Division of Cancer Prevention

CP-CTNet CONCEPT PROPOSAL SUBMISSION FORM

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

1. *Please complete **all** sections and do not alter the form*
2. *Please use no smaller than 10-point font*
3. *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*

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submission (provisional certification) and 30 days post CIRB approval (final certification). Note that final DCP approval <u>will not</u> 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 <u>registered</u> per month <u>per site</u>:**

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.

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