

Division of Cancer Prevention

CP-CTNet CONCEPT PROPOSAL SUBMISSION FORM

Instructions for filling out this form (please delete all italicized instructions prior to submission):

- Please complete **all** sections and do not alter the form*
- Please use no smaller than 10-point font*
- Please limit concept to 10 pages (excluding the references section and supplementary documentation)*

I. ADMINISTRATIVE INFORMATION

A. **Submission Date:**

B. **CP-CTNet Lead Academic Organization Name:**

NCI Institution Code:

C. **LAO PI:**

Email Address:

Phone:

D. **Title of Proposal:**

E. **Study PI:**

Email Address:

Phone:

F. **IND support anticipated? [Yes or No] IND Holder: DCP _____ Investigator _____ Other _____**

G. **Are there other funding sources? [Yes or No]**

- If yes, is this Concept supported by a federally funded grant? [Yes or No]
- If yes, enter grant number: [Enter grant number]
- Is this study supported by a non-federally funded grant (ACS, foundations, etc.)? [Yes or No] Please Specify:

H. **Is there any related Financial Conflict of Interest (FCOI)**

((<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-210.html>)? [Yes or No]

- If yes, please specify the conflict here _____

II. SCIENTIFIC INFORMATION & STUDY DESIGN

A. **Agent(s):**

B. **Agent Supplier** (if a pharmaceutical partner is involved, a letter of support should be provided):

C. **Target Organ:**

D. **Study Population Description:**

E. **Phase of Study:**

F. **Rationale/Hypothesis:**

G. **Objectives (Specify one primary objective and a prioritized list of secondary objectives):**

H. **Study Plan:**

I. **Laboratory Correlates, Biomarkers:**

J. **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/>). The Investigator's Genomic Data Sharing Plan (GDSP) should be submitted with the concept (template at <https://datascience.cancer.gov/sites/default/files/2019-02/nci-dsp.pdf>). The Institutional Certifications (provisional and final) can be accessed at <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.

K. Endpoints/Statistical Considerations:

- L. **If an agent is proposed that is not DCP supplied, describe the next steps in agent development should this clinical trial have positive results.**

III. STRUCTURE, FACILITIES, PRIOR EXPERIENCE

NOTE: If a proposed participating institution is not on any LAO's roster, it will need to be added prior to protocol submission.

A. Describe the proposed organizational structure including:

- Affiliate Organizations (AOs), including NCI Institution Codes: On Roster: [Yes or No]
- Key Personnel (*Letter of Commitment from study PI only*):
- Roles and Responsibilities:

B. Detail the qualifications and experience of key personnel. Include academic credentials, experience with biomarkers, related agents, and similar cohorts.

C. Describe facilities for recruitment, study conduct and biomarker analysis.

IV. RECRUITMENT CAPABILITY

A. Planned duration of accrual:

B. Expected accrual rate per month:

C. Proposed Start Date: / / End Date: / /

D. Number of expected participants registered per month per site:

E. Describe accrual capabilities, including inclusion of women and minorities, for each site:

F. List previous similar trials that document the accrual capabilities of the proposed investigators:

- Trial Name, Trial Dates, Agent, Cohort, Primary Endpoint [*Enter the average # of participants who started agent /month*]

G. List ongoing or planned clinical trials from any source (pharmaceutical, government grant or contract, etc.) that might compete for the same cohort proposed in the Concept including relevant non-prevention trials. Provide information on impact on the study proposed in this Concept.

- Trial Name, Trial Dates, Agent, Cohort, Primary Endpoint [*Enter study*]

V. REFERENCES

NOTE: References do not count towards the 10-page limit.