NIH NATIONAL CANCER INSTITUTE

NCI Community Oncology Research Program (NCORP)

Concept Evaluation Forms (Statistical)

GUIDELINES FOR CONCEPT EVALUATORS

You have been asked to provide an evaluation of a cancer care delivery research NCI Community Oncology Research Program (NCORP) concept proposal. Your responsibilities as an evaluator consist of reviewing the concept, submitting this form with your written comments, and participating in a teleconference to discuss the concept and your review.

A concept is the investigator's statement demonstrating that the proposed research answers an important question, will result in new and generalizable knowledge ultimately leading to improved delivery of cancer care, the methods and analysis are appropriate to address the research question(s), and that the research is feasible. The primary purpose of the review is to determine whether the concept provides convincing evidence that the study can achieve these goals.

Please keep the definition of Cancer Care Delivery Research (CCDR) in mind as you complete this evaluation: **CCDR 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.**

The purpose of a concept proposal is to allow the review panel to determine whether the concept has sufficient merit to proceed to the development of a full protocol. Thus, the concept form submitted by the proposed investigators will not have the extensive detail regarding the study design or statistical analyses such as you would find in a complete protocol.

Concepts are limited to no more than 10 pages. A restriction on page length means that many details cannot be included in the concept; however, investigators are expected to include all key information needed to adequately evaluate the study.

Please keep the distinctions between a concept and a full protocol in mind when you are completing your review and writing your critique.

Please see next page for Concept Evaluation Form

EXAMPLE STATISTICAL REVIEW FORM

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CONCEPT EVALUATION FORM (Statistical)

It is understood that by agreeing to assist in this evaluation, you have no conflicts of interest with this concept. All unpublished information, reports and discussions are strictly confidential.

Information

Evaluator's Name:

Date of Evaluation Meeting:

Concept ID Number and Title:

Concept PI:

A. Detailed Assessment

Rating of Specific Criteria

Rigor of Study Approach Choose an item

EXAMPLE STATISTICAL REVIEW FORM

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1. Rigor of Study Approach

- Does the study design as outlined offer a rigorous approach to addressing the study hypotheses, objectives and primary endpoint, in particular:

A. Study Design

- Will the proposed design allow the investigators to meet their primary objective?
- Are the proposed primary endpoints aligned with the primary study objective?
- Are the proposed measures scientifically valid and consistent with the primary endpoint?

B. Study Methodology

- Is the study methodology appropriate and sufficient to achieving the study objectives?
- Does the concept clearly define the population of interest and is that population consistent with the study hypothesis and objectives?
- Is the data collection plan, including staff training, clearly outlines and likely to generate high quality data?
- Are there initial plans to minimize the most likely sources of bias, such as missing data, observer bias, or recall bias?

EXAMPLE STATISTICAL REVIEW FORM

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C. Analytic Plan and Sample Size

- Does the concept include an initial analysis plan consistent with the primary objective?
- Are the sample size and sampling plan appropriate and justified?

Other Statistical Concerns

[Optional] Advocates may choose to complete any or all of the following questions (#2-5):

*If you choose not to answer the optional ratings, click **here** to be taken to Parts B and C.*

Rating of Specific Criteria

Consistent with Goals of CCDR	Choose an item
Potential to Improve Clinical Outcomes	Choose an item
Sufficient Rationale for Study Aims	Choose an item
Feasibility in Community Network	Choose an item

EXAMPLE STATISTICAL REVIEW FORM

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2. Consistent with Goals of CCDR

- Does the focus of this concept fit the definition of CCDR (intervening on patient, clinician, and organizational factors that influence care delivery)?

3. Potential Impact on Clinical Outcomes

- Are the study results likely to lead to a meaningful impact on clinical outcomes and patient well-being?

4. Sufficient Rationale for Study Aims

- Does the description of the current state of knowledge provide a strong rationale for the study?
- Are the study hypotheses and objectives clear and consistent with the scientific rationale?
- Is the intervention appropriate for the study objective?

5. Feasibility of Conducting the Study in the NCORP Network

- Do you perceive any barriers to conducting this study in the NCORP network/community setting? If so, how might they be addressed?
- How likely are providers and/or organizations to enroll in the study? Would it fit into clinical workflow?
- How sustainable is this study/intervention?

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B. Please list 1 specific question you would like the CCDR Steering Committee to consider asking the Study PI(s) during the review call.

The CCDR SC Chairs will review the questions submitted by evaluators and a list of Preliminary Questions will be sent to the Study PIs ahead of the review call. Please note that your submitted questions will be anonymized and during the review call the questions will be directed to the Study PIs by the CCDR SC Co-chairs.

Question:

Optional: Other Comments, Including Suggestions for the Protocol

C. Evaluator Recommendation to the Steering Committee (Check One):

☐ Approve

The Steering Committee approves the concept and does not need to evaluate a revised concept. The research base can begin to develop the protocol. Certain concept details and minor modifications will be negotiated with the NCI. Major comments from the Steering Committee reviewers may be included in the approval letter sent by DCCPS/DCP to the investigators.

☐ Pending

The Committee had several concerns regarding the study as explained in the Consensus Evaluation. Given these concerns, the Committee did not approve the concept. Instead, the Committee gave the concept a status of "pending" to indicate that approval of the concept might be warranted if the investigators can satisfactorily address, within 60 days, the Committee's concerns and suggestions regarding changes to the concept as outlined in the Consensus Evaluation.

☐ Disapprove

Concepts should be disapproved when the Steering Committee has determined that the concept as written is not feasible and/or lacks adequate scientific merit, and that the changes necessary to address these concerns would result in a study that is substantially different from the study proposed. A future concept from the investigators for such a "substantially different" study would be accepted as a new concept for review.