# NCI SYMPTOM MANAGEMENT AND QUALITY OF LIFE STEERING COMMITTEE WRITTEN COMMENTS FORM FOR PATIENT ADVOCATES

**Evaluators Name:**

**Date of Evaluation:**

**Concept ID Number and Title:**

### *INSTRUCTIONS FOR NON-NCI EVALUATORS*

You have been asked provide an evaluation of the concept listed above. Your responsibilities as an evaluator consist of evaluating the concept and completing this form with your written comments and score by filling out the fields that follow each question.

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 All unpublished information, reports and discussions are strictly confidential.**

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## Patient Advocate Issues

1. **Is the proposed study one that will likely be considered important to persons with this disease?** Is relief (or partial relief) of the condition something that is important to patients? Is it likely to be attractive to potential study participants resulting in brisk accrual? If not, what aspects of the proposed study may be problematic? Are there changes to the study design that might enhance participation rates?

2. **a. Is the required activity something that patients are willing and able to do?**

   **b. How acceptable is the proposed intervention likely to be to patients with regard to side effects and burden (e.g. size of pills, # doses per day, timing and duration of behavioral intervention)?**

**c. How acceptable is the assessment schedule likely to be to patients (e.g. frequency and length of questionnaires, required clinic visits in addition to routine visits, clinical testing only required for the study)?**

**3. Is the answer to the study question something that will improve patient quality of life and/or tolerance of disease treatment?**

**4. Are there other issues related to the proposed study that you think should be considered at the Concept Evaluation Meeting?**

**OVERALL CONCEPT REVIEW:** _____

**Overall thoughts at this time regarding this concept:**

**(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.

**Unsure and/or pending discussion at the conference call**