# Division of Cancer Prevention

# CP-CTNet RAPID RESPONSE RESTRICTED FUND

# BIOMARKER DEVELOPMENT CONCEPT PROPOSAL SUBMISSION FORM AND BUDGET INSTRUCTIONS

***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 5 pages (excluding the references section and supplementary documentation)*

# I. ADMINISTRATIVE INFORMATION

1. **Submission Date:**
2. **CP-CTNet Lead Academic Organization Name: NCI Institution Code:**
3. **LAO PI: Email Address: Phone:**
4. **Title of Proposal:**
5. **Study PI: Email Address: Phone:**

# II. SCIENTIFIC INFORMATION & STUDY DESIGN

1. **Biomarker to be Studied, Rationale, and Hypothesis:**
2. **Background and Preliminary Data:**
3. **Study Design and Methodology:**
4. **Sample Size:**
5. **Statistical Considerations:**
6. **Access to Samples and Study Duration:**
7. **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/) **).** *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*](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/*](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.*

# III. STRUCTURE, FACILITIES, PRIOR EXPERIENCE

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

1. **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:

1. **Detail the qualifications and experience of key personnel. Include academic credentials, experience with biomarkers analysis, related agents, and similar cohorts.**
2. **Describe facilities for conducting and interpreting the biomarker analysis.**

**V. REFERENCES**

***NOTE: References do not count towards the 5-page limit.***

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**BIOMARKER DEVELOPMENT CONCEPT BUDGET INSTRUCTIONS**

***Submit a separate pdf to include a cover letter summarizing the total costs needed, anticipated duration of the study, and pages 4, 5 and the checklist form PHS 398. Adequate budget justification is needed for direct costs. Clearly indicate in the cover letter the total amount that is requested for each applicable fiscal year****.*

# <https://grants.nih.gov/grants/funding/phs398/phs398.html>