GUIDELINES FOR CONCEPT EVALUATORS

You have been asked to provide an evaluation of a symptom management/quality of life Community Clinical Oncology Program (CCOP) 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.

A concept is the investigator's statement demonstrating that the proposed research answers an important question that will lead to improved clinical care, that the methods and analysis are appropriate to evaluate the research question, 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.

The concept proposal describes a research study systematically so that the review can 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, recruitment, or statistical analyses, for example, as you would find in a complete protocol. Concept review is designed to save investigators time in preparing a complete study protocol on research ideas that are not judged to have sufficient background information to determine the scientific basis for the study, may not be feasible to complete in a community setting, and/or are not a major priority of the Division of Cancer Prevention (DCP)/National Cancer Institute (NCI) given budgetary restrictions and competing research concepts/protocols.

What a concept must contain, and what you are to evaluate the concept on, are the following criteria:

- rationale for the study and its scientific basis
- study's clinical value
- objectives and hypotheses
- appropriateness of the planned study design and analysis plan
- feasibility of conducting the proposed study in multisite, cooperative group institutions and community medical practices.

Concepts are limited to no more than 10 pages, with a recommendation to limit the submission to 5-7 pages. This is to keep the focus of the concept on the scientific basis, the study objectives and hypotheses, and basics of the proposed study design. A restriction on page length means that many details cannot be included in the concept. For example, most concepts will not require text describing the pharmacodynamics of the agent. However, investigators are expected to include important information about an intervention, such as a brief description of the rationale for the dose and schedule, along with documentation regarding availability of the agent for the proposed 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

CONCEPT EVALUATION FORM

After completing this form, please save and attach it to an email message to Yvette Ortiz (yortiz@emmes.com) referencing the concept number and title. Your written comments will be viewed by other evaluators of this concept. Please **submit** your evaluation **by 5 p.m. Eastern Time on the Tuesday prior to the conference call** (sooner if possible) to allow the Steering Committee members time to read it.

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.

Evaluator's Name:

Date of Evaluation Meeting:

Concept ID Number and Title:

Concept PI:

1. Scientific Rationale (e.g., How well do the descriptions of current state of knowledge; and adequacy of preclinical and clinical data support the rationale for the study?)

2. Value of the Research Question in Contributing to Overall Patient Management (Is the study likely to make a meaningful contribution to patient care or survivorship? Is the research question novel? Is the research question duplicative and/or being appropriately addressed in other research forums? Are the interventions being tested generally applicable to substantial numbers of cancer patients and/or survivors?)

3. Study Objectives and Hypotheses (Are the study objectives clear, appropriate, and measurable?)

4. Study Methodology (including study design, statistical design/QOL measures/etc.) (Are the study design and intervention plan [study sample, eligibility criteria, outcome measures, timing of data collection, sample size, and power calculations for the primary study outcomes] appropriate for providing information required for addressing the study objectives and hypotheses?)

5. Feasibility of Conducting the Study in the CCOP Network (Do previous experience or evidence of the investigators' ability to conduct the intervention support the likelihood of achieving the proposed accrual rates and study duration as specified in the Concept? Have the investigators addressed the issue of compatibility of the intervention and CCOP experience/resources? Is there a source of funding for costs other than data management [e.g. study drug, lab work or behavioral intervention])?

6. Concept Recommendation (Approval, Revise and Resubmit, or Disapproval)

Concept recommendation:

1) Approval with or without recommendations: 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 DCP to the investigators.

2) Revise and Resubmit: The Steering Committee has determined that the concept requires additional information or has design issues that can be addressed within the next two to three months and asks that the investigators to address that information in a revised concept. "Revise and Resubmit" can also be used to indicate that the Steering Committee has determined that the concept **as written** lacks adequate scientific merit or has problems with feasibility, but that relatively modest changes to the study design might address these concerns. The deadline for resubmission will be included in the Consensus Evaluation letter sent to the Research Base/Study PI.

3) Disapproval: Concepts should be disapproved when the SC has determined that the concept as written is not feasible and/or lack 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. "Disapproval" can also indicate that preclinical/early phase studies do not exist to support conduct of the proposed phase II or III trial, in which case a "substantially similar" concept would be accepted as a new concept for review if accompanied by results from relevant early phase studies.

[NOTE: One reason for differentiating between “disapproval” and “revise and resubmit” is to keep the Steering Committee focused on studies that are in active development and require review. A revised concept might be expected for re-review within one to three months, whereas a disapproved concept might require one or more years to conduct early phase studies or to design a new study. Metrics will show shorter time from concept submission to protocol activation if studies with many problems are removed from the queue while they are being redeveloped.]

7. Study concepts are reviewed by the Symptom Management and Quality of Life Steering Committee (SxQOL SC) on conference calls. Study PIs are invited to join an open portion of the concept review calls when their concept proposals are being reviewed. Please list specific questions you would like the Study PI to be asked during this call. Please note that specific questions from reviewers will be de-identified and asked by the SxQOL SC Co-chair on the call.