Enrollment Form
CDDP Colorectal (CRC)

Instructions: *The Enrollment Form should be completed for each CDDP 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 CDDP 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: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
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 CDDP, 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 CDDP 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	Patient 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 CDDP. 649
6	Patient 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 CDDP. 651
7*	Race	☐ American Indian or Alaska Native ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander: ☐ Not Reported ☐ 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 Islands.*

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#	Data Element	Entry Alternatives	Working Instructions
8	Ethnicity	☐ Not Hispanic or Latino: ☐ Hispanic or Latino: ☐ Not Reported ☐ 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			
9*	Has the patient had any prior cancer diagnosed?	☐ None ☐ History of Prior Malignancy ☐ History of Synchronous / Bilateral Malignancy ☐ Both History of Synchronous / Bilateral and Prior 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 for CDDP. 3382736 If this question cannot be answered because the answer is unknown, the case will be excluded from CDDP. 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 CDDP. 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.
10	Did the patient have a history of synchronous colon/rectal tumor(s) at the time of tissue collection?	☐ Yes ☐ No	Indicate whether the patient had a history of colon/rectal cancer at the time the CDDP tumor was procured. 2185953
11	Did the patient have a history of colon polyps at the time of tissue collection?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a history of colon polyps at the time the CDDP tumor was procured. 3107197
12	Were colon polyps present at the time of tissue collection?	☐ Yes ☐ No	Indicate whether the patient had colon polyps present at the time the CDDP tumor was procured. 64184
13	Number First Degree Relative Relatives with a History of Colon/ Rectal Cancer?	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ > 3 ☐ Unknown	Indicate the number of first degree relatives (parent, sibling and/or child) associated with a diagnosis of colon or rectal cancer. 3107205
14	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
15	Tobacco Smoking Year of Onset	_____ _____ _____ _____	If the patient is a current or reformed smoker, indicate the year in which the patient began smoking. 2228604
16	Tobacco Smoking Year of Quitting	_____ _____ _____ _____	If the patient is a reformed smoker, indicate the year in which the patient quit smoking. 2228610
17	Number Pack Years Smoked at Time of Diagnosis	_____ _____ _____ _____	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

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#	Data Element	Entry Alternatives	Working Instructions
18	Performance Status Scale: Eastern Cooperative Oncology Group (ECOG) at Time of Diagnosis	☐ 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
19	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 ***Not Evaluated*** ***Unknown***
CDDP Tumor Information			
Anatomic Information			
20*	Primary Site of Disease	☐ Colon	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for CDDP. 3427536
21	Region of Tumor	☐ Colon, NOS ☐ Ascending Colon ☐ Cecum ☐ Hepatic Flexure ☐ Sigmoid Colon ☐ Descending Colon ☐ Splenic Flexure ☐ Transverse Colon	Using the patient's pathology/laboratory report, select the anatomic organ sub-division of the tumor used for CDDP. 3108203
Pathologic Information			
22*	Histological Subtype	☐ Colon Adenocarcinoma ☐ Colon Mucinous Adenocarcinoma	Indicate the histologic subtype of the malignant sample submitted. 3081934
23*	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)
24	Method of Initial Pathologic Diagnosis	☐ Right Hemicolectomy ☐ Left Hemicolectomy ☐ Transverse Colectomy ☐ Sigmoid Colectomy ☐ Total Colectomy ☐ Pan-Procto Colectomy ☐ Low Anterior Colon Resection ☐ Other Surgical Resection	Provide the procedure used to initially diagnose the patient. This is the method used on the date provided above. 2757941
25	Non-nodal Tumor Deposits (TD) in Resected Specimen	☐ Yes ☐ No ☐ Unknown	Indicate the pathologic presence of tumor deposits in the pericolic fat or in adjacent mesentery away from the leading edge of the tumor submitted to CDDP. 3107051
26	Circumferential Resection Margin (CRM) (also known as radial surgical clearance)	_____ (mm)	Indicate the measured length (mm) between a malignant lesion of the colon and the nearest radial (or circumferential) border of tissue removed during surgery for the tumor submitted to CDDP. 64202
27	Vascular Invasion Present	☐ Yes ☐ No ☐ Unknown	Indicate if large vessel or venous invasion was pathologically present in the tumor specimen submitted to CDDP. 64358

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28	Lymphatic Invasion Present	☐ Yes ☐ No ☐ Unknown	Indicate if malignant cells are pathologically present in small or thin walled vessels suggesting lymphatic involvement in the tumor submitted to CDDP. 64171
29	Perineural Invasion Present	☐ Yes ☐ No ☐ Unknown	Indicate if perineural invasion or infiltration of tumor or cancer is pathologically present in tumor submitted to CDDP. 64181
30	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 CDDP. 2608702
31	Were Lymph Nodes Examined at the time of Primary Presentation?	☐ Yes ☐ No	Indicate whether any lymph nodes were examined at the time of the primary resection for the tumor submitted to CDDP. 2200396
32	Number of Lymph Nodes Examined	_____	If the patient's lymph nodes were examined, using the patient's pathology/laboratory report, indicate the number of lymph nodes examined. 3
33	Number of Lymph Nodes Positive by H&E Light Microscopy	_____	If the patient had at least one positive lymph node, using the patient's pathology/laboratory report, indicate the number of lymph nodes determined to be positive by H&E microscopy. 3086388
34	Number of Lymph Nodes Positive by IHC Keratin Staining ONLY	_____	If the patient had at least one positive lymph node, using the patient's pathology/laboratory report, indicate the number of lymph nodes determined to be positive by IHC keratin staining. 3086383
35*	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 for CDDP. 3370189
36*	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
Pathologic Information			
37	Primary Tumor: Pathologic (pT)	☐TX ☐T0 ☐Tis ☐T1 ☐T1a ☐T1b ☐T2 ☐T2a ☐T2b ☐T3 ☐T4 ☐T4a ☐T4b	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
38	Regional Lymph Nodes: Pathologic (pN)	☐ NX ☐ N0 ☐ N1 ☐ N1a ☐ N1b ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ 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
39	Distant Metastasis: 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
40	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
Clinical Information			
41	Primary Tumor: Clinical (cT)	☐TX ☐T0 ☐Tis ☐T1 ☐T1a ☐T1b ☐T2 ☐T2a ☐T2b ☐T3 ☐T4 ☐T4a ☐T4b	Using 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

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#	Data Element	Entry Alternatives	Working Instructions
42	Regional Lymph Nodes: Clinical (cN)	☐ NX ☐ N0 ☐ N1 ☐ N1a ☐ N1b ☐ N1c ☐ N2 ☐ N2a ☐ N2b ☐ N3	Using the patient's medical record, select the code for the clinical N (nodal) as defined by the American Joint Committee on Cancer (AJCC). 3440330
43	Distant Metastasis: 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
44	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
45	Preoperative / Pretreatment CEA Level	_____ (ng/ml)	Provide the carcinoembryonic antigen or CEA level (ng/ml) prior to the resection of tumor submitted to CDDP. 2716510
Molecular/Genomic Information			
46	Microsatellite Instability (Abnormal at >33% loci tested)	☐ Yes ☐ No ☐ Unknown	Indicate whether microsatellite instability was present in more than 33% of loci tested in the tumor submitted to CDDP. 3123142
47	Number of Loci Tested	_____	If microsatellite instability was identified, indicate the number of loci tested to detect recessive mutations in the tumor submitted to CDDP. 3107127
50	Number of Abnormal Loci	_____	Indicate the number of loci found to be abnormal during testing to detect microsatellite instability in the tumor submitted to CDDP. 3107129
51	Was Loss of Expression of Mismatch Repair Proteins Tested (by IHC)?	☐ Yes ☐ No ☐ Unknown	Indicate if testing was performed to identify any loss of expression in mismatch repair proteins tested by immunohistochemistry (IHC). 3123153 ***Note: If not performed, skip to the KRAS gene questions.***
52	Loss of Expression of mismatch Repair Proteins by IHC	**Gene** / **Expressed** / **Not Expressed** MLH1 ☐ ☐ MSH2 ☐ ☐ PMS2 ☐ ☐ MSH6 ☐ ☐	Indicate if any loss of expression of mismatch repair proteins by immunohistochemistry (IHC) is expressed for each of the listed genes. 3105496
53	KRAS Gene Analysis Performed	☐ Yes ☐ No ☐ Unknown	Indicate if KRAS gene analysis was performed on the tumor submitted for CDDP. ***Note: If not performed, skip to BRAF gene questions.*** 3123147
54	Mutation Found (KRAS)	☐ Yes ☐ No	If KRAS Gene Analysis was performed, indicate if KRAS Mutation was found. 2932340
55	If KRAS Mutation Identified, What Codon?	☐ 12 ☐ 61 ☐ 13 ☐ Other	If KRAS mutation was identified, indicate the specific codon. 3124509
56	BRAF Gene Analysis Performed?	☐ Yes ☐ No ☐ Unknown	Indicate if BRAF gene analysis was performed on tumor submitted for CDDP. 3123151
57	BRAF Gene Analysis Results	☐ Normal ☐ Abnormal	If BRAF gene analysis was performed, indicate the result. 3107189
Treatment Information			

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#	Data Element	Entry Alternatives	Working Instructions
58*	History of Neo-adjuvant Treatment for Sample Submitted for CDDP	☐ 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 for CDDP. 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 CDDP submitted tissue) given prior to the procurement of the sample submitted for CDDP are exclusionary.
59*	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.
60*	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.
61	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
Survival Information			
62*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
63	Date of Last Contact	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	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) Do not answer if patient is deceased.
64	Date of Death	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
65*	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 CDDP study) at the date of last contact or death. 2759550
New Tumor Event Information		*Complete the section below 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.*	
66*	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 to CDDP. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
67	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)
68	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 for CDDP; or a new primary tumor. 3119721
69	Anatomic Site of New Tumor Event	☐ Bone ☐ Retroperitoneum ☐ Lung ☐ Lymph Node(s) ☐ Liver ☐ Other, specify	Indicate the site of this new tumor event. 3108271

#	Data Element	Entry Alternatives	Working Instructions
70	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
71	Diagnostic Evidence of Recurrence / Relapse (check all that apply)	☐ Biopsy with 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
72	Additional Surgery for New Tumor Event	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new metastatic tumor event in question. 3427611
73	Additional Treatment of New Tumor Event: Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
74	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	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 (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.
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	_____	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. 3008273 Do not answer this question if the patient is deceased.
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