NCI Community Oncology Research Program

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

Template for NCORP CCDR Study Concept Submission to the NCI Cancer Care Delivery Research Steering Committee (CCDR SC)

The concept is the investigators' opportunity to demonstrate that the proposed research answers an important cancer care delivery research[1] question, that the research will lead to improved clinical outcomes and patient well-being, that the general methods and analysis are appropriate to evaluate the research question, and that the research is feasible.

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).

The purposes of the concept proposal are to:

- Provide basic information to establish the scientific rationale for the proposed study
- Describe the value of the study in producing information that will improve cancer care delivery and clinical outcomes and patient well-being
- Propose clear study objectives and hypotheses
- Provide a general overview of the study design and methodology
- Describe the statistical methods to address the primary question
- Provide evidence of the feasibility of recruiting to and conducting a successful study

Concept proposals must be:

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

[1] *Cancer care delivery research is a multidisciplinary science that seeks to improve clinical outcomes and patient well-being by intervening on patient, clinician, and organizational factors that influence care delivery.*

NCORP CCDR Concept Proposal Requirements

I. 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

II. Background *(recommended maximum 3 pages)*

The background provides the reviewers with basic information to establish the scientific rationale for the proposed study and to assess the value of the study in producing information that will improve cancer care delivery and patient outcomes.

The background should include:

- Focused review of relevant literature with citations demonstrating the significance of the problem to be studied
- Clear statement of the gap this study will address
- Brief summary of any pilot or preliminary data (if available)
- Clear statement of the study objectives and hypothesis and how the proposed research will improve cancer care delivery and patient outcomes

Inclusion of a conceptual model, illustrating the causal relationships underpinning the hypothesis and how the intervention or new information is expected to result in change, is recommended.

III. Study Objective(s) *(recommended maximum 1 page)*

Clearly state hypothesis, primary objectives, secondary objectives, and endpoints. All objectives must have endpoints and vice versa.

IV. Study Methods *(recommended maximum 4 pages)*

The study methods section outlines how the objectives will be met, briefly justifies the selection of study design, and should include:

- Succinct description of the study design
- Succinct description of the intervention plan (if any)
- Study population and eligibility criteria (including patient and nonpatient participants)
- Outcome measures for primary endpoints
- Timing of data collection
- Sample size and power calculations for the primary study endpoint(s)
- Preliminary analysis plan for the primary endpoint(s)

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

If the proposed study is complex, *consider including graphic aids, such as a diagram of study flow or a table to clarify the relationship between objectives, endpoints, and measure*s.

V. Feasibility *(recommended maximum 2 pages)*
This section should demonstrate that the proposed study can be completed effectively and in a timely manner through the NCORP network.

The feasibility section should include:

- Data to support the anticipated accrual rate for the proposed target population and the level of interest expressed by the NCORP components and subcomponents
- Outline of how the study will address diversity issues related to patients, nonpatient participants, and organizations
- Description of the time commitment of patients, research staff, providers, or other study participants
- Information on the anticipated availability of organizational, financial and other administrative data, as relevant
- Previous experience of the investigators relevant to successful conduct of the study
- Whether the protocol requires resources beyond those available through NCORP; e.g., the study will involve costs for implementation of an intervention or activities in addition to data collection and management *(if applicable, briefly describe any such costs and indicate the source of additional funding)*

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

VII. Appendix *(maximum 3 additional pages)*
Up to 3 additional pages of materials 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

Concepts do not need to include consent forms or case report forms, although they should include (as Appendices) all of the questionnaires or measurement instruments to be used for the primary endpoint.

Submission to DCP Protocol Information Office
NCORP CCDR 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