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

NOTE: Concepts must complete required internal processes at the responsible Research Base before being formally submitted to the NCI Division of Cancer Prevention Protocol Information Office at NCI_DCP_PIO@mail.nih.gov. NCI has no role in those processes.

Purpose of the Concept

The study concept is the investigators' opportunity to demonstrate that the proposed research answers an important cancer care delivery research question that will lead to improved clinical outcomes and patient well-being. In addition, investigators are asked to establish that the research methods are feasible and appropriate to address the research question.

Purpose of the Review

The role of the CCDR SC is to determine whether a concept has sufficient merit to proceed to the development of a full protocol. The SC makes this determination based on an assessment of the following criteria:

- Consistency with the Goals of CCDR
- Potential Impact on Clinical Outcomes and Patient Well-Being
- Rationale for Study Aims
- Rigor of Study Approach
- Feasibility of Conducting the Study in the NCORP Network

Concept Formatting Requirements

Concepts must be no longer than 10 pages, excluding the title page, references, and appendix. The maximum allowable page margin is one inch on all sides. The font should be 11 point or larger, with single spacing.

The Title Page must include, but is not limited to, these elements:

- Title of study
- Date of document
- Name of the Research Base submitting the concept and the assigned concept number
- Name of a single Study Chair who will be responsible for the study, along with the Chair's institution, address, phone and fax numbers, and e-mail address

The NCORP Cancer Care Delivery Document Submission Worksheet must be included with all submissions.

Concept Content

Applicants are strongly encouraged to follow the outline below, which is designed to help investigators address the review criteria within the formatting requirements.

I. Background (*recommended maximum 3 pages*) – Provide a focused review of relevant literature, addressing the following considerations:

- Rationale for proposed study based on current state of clinical and scientific knowledge, including the gap(s) of most interest
- Fit with the NCORP definition of CCDR, which is to improve clinical outcomes and patient well-being by intervening on patient, clinician, and organizational factors that influence care delivery (concepts proposing observational studies should address how the results will lead to identification of modifiable factors that could be the target of future interventions)
- Potential for the results to have a meaningful impact, including relevance of the study to challenges faced by the diverse groups of patients, clinicians, and organizations in NCORP Community Sites and Minority/Underserved Community Sites
- Brief summary of preliminary data, if any, that provide justification for the study

Inclusion of a legible and easily understood conceptual figure illustrating the factors of interest, their relationship, and how the results will improve care delivery may be useful.

II. Study Objective(s) (*recommended maximum 1 page*) – Clearly state a single primary objective with a single primary endpoint and explain how they are consistent with the rationale provided in the Background. Briefly state any secondary and exploratory aims, and their accompanying endpoints. Hypotheses should be included if possible, particularly for the primary aim.

III. Study Methods *(recommended maximum 4 pages)* – Outline how the aims will be met, including succinct descriptions of and rationale for the:

- Study design
- Study population, * including key eligibility criteria and an overview of recruitment and retention plans, incorporating if relevant a description of efforts to engage health disparities populations and low resource clinical settings
- Intervention plan
- Primary endpoint measure and validation (per item VI below, include the specific measure in the Appendix)
- Timing of data collection (including all endpoints)
- Plans for stratified sampling or randomization of individuals or clusters (if any)
- Sample size and power calculations for the primary endpoint
- Preliminary analysis plan for the primary endpoint
- Identification of major potential challenges and mitigation approaches (examples include but are not limited to recruitment strategies intended to reduce participation bias; assessment of intervention fidelity to capture unintended local adaptations; and strategies to prevent or analytically address missing data that could reduce study power or bias the study results)

If the proposed study is complex, consider including explanatory figure(s), such as a study schema, diagram of the intervention components, or a table clarifying the relationships between study objectives, endpoints, and measures.

IV. Feasibility (*recommended maximum 2 pages)* – Provide an initial assessment of potential barriers to conducting the study, and strategies to address those barriers, addressing considerations such as:

- Level of interest expressed by NCORP Community Sites and Minority/Underserved Community Sites, including a brief description of the approach used to communicate with Sites about the concept and any adjustments made based on their feedback

* "study population" refers to any source from which data will be collected, typically patients, nonpatient individual participants such as clinicians, organizations, or a combination of those three

- Potential participant burden (note that "participant" refers to any source from which data will be collected, typically patients, nonpatient individual participants such as clinicians, organizations, or a combination of those three)

- Clinician, staff and organizational effort required to complete the study, including recruitment, data collection, and intervention delivery

- Availability, quality, and accessibility of routinely collected clinical and other data to be used in the study (if any)

- Fit of study, particularly an intervention, within clinical workflow

- Results from pilot or other studies that provide evidence of feasibility or support sample size estimates

- Prior relevant experience of the study team

V. References (*no page limit*) – Use any common citation style.

VI. Appendix (*no page limit*) – The Appendix is limited to the primary endpoint measure (e.g., survey questions); no other information should be included. The primary endpoint measure should be provided only if it has been published. Unpublished measures should be described within the 10 pages of the concept.