11 □ 03 □ 06 □ 09 □ 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. 3104044
<u>62</u>	Day of New Tumor Event	01 08 14 20 26 02 09 15 21 27 03 10 16 22 28 04 11 17 23 29 05 12 18 24 30 06 13 19 25 31	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
63	Year of New Tumor Event		If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
<u>64</u>	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
<u>65</u>	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
<u>66</u>	Additional treatment for New Tumor Event: Surgery	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611

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#	Data Element	Entry Alternatives		Working Instructions
<u>67</u>	Month of Additional Surgery for New Tumor Event	□ 02 □ 05 □ 08 □	□ 10 □ 11 □ 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612
<u>68</u>	Day of Additional Surgery for New Tumor Event	01 08 14 20 02 09 15 21 03 10 16 22 04 11 17 23 05 12 18 24 06 13 19 25 07	□ 26 □ 27 □ 28 □ 29 □ 30 □ 31	If the patient had surgery for the new tumor event, provide the day this surgery was performed. 3427613
<u>69</u>	Year of Additional Surgery for New Tumor Event			If the patient had surgery for the new tumor event, provide the year this surgery was performed. 3427614
<u>70</u>	Additional treatment for New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown		Indicate whether the patient received radiation treatment for this new tumor event. $\underline{3427615}$
71	Additional treatment for New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown		Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

		/ /
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Principal Investigator or Designee Signature	Print Name	Date