NCI Community Oncology Research Program

A program of the National Cancer Institute of the National Institutes of Health

**Guidelines for NCORP CPSC Study Concept Submission to the NCI Cancer Prevention Steering Committee (CPSC)**

The CPSC concept submission allows the investigators to present a concise summary of their proposed research plan.

The concept proposal should:

- Present how the research is focused on an important cancer prevention, screening or surveillance question and will provide information or lead to an improvement in cancer outcomes
- Present the scientific rationale and relevance of the proposed study
- Present the study hypothesis and the study objectives/endpoints
- Present the rationale/evidence/validation supporting the choice of the intervention, endpoints/biomarkers, and disease site.
- Provide a general overview of the study design and methodology
- Provide evidence of the feasibility to recruit the population needed to meet the study objectives
- Describe the statistical methods and their justification including estimate of effect size and justification for sample size that will answer the primary and secondary objectives
- For screening and surveillance studies, the proposal should discuss:
    1. the management of positive tests and how cancer status will be established during follow-up,
    2. how technology changes over time will affect trial relevance and recruitment,
    3. potential financial/payment issues for non-standard studies.
- The concept needs to complete appropriate internal processes at the Research Base before submission to the NCI Division of Cancer Prevention (DCP) Protocol Information Office (PIO).

**Concept proposals must be:**

- **11-point font**
- **Single spaced**
- **1" page margins**
- **No longer than 10 pages** (excluding title page, references, and appendix)

**NCORP CPSC Concept Proposal Requirements**

1. **Title page**
   The title page should include the following elements:
   - Title of study
   - Date of document
   - Local concept number (i.e., institution or group number)
   - Study chair who will be responsible for the study, including his or her name, institution, address, phone and fax numbers, and e-mail address
   - Full name of research base submitting the study

2. **Background** *(recommended maximum 3 pages)*
   The background provides the reviewers with basic information to establish the scientific rationale and justification for the proposed study and determine that the study objectives will provide information that will/may lead to improved cancer prevention outcomes.

   The background should include:
   - Focused review of relevant preclinical and clinical literature (with citations) addressing the problem to be studied
   - For screening and surveillance studies, review of the literature on the impact of the proposed intervention on the target populations mortality, morbidity, QOL and economic endpoints
   - Brief summary of any pilot or preliminary data (as available; expected for most concepts)
   - Clear statement of the unaddressed questions this study addresses
   - Clear statement of the relevance of study objectives to the overall goal of cancer prevention.

   *Inclusion of a conceptual model, illustrating the causal relationships underpinning the hypothesis and the potential impact of the intervention (or new insights) is recommended.*

3. **Study Objective(s)** *(recommended maximum 1 page)*
   Clearly state hypothesis, primary objectives, secondary objectives, and endpoints. All objectives must have endpoints and vice versa. The primary endpoint should drive the projected sample size with a description of the study's power to observe a statistically and clinically meaningful difference. Additionally, estimates of secondary endpoints' power to illuminate key mechanisms, side effects, or other ancillary effects should be shared. Discuss the justification for each of the proposed endpoints as well as their potential impact on cancer prevention research or on the practice of cancer prevention.

4. **Study Methods** *(recommended maximum 4 pages)*
   The study methods section outlines how the objectives will be met, briefly justifies the selection of the proposed study design, and should include succinct descriptions and justifications for:
   - Study design
   - Both control and active intervention(s) and intervention plan (where applicable, including dose, duration, frequency, route)
   - Study population and eligibility criteria

- Schedule and Timing of data collection
- Primary outcome measure(s) (with QC plans if laboratory based)
- Justification of effect size
- Sample size and power calculations for the primary study endpoint
- Preliminary statistical analysis plan for the primary and secondary endpoint(s)

The concept does not need to include detailed plan to address bias; however, identification of likely sources of bias and disclosure of approaches to mitigate such biases is expected.

**4.A. If a drug treatment trial:**

1. Discuss the mechanism and the underlying hypothesis for use as a cancer prevention agent.
2. Discuss existing pilot trials with the agent and the side effect profile.
3. Provide dose, schedule and duration of the intervention along with justification
4. Identify the drug(s) (and placebo, if relevant) provider, if determined.
5. Specify if the drug(s) is currently available to the research base for the trial.
6. If drug(s) are being requested from DCP, provide a listing of each agent by name and NSC number.
7. State whether it is expected that the study will be conducted under an IND.

**4.B. If a natural product trial:**

1. Discuss the proposed mechanism of the product and the underlying hypothesis for use as a cancer prevention agent.
2. Discuss the existing pilot trials with the product and the anticipated side effect profile.
3. Give dose, schedule and duration for the proposed intervention along with justification.
4. Specify probable manufacturer of the product to be used. Include history of company's involvement in clinical trials.
5. Provide information on quality control, shelf life, lot-to-lot variability.
6. Discuss availability of agent in the marketplace.

**4.C. If a behavioral intervention trial:**

1. Discuss the underlying hypothesis and proposed mechanism of the intervention.
2. Discuss pilot trials with the behavioral intervention, the strength of evidence and an estimate of effect size.
3. Provide the "dose" of the intervention (frequency, engagement, time, schedule) and justification for their choice.
4. Discuss plans for a control arm, the monitoring of compliance of the intervention, and plans for potential advances in technology.
5. Identify the provider /interventionist / vender of the intervention (e.g., website, mobile device manufacturer, motivational interviewing experts/protocols, etc.).
6. Specify if the behavioral intervention is currently available and in use at NCORP sites.

7. Discuss the training needed for the successful introduction of the intervention to NCORP sites.

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**4.D. If a trial has a biomarker as a primary or secondary endpoint:**

1. Discuss the feasibility and experience of obtaining the proposed sample collection or tissue biopsies for biomarker analysis.
2. Discuss the known studies of the biomarker(s) in normal, pre-malignant and malignant tissue.
3. Discuss the available studies to suggest that the endpoints studied, and their modification fulfill the role as an "intermediate endpoint" of cancer or cancer risk.
4. Discuss where the analysis of the biomarker(s) will be completed (single or central lab) and the requirements for shipping samples if needed.
5. Discuss the QC of the analytic methods.
6. prespecify cutpoint(s) for biomarker analyses and rationale for those cutpoints

**4.E. Patient Advocate Summary** (to be included as an addendum to the concept)

1. Provide a clear outline of the intervention and a schema in "lay" terms,
2. Provide an explanation on why the trial is being proposed and how it will advance cancer prevention, screening or surveillance.
3. Provide a plan to accrue minority and underserved populations.
4. Provide a discussion of the risks/benefits of the trial, explaining the possible risks if a patient participates and their possible benefits.
5. Explain the alternatives if they choose not to participate.

**5. Feasibility** *(recommended maximum 2 pages)*

This section should demonstrate that the proposed study can be completed in a timely manner through the NCORP network.

The feasibility section should include:

- Previous experience and pilot studies conducted by the investigator/research base or published data to support the anticipated accrual rate of the specific proposed target population, including the level of interest expressed by surveyed NCORP components and subcomponents. Whenever prior/preliminary data are available, they should be included.
- Address the compatibility of protocol complexity with NCORP resources, including a description of the time commitment of patients/participants, research staff, providers, or other study personnel.
- Outline of how the study will address diversity issues related to patients, non-patient participants, and organizations.
- Information on the anticipated availability of organizational, financial and other administrative data, if relevant.
- Statement as to whether the protocol requires resources beyond those available through NCORP.

6. **References** *(no page limit)*
   Bibliography and references cited.

7. **Appendix** *(maximum 4 additional pages)*
   Up to 4 additional pages of materials (to include the patient advocate summary) that are integrated with and complementary to the text may be included in an appendix.

   Appropriate types of appendix materials include:
   - Study schema
   - Conceptual models
   - Data flow diagrams
   - Data collection timelines
   - Tables demonstrating the relationship between goals, objectives, endpoints, and measures
   - Patient Advocate Summary

   *Inclusion of consent forms, case report forms, or data collection instruments is not recommended.*

**Submission to DCP Protocol Information Office**
NCORP CPSC concepts proposals should be submitted electronically by the study chair or their designee to NCI_DCP_PIO@mail.nih.gov.

Website: https://prevention.cancer.gov/clinical-trials/clinical-trials-management/protocol-information-office