

NCORP Clinical Trial Screening Adult CRF: DCP-001

OPEN PROTOCOL ENROLLMENT

Please Note: The following four questions pertain specifically to DCP-001

1. Has informed consent been obtained (select only one):
 Yes (Answer 1a.) No (If NO, click Continue three times: DO NOT answer additional questions)
1 a. If Yes, was consent obtained in (select only one): writing (Answer 1 b.) verbally by phone (Answer 1 b.)
1 b. Was patient previously enrolled (select only one):
 Yes (Answer 1 c.) No (Skip to question 2.)
1 c. If yes, provide previous Patient ID #(s):

OPEN DEMOGRAPHICS

2. Ethnicity (select only one): Hispanic or Latino Not-Hispanic/Latino Not Reported Unknown
3. Gender (select only one): Male Female Unknown
4. Race (select all that apply): American Indian or Alaska Native Native Hawaiian or Other Pacific Islander
 Asian Black or African American White Not Reported Unknown

ADDITIONAL DEMOGRAPHICS

5. Screening Completion Date (ex. MM/DD/YYYY):
(Only respond if patient is being screened for a DCP Clinical Trial (Cancer Control/Prevention/CCDR)
(If you respond "Yes" on question 6, answer question 6a. If you answer "No" on question 6, skip to question 7)
6. Is the patient enrolled on a treatment clinical trial (select only one): Yes (Answer 6 a.) No (Skip to 7)
a. If the patient is enrolled on a treatment clinical trial, indicate the sponsor (select only one):
 NCI Pharma Other Sponsor

Please Note: if the patient is less than 18 yrs of age, complete questions 8-14 with the primary caregiver's status

7. Age (ex 43):
8. Marital Status (select only one): Married Never Married Separated Widowed Divorced
 Domestic Partnership
9. Rural (select only one): Yes, defined by provider shortages Yes, lack of proximity to cancer practice/center No
10. Highest Level of Education (If patient/caregiver refuses, skip to question 11) (select only one): No formal education
 Grade school Not high school graduate High school graduate (including equivalency)
 Graduate or professional degree Some college or associate degree Bachelor's degree
 Master's degree Doctoral degree or professional degree
11. Employment Status (select only one): Employed 32 hrs or more per week Employed less than 32 hrs per week
 Full-time student Part-time student Homemaker Retired Unemployed
 Only temporarily laid off, sick leave or maternity leave On medical leave Disabled Unknown
12. Household Income (select only one): < 25,000 25,000-50,000 51,000-100,000 > 100,000 Patient Refused
(If the patient does not have a cancer diagnosis, select NA and skip to question 14)
13. Was patient insured at time of diagnosis (select only one): Yes (Answer 13 b.) No (Answer 13 a.) NA (Skip to 14)
a. If no, was insurance obtained later (select only one): Yes (Answer 13 b) No (Skip to 14)
b. If yes, was the patient insured through the Affordable Care Act (select only one): Yes No
14. Current Method of Payment (select only one): Unknown Private Insurance Medicare
 Medicare and Private Insurance Managed Care/Medicare Medicaid
 Medicaid and Medicare Military or Veterans Sponsored NOS
 Veterans Sponsored Military Sponsored (including CHAMPUS & TriCare)
 State Supplemental Health Insurance Self-Pay (No Insurance)
 No Means of Payment (No Insurance) Other
15. Method of Diagnosis (what brought patient to medical attention) (select only one):
(Do not answer for patients enrolled as healthy controls or to prevention trials)
 Screening test (done without symptoms, e.g., screening mammogram)
 Symptom/mass noted by patient Symptom/mass noted by clinician
 Imaging for other indication (e.g. pre-operative CXR)

16. Comorbidity (select all that apply): Hypertension Diabetes Heart Disease Hypercholesterolemia
 Diabetic Neuropathy Other Cancer within 5 years Other Nonmalignant Systemic Disease
 None

17. Presence of genetic cancer predisposition (select only one): Yes No

ADULT PROTOCOL SELECTION

18. The patient is being screened on: (select only one): Adult Cancer Control/Prevention/CCDR Trial
 Adult Treatment Trial

19. Protocol Number (select only one):

20. Disease Code (Pertains to cancer disease code at time of diagnoses) (select only one):

(For patients without a disease code, do not answer staging questions)

21. Was cancer staged using AJCC criteria (select only one): Yes (Skip to 22) No (Answer 21 a.)

a. If no, indicate stage (If no staging used, insert NA and skip to 29):

22. Disease Stage (select only one): IV IIIC IIIB IIIA III IIB IIA II IB IA I 0

23. Clinical T Stage (select only one): T4d T4c T4b T4a T4 T3 T2 T1c T1b T1a T1 T0
 Tis (Paget's) Tis (LCIS) Tis (DCIS) Tis TX

24. Pathologic T Stage (select only one): T4d T4c T4b T4a T4 T3 T2 T1mi T1c T1b T1a T1
 Tis (Paget's) Tis (LCIS) Tis (DCIS) Tis T0 TX

25. Clinical N Stage (select only one): N3c N3b N3a N3 N2b N2a N2 N1 N0 NX

26. Pathologic N Stage (select only one): N0 N0(i+) N0 (i-) N0 (mol+) N0 (mol-) N1
 N1a N1b N1c N1mi N2 N2a N2b N3 N3a N3b N3c NX

27. Clinical M Stage (select only one): M1 cM0(i+) M0 Mx

28. Pathologic M Stage (select only one): M1 cM0(i+) M0 Mx

ADULT ELIGIBILITY CRITERIA

29. Did the patient enroll in the protocol (select only one): Yes (CRF complete) No (Answer 30)

30. If the patient did not enroll in the protocol, indicate the reason why (select only one):

- Patient did not meet trial eligibility criteria (Skip to question 31)
- Patient was eligible but declined participation (Skip to question 35)
- Patient was eligible but MD declined to offer participation (CRF complete)
- Patient was eligible but study suspended (CRF complete)

31. If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply):

- Abnormal labs/tests (e.g., LFTs, EKG, MUGA, PFTs) (Skip to question 32)
- Does not meet biomarker testing criteria (CRF complete)
- Trial prohibited concurrent disease/condition (e.g. uncontrolled HTN, diabetes, 2nd malignancy) (Skip to question 33)
- Patient unwilling/unable to comply with eligibility criteria(e.g. stop prohibitive medication) (CRF complete)
- Patient unwilling or unable to provide informed consent (e.g. language barrier, cognitive problem) (CRF complete)
- Performance status (CRF complete)
- Non-English speaking (Skip to question 34)
- Other: (Specify)

32. If the patient did not meet trial eligibility criteria related to abnormal labs/tests, indicate which labs/tests prohibited eligibility (select all that apply): Alanine Aminotransferase (ALT or SGPT), Serum Albumin, Serum Alkaline Phosphatase, Serum Aspartame Aminotransferase (AST or SGOT), Serum Beta Choriogonadotropin (BHCG), or Pregnancy Test, Spot Urine Bilirubin, Total, Serum Beta Choriogonadotropin BHCG, or Pregnancy Test, Serum Blood Urea Nitrogen (BUN), Serum Blood Urea Nitrogen (BUN)/Creatinine Ratio, Serum Calcium, Serum Cholesterol, Serum Creatinine Clearance, 24 hour, Urine Creatinine, Serum Glucose, Fasting, Serum Glucose, Serum Hematocrit, %, Blood Hemoglobin, Blood Partial Prothromboplastin Time (PTT), Blood Platelets, Blood Prothrombin Time (PT), Blood Triglycerides, Serum White Blood Cells (WBC)#, Blood
33. If the patient did not meet trial eligibility criteria related to concurrent disease/condition, indicate the disease/condition that prohibited eligibility (select all that apply): Allergies Anemia Arrhythmia Arthritis Asthma Atrial Fibrillation Blood Clots Calcium Channel Blockers Cancer Cerebrovascular Disease Congestive Vascular Disease (CRF) Connective Tissue Disorder COPD Coronary Artery Disease Diabetes Epilepsy Heart Disease Hepatitis Hypercholesterolemia Hyperlipidemia Hypertension Inflammatory Bowel Disease Kidney Disease Liver Cirrhosis (Liver Disease) Peptic Ulcer (Ulcer) Peripheral Vascular Disease Pulmonary Fibrosis Renal Insufficiency Rheumatologic Disease Smoking Ulcerative Colitis Other
34. If the patient did not meet trial eligibility criteria related to a language barrier, indicate the language spoken (select only one): Chinese Filipino French Japanese Korean Russian Spanish Vietnamese Hmong Italian Somalin Hungarian Portuguese German Other language
35. If the patient was eligible but the patient declined participation, indicate the patient-related reason why (select all that apply): No insurance Underinsured Patient preferred another trial No desire to participate in research Did not return to institution Insurance company declined coverage Excessive financial burden (e.g. lost wages, excessive out of pocket expenses/co-payments) Perceived side effects/toxicities too great Travel & transportation issues Social issues (e.g., housing, childcare, family) Other (Skip to question 36)
36. If the patient was eligible but the patient declined participation and there was "Other" selected as the patient-related reason why, indicate the reason: