Follow-up Form: Lung

V4.0

Tissue Source Site (TSS) Name: _______________________ TSS Identifier: ___________ TSS Unique Patient #: _______________

Completed By: ____ Completion Date (MM/DD/YYYY): ________________________

Form Notes: *A Follow-up Form is to be completed for any of the following reasons: 1) For each additional new tumor event identified at the time of enrollment or follow-up submission; or 2) 12 months after a case is shipped to the Biospecimen Core Resource (BCR) for cases that have qualified. 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. Questions regarding this form should be directed to the Tissue Source Site's (TSS) primary Clinical Outreach Contact at the BCR.*

The following definitions for the use of "Unknown" and "Not Evaluated" on this form are as follows:

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 the 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 due to the test not being performed.

Question #	Data Element Label	Data 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 time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box to the left. ***Note 1: Provided time intervals must begin with the date of initial pathologic diagnosis.*** **(i.e, biopsy or resection)** ***Note 2: 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	Reason For Follow-up Form Submission	☐ Scheduled (Routine) Follow-up Submission ☐ Additional New Tumor Event	3233305 Indicate the reason for submission of this follow-up form. If scheduled follow-up, complete entire form. If additional new tumor event, complete only questions pertaining to new tumor.
3	Is This Patient Lost to Follow-up?	☐ Yes ☐ No	61333 Indicate whether the patient is lost to follow-up as defined by the ACoS Commission on Cancer. This only includes cases where updated information has not been collected within the last 15 months. If the patient is lost to follow-up, the remaining questions may be left unanswered. ***Note: 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.***
4	Adjuvant Post-operative: Radiation Therapy	☐ Yes ☐ No ☐ Unknown	2005312 Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***Note: If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.***
5	Adjuvant Post-operative: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	2785850 Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed***
6	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies)	☐ Not Applicable ☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Unknown	2786727 Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies).
7	Vital Status	☐ Living ☐ Deceased	5 Indicate whether the patient was living or deceased at the date of last contact.

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Question #	Data Element Label	Data Entry Alternatives	Working Instructions
Date of Last Contact			
8	Month of Last Contact	☐☐ (MM)	2897020 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). ***Note: Do not answer this question if the patient is deceased***
9	Day of Last Contact	☐☐ (DD)	2897022 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). ***Note: Do not answer this question if the patient is deceased.***
10	Year of Last Contact	☐☐☐☐ (YYYY)	2897024 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). ***Note: Do not answer this question if the patient is deceased.***
11	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	____________________	3008273 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. ***Note: 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			
12	Month of Death	☐☐ (MM)	2897026 If the patient is deceased, provide the month of death.
13	Day of Death	☐☐ (DD)	2897028 If the patient is deceased, provide the day of death.
14	Year of Death	☐☐☐☐ (YYYY)	2897030 If the patient is deceased, provide the year of death.
15	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	____________________	3165475 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. ***Note: 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.***
16	Tumor Status	☐ Tumor Free ☐ With Tumor ☐ Unknown Tumor Status	2759550 Indicate whether the patient was tumor/disease free from the tumor submitted for TCGA at the date of last contact or death.

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Question #	Data Element Label	Data Entry Alternatives	Working Instructions
17	Performance Status Score: Karnofsky Score	☐ 100 Normal, no complaints; no evidence of disease ☐ 90 Able to carry on normal activity; minor signs or symptoms of disease ☐ 80 Normal activity with effort; some signs or symptoms of disease ☐ 70 Cares for self; unable to carry on normal activity or to do active work ☐ 60 Requires occasional assistance; but is able to care for most of his/her needs ☐ 50 Requires considerable assistance and frequent medical care ☐ 40 Disabled; requires special care ☐ 30 Severely disabled ☐ 20 Very sick; requiring hospitalization ☐ 10 Moribund; fatal processes progressing rapidly ☐ 0 Dead ☐ Not Evaluated ☐ Unknown	2003853 Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient.
18	Performance Status Score: Eastern Cooperative Oncology Group (ECOG)	☐ 0 Asymptomatic ☐ 1 Symptomatic, but fully ambulatory ☐ 2 Symptomatic, in bed less than 50% of day ☐ 3 Symptomatic, in bed more than 50% of day, but not bed-ridden ☐ 4 Bed-ridden ☐ Not Evaluated ☐ Unknown	88 Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient.
19	Performance Status Score: Timing	☐ Pre-Operative ☐ Other ☐ Pre Adjuvant Therapy ☐ Unknown ☐ Post-Adjuvant Therapy ☐ Not Evaluated	2792763 Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories.
20	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	3121376 Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after their initial treatment for the tumor submitted to TCGA. ***Note: If the patient had multiple new tumor events, a follow-up form should be completed for each new tumor event.***
Date of New Tumor Event After Initial Treatment		☐ Not Applicable	
21	Month of New Tumor Event	☐☐ (MM)	3104044 If the patient had a new tumor event, provide the month of diagnosis for this new tumor event.
22	Day of New Tumor Event	☐☐ (DD)	3104042 If the patient had a new tumor event, provide the day of diagnosis for this new tumor event.
23	Year of New Tumor Event	☐☐☐☐ (YYYY)	3104046 If the patient had a new tumor event, provide the year of diagnosis for this new tumor event.

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Question #	Data Element Label	Data Entry Alternatives	Working Instructions
24	Number of Days from Date of Diagnosis to Date of New Tumor Event After Initial Treatment	____________________	3392464 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 new tumor event after initial treatment. ***Note: 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.***
25	Type of New Tumor Event (check all that apply)	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	3119721 Indicate whether the patient's new tumor event was a locoregional recurrence or a distant metastasis of the tissue submitted for TCGA; or a new primary tumor.
26	Diagnostic Evidence of Recurrence / Relapse (check all that apply)	☐ Biopsy w/Histologic Confirmation ☐ Convincing Imaging (i.e. CT, PET, MRI) ☐ Positive Biomarker(s)	2786205 Indicate the procedure or testing method used to diagnose tumor recurrence or relapse.
27	Additional Surgery for New Tumor Event: Loco-Regional	☐ Yes ☐ Unknown ☐ No	3008755 Using the patient's medical records, indicate whether the patient had surgery for the new loco-regional tumor event in question.
Date of Additional Surgery for New Tumor Event: Loco-regional		☐ Not Applicable (No Loco-regional Procedure)	
28	Month of Additional Surgery for New Tumor Event: Loco-Regional	☐☐ (MM)	2897032 If the patient had surgery for the new loco-regional tumor event, provide the month of surgery for this new, loco-regional tumor event.
29	Day of Additional Surgery for New Tumor Event: Loco-Regional	☐☐ (DD)	2897034 If the patient had surgery for the new loco-regional tumor event, provide the day of surgery for this new, loco-regional tumor event.
30	Year of Additional Surgery for New Tumor Event: Loco-Regional	☐☐☐☐ (YYYY)	2897036 If the patient had surgery for the new loco-regional tumor event, provide the year of surgery for this new, loco-regional tumor event.
31	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event: Loco-Regional	____________________	3408572 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). ***Note: 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.***
32	Additional Surgery for New Tumor Event: Metastasis	☐ Yes ☐ Unknown ☐ No	3008757 Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question.
Date of Additional Surgery for New Tumor Event: Metastasis		☐ Not Applicable (No Surgical Procedure for	Metastatic Tumor Recurrence / Progression)
33	Month of Additional Surgery for New Tumor Event: Metastasis	☐☐ (MM)	2897038 If the patient had surgery for the new metastatic tumor event, provide the month of surgery for this new metastatic tumor event.
34	Day of Additional Surgery for New Tumor Event: Metastasis	☐☐ (DD)	2897040 If the patient had surgery for the new metastatic tumor event, provide the day of surgery for this new metastatic tumor event.
35	Year of Additional Surgery for New Tumor Event: Metastasis	☐☐☐☐ (YYYY)	2897042 If the patient had surgery for the new metastatic tumor event, provide the year of surgery for this new metastatic tumor event.

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Question #	Data Element Label	Data Entry Alternatives	Working Instructions
36	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event: Metastasis	____________________	3408682 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 (metastasis). ***Note: 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.***
37	Additional Treatment of New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown	3008761 Indicate whether the patient received radiation treatment for this new tumor event.
38	Additional Treatment of New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	2650646 Indicate whether the patient received pharmaceutical treatment for this new tumor event.
39	Measure of Success of Outcome at the Completion of This Follow-up Submission	☐ Not Applicable ☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Unknown	3104050 Provide the patient's outcome of treatment up to the point of the current follow-up data submission.

Comments:
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Principal Investigator Name: _________________________ Principal Investigator Signature: __________________________

Date Signed (MM/DD/YYYY): _________________________