

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR COMPLEMENTARY
AND INTEGRATIVE HEALTH**

**NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY
AND INTEGRATIVE HEALTH
MINUTES OF THE FIFTY-SIXTH MEETING
August 26, 2015
Teleconference**

NACCIH Members Present

Dr. Martin Blaser, New York, NY
Dr. David Borsook, Waltham, MA
Dr. Alice Clark, University, MS
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Christine Goertz, Davenport, IA
Dr. Tracy Gaudet, Washington, DC
Dr. Jane Gultinan, Seattle, WA
Dr. Frances Henderson, Jackson, MS
Dr. Steven Hersch, Charleston, MA
Dr. Janice Kiecolt-Glaser, Columbus, OH
Dr. Helene Langevin, Boston, MA
Dr. Richard Niemtzow, Alexandria, VA
Dr. Deborah Powell, Minneapolis, MN
Dr. Lynda Powell, Chicago, IL
Dr. Eric Schoomaker, Bethesda, MD
Dr. Reed Tuckson, Sandy Springs, GA
Dr. Chenchen Wang, Boston, MA

NACCIH Members Not Present

Dr. Donald Brater, Indianapolis, IN
Dr. Scott Haldeman, Santa Ana, CA

NIH Staff Present

Dan Xi, NCI, CSR

Members of the Public

James Marzolf

I. Open Session—Call to Order

The first portion of the fifty-sixth meeting of the National Advisory Council for Complementary and Integrative Health (NACCIH) was an open session. Dr. Martin Goldrosen, NACCIH Executive Secretary, called the meeting to order and convened the open session at 1 p.m.

II. NCCIH Director's Welcome

NCCIH Director Dr. Josephine Briggs welcomed the members and noted that the teleconference was intended to address some administrative action items toward the end of the fiscal year that require Council's input and potential action in order to be completed. In the open session, a concept will be presented regarding how to build a more effective phased approach to complex interventions. In the closed session, Council will discuss several major grant applications.

III. Concept Clearance: Mechanistic Studies of Complementary and Integrative Mind and Body Interventions Supported by NCCIH

Dr. Wen Chen, program director in the Basic and Mechanistic Branch of the Division of Extramural Research, gave a brief presentation of a research concept, "Phased Innovation Award for Mechanistic Studies To Optimize Mind and Body Interventions in NCCIH High Priority Research Topics."

Dr. Chen opened by recalling that NCCIH's Framework for Research on Developing and Testing Complementary and Integrative Health Mind and Body Interventions was presented to Council at the February 2014 meeting. Dr. Chen summarized several major points from that earlier meeting. First, research on mind and body interventions can be considered and studied in three major steps: (1) exploratory/pilot studies, (2) efficacy/effectiveness studies, and (3) dissemination and implementation studies. Second, the importance of mechanistic studies as part of the exploratory/pilot studies for mind and body interventions was supported by Council. The nature of such mechanistic work represents an iterative process between identification of clinically meaningful mechanistic signals and intervention development and optimization.

The first phase of studies in the present concept would aim to identify potential, modifiable mechanisms or processes of a mind and body intervention. If such a study is successful, it may be supported in a phase 2 study designed to build validated clinical research tools and/or strengthen clinical impact of the interventions. Dr. Chen emphasized that these initiatives are not intended for randomized clinical trials with primary objectives to determine efficacy or effectiveness.

Dr. Chen provided examples of the types of research that may be suitable for the proposed initiative. She emphasized that research proposals should not be limited to these examples.

Example one focused on pain and pain management. In phase 1, an investigator might identify specific neural circuits and activities affected by a mind and body intervention in pain processing. In phase 2, the investigator may develop and test devices that can monitor changes in, or enhance the activities of, the identified neural circuits to augment the effects of the mind and body intervention in a chronic-pain population.

Example two focused on examination of the mechanisms of a mind and body intervention in people with mild-to-moderate depression. Again, in phase 1, an investigator might identify psychological or behavioral traits affected by a mind and body intervention in a specific depression population. If successful, the investigator may validate in phase 2 the robustness

and/or consistency of the relationship(s) between the identified traits and the clinical outcomes influenced by the intervention in a larger depression population.

Example three was a study of the mechanisms of a mind and body intervention for sleep regulation and sleep disorder. In phase 1, an investigator might identify specific molecular signaling pathways affected by an intervention of this type in the regulation of sleep. Then, in phase 2, the investigator may examine the potential synergy of the intervention with another therapy already shown to affect the same signaling pathways in a population with a sleep disorder.

Dr. Chen closed by noting that the Center hopes that this phased approach for mechanistic studies will be an effective way to dissociate exploratory mechanistic studies from fully powered clinical trials focusing on efficacy and effectiveness and will consequently allow for creative pilot studies to enhance and optimize mind and body interventions.

Discussion

Dr. Briggs noted that all members who have accumulated time on Council have seen examples of efficacy studies that were submitted without adequate earlier work, e.g., when researchers move too quickly to randomized controlled trials without well-validated interventions or tools. This initiative is intended to help address this problem and encourage the Center's investigator community to think in a more phased way about development.

Dr. Lynda Powell praised the concept. She asked whether in phase 2 studies the Center would also look at heterogeneity of response across important subgroups. Dr. Briggs responded affirmatively. Dr. Powell added that often in large clinical trials researchers include a specific aim for evaluation of moderators of treatment. But at the point of a clinical trial, researchers should not be looking at moderators; rather, they should be determining if there is differential effectiveness in subgroups in these preliminary studies and then potentially tailoring the treatment so that it is equally as effective through all subgroups.

Dr. Briggs commented that NCCIH sees phased awards as a very useful way to create a partnership with the investigator throughout the various stages of investigation. This approach can work very well, as has been seen in the NIH Collaboratory.

Council unanimously passed a motion to approve the concept.

IV. Closed Session

The final portion of the meeting was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

A total of six (6) applications were assigned to NCCIH. Of these, zero were reviewed by NCCIH, four (4) by Center for Scientific Review, and two (2) by NHLBI. Applications that were noncompetitive, not discussed, or were not recommended for further consideration by the scientific review groups were not considered by Council.

Council agreed with staff recommendations on 5 applications and voted to concur with IRG on 1 application requesting \$5,946,039 in total costs.

V. Adjournment

The meeting adjourned at 2:00 p.m.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Martin Goldrosen, Ph.D.
Executive Secretary
National Advisory Council for
Complementary and Integrative
Health

Josephine Briggs, M.D.
Chairperson
National Advisory Council for
Complementary and Integrative
Health