# DCP Cancer Prevention Clinical Trials Network (CP-CTNet)**Protocol Submission Worksheet** v5.0

**Protocol Information Office, DCP, NCI**

**Phone:** 240-276-7130

*Submit documents electronically to:*

*nci\_dcp\_pio@mail.nih.gov*

## Section 1: Overview of Protocol Information

Lead Academic Organization Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CP-CTNet Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

DCP Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Local Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Protocol Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Protocol Principal Investigator Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
Study Phase □ 0 □ I □ I/II □ II □ N/A (for trials without phases)
Is this a multi-institutional study: □yes □ no

 *If yes, list the name of each participating site and investigators directly on the protocol title page(s).*

Will additional funding be used from other NIH funding mechanisms? □ yes □ no □ pending

 *If yes, provide the Grant No. or CA No.* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Are you receiving support from non-NCI sources (e.g., industry, American Cancer Society, etc.), for this study?

□ yes □ no □ pending

 *If yes, specify the source and use of funds.* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is this study monitored by a Data Monitoring Committee? □ yes □ no

Does the study produce Genomic Data? [Yes or No] *If yes, a Genomic Data Sharing Plan (GDSP) is applicable (policy at* [*https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/*](https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/) ).If the Genomic Data Sharing Plan was not previously submitted (e.g., with the concept), it should be submitted now. *The  Institutional Certifications (provisional and final) can be accessed at* [*https://osp.od.nih.gov/scientific-sharing/institutional-certifications/*](https://osp.od.nih.gov/scientific-sharing/institutional-certifications/) *and will be due at protocol submission (provisional certification) and 30 days post CIRB approval (final certification). Note that final DCP approval will not be delayed for receipt of Final Institutional Certification.*

## Section 2: Purpose of Submission

|  |  |  |
| --- | --- | --- |
| □ First submission to DCP PIO | NCI Version Date: | Version Number: |
| □ Revised Protocol (changes made prior to NCI approval) | NCI Version Date: | Version Number: |
| □ Amendment to Protocol (changes made after NCI approval) | NCI Version Date: | Version Number: |
| □ Other, specify |  | NCI Version Date: | Version Number: |

Is this document submitted in response to a DCP review? □ yes □ no

*If yes, date of DCP review letter:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section 3a: Study Agent(s)

|  |  |  |  |
| --- | --- | --- | --- |
| Agent Name: | Request for DCP Supplied? | CAS Registry No. *(if known)* | Dose and Schedule |
|  |  □ yes □ no |  |  |
|  |  □ yes □ no |  |  |
|  |  □ yes □ no |  |  |
|  |  □ yes □ no |  |  |

Will this study be conducted under an IND? □ yes □ no □ unknown

*If yes, IND Number:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *IND sponsor: □ DCP □ Investigator (name):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *□ Pharmaceutical Company (name):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section 3b: Study Device(s)

Is an IDE required? 🞎 Yes 🞎 No

| Device Brand Name | Device Common Name | Is the device investigational? | IDE Number  | IDE Holder | IDE Exempt? |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

## Section 4a: Accrual Information

|  |  |  |
| --- | --- | --- |
| Projected Study Start Date: | Planned Sample Size (#Evaluable):Target Enrollment: (Maximum #): | Projected Monthly Accrual Rate:Projected completion date of accrual: |
| Expected # Subjects/Site: | # Case Report Forms per Participant: | Estimated # Participants Screened: |

The Study Dates below must be the same dates entered in eRA Commons (HSS) and CT.gov:

Actual Study Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Actual Study State Date Definition: The date the first participant was enrolled.***

Anticipated Primary Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Primary Completion Date Definition: The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated****.*

Actual Primary Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Anticipated Study Completion Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Section 4b: Required Gender and Minority Accrual Estimates

***Enter actual estimates, whole numbers only (percentages, fractions, or decimals are not acceptable). The total provided for Ethnicity must match the total given for Race.***

### Planned Accrual EstimatesDOMESTIC PLANNED ENROLLMENT REPORT

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Female** (*not* Hispanic or Latino) | **Male** (*not* Hispanic or Latino) | **Female** (Hispanic or Latino) | **Male** (Hispanic or Latino) | **TOTAL** |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White  |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| Total |  |  |  |  |  |

### INTERNATIONAL (including Canadian participants) PLANNED ENROLLMENT REPORT

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Racial Categories** | **Female** (*not* Hispanic or Latino) | **Male** (*not* Hispanic or Latino) | **Female** (Hispanic or Latino) | **Male** (Hispanic or Latino) | **TOTAL** |
| American Indian/Alaska Native |  |  |  |  |  |
| Asian |  |  |  |  |  |
| Native Hawaiian or Other Pacific Islander |  |  |  |  |  |
| Black or African American |  |  |  |  |  |
| White  |  |  |  |  |  |
| More Than One Race |  |  |  |  |  |
| Total |  |  |  |  |  |

## Section 5: Treatment Assignment Code Information

Please include agent name, dose, route, duration, and schedule (i.e., Cure-all 150mg PO QD x 4 weeks, every 28 days).

|  | **Treatment Assignment Code** | **Description** |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Section 6: Name and Title of Person Completing Worksheet

|  |  |
| --- | --- |
| Name: | Title: |
| Email: | Telephone: | Date: |