CONTENT OF CONCEPTS SUBMITTED FOR REVIEW BY THE SYMPTOM MANAGEMENT AND QUALITY OF LIFE STEERING COMMITTEE (SXQOL SC)

The concept is the investigator's opportunity to demonstrate 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 concept needs to complete appropriate internal processes at the Research Base before submission to the NCI Division of Cancer Prevention (DCP).

The purposes of the concept 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 be clinically relevant for cancer symptom management and/or quality of life
- Propose clear study objectives and hypotheses
- Provide a brief description of the study design and methodology
- Provide evidence of the feasibility of recruiting to and conducting a successful study
- Describe the statistical methods to address the primary questions/outcomes.

Concepts do not need to include consent forms or case report forms. They should, however, include copies of all assessment tools.

All concept proposals are recommended to be 5-7 pages, but cannot be longer than 10 pages. This does not include the title page, schema and references. Submission of appendix materials, other than assessment tools, is discouraged.

Please refer to pages 2-4 of this document for an outline for writing the concept proposal.

The following is an outline for the concept proposal. All concepts should include the information listed below, as applicable.

Concept Requirements Outline

I. Title page:

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. Schema: This one page diagram provides an overview of the study design.

III. Background

A. Rationale for Proposed Study:

The background is one of the most important sections of the concept and often accounts for the bulk of the concept document. It provides the reviewers with relevant information supporting the rationale of the proposed study. The scientific justification for the intervention should include a focused review of relevant literature with citations covering significance of the condition to be studied, current knowledge of etiology and pathophysiology of the condition as related to the concept, a limited review of studies that have contributed information applicable to the proposed study, and brief summary of pilot or preliminary data.

B. Significance of the Study

The background section should clearly state how the proposed research will further science in symptom management and quality of life. This should include a brief discussion of how the intervention will be determined to be clinically relevant. For example, the investigator should provide evidence that the measurement tool is sufficiently sensitive to detect a clinically important difference. Also, measures of the

number needed to treat (NNT) to see an effect or a description of the degree of improvement that a patient would experience, may be relevant to include.

IV. Study objective(s) and hypotheses

Clearly state all primary and secondary objectives.

V. Study Methods

The study design section will outline how the objectives/primary endpoints will be met. This section is a succinct description of the study design and intervention plan, and includes the study population and eligibility criteria, outcome measures, timing of data collection, sample size, and power calculations for the primary study outcomes. In addition, please include the following information as specified by the type of intervention/agent.

A. <u>If a drug treatment trial</u>:

1. 1. Give dose and schedule for intervention together with justification (or potential doses/schedules of agent[s])

2. Identify the provider of drug, if determined.

3. Specify if the drug is currently available to the research base for the trial.

4. If agents are being requested from DCP, provide a listing of each agent by name and NSC number.

5. State whether it is expected that the study will be conducted under an IND.

B. <u>If complementary and alternative medicine agent</u>:

1. Specify probable manufacturer of the product to be used. Include history of company's involvement in clinical trials.

2. Provide information on quality control, shelf life, lot-to-lot variability

3. Discuss availability of agent in the marketplace.

C. <u>If a behavioral intervention is planned:</u>

1. Briefly describe the intervention.

2. Include a brief discussion of the availability of resources in the CCOP setting (e.g. staff, facilities, equipment) to implement the intervention.

3. Provide justification for the proposed control group (if applicable).

VI. Feasibility

Provide data to support the anticipated accrual rate for the proposed target population and the level of interest expressed by the CCOPs. Address the compatibility of protocol complexity with CCOP resources. Describe the previous experience of the investigators relevant to successful conduct of the intervention. If the study will involve costs in addition to data management, briefly describe them and include a source of funding.