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U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
National Institutes of Health

April 15, 2011

Updated requirements, processes, and guidelines for preparing and submitting clinical trial concepts to be reviewed by the NCI Symptom Management and Quality of Life Steering Committee

Dear CCOP Research Base PIs, Cancer Control Committee Chairs, and Program Administrators,

The NCI Symptom Management and Quality of Life Steering Committee (SxQOL SC)* (http://transformingtrials.cancer.gov/steering-committees/symptom-management) recently updated its requirements, processes, and guidelines for preparing and submitting clinical trial concepts for review by the SxQOL SC, as described below.

The new requirements and processes will be implemented beginning with concepts reviewed on the July 12, 2011 SxQOL SC call (concept submission deadline: June 14, 2011).

Please disseminate this information and the attached forms to anyone who may find it relevant.

CONCEPT CONTENT AND SUBMISSION

A "concept" refers to any study that is being evaluated by the SxQOL SC. The following types of studies will not be reviewed by the SxQOL SC and will be referred to the Division of Cancer Prevention (DCP) (http://dcp.cancer.gov): 1) single arm; 2) non-randomized; 3) studies proposing to enroll fewer than 100 participants; 4) and/or pediatric studies.

Submitted concepts should adhere to guidance provided in the **"SxQOL SC Concept Template and Guidelines" (attached).** This form will be provided to concept evaluators for reference.

When preparing concepts, concept submitters should refer to the **"SxQOL SC Concept Evaluation Form" (attached)** that reviewers use to evaluate a concept and includes guidelines for concept reviewers. Concept submitters should also refer to the **"SxQOL SC Patient Advocate Evaluation Form" (attached)** that patient advocates use to evaluate a concept. If a concept will propose the use of dietary supplements, it may also be useful to refer to the **"NIH ODS Assessment of Dietary Supplements" (attached).**

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.

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

Concepts are usually developed by symptom management or quality of life committees within the CCOP Research Bases; however, they can also be developed by collaborations between CCOPs, Groups, Consortia, etc. or by a Task Force.

Investigators from other NCI or federally-funded multi-site clinical trials Groups/Networks not affiliated with a Research Base must submit concepts through a Research Base.

CCOP Research Bases will follow existing procedures for submitting concepts to the Protocol and Information Office (PIO) of the DCP.

As a reminder, essential biomarker, imaging, and QOL studies which are associated with clinical trial concepts are eligible for funds through the Biomarker, Imaging, and Quality of Life Studies Funding Program (BIQSFP); http://biqsfp.cancer.gov/. The BIQSFP component of the concept must be submitted with the trial concept. The concept and BIQSFP may be reviewed together or at a separate time.

Revised concepts: Concepts receiving a review outcome of Revise and Resubmit from the SxQOL SC may be revised and resubmitted to the DCP PIO **one time** within the timeline that is outlined in the Consensus Review letter.

CONCEPT RECEIPT

New and revised concepts received in the DCP PIO **by 10 AM Eastern Time on the day that is four weeks prior to a scheduled monthly meeting of the Steering Committee** will be scheduled for review during that meeting. Please refer to the **"2011 SSC Meeting Schedule and Concept Deadlines"** (attached, and also posted at: (http://transformingtrials.cancer.gov/files/2011SSCMeetingScheduleandConceptDeadlines.pdf). Concepts received after that time will be scheduled for review during the following month's meeting.

CONCEPT EVALUATION

NCI Staff will notify the Concept Lead Investigator(s) of the date and time of the evaluation in advance of the meeting and ask the Concept Lead Investigator(s) to be available to call in at the beginning of the review of the concept. If the Concept Lead Investigator cannot participate in the call, it is their responsibility to name an alternate representative (preferably a Co-PI) to participate. The Concept Lead Investigator(s) may invite additional members of the study group to participate in the open session at the beginning of the concept review. However, the Lead Investigator is responsible for notifying other study group members to connect to the call when it is time for them to participate in the concept review.

Please do not hesitate to contact me should you have any questions related to the above or to the SxQOL SC in general.

Sincerely,

Jennifer

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* As part of NCI's restructuring of the clinical trials enterprise, the Clinical Trials Working Group (CTWG) Report recommended that a Symptom Management and Quality of Life Steering Committee (SxQOL SC) be established to review and prioritize symptom management intervention clinical trial concepts conducted through the Community Clinical Oncology Program (CCOP) mechanism. The CTWG Report was accepted by the National Cancer Advisory Board (NCAB) in 2005.

The **major goal** of all NCI Scientific SCs is to evaluate and prioritize clinical trials based on their scientific merit and increase the efficiency of clinical trial collaboration, reduce trial redundancy, and increase information exchange at an early stage of trial development. Other specific goals for this SxQOL Steering Committee include:

1. To provide expertise in patient-reported outcome (PRO) measures and symptom control to disease-specific steering committees.
2. To increase the availability of biologically plausible, feasible interventions (both pharmacologic or non-pharmacologic) for clinical trials in NCI networks that have the potential to reduce cancer treatment-related toxicity or disease-related symptoms.

The SxQOL SC is designed not only to provide robust peer review of proposed concepts, but also to facilitate the sharing of ideas among a broad range of clinical, behavioral and translational scientists, NCI staff, community oncologists and patient advocates in the development of those concepts. Convening clinical trial planning meetings is part of this process and helps identify critical questions and priority areas for investigation. The result of the SxQOL SC efforts should be scientifically rigorous concepts that have been optimized through the collaborative effort and expertise of an extramural clinical trials community empowered to create the best-designed trials asking the most important questions.