Enrollment Form
CDDP LUAD

Instructions: *The Enrollment Form should be completed for each 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 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 in OpenClinica)*: _____Completed Date: _____

#	Data Element	Entry Alternatives	Working Instructions
General Information			
Collection Information			
1	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 the project, 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 project contract was executed, the tissue has been collected retrospectively. 3088528
Patient Information			
Demographics			
3*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604
4*	Date of Birth	____ ____ ____ ____ ____ ____ ____ ____ *Month* *Day* *Year*	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
5*	Race	☐ American Indian or Alaska Native ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander: ☐ Not Evaluated ☐ Unknown	Provide the patient's race using the defined categories. 2192199 ***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 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 Island.*
6	Ethnicity	☐ Not Hispanic or Latino ☐ Hispanic or Latino ☐ Not Evaluated ☐ Unknown	Provide the patient's ethnicity using the defined categories. 2192217 ***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.*
Medical/Health History			
7*	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 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.

#	Data Element	Entry Alternatives	Working Instructions
		☐ Both History of synchronous/Bilateral and Prior Malignancy	3382736 If this question cannot be answered because the answer is unknown, the case will be excluded. 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. 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.
8*	Tobacco Smoking Status at Time of Diagnosis	☐ Lifelong Non-smoker (<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
9	Tobacco Smoking Year of Onset	_____ _____ _____ _____	If the patient is a current or reformed smoker, indicate the year in which the patient began smoking. 2228604
10	Tobacco Smoking Year of Quitting	_____ _____ _____ _____	If the patient is a reformed smoker, indicate the year in which the patient quit smoking. 2228610
11	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
12	Performance Status Score: Eastern Cooperative Oncology Group (ECOG) at Time of Diagnosis	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ Unknown ☐ Not Evaluated	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
13	Performance Status Score: Karnofsky Score At Time of Diagnosis	☐ 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
Tumor Information			
Anatomic Information			
14*	Primary Site of Disease	☐ Lung	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted. 3427536
15*	Laterality	☐ Left ☐ Right	Using the patient's pathology/laboratory report, select the laterality of the disease. Include all areas of invasion. 827

Enrollment Form
CDDP LUAD

#	Data Element	Entry Alternatives	Working Instructions
16	Region of Tumor	☐ Upper Lobe ☐ Middle Lobe ☐ Lower Lobe ☐Bronchus ☐Other *(please specify)*	Using the patient's pathology/laboratory report, select the anatomic organ sub-division of the tumor submitted. 3108203
17	Other Region of Tumor	_____	If the anatomic organ sub-division is not included in the provided list, specify the other anatomic organ sub-division of the tumor submitted. 3407703
18	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
Pathologic Information			
19*	Histological Subtype	☐ Lung Adenocarcinoma, Mixed Subtype ☐ Lung Acinar Adenocarcinoma ☐ Lung Papillary Adenocarcinoma ☐ Lung Bronchioloalveolar Carcinoma, Mucinous ☐ Lung Bronchioloalveolar Carcinoma, Non-Mucinous ☐ Lung Solid Pattern Predominant Adenocarcinoma ☐ Lung Micropapillary Adenocarcinoma ☐ Lung Fetal Adenocarcinoma ☐ Mucinous Cystadenocarcinoma ☐ Mucinous (Colloid) Adenocarcinoma ☐ Lung Signet Ring Adenocarcinoma ☐ Lung Clear Cell Adenocarcinoma ☐ Lung Adenocarcinoma, Not Otherwise Specified (NOS)	Indicate the histologic subtype of the malignant sample submitted. 3081934
20*	Date of Initial Pathological Diagnosis	____ ____ ____ ____ ____ ____ ____ ____ *Month* *Day* *Year*	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted. 2896956 (month), 2896958(day), 2896960 (year)
21	Method of Initial Pathologic Diagnosis	☐ Fine Needle Aspiration Biopsy ☐ Incisional Biopsy ☐ Excisional Biopsy ☐ Surgical Resection ☐ Other (please specify)	Provide the procedure used to initially diagnose the patient. 2757941 Please note that this method is referring to the procedure performed on the Date of Initial Pathologic Diagnosis, provided in the previous question.
22	Other Method of Initial Pathologic Diagnosis	_____	If the method of initial pathologic diagnosis is not included in the list above, provide the method used. 2757948
23	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. 2608702
24*	What type of staging information is available for this diagnosis? *(check all that apply)*	☐ Pathologic ☐ Clinical	Indicate whether pathologic, clinical or both pathologic and clinical staging information is available for the patient's diagnosis of cancer that yielded the tumor submitted. 3370189
25*	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 at the time of diagnosis to answer the following staging questions. 2722309
26	Primary Tumor: Pathologic (pT)	☐TX ☐T0 ☐T1 ☐T1a ☐T1b ☐T2 ☐T2a ☐T2b ☐T3 ☐T4	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
27	Regional Lymph Nodes: Pathologic (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). 3203106
28	Distant Metastases: Pathologic (M)	☐ MX ☐ M0 ☐ M1 ☐ M1a ☐ M1b	Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the code for pathological M (metastasis) as defined by the American Joint Committee on Cancer (AJCC). 3045439
29	Overall Stage: Pathologic	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ 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). 3203222

Enrollment Form
CDDP LUAD

#	Data Element	Entry Alternatives	Working Instructions
Clinical Information			
30	Primary Tumor: Clinical (cT)	☐TX ☐T0 ☐T1 ☐T1a ☐T1b ☐T2 ☐T2a ☐T2b ☐T3 ☐T4	Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the code for the clinical T (primary tumor) as defined by the American Joint Committee on Cancer (AJCC). 3440328
31	Regional Lymph Nodes: Clinical (cN)	☐ NX ☐ N0 ☐ N1 ☐ N2 ☐ N3	Using the patient's pathology/laboratory report in conjunction with the patient's medical record, select the code for the clinical N (nodal) as defined by the American Joint Committee on Cancer (AJCC). 3440330
32	Distant Metastases: Clinical (M)	☐ 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 M (metastasis) as defined by the American Joint Committee on Cancer (AJCC). 3440331
33	Overall Stage: Clinical	☐ Stage I ☐ Stage IA ☐ Stage IB ☐ Stage II ☐ Stage IIA ☐ Stage IIB ☐ Stage III ☐ Stage IIIA ☐ 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). 3440332
Clinical Information: Pulmonary Function Tests			
34*	Pulmonary Function Tests Performed?	☐ Yes ☐ No	Indicate whether the patient had formal Pulmonary Function Tests (PFTs) performed. *Note: If surgery is performed, pre-operative PFTs are preferred.* 2556486
35	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
36	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
37	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
38	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
39	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
Molecular/Genomic Information			
40	Was KRAS analysis performed for this patient?	☐ Yes ☐ No ☐ Unknown	Indicate if KRAS Mutation gene analysis was performed on the tumor submitted. *Note: If not performed, skip to EGFR Mutation Question.* 3123147
41	If KRAS analysis was performed, was a mutation identified?	☐ Yes ☐ No ☐ Unknown	If KRAS Mutation Gene Analysis was performed, indicate whether KRAS mutation was identified 2932340
42	If a KRAS mutation was identified, what was the specific mutation?	☐ G12A ☐ G12C ☐ G12D ☐ G12R ☐ G12S ☐ G12V ☐ G13D ☐ Other	If KRAS mutation was identified, indicate the specific mutation identified. 3147614

#	Data Element	Entry Alternatives	Working Instructions
43	Was EGFR analysis performed for this patient?	☐ Yes ☐ No ☐ Unknown	Indicate if EGFR Mutation analysis was performed on the tumor submitted. *Note: If not performed, skip to EML4/ALK Question.* 3139429
44	If EGFR analysis was performed, was a mutation identified?	☐ Yes ☐ No ☐ Unknown	If EGFR analysis was performed, indicate whether an EGFR mutation was identified. 4588601
45	If an EGFR mutation was identified, what was the specific mutation?	☐ G719X ☐ T790M ☐ L858R ☐ L861Q ☐ Exon 19 Deletion ☐ Exon 20 Insertion ☐ Other	If EGFR mutation analysis was performed, indicate the specific EGFR mutation identified. 3147627
46	Was EML4-ALK analysis performed for this patient?	☐ Yes ☐ No ☐ Unknown	Indicate if EML4/ALK Translocation status was assessed for the tumor submitted. *Note: If not assessed, skip to Vital Status Question.* 3139437
47	Method of EML4-ALK Analysis	☐ IHC ☐ FISH ☐ RT-PCR ☐ Other	If EML4/ALK Translocation status was assessed, indicate the analysis method utilized. 3139449
48	If EML4-ALK analysis was performed, was a translocation identified?	☐ Yes ☐ No ☐ Unknown	If EML4-ALK analysis was performed, indicate whether an EML4-ALK translocation was identified. 4588602
49	If EML4-ALK Translocation Identified, Which Variant?	_____	If EML4/ALK Translocation status was assessed, indicate the specific variant identified. 4588603
Treatment Information			
50*	History of Neo-adjuvant Treatment for Sample Submitted	☐ None ☐ Radiation prior to sample procurement* ☐ Pharmaceutical treatment prior to sample procurement* ☐ Both pharmaceutical treatment and radiation prior to sample procurement*	Indicate whether the patient received therapy for this cancer prior to the sample procurement of the tumor submitted. If the patient did receive treatment for this cancer prior to procurement, the TSS should contact the BCR for further instruction. 3382737 *Systemic therapy and certain localized therapies (those administered to the same site as the submitted tissue) given prior to the procurement of the sample submitted are exclusionary.
51*	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy *for the tumor submitted*. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.
52*	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy *for the tumor submitted*. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
53*	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and/or adjuvant therapies)	☐Progressive Disease ☐Stable Disease ☐Partial Response ☐Complete Response ☐Not Applicable ☐Unknown	Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies). 2786727
Survival Information			
54*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
55	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

#	Data Element	Entry Alternatives	Working Instructions
			member, or caregiver). 2897020 (Month), 2897022 (Day), 2897024 (Year) Do not answer if patient is deceased.
56	Date of Death	____ ____ ____ ____ ____ ____ ____ ____ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
57*	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown tumor status	Indicate whether the patient was tumor/disease free (i.e. free of the malignancy that yielded the sample submitted for the study) at the date of last contact or death. 2759550
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 question below, and the remainder of this section can be skipped.*	
58*	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 for the tumor submitted. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
59*	Date of New Tumor Event After Initial Treatment	____ ____ ____ ____ ____ ____ ____ ____ *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)
60	Type of New Tumor Event	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a locoregional recurrence or a distant metastasis of the tissue submitted; or a new primary tumor. 3119721
61	Anatomic Site of New Tumor Event	☐ Bone ☐ Retroperitoneum ☐ Lung ☐ Lymph Node(s) ☐ Liver ☐ Other, specify	Indicate the site of this new tumor event. 3108271
62	Other Anatomic 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
63	Diagnostic Evidence of Recurrence / Relapse	☐ 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
64	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
65	Additional Treatment of New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
66	Additional Treatment of New Tumor Event: Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616

Time Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form.

- Please 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.

#	Question	Entry Alternatives	Working Instructions
i*	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**: 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).
ii	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	_____ days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth. 3008233
iii	Age at Initial Diagnosis	_____ days	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657
iv	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____ days	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. Do not answer this question if the patient is deceased. 3008273
v	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____ days	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
vi	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____ days	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

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

Principal Investigator or Designee Signature | Print Name | Date