Enrollment Form
Lung Adenocarcinoma

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: _____

#	Data Element	Entry Alternatives	Working Instructions
Enrollment Information			
1*	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. Provided time intervals must begin with the date of initial pathologic diagnosis (e.g. 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.
Patient Information			
2*	Primary Site of Disease	☐ Lung	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
3	Diagnosis	☐ Lung Adenocarcinoma	Using the patient's pathology/laboratory report, select the histologic diagnosis of the tumor submitted for TCGA. 3081932
4*	Histological Subtype (Adenocarcinoma)	☐ Adenocarcinoma, Mixed Subtype ☐ Acinar Adenocarcinoma ☐ Papillary Adenocarcinoma ☐ Bronchioloalveolar Carcinoma, Mucinous ☐ Bronchioloalveolar Carcinoma, Non-Mucinous ☐ Solid Pattern Predominant Adenocarcinoma ☐ Micropapillary Adenocarcinoma ☐ Fetal Adenocarcinoma ☐ Mucinous Cystadenocarcinoma ☐ Mucinous (Colloid) Adenocarcinoma ☐ Signet Ring Adenocarcinoma ☐ Clear Cell Adenocarcinoma ☐ Adenocarcinoma, Not Otherwise Specified (NOS)	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. All other subtypes not listed are excluded from this study. 3081934

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5	Anatomic Organ Sub-division	☐Right Upper Lobe ☐Right Middle Lobe ☐Right Lower Lobe ☐Bronchus ☐Left Upper Lobe ☐Left Lower Lobe ☐Other *(please specify)*	Using the patient's pathology/laboratory report, select the anatomic organ sub-division of the tumor used for TCGA. 2008006
6	Other Anatomic Organ Sub-Division	_____	If the anatomic organ sub-division is not included in the provided list, specify the other anatomic organ sub-division of the tumor used for TCGA 3407703
7	Location in Lung Parenchyma	☐ Peripheral Lung ☐ Central Lung ☐ Unknown	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record select the location of the tumor within the lung parenchyma. 3139453
8	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
9	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
10*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
Date of Birth			
11*	Date of Birth	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
12	Number of Days from Date of Initial Pathological Diagnosis to Date of Birth	_____	3008233 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth. 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.
13	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 ☐ Unknown	Provide the patient's race using the defined categories. 2192199
14	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 ☐ Unknown	Provide the patient's ethnicity using the defined categories. 2192217

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#	Data Element	Entry Alternatives	Working Instructions
15*	Has the Patient Had Any Prior Cancer Diagnosed?	☐ No ☐ History of Prior Malignancy ☐ History of Synchronous / Bilateral Malignancy	Indicate whether the patient has a history of prior malignancies. If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. If the patient has any history of prior malignancies, 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 patient has a history of multiple diagnoses of basal and/or squamous cell skin cancers, complete an "Other Malignancy Form" for the first diagnosis for each of these types. 3382736
16*	History of Neo-Adjuvant Treatment to Tumor Specimen Submitted for TCGA	☐ No ☐ Radiation Prior to Sample Procurement ☐ Pharmaceutical Treatment Prior to Sample Procurement ☐ Both Pharmaceutical and Radiation Treatment Prior to Sample Procurement	Indicate whether the patient received therapy for this cancer prior to sample procurement of the tumor submitted for TCGA. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instructions. Systemic treatment and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to procurement of the sample submitted for TCGA are exclusionary. 3382737
Date of Initial Pathologic Diagnosis *(of Lung Tumor Associated with Tissue Procurement for TCGA)*			
17*	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)
18	Residual Tumor	☐ RX ☐ R0 ☐ R1 ☐ R2 ☐ Not Evaluated	Using the patient's pathology/laboratory report, select the tissue margin status at time of surgical resection for the tumor submitted for TCGA. 2608702
19*	AJCC Cancer Staging Handbook Edition	☐ First Edition (1978-1983) ☐ Second Edition (1984-1988) ☐ Third Edition (1989-1992) ☐ Fourth Edition (1993-1997) ☐ Fifth Edition (1998-2002) ☐ Sixth Edition (2003-2009) ☐ Seventh Edition (2010-Current)	Indicate the AJCC Cancer Staging Edition that was used to answer the following staging questions. 2722309
20*	Pathologic Spread: Primary Tumor (pT)	☐TX ☐T1a ☐T2a ☐T3 ☐T0 ☐T1b ☐T2b ☐T4 ☐T1 ☐T2	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC). 3045435
21*	Pathologic Spread: Lymph Nodes (pN)	☐ NX ☐ N0 ☐ N1 ☐ N2 ☐ N3	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) as defined by the American Joint Committee on Cancer (AJCC). 3065858
22*	Pathologic Spread: Distant Metastases (M) (clinical and/or pathological)	☐ MX ☐ M0 ☐ M1 ☐ M1a ☐ M1b	Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the code for the clinical or pathological M (metastasis) as defined by the American Joint Committee on Cancer (AJCC). 3045439
23*	Tumor Stage (Pathological and/or Clinical)	☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IA ☐ Stage IIA ☐ Stage IIIA ☐ Stage IB ☐ Stage IIB ☐ Stage IIIB ☐ Stage IV	Using the patient's pathology/laboratory report, in conjunction with the patient's medical record select the stage as defined by the American Joint Committee on Cancer (AJCC). 3065862
24*	Vital Status	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
Date of Last Contact *(If patient is living)*			
25*	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)

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26	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. 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. 3008273
Date of Death			
27*	Date of Death	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
28	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.
29	Tumor Status	☐ Tumor Free ☐ With Tumor ☐ Unknown Tumor Status	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
Prognostic/Predictive/Lifestyle Features for Tumor Prognosis or Responsiveness to Treatment			
30*	Pulmonary Function Tests Performed?	☐ Yes ☐ No	Indicate whether the patient had formal Pulmonary Function Tests (PFTs) performed. If surgery is performed, pre-operative PFTs are preferred. 2556486
31	FEV1% REF, pre-bronchodilator: *(Pre- Bronchodilator Lung Forced Expiratory Volume I Test Lab Percentage Value)*	_____**%**	Identify the results for the pre-operative PFTs and indicate the percentage comparison to a normal value reference range of the volume of air that a patient can forcibly exhale from the lungs in one second **pre-bronchodilator.** 3302947
32	FEV1% REF, post-bronchodilator: *(Post- Bronchodilator Lung Forced Expiratory Volume I Test Lab Percentage Value)*	_____**%**	Identify the results for the pre-operative PFTs and indicate the percentage comparison to a normal value reference range of the volume of air that a patient can forcibly exhale from the lungs in one second **post-bronchodilator.** 3302948
33	FEV1/FVC pre-bronchodilator: *(Pre- Bronchodilator FEV1/FVC Percentage Value)*	_____**%**	Identify the results for the pre-operative PFTs and indicate the percentage value that represents the result of Forced Expiratory Volume in one second (FEV1) divided by the Forced Vital Capacity (FVC) **pre- bronchodilator.** 3302955
34	FEV1/FVC post-bronchodilator: *(Post- Bronchodilator FEV1/FVC Percentage Value)*	_____**%**	Identify the results for the pre-operative PFTs and indicate the percentage value that represents the result of Forced Expiratory Volume in one second (FEV1) divided by the Forced Vital Capacity (FVC) **post- bronchodilator.** 3302956
35	DLCO % REF: *(Lung Carbon Monoxide Diffusing Capability Test Assessment Predictive Percentage Value)*	_____**%**	Identify the results of the pre-operative PFTs and indicate the percentage value that represents the results of the patient's predicted DLCO. If both the corrected and uncorrected DLCO values are available, record the corrected value. 2180255
36	KRAS Mutation Gene Analysis Performed	☐ Yes ☐ No ☐ Unknown	Indicate if KRAS Mutation gene analysis was performed on the tumor submitted for TCGA. If not performed, skip to EGFR Question. 3123147
37	Mutation Found (KRAS)	☐ Yes ☐ No	If KRAS Mutation Gene Analysis was performed, indicate whether KRAS mutation was identified. 2932340
38	If KRAS Mutation Identified, Which One	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13D ☐ Other	If KRAS mutation was identified, indicate the specific mutation identified. 3147614

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#	Data Element	Entry Alternatives	Working Instructions
39	EGFR Mutation Status Assessed	☐ Yes ☐ No ☐ Unknown	Indicate if EGFR Mutation analysis was performed on the tumor submitted for TCGA. If not performed, skip to EML4/ALK Question. 3139429
40	If EGFR Mutation Identified, Which One	☐ G719X ☐ T790M ☐ L858R ☐ L861Q ☐ Exon 19 Deletion ☐ Exon 20 Insertion ☐ Other	If EGFR mutation analysis was performed, indicate the specific EGFR mutation identified. 3147627
41	EML4/ALK Translocation Status Assessed	☐ Yes ☐ No ☐ Unknown	Indicate if EML4/ALK Translocation status was assessed for the tumor submitted for TCGA. If not assessed, skip to Tobacco Smoking History Question. 3139437
42	If EML4/ALK Translocation Found, Which Variant	☐ Variant 1 ☐ Variant 3 ☐ Variant 5 ☐ Variant 2 ☐ Variant 4	If EML4/ALK Translocation status was assessed, indicate the specific variant identified. 3139445
43	Method of EML4/ALK Analysis	☐ IHC ☐ FISH ☐ RT-PCR ☐ Other	If EML4/ALK Translocation status was assessed, indicate the analysis method utilized. 3139449
44*	Tobacco Smoking History Indicator	☐ Lifelong Non-smoker (less than 100 cigarettes smoked in Lifetime) ☐ Current smoker (includes daily smokers and non-daily smokers or occasional smokers) ☐ Current reformed smoker for > 15 years (greater than 15 years) ☐ Current reformed smoker for ≤15 years (less than or equal to 15 years) ☐ Current reformed smoker, duration not specified ☐ Smoking History not Documented	Indicate the patient's current smoking status or smoking history as self-reported by the patient. 2181650
45	Year of Onset of Tobacco Smoking	_____ _____ _____ _____	If the patient is a current or reformed smoker, indicate the year in which the patient began smoking. 2228604
46	Year of Quitting Tobacco Smoking	_____ _____ _____ _____	If the patient is a reformed smoker, indicate the year in which the patient quit smoking. 2228610
47	Number Pack Years Smoked	_____ _____ _____ _____	Indicate the lifetime tobacco exposure of the patient. Number of pack years is defined as the number of cigarettes smoked per day times (x) the number of years smoked divided (/) by 20. 2955385
48	Performance Status Score: Karnofsky Score (Pre-Operative)	☐ 100 ☐ 90 ☐ 80 ☐ 70 ☐ 60 ☐ 50 ☐ 40 ☐ 30 ☐ 20 ☐ 10 ☐ 0 ☐ Not Evaluated ☐ Unknown	Provide the patient's Karnofsky Score using the defined categories. This score represents the functional capabilities of the patient. 2003853 ***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:*** *Not provided or available.* ***Unknown:*** *Could not be determined or unsure.*

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#	Data Element	Entry Alternatives	Working Instructions
49	Performance Status Score: Eastern Cooperative Oncology Group (ECOG)	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Not Evaluated ☐ Unknown	Provide the patient's Eastern Cooperative Oncology Group (ECOG) score using the defined categories. This score represents the functional performance status of the patient. 88 ***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:*** *Not provided or available.* ***Unknown:*** *Could not be determined or unsure.*
50	Performance Status Score: Timing	☐ Pre-Operative ☐ Other ☐ Pre-Adjuvant ☐ Unknown ☐ Post-Adjuvant ☐ Not Evaluated	Provide a time reference for the Karnofsky score and/or the ECOG score using the defined categories. 2792763
Primary Treatment			
51	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
52	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
53	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and/or adjuvant therapies)	☐Progressive Disease ☐Complete Response ☐Stable Disease ☐Not Applicable ☐Partial Response ☐Unknown	Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies). 2786727
New Tumor Event Information: Complete this section if the patient had a new tumor event after tissue procurement and prior to submission of the Enrollment Form. If the patient did not have a new tumor event, or if the TSS does not know, indicate this in the first question below; and then skip the remainder of this form.			
54*	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 the date of initial diagnosis. 3121376 *If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.*
Date of New Tumor Event after Initial Treatment			
55	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)
56	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 described on this form 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.*
57	Type of New Tumor Event (check all that apply)	☐ Locoregional ☐ Distant Metastasis ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. 3119721
58	Diagnostic Evidence of Recurrence / Relapse (check all that apply)	☐ Biopsy w/Histologic Confirmation ☐ Convincing Imaging (i.e. CT, PET, MRI) ☐ Positive Biomarker(s)	Indicate the procedure or testing method used to diagnose tumor recurrence or relapse. 2786205
59	Additional Surgery for New Tumor Event Loco-Regional Procedure	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new loco-regional tumor event in question. 3008755

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#	Data Element	Entry Alternatives	Working Instructions
Date of Additional Surgery for New Tumor Event Loco-regional			
60	Date of Additional Surgery for New Tumor Event Loco-regional Procedure	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had surgery for the new loco-regional tumor event, provide the date of surgery for this new loco-regional tumor event. 2897032 (Month), 2897034 (Day), 2897036 (Year)
61	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event - Locoregional	_____	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 (locoregional). 3408572 *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.*
62	Additional Surgery for New Tumor Event Metastasis Procedure	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question. 3008757
Date of Additional Surgery for New Tumor Event Metastasis			
63	Date of Additional Surgery for New Tumor Event Metastasis	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had surgery for the new metastatic tumor event, provide the date of surgery for this new metastatic tumor event. 2897038 (Month), 2897040 (Day), 2897042 (Year)
64	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event – Metastasis	_____	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). 3408682 *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.*
Additional Treatment			
65	Additional Treatment of New Tumor Event Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3008761
66	Additional Treatment of New Tumor Event Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 2650646

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

Principal Investigator or Designee Signature | Print Name | Month/Day/Year