

## Enrollment Form Melanoma of the Skin (SKCM)

**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 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 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.  <i>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.</i>
2	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. <a href="#">3088492</a>
3	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. <a href="#">3088528</a>

### Patient Information

#	Data Element	Entry Alternatives	Working Instructions
<b>Date of Birth</b>			
4	Month of Birth	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	Provide the month the patient was born. <a href="#">2896950</a>
5	Day of Birth	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	Provide the day the patient was born. <a href="#">2896952</a>
6	Year of Birth	_____	Provide the year the patient was born. <a href="#">2896954</a>

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#	Data Element	Entry Alternatives	Working Instructions
7	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. <a href="#">3008233</a> <i>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.</i>
8	Gender	<input type="checkbox"/> Female <input type="checkbox"/> Male	Provide the patient's gender using the defined categories. <a href="#">2200604</a>
9	Height (at time of diagnosis)	_____ (cm)	Provide the patient's height (in centimeters) at the time the patient was diagnosed with the malignancy being submitted for TCGA. <a href="#">649</a>
10	Weight (at time of diagnosis)	_____ (kg)	Provide the patient's weight (in kilograms) at the time the patient was diagnosed with the malignancy being submitted for TCGA. <a href="#">651</a>
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: <i>Not provided or available.</i> <input type="checkbox"/> Unknown: <i>Could not be determined or unsure.</i>	Provide the patient's race using the defined categories. <a href="#">2192199</a>
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: <i>Not provided or available.</i> <input type="checkbox"/> Unknown: <i>Could not be determined or unsure.</i>	Provide the patient's ethnicity using the defined categories. <a href="#">2192217</a>
13	History of Other Malignancy (Non-melanoma malignancies only)	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether the patient has a history of 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. <a href="#">3382736</a> <i>If this question cannot be answered because the answer is unknown, please contact the BCR.</i>  <i>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>

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#	Data Element	Entry Alternatives	Working Instructions
14	Neo-adjuvant (pre-operative) therapy for tumor submitted for TCGA	<input type="checkbox"/> Yes <input type="checkbox"/> No	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. <a href="#">3382737</a>  <i>Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the resection of the sample submitted for TCGA is exclusionary.</i>  <i>Interferon treatment prior to procurement is acceptable, if administered at least 90 days prior to tumor procurement.</i>
15	Tumor Status (at time of last contact or death)	<input type="checkbox"/> Tumor free <input type="checkbox"/> With tumor <input type="checkbox"/> Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. <a href="#">2759550</a>
16	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. <a href="#">5</a>
<b>Date of Last Contact (If patient is living)</b>			
17	Month of Last Contact	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 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). <a href="#">2897020</a>
18	Day of Last Contact	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	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). <a href="#">2897022</a>
19	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). <a href="#">2897024</a>
20	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. <a href="#">3008273</a>  <i>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.</i>
<b>Date of Death</b>			
21	Month of Death	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	If the patient is deceased, provide the month of death. <a href="#">2897026</a>
22	Day of Death	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	If the patient is deceased, provide the day of death. <a href="#">2897028</a>
23	Year of Death	_____	If the patient is deceased, provide the year of death. <a href="#">2897030</a>
24	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. <a href="#">3165475</a>  <i>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.</i>

### Pathologic/Prognostic Information

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#	Data Element	Entry Alternatives	Working Instructions
<b>Primary Melanoma</b>			
<i>Note: The primary melanoma is not necessarily the event that yielded the biospecimen sent to the BCR.</i>			
25	Did the patient have a known diagnosis of primary melanoma?	<input type="checkbox"/> Yes (known primary) <input type="checkbox"/> No (unknown primary)	Indicate whether the patient had a known primary melanoma at the time of initial diagnosis. <i>If the patient did not have a known primary, skip #s 26-34 and continue with the "Initial Melanoma Diagnosis" section.</i> <a href="#">3108462</a>
26	Did the patient have multiple known primaries at the time of initial melanoma diagnosis?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If the patient had a known primary, indicate if there were multiple known primaries at initial diagnosis. <a href="#">64186</a>
27	Number of known primaries at the time of initial melanoma diagnosis	_____	If the patient had multiple known primaries at the time of initial melanoma diagnosis, provide the number of known melanoma primaries. <a href="#">3427429</a>
28	Location(s) of Primary Melanoma(s)	<i>Location</i>	If the patient had known primary melanomas, provide the location of the primaries and the number of primaries in each location. <a href="#">3427526</a> , <a href="#">3427609</a>
		<i># of Primaries in this Location</i>	
		<input type="checkbox"/> Head and Neck <input type="checkbox"/> Trunk <input type="checkbox"/> Extremities <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> Unknown	
29	Other Location(s) of Primary Melanoma(s)	_____	If the patient had known primary melanomas, and the location(s) of the primaries were not included in the provided list, specify the location(s). <a href="#">61390</a>
30	Breslow Tumor Thickness at Diagnosis	_____ (mm, to .01mm significance)	If the patient had a known primary, provide the Breslow depth. For patients with multiple primaries at initial diagnosis, use the thickest Breslow measurement. <a href="#">2593055</a>
31	Clark Level at Diagnosis	<input type="checkbox"/> I <input type="checkbox"/> IV <input type="checkbox"/> II <input type="checkbox"/> V <input type="checkbox"/> III <input type="checkbox"/> Unknown	If the patient had a known primary, provide the Clark level. For patients with multiple primaries at initial diagnosis, use the highest Clark level. <a href="#">2593051</a>
32	Primary Tumor Ulceration at Diagnosis	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If the patient had a known primary, indicate if it was ulcerated. For patients with multiple primaries at initial diagnosis, designate yes if any were ulcerated. <a href="#">3108478</a>
33	Highest mitotic rate among known primaries included at initial diagnosis	_____ (mitoses per mm <sup>2</sup> )	If the patient had a known primary, provide the mitotic rate using the patient's pathology report. For patients with multiple primaries at initial diagnosis, use the highest mitotic rate recorded. <a href="#">3119292</a>
34	Did the patient receive radiation therapy at the site of the primary?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If the patient had a known primary, indicate whether they received radiation to the site of the primary. <a href="#">3162807</a>
<b>Initial Melanoma Diagnosis</b>			
<i>Note: The initial melanoma diagnosis may or may not be the primary tumor, and the initial melanoma diagnosis is not necessarily the event that yielded the biospecimen sent to the BCR.</i>			
<b>Date and Method of Initial Pathologic Diagnosis</b>			
35	Month of <i>Initial Melanoma Diagnosis</i>	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	Provide the month the patient was initially pathologically diagnosed with melanoma. <a href="#">2896956</a>
36	Day of <i>Initial Melanoma Diagnosis</i>	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	Provide the day the patient was initially pathologically diagnosed with melanoma. <a href="#">2896958</a>

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#	Data Element	Entry Alternatives	Working Instructions
37	Year of <i>Initial Melanoma Diagnosis</i>	_____	Provide the year the patient was initially pathologically diagnosed with melanoma. <a href="#">2896960</a>
38	Age at Initial Melanoma Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed with melanoma. <a href="#">2006657</a> <i>Only complete this question if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.</i>
39	AJCC Cancer Staging Edition used At Initial Diagnosis	<input type="checkbox"/> 1 <sup>st</sup> Edition (1978-1983) <input type="checkbox"/> 2 <sup>nd</sup> Edition (1984-1988) <input type="checkbox"/> 3 <sup>rd</sup> Edition (1989-1992) <input type="checkbox"/> 4 <sup>th</sup> Edition (1993-1997) <input type="checkbox"/> 5 <sup>th</sup> Edition (1998-2002) <input type="checkbox"/> 6 <sup>th</sup> Edition (2003-2009) <input type="checkbox"/> 7 <sup>th</sup> Edition (2010-present)	Please select the AJCC Cancer Staging Edition used to answer the following questions (#s 40-44). <a href="#">2722309</a>
40	Primary Tumor (T) category at Initial Diagnosis (per Staging Edition Indicated)	<input type="checkbox"/> TX <input type="checkbox"/> T1b <input type="checkbox"/> T3a <input type="checkbox"/> T0 <input type="checkbox"/> T2, NOS <input type="checkbox"/> T3b <input type="checkbox"/> Tis <input type="checkbox"/> T2a <input type="checkbox"/> T4, NOS <input type="checkbox"/> T1, NOS <input type="checkbox"/> T2b <input type="checkbox"/> T4a <input type="checkbox"/> T1a <input type="checkbox"/> T3, NOS <input type="checkbox"/> T4b	If the patient had a known primary melanoma, provide the AJCC T category of the primary tumor at initial diagnosis <a href="#">3045435</a>
41	Regional Nodes (N) category at Initial Diagnosis (per Staging Edition Indicated)	<input type="checkbox"/> NX <input type="checkbox"/> N2, NOS <input type="checkbox"/> N0 <input type="checkbox"/> N2a <input type="checkbox"/> N1, NOS <input type="checkbox"/> N2b <input type="checkbox"/> N1a <input type="checkbox"/> N2c <input type="checkbox"/> N1b <input type="checkbox"/> N3, NOS	Provide the AJCC N category at initial diagnosis <a href="#">3203106</a>
42	Distant Metastasis (M) category at Initial Diagnosis (per Staging Edition Indicated)	<input type="checkbox"/> M0 <input type="checkbox"/> M1 <input type="checkbox"/> M1a <input type="checkbox"/> M1b <input type="checkbox"/> M1c	Provide the AJCC M category at initial diagnosis. <a href="#">3045439</a>
43	Serum Lactate Dehydrogenase (LDH) Level at Initial Diagnosis (per Staging Edition Indicated)	<input type="checkbox"/> Normal/ Not Elevated <input type="checkbox"/> Elevated <input type="checkbox"/> Not Evaluated <input type="checkbox"/> Unknown	Provide the patient's LDH level at the time of initial diagnosis. <a href="#">3113468</a> <i>This question should only be completed if the patient was staged with M1 (Stage IV) under the AJCC staging classification.</i>
44	Overall Stage (pathological) At Initial Diagnosis (per Staging Edition Indicated)	<input type="checkbox"/> 0 <input type="checkbox"/> II, NOS <input type="checkbox"/> IIIA <input type="checkbox"/> I, NOS <input type="checkbox"/> IIA <input type="checkbox"/> IIIB <input type="checkbox"/> IA <input type="checkbox"/> IIB <input type="checkbox"/> IIIC <input type="checkbox"/> IB <input type="checkbox"/> IIC <input type="checkbox"/> IV <input type="checkbox"/> I/II, NOS <input type="checkbox"/> III, NOS	Provide the overall AJCC stage at initial diagnosis. <a href="#">3203222</a>
<b>Biospecimen Submitted to the BCR for TCGA</b>			
<b>Note: The biospecimen submitted to the BCR for TCGA may or may not include the primary and/or the first melanoma diagnosis.</b>			
45	Month of <i>Diagnosis of Submitted Sample</i>	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	Provide the month the patient was diagnosed with the tumor that yielded the biospecimen submitted to the BCR for TCGA. It is possible that this is the same date as the "Date of Initial Melanoma Diagnosis." <a href="#">3427547</a>
46	Day of <i>Diagnosis of Submitted Sample</i>	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	Provide the day the patient was diagnosed with the tumor that yielded the biospecimen submitted to the BCR for TCGA. It is possible that this is the same date as the "Date of Initial Melanoma Diagnosis." <a href="#">3427551</a>
47	Year of <i>Diagnosis of Submitted Sample</i>	_____	Provide the year the patient was diagnosed with the tumor that yielded the biospecimen submitted to the BCR for TCGA. It is possible that this is the same date as the "Date of Initial Melanoma Diagnosis." <a href="#">3427552</a>

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#	Data Element	Entry Alternatives	Working Instructions
48	Number of Days from Date of Initial Pathologic Diagnosis to the Date of Diagnosis of the Submitted Sample	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date the patient was diagnosed with the tumor that yielded the biospecimen submitted to the BCR for TCGA. <a href="#">3430945</a> <i>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.</i>
49	Site of Disease	<input type="checkbox"/> Primary tumor <input type="checkbox"/> Regional lymph node <input type="checkbox"/> Regional cutaneous or subcutaneous tissue <i>(includes satellite &amp; in-transit metastasis)</i> <input type="checkbox"/> Distant metastasis, specify	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. <a href="#">3427536</a>
50	Site of <i>Distant Metastasis</i>	_____	If the specimen submitted to for TCGA was a distant metastasis, specify the anatomic site of the submitted tumor. <a href="#">2961431</a>
51	What is the type of skin upon which the melanoma arose?	<input type="checkbox"/> Non-glabrous skin <input type="checkbox"/> Glabrous skin (palms or soles), Nail apparatus or Mucosa <i>(case is excluded)</i>	Using the patient's pathology/laboratory report, select the type of skin where the melanoma arose. This should be answered for the biospecimen submitted to the BCR for TCGA. <a href="#">3108474</a>
52	Prior to the resection of the tumor submitted to the BCR, did the patient receive radiation therapy to the site of that tumor?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received radiation therapy to the site of the tumor submitted to the BCR for TCGA. <a href="#">944</a> <i>If the answer to this question is "yes" or "unknown," this case will be excluded.</i>
53	Prior to the resection of the tumor submitted to the BCR, did the patient receive systemic therapy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received systemic therapy prior to the resection of the tumor submitted to the BCR for TCGA. <a href="#">64176</a> <i>If the answer to this question is "unknown," this case will be excluded.</i>
54	If systemic therapy was given prior to the resection of the tumor submitted for TCGA, what therapy was used? <i>Check all that apply</i>	<input type="checkbox"/> Interferon (IFN) <i>ONLY</i> <input type="checkbox"/> Chemotherapy +/-IFN <i>(this case is excluded)</i> <input type="checkbox"/> Immunotherapy/ Vaccine +/- IFN <i>(this case is excluded)</i> <input type="checkbox"/> Other <i>(this case is excluded)</i> <input type="checkbox"/> Unknown <i>(this case is excluded)</i>	If the patient received systemic therapy prior to the resection of the tumor submitted to the BCR for TCGA, indicate the type of treatment used. <a href="#">3119700</a>
55	If IFN was the only systemic therapy administered prior to resection of tumor submitted to BCR, was the IFN administered at least 90 days prior to the resection of the TCGA tumor?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Indicate whether the patient received Interferon therapy at least 90 days prior to resection of the submitted specimen. <a href="#">3162803</a> <i>If the answer to this question is "no" or "unknown," this case will be excluded.</i>
56	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. <b><i>IF the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.</i></b> <a href="#">2005312</a>
57	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. <b><i>IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.</i></b> <a href="#">3397567</a>

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**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.

**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
58	New Tumor Event Include tumor events from the date of initial melanoma diagnosis to the "Date of Last Contact" (reference #s 17-19).	<input type="checkbox"/> Yes – Tumor Submitted for TCGA <i>(see working instructions)</i> <input type="checkbox"/> Yes – Melanoma Related Only <input type="checkbox"/> Yes – Non-Melanoma related Only <input type="checkbox"/> Yes – Melanoma & Non-Melanoma Related <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 the date of initial melanoma diagnosis. If the tumor that yielded the sample submitted for TCGA was a new tumor event (i.e. it was diagnosed after the initial diagnosis), the remaining questions should <b>not</b> be completed. <a href="#">3121376</a>  <i>If the patient did not have a new tumor event, the remaining questions can be skipped.</i>
59	Were any of these New Tumor Events diagnosed prior to the diagnosis of the tumor that yielded the sample submitted for TCGA?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Indicate whether any of the new tumor events described in the previous question were diagnosis after the diagnosis of the tumor that yielded the sample submitted for TCGA. <a href="#">3427563</a>  <i>An Other Malignancy Form should NOT be completed for melanoma related tumors that were diagnosed prior to the TCGA tumor.</i>
<i>Date of New Tumor Event after Initial Treatment</i>			
60	Month of New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. <a href="#">3104044</a>
61	Day of New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. <a href="#">3104042</a>
62	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. <a href="#">3104046</a>
63	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. <a href="#">3392464</a>  <i>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.</i>
64	Additional Surgery for New Tumor Event	<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 tumor event in question. <a href="#">3427611</a>
<i>Date of Additional Surgery for New Tumor Event (when applicable)</i>			
65	Month of Additional Surgery for New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 04 <input type="checkbox"/> 07 <input type="checkbox"/> 10 <input type="checkbox"/> 02 <input type="checkbox"/> 05 <input type="checkbox"/> 08 <input type="checkbox"/> 11 <input type="checkbox"/> 03 <input type="checkbox"/> 06 <input type="checkbox"/> 09 <input type="checkbox"/> 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. <a href="#">3427612</a>
66	Day of Additional Surgery for New Tumor Event	<input type="checkbox"/> 01 <input type="checkbox"/> 08 <input type="checkbox"/> 14 <input type="checkbox"/> 20 <input type="checkbox"/> 26 <input type="checkbox"/> 02 <input type="checkbox"/> 09 <input type="checkbox"/> 15 <input type="checkbox"/> 21 <input type="checkbox"/> 27 <input type="checkbox"/> 03 <input type="checkbox"/> 10 <input type="checkbox"/> 16 <input type="checkbox"/> 22 <input type="checkbox"/> 28 <input type="checkbox"/> 04 <input type="checkbox"/> 11 <input type="checkbox"/> 17 <input type="checkbox"/> 23 <input type="checkbox"/> 29 <input type="checkbox"/> 05 <input type="checkbox"/> 12 <input type="checkbox"/> 18 <input type="checkbox"/> 24 <input type="checkbox"/> 30 <input type="checkbox"/> 06 <input type="checkbox"/> 13 <input type="checkbox"/> 19 <input type="checkbox"/> 25 <input type="checkbox"/> 31 <input type="checkbox"/> 07	If the patient had surgery for the new tumor event, provide the day this surgery was performed. <a href="#">3427613</a>
67	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. <a href="#">3427614</a>

## Enrollment Form Melanoma of the Skin (SKCM)

#	Data Element	Entry Alternatives	Working Instructions																
68	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event	_____	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 additional surgery for new tumor event (loco-regional). <a href="#">3008335</a> <i>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.</i>																
69	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. <a href="#">3427615</a> <i>The Radiation Supplemental form does NOT need to be completed if the answer to this question is yes.</i>																
70	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. <a href="#">3427616</a> <i>The Pharmaceutical Supplemental form does NOT need to be completed if the answer to this question is yes.</i>																
71	Type of New <b>Melanoma Related</b> Tumor Event	<input type="checkbox"/> Locoregional ( <i>local and/or intransit metastasis</i> ) <input type="checkbox"/> Regional lymph node ( <i>metastasis</i> ) <input type="checkbox"/> Distant Metastasis <input type="checkbox"/> New Primary Melanoma	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis, a new primary tumor (not melanoma), or a new primary melanoma. <a href="#">3119721</a>																
72	Site of New <b>Distant Metastasis</b> Tumor Event	<input type="checkbox"/> Lung <input type="checkbox"/> Bone <input type="checkbox"/> Liver <input type="checkbox"/> Brain <input type="checkbox"/> Other, specify <input type="checkbox"/> Unknown	If the answer to the previous question was Distant Metastasis, this question should be answered. Otherwise, this question can be skipped. <a href="#">3430936</a> <i>If the answer to question #71 was Distant Metastasis, this question should be answered. Otherwise, this question can be skipped.</i>																
73	Other Site of New <b>Distant Metastasis</b> Tumor Event	_____	If the patient had a new distant metastasis event and the site of this tumor was not included in the provided list of distant metastasis, describe the site. <a href="#">3427578</a>																
74	Location(s) of <b>New Primary Melanoma</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Location</th> <th style="width: 40%;"># of Primaries in this Location</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> Head and Neck</td> <td style="text-align: center;">_____</td> </tr> <tr> <td><input type="checkbox"/> Trunk</td> <td style="text-align: center;">_____</td> </tr> <tr> <td><input type="checkbox"/> Extremities</td> <td style="text-align: center;">_____</td> </tr> <tr> <td><input type="checkbox"/> Other, specify</td> <td style="text-align: center;">_____</td> </tr> <tr> <td><input type="checkbox"/> Unknown</td> <td style="text-align: center;">_____</td> </tr> </tbody> </table>	Location	# of Primaries in this Location	<input type="checkbox"/> Head and Neck	_____	<input type="checkbox"/> Trunk	_____	<input type="checkbox"/> Extremities	_____	<input type="checkbox"/> Other, specify	_____	<input type="checkbox"/> Unknown	_____	If the patient had a new primary melanoma, provide the site of this new tumor event. <a href="#">3430941, 3427609</a>				
Location	# of Primaries in this Location																		
<input type="checkbox"/> Head and Neck	_____																		
<input type="checkbox"/> Trunk	_____																		
<input type="checkbox"/> Extremities	_____																		
<input type="checkbox"/> Other, specify	_____																		
<input type="checkbox"/> Unknown	_____																		
75	Other Site of <b>New Primary Melanoma</b>	_____	If the patient had a new primary melanoma and the site of this tumor was not included in the list provided, describe the site. <a href="#">3427598</a>																
76	Histologic Type of New <b>Non-Melanoma</b> Tumor Event	_____	Using the patient's pathology/laboratory report, select the histology and/or subtype of the other malignancy. <a href="#">3427610</a>																
77	Primary Site of New <b>Non-Melanoma</b> Tumor Event	<table style="width: 100%;"> <tr> <td><input type="checkbox"/> Anus</td> <td><input type="checkbox"/> Kidney</td> </tr> <tr> <td><input type="checkbox"/> Bladder</td> <td><input type="checkbox"/> Liver</td> </tr> <tr> <td><input type="checkbox"/> Bone</td> <td><input type="checkbox"/> Lung</td> </tr> <tr> <td><input type="checkbox"/> Brain</td> <td><input type="checkbox"/> Lymph Node(s)</td> </tr> <tr> <td><input type="checkbox"/> Cervix</td> <td><input type="checkbox"/> Prostate</td> </tr> <tr> <td><input type="checkbox"/> Colon</td> <td><input type="checkbox"/> Trunk</td> </tr> <tr> <td><input type="checkbox"/> Extremities</td> <td><input type="checkbox"/> Other</td> </tr> <tr> <td><input type="checkbox"/> Head &amp; Neck</td> <td><input type="checkbox"/> Unknown</td> </tr> </table>	<input type="checkbox"/> Anus	<input type="checkbox"/> Kidney	<input type="checkbox"/> Bladder	<input type="checkbox"/> Liver	<input type="checkbox"/> Bone	<input type="checkbox"/> Lung	<input type="checkbox"/> Brain	<input type="checkbox"/> Lymph Node(s)	<input type="checkbox"/> Cervix	<input type="checkbox"/> Prostate	<input type="checkbox"/> Colon	<input type="checkbox"/> Trunk	<input type="checkbox"/> Extremities	<input type="checkbox"/> Other	<input type="checkbox"/> Head & Neck	<input type="checkbox"/> Unknown	Using the patient's pathology/laboratory report, select the anatomic site of the other malignancy. <a href="#">3108271</a>
<input type="checkbox"/> Anus	<input type="checkbox"/> Kidney																		
<input type="checkbox"/> Bladder	<input type="checkbox"/> Liver																		
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<input type="checkbox"/> Head & Neck	<input type="checkbox"/> Unknown																		

\_\_\_\_\_  
Principal Investigator or Designee Signature

\_\_\_\_\_  
Print Name

\_\_\_\_/\_\_\_\_/\_\_\_\_\_  
Date