Follow-Up Form
Melanoma of the Skin (SKCM)

Instructions: *The Follow-up Form is to be completed 12 months after a case enters the Biospecimen Core Resource (BCR). All information provided on this form includes activity from the "Date of Last Contact" provided on the TCGA Enrollment Form to the most recent date of contact with the patient. This form should only be completed by the Tissue Source Site if updated information can be provided to TCGA. Please direct any questions to the Clinical Outreach team at the BCR.*

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

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

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

General Information

#	Data Element	Entry Alternatives	Working Instructions
1	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	Please note that the time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box. *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.*
2	Is this Patient Lost to Follow-up?	☐ Yes ☐ No	Indicate whether the patient is lost to follow-up, as defined by the ACoS Commission on Cancer. This only includes cases where updated follow-up information has not been collected within the past 15 months and all efforts to contact the patient have been exhausted (this includes reviewing the Social Security death index). If the patient is lost to follow-up, the remaining questions can be left unanswered. 61333 *If the patient is **deceased** and a TCGA follow-up form has not yet been completed, the answer to this question should be "no," and the remaining applicable questions should be completed.*

Follow-Up Information

#	Data Element	Entry Alternatives	Working Instructions
3	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***IF the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed***. 2005312
4	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. ***IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed***. 3397567
5	Tumor Status *(at date 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
6	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 2939553

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#	Data Element	Entry Alternatives	Working Instructions
Date of Last Contact *(If patient is living)*			
7	Month of Last Contact	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 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
8	Day of Last Contact	☐ 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	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
9	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
10	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			
11	Month of Death	☐ 01 ☐ 04 ☐ 07 ☐ 10 ☐ 02 ☐ 05 ☐ 08 ☐ 11 ☐ 03 ☐ 06 ☐ 09 ☐ 12	If the patient is deceased, provide the month of death. 2897026
12	Day of Death	☐ 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	If the patient is deceased, provide the day of death. 2897028
13	Year of Death	_____	If the patient is deceased, provide the year of death. 2897030
14	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.*
15	Did the patient have subsequent known primary melanoma(s) during the follow-up period?	☐ Yes ☐ No ☐ Unknown	Following the initial melanoma diagnosis and regardless of multiple primaries throughout the TCGA Enrollment period, indicate whether the patient had any known primary melanoma(s) during the current TCGA follow-up reporting period. 3430950

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
16	New Tumor Event *Include tumor events from the "Date of Last Contact" on the TCGA Enrollment form to the "Date of Last Contact" on this form.*	☐ Yes – Melanoma Related Only ☐ Yes – Non-Melanoma related Only ☐ Yes – Melanoma & Non-Melanoma Related ☐ No ☐ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after the "Date of Last Contact" on the TCGA Enrollment form. 3121376 *If the patient did not have a new tumor event, the remaining questions can be skipped.*

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#	Data Element	Entry Alternatives	Working Instructions
Date of New Tumor Event after Initial Treatment			
17	Month of New Tumor Event	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient had a new tumor event, provide the month of diagnosis for this new tumor event. 3104044
18	Day of New Tumor Event	☐ 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	If the patient had a new tumor event, provide the day of diagnosis for this new tumor event. 3104042
19	Year of New Tumor Event	_____	If the patient had a new tumor event, provide the year of diagnosis for this new tumor event. 3104046
20	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.*
21	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
Date of Additional Surgery for New Tumor Event (when applicable)			
22	Month of Additional Surgery for New Tumor Event	☐ 01 ☐ 02 ☐ 03 ☐ 04 ☐ 05 ☐ 06 ☐ 07 ☐ 08 ☐ 09 ☐ 10 ☐ 11 ☐ 12	If the patient had surgery for the new tumor event, provide the month this surgery was performed. 3427612
23	Day of Additional Surgery for New Tumor Event	☐ 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	If the patient had surgery for the new tumor event, provide the day this surgery was performed. 3427613
24	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
25	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). 3008335 *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.*
26	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615 *The Radiation Supplemental form does NOT need to be completed if the answer to this question is yes.*
27	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616 *The Pharmaceutical Supplemental form does NOT need to be completed if the answer to this question is yes.*

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#	Data Element	Entry Alternatives	Working Instructions
28	Type of New ***Melanoma Related*** Tumor Event	☐ Locoregional *(local and/or intransit metastasis)* ☐ Regional lymph node *(metastasis)* ☐ Distant Metastasis ☐ 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. 3119721
29	Site of New ***Distant Metastasis*** Tumor Event	☐ Lung ☐ Bone ☐ Liver ☐ Brain ☐ Other, specify ☐ Unknown	If the answer to the previous question was Distant Metastasis, this question should be answered. Otherwise, this question can be skipped. 3430936 *If the answer to question #29 was Distant Metastasis, this question should be answered. Otherwise, this question can be skipped.*
30	Other Site of New ***Distant Metastasis*** 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. 3427578
31	Site of ***New Primary Melanoma***	*Location*: ☐ Head and Neck; ☐ Trunk; ☐ Extremities; ☐ Other, specify; ☐ Unknown *# of Primaries in this Location*: _____ _____ _____ _____	If the patient had a new primary melanoma, provide the site of this new tumor event. 3430941, 3427609
32	Other Site of ***New Primary Melanoma***	_____	If the patient had a new primary melanoma and the site of this tumor was not included in the list provided, describe the site. 3427598
33	Histologic Type of New ***Non-Melanoma*** Tumor Event	_____	Using the patient's pathology/laboratory report, select the histology and/or subtype of the other malignancy. 3427610
34	Primary Site of New ***Non-Melanoma*** Tumor Event	☐ Anus ☐ Bladder ☐ Bone ☐ Brain ☐ Cervix ☐ Colon ☐ Extremities ☐ Head & Neck ☐ Kidney ☐ Liver ☐ Lung ☐ Lymph Node(s) ☐ Prostate ☐ Trunk ☐ Other ☐ Unknown	Using the patient's pathology/laboratory report, select the anatomic site of the other malignancy. 3108271

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

Principal Investigator or Designee Signature | Print Name | Date