

## ACNP Website regarding Study Group

Title: The Challenge: Rigorous Assessment of CAM Therapies  
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Participants: David Mischoulan, MD  
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The goal of the Study Group was to discuss the challenges faced in developing more rigorous Complementary and Alternative Medicine (CAM) studies for the Neurosciences. We attempted to discuss the following series of questions: (1) What are appropriate comparative conditions for CAM interventions, (2) how does one deal with challenges regarding compound formulation and standardization, (3) how does one deal with expectancy effects in CAM trials, and (4) how does one bring together groups of investigators from disparate philosophical backgrounds to create a unified working team? The Study Group was organized in a fashion where participants spent five minutes describing their experiences working with the National Center for Complementary and Alternative Medicine, their work with CAM research trials, and identifying specific challenges that they thought could be improved by thoughtful discourse. The NCCAM representative, Dr. John Glowa, presented the NCCAM program staff's observations about the challenges they have seen with trials that they have funded at NCCAM. The Study Group was enriched by the participation of a number of other investigators who had been funded by NCCAM or were involved with NCCAM research, as well as one member of the National Advisory Council for NCCAM and the incoming Scientific Director for the Division of Extramural Research at NCCAM, Dr. Emmeline Edwards.

Dr. Glowa's presentation of the NCCAM program staff's perception of reasons for challenges in trials included: Problems with recruitment, enrollment, and accrual due to restrictive inclusion criteria, trial feasibility, and lack of access to appropriate populations. Dr. Glowa also discussed NCCAM's concerns about placebo effects, small differences in effect size for CAM therapies, issues around standardization, and the role that expectations of both practitioner and subjects may have on results. There was a lively discussion about the issue around the selection of appropriate controls for CAM trials. (Drs. Glowa and Edwards stated that NCCAM was organizing a workshop around this topic). There were also discussions about challenges identifying appropriate dosages for interventions for CAM trials. This presentation led to a robust discussion both by the audience and by the panel participants, and there was a general agreement that: (1) many of these issues are similar to ones present in pharmacological trials and, in particular, psychotherapy trials. There is a wealth of knowledge that could be brought to NCCAM by sophisticated investigators with experience in such trials. A second point of discussion was the difficulty, at times, getting investigators trained in non-traditional approaches to appreciate the need for objective, inferential approaches that are required to demonstrate efficacy. Several members of the panel and participants at the Study

Group discussed the challenges they had faced creating a consensus about design issues when co-investigators come from radically different backgrounds. It was thought that there was a need for creating a more unified and standardized approach to trial design and that there might be a need to create working groups to develop such a consensus. There was considerable discussion about the challenges that CAM trials pose: (a) in defining appropriate control conditions and (b) in controlling for factors like credibility and expectancy. There was a discussion of how these issues had been addressed in psychotherapy research, and there was a convergence of belief that such approaches might be helpful for CAM trials.

Another point of considerable concern in the Study Group was the quality of review that occurred within NCCAM. Many investigators expressed concerns that the Review Committees did not have the expertise necessary to fully appreciate how a well-done trial should be performed. Many participants in the Symposium voiced dismay about the quality of ongoing NCCAM reviews. There was a thought that reviews were uneven in nature and that frequently, a Review Committee did not contain the expertise necessary to adequately judge the submitted work. The consensus of the Study Group was that this was a subject that merited further scrutiny.

The recommendations of the Study Group were to consider the development of: (1) an opinion paper more fully discussing the challenges faced in performing NCCAM trials in the neurosciences, and (2) that there may be a need for NCCAM to consider developing a trials network that could facilitate the performance of truly definitive trials of CAM treatments in the neurosciences, as well as serve as a mechanism for training the diverse investigators involved in NCCAM studies in appropriate study methodology.