EXAMPLE ADVOCATE REVIEW FORM

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NCI Community Oncology Research Program (NCORP)

Concept Evaluation Forms (Advocate)

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

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CONCEPT EVALUATION FORM (Advocate)

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 All unpublished information, reports and discussions are strictly confidential.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

Consistent with Goals of CCDR — Choose an item

Potential to Improve Clinical Outcomes — Choose an item

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1. 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)?

2. Potential to Improve Clinical Outcomes

- How relevant is this study to challenges that patients experience in the delivery of cancer care?

3. Feasibility of Recruiting and Retaining Patients

Please rate the level of patient and provider/clinic/site burden associated with conducting this study. If selecting "Moderate" or "High" ratings, please explain and suggest ways to minimize the burden on the patients and/or sites.

Rating of Burden

Patient Burden Choose an item

Provider/clinic/site burden Choose an item

- What aspect(s) of this study might encourage or discourage participant enrollment? Please identify any specific barriers or challenges, and if possible, suggest alternatives or solutions.

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- Are participants likely to complete all activities in this study? Please identify any specific barriers or challenges and, if possible, suggest alternatives or solutions.

[Optional] Advocates may choose to complete any or all of the following questions (#4-6):

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

Rating of Specific Criteria

Sufficient Rationale for Specific Aims	Choose an item
Rigor of Study Approach	Choose an item
Feasibility in Community Network	Choose an item

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?

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5. 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:
  - Can the design credibly answer the study objective?
  - Is the target population(s) appropriate?
  - Is the proposed primary endpoint aligned with the primary study objective?
  - Are the proposed measures scientifically valid and consistent with the primary endpoint?

6. 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.