

**National Center for Complementary and  
Alternative Medicine (NCCAM)  
Research Centers Program  
Expert Panel Review**

## **Executive Summary**

This report summarizes the deliberations, findings, and recommendations of the expert panel convened on June 18, 2002, by the NCCAM Director to review NCCAM's Research Centers Program. This program assessment was prompted by the evolution of NCCAM's research portfolio since the Center's founding in 1998 and the approaching end of the initial funding cycle for the first group of NCCAM research centers.

## **Charge to the Panel**

The panel was asked to reflect on NCCAM's current system of research centers and determine whether modifications to their present organization and funding were merited. In particular, the panel was asked to consider issues such as:

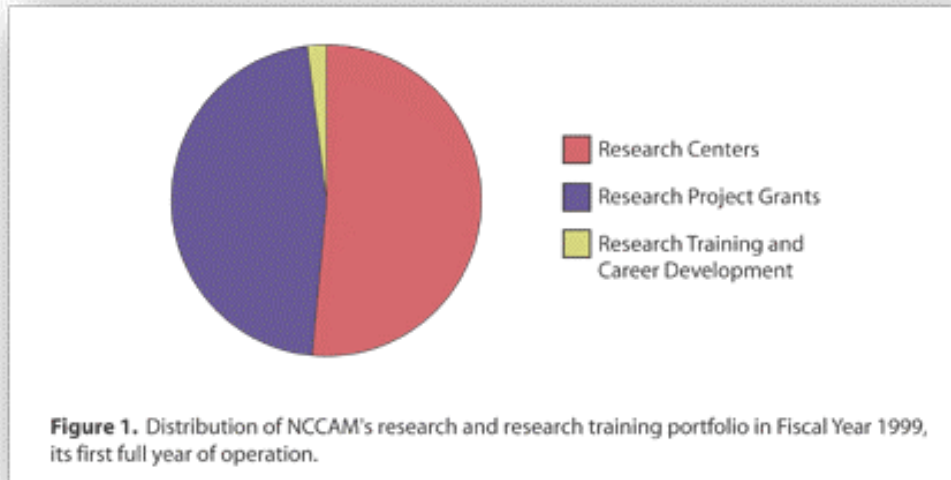
- The role that research centers have played in advancing NCCAM's mission and how—if at all—that role should change in the future
- Important characteristics for future NCCAM research centers
- The most suitable funding mechanisms for various types of centers conducting complementary and alternative medicine research.

## **Overview of NCCAM Research Centers**

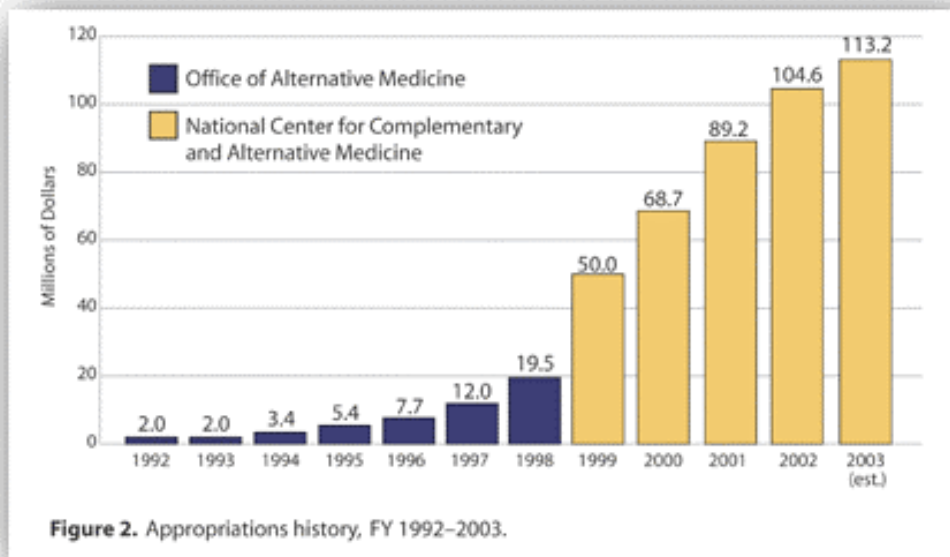
### Background and History

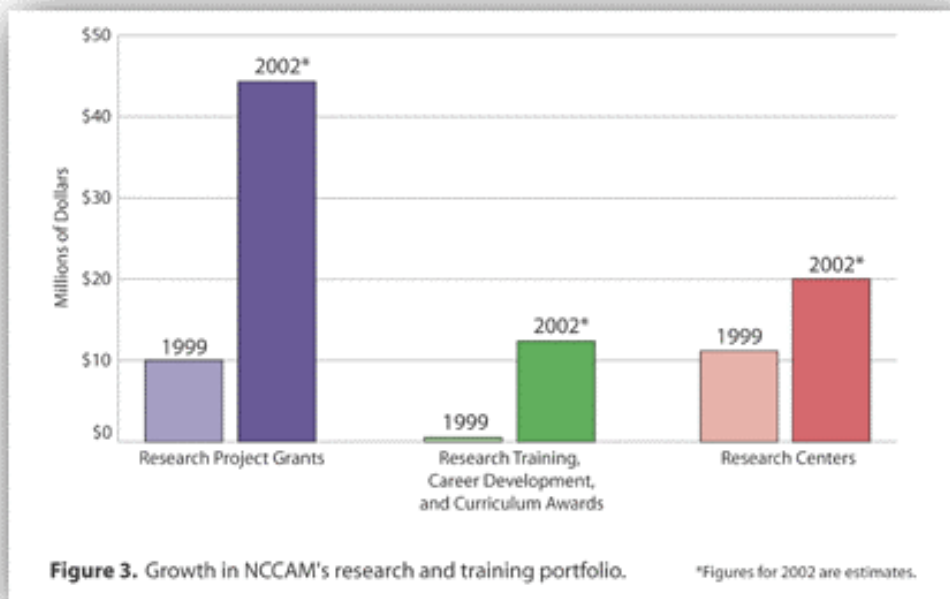
From the start, research centers have been an integral part of NCCAM's portfolio of research and related activities in complementary and alternative medicine (CAM). Even before NCCAM was founded, the NIH Office of Alternative Medicine established a series of CAM research centers in 1994. When Congress created NCCAM, it recognized the value of collaborative research and charged NCCAM with maintaining a program of multipurpose research centers.

In fact, in 1999, NCCAM's first year of operation, more than half of its research and research training portfolio was devoted to the Research Centers Program (Figure 1).

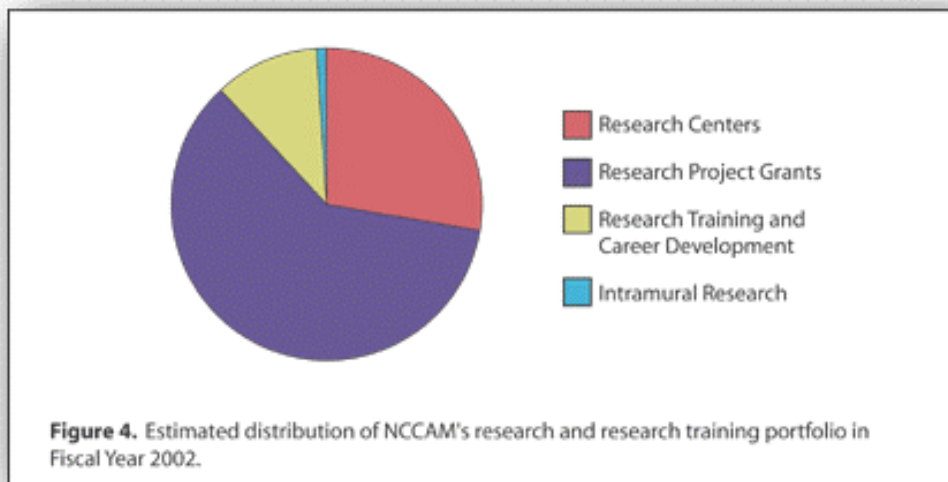


Since then, NCCAM's budget has more than doubled (Figure 2) and a substantial portion of the new funds has been devoted to research project grants, research training, career development, and curriculum awards (Figure 3).





Today, NCCAM's research and research training portfolio includes both intramural and extramural research, and it is more uniformly distributed among research centers and other activities (Figure 4).



## Development of Complementary and Alternative Medicine Research Centers

The earliest NIH-funded alternative medicine research centers, established under the auspices of the Office of Alternative Medicine, were expected to emphasize outreach to researchers, academic institutions, and the public. In addition to conducting research, each of the centers was to provide technical assistance to investigators, develop bibliographic resources, foster connections between experienced investigators from conventional medicine and those from the CAM community, and establish linkages among academic centers studying alternative medicine.

Many of the 10 U24 “exploratory centers” supported by the Office of Alternative Medicine between 1994 and 1998 found it difficult to effectively fulfill the numerous goals set for them. Those familiar with the early alternative medicine research centers attribute their mixed success to:

- **Numerous nonscientific responsibilities**—Organizing bibliographic resources and extensive outreach activities left little time for research.
- **Underfunding**—The U24 exploratory centers received \$450,000 annually, too little to make substantive research progress and also fulfill their other obligations.
- **Minimal expectations for research and research training**—The pilot research projects undertaken by the centers were only one year in length and did not undergo NIH peer review. Likewise, research training opportunities were short-term and limited to workshops and seminars.

As a result of these limitations, when the U24 research centers reached the end of their funding cycle, the goals for alternative medicine research centers were revised and a different funding mechanism was adopted.

NCCAM’s present-day Research Centers Program, which replaced the U24 exploratory centers, was designed to reflect the developing maturity of CAM research and enhance the research productivity of centers. The majority of NCCAM’s current research centers employ the P50 “specialized center of research” grant mechanism and feature:

- **Financial support consistent with their missions**—\$1.0 to 1.5 million annually.
- **Rigorous research and research training**—Today’s centers are expected to carry out three or four R01-like research projects (which undergo NIH peer review), conduct pilot research projects, and provide continuing opportunities for research career development.
- **Local control and accountability**—Each of NCCAM’s current centers is guided by a local advisory committee.

The only research center in NCCAM’s current centers program that was not originally designed to be funded through a P50 award is also NCCAM’s longest-running center: a consortium of institutions and investigators conducting chiropractic research, supported

through a U01 “cooperative agreement.” Before the end of 2002, the NCCAM’s centers program is expected to expand in yet another direction, with the addition of small P20 exploratory research centers focusing on “frontier medicine,” that is, complementary and alternative medicine practices (such as energy healing) that biomedical science cannot yet explain.

#### Office of Dietary Supplements/NCCAM Research Centers

In addition to the 12 research centers that constitute NCCAM’s formal Research Centers Program, NCCAM also jointly supports five botanical research centers with the NIH Office of Dietary Supplements (ODS). Four of the five research centers are P50 specialized centers; the remaining one is a P01 program project grant. NCCAM and ODS share scientific oversight of these centers, but NCCAM administers most of the awards.

The botanical research centers are similar to the other NCCAM-sponsored research centers in size and structure. Each receives \$1.5 million annually and is expected to conduct three or four R01-like research projects, pursue pilot research projects, and provide opportunities for research training and career development. Like the NCCAM centers in CAM research, the botanical research centers are widely regarded as a galvanizing force in their field.

### **Current Center Directors’ Perspective**

In the course of their deliberations, the panel heard from the directors of two of NCCAM’s current P50 research centers (chosen by the other P50 center directors to represent them), as well as the director of NCCAM’s single U01 consortial research center.

The center directors stressed the importance of research center awards in providing infrastructure support and building a critical mass of investigators. The P50 center directors both noted that the designation “research center” conferred distinction on their work, increasing interest in and support of CAM research among their medical school leaders and colleagues, attracting additional funding, and supplying a valuable incentive in recruiting new faculty, staff, and trainees.

The director of the chiropractic consortium echoed many of the same themes and underscored the important role of research centers in building research infrastructure in CAM institutions. Unlike research center awards granted to established research universities, which often focus existing resources on a neglected area of research, centers awarded to CAM institutions help develop and maintain research resources that may never have existed before. Moreover, research centers located in CAM institutions foster a heightened respect for scientific careers and the scientific process among CAM

practitioners—and for the capacities of CAM professionals among traditional investigators.

Though strongly positive in their view of NCCAM research centers, the center directors were also forthright in discussing the obstacles they have faced. For some, the administrative challenges inherent in managing the wide range of duties assigned to research centers took time to master. Others reported difficulties with their research projects (particularly the clinical research projects), such as recruiting a diverse population of patients, delays in obtaining Institutional Review Board approval, and confusion as to the circumstances requiring IND approval from the FDA.

## **NIH Approaches to Funding Research Centers**

Overall, NIH devotes approximately 9 percent of its funding to research center awards. Levels of spending vary from institute to institute, however, because they are based on the scientific needs and administrative choices of each. In FY 2000, for example, the National Institute of Allergy and Infectious Diseases allocated just over 1 percent of its budget to research centers, while the National Center for Research Resources devoted nearly 64 percent, largely in support of its General Clinical Research Centers Program. That same year, NCCAM reported higher-than-average spending for centers, with more than 22 percent of its budget dedicated to research centers.<sup>1</sup>

In addition to the standard research center funding mechanisms (P20s, P30s, P50s, P60s, etc.), the wide range of NIH funding options available includes other awards that can be employed to support research center programs. For instance, P01 research program project grants, U01 and U19 cooperative agreements, and R24 resource-related research project awards are all used to fund various types of research centers programs at the NIH. One difference among center funding mechanisms is the level of NIH staff involvement commonly associated with each: generally low with awards such as the P01; higher with P20s, P30s, and P50s; and higher still with cooperative agreement mechanisms such as the U19.

## **Expert Panel Findings**

### Current NCCAM Research Centers

Targeted research initiatives supported by the NIH are often designed to foster specific fields of research at particular points in their development. Such is the case with NCCAM's research centers, which were designed to advance CAM research beyond its early stages. When plans for today's research centers were under development, the U24

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<sup>1</sup>Among the 20 NIH institutes supporting research centers in Fiscal Year 2000, the median level of spending on research centers was 6.7 percent.

exploratory research centers instituted by the Office of Alternative Medicine were approaching the end of their first funding cycle with mixed results.

Replacing the U24 exploratory research centers with a series of P50 specialized research centers that included peer-reviewed research projects, shared resources and facilities, developmental research, and career development activities allowed NCCAM to cultivate research, resources, and new investigators simultaneously—at a time when NCCAM was newly established and just beginning to build its own portfolio of CAM research. Furthermore, by requiring rigorous review of proposed research projects, encouraging local control, and granting greater resources to the new centers, NCCAM sought to eliminate the features that contributed to the uneven productivity of the U24 exploratory research centers.

Several years into their missions, the current NCCAM research centers have clearly played a role in establishing the visibility and credibility of CAM research, building research infrastructure, and drawing investigators into the field. For these reasons, panel members soundly endorsed the continuation of a vigorous NCCAM Research Centers Program.

Yet despite their realization of many of NCCAM’s initial goals, the current P50 research centers have not yet developed a consistent record of hypothesis-driven research and publications based on their findings. Indeed, some panel members suggested that the expectation that they could effectively do so in the absence of a mature CAM research enterprise may have been unrealistic. The panel agreed that the design of NCCAM’s centers program should continue to adapt to meet NCCAM’s current and anticipated needs in the years ahead and increasingly emphasize hypothesis-driven, peer-reviewed, high-quality research on top priority questions in complementary and alternative medicine.

### Recommendations for the Next Generation of NCCAM Research Centers

In considering guiding principles for the next generation of NCCAM research centers, the panelists agreed that one of the primary objectives of the centers is to strengthen CAM research capacity. Accordingly, the panel members urged that future NCCAM research centers be structured to focus on two or three of the following:

- A particular disease or class of diseases treated by CAM
- A specific group of CAM therapies or treatment approaches
- Mechanisms (or processes) of action of CAM therapies and approaches.

Exceptions to this general rule might be centers organized around specific research approaches, such as wellness or the placebo effect, or resource centers, such as those providing botanical product standardization and analysis.<sup>2</sup>

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<sup>2</sup> The panel also discussed resource centers focusing on specific technologies or infrastructure, such as neuroimaging and clinical research support.

In view of the many forms of research center support in use throughout the NIH today, the panel recommended that NCCAM adopt a more flexible approach to its Research Centers Program in the years ahead. For example, the panel suggested that there may be scientific and fiscal advantages to funding mechanisms other than the P50 specialized centers of research that dominate NCCAM's current research centers portfolio.

Although it did not stipulate specific funding mechanisms, the panel encouraged NCCAM to consider P01s, P20s, P30s, R24s, U01s, and U19s and to select types of awards (such as P01s) that encourage investigator autonomy wherever possible. Generally, the panel recommended that decisions about center funding mechanisms be guided by factors such as the nature of the center's focus, the complexity of the planned research (i.e., the extent to which it entails multiple steps and contributors, as clinical trials often do), and the investigators' expertise in CAM research. For example, panel members suggested that complex clinical studies could benefit from funding mechanisms (such as U01s or U19s) that allow for greater NCCAM staff involvement and oversight, while research centers within CAM institutions might be supported appropriately by exploratory awards (such as P20s or R24s) designed for new or emerging fields and institutions.

In considering other key research center characteristics, panel members urged that future NCCAM centers:

- Incorporate more basic science research in complementary and alternative medicine than at present
- Provide opportunities for the institution's investigators to propose and conduct peer-reviewed pilot research projects
- Supply necessary research support and infrastructure (e.g., laboratory, biostatistics, and administrative support) to center investigators and, where appropriate, to investigators conducting related research elsewhere at the institution or at other institutions
- Devote resources to developing standardized treatments and therapeutic approaches for study in large-scale clinical trials, especially those involving natural products
- Develop strategies for timely Institutional Review Board approval and support for patient recruitment when multiple clinical research projects are planned
- Involve CAM practitioners as investigators, either independently or through formal partnerships with CAM institutions
- Provide career development opportunities for conventional and CAM clinicians who have completed their clinical training, especially junior faculty
- Offer opportunities to conduct cost-effectiveness or health services research when merited by research results and related to the center's primary focus (e.g., a



research center devoted to acupuncture might study the cost-effectiveness of treating chemotherapy-induced nausea with acupuncture).

In administering the next generation of research centers, panelists suggested that NCCAM consider providing opportunities beyond the current annual meeting for center directors, investigators, and fellows to interact and share information on scientific and administrative issues (e.g., a listserv, periodic conference calls, or informal meetings). Finally, panelists recommended that NCCAM carefully monitor the accomplishments of future centers and continue to support only those with exemplary research records.

## **Conclusion**

From the beginning, research centers have played a fundamental role in fulfilling NCCAM's mission. The specialized research centers introduced in 1998 allowed NCCAM to cultivate research, scientific resources, and new investigators simultaneously, at a time when NCCAM was new and just beginning to build its portfolio of research, training, and related activities. Yet despite their vital role in fulfilling many of NCCAM's initial goals, the research centers have not yet developed an impressive record of research results. In the years ahead, new NCCAM research centers should increasingly emphasize their role in CAM research and strive to make substantial contributions in the research arena.

In their increasing emphasis on research, NCCAM centers should focus on determining the efficacy of CAM therapies or treatment approaches in a particular disease or class of diseases and on understanding the mechanisms of action associated with CAM therapies or approaches. Their responsibilities in CAM research will require NCCAM centers to continue to play a leading role in building research infrastructure in this field and in standardizing CAM therapies and treatment approaches for testing.

Given this variety of research goals, it is likely that a diverse range of funding mechanisms will be required to support the next generation of NCCAM research centers. In designing the structure of future research centers and determining which grant mechanisms should be used to support them, NCCAM should be guided by the nature of the centers, the complexity of the planned research, and the investigators' expertise with CAM research to select types of awards that are investigator driven wherever possible. As new research centers are established, NCCAM has an essential integrative role to play in bringing centers together and identifying and supporting synergistic research activities. Even more important, NCCAM must carefully monitor the accomplishments of future centers and continue to support only those with exemplary research records.

## **Appendix A**

### **Expert Panel to Assess NCCAM Research Centers**

#### Chairman

Ralph Snyderman, M.D.  
Chancellor for Health Affairs  
Duke University Medical Center  
Durham, North Carolina

#### Panel Members

Deborah Cotton, M.D., M.P.H.  
Professor of Medicine, Epidemiology  
and Biostatistics  
Boston University School of Medicine  
Chief of Medicine  
VA Boston Health Care System  
West Roxbury, Massachusetts

David Eisenberg, M.D.  
Bernard Osher Associate Professor of  
Medicine  
Director, Division for Research and  
Education in Complementary and  
Integrative Medical Therapies  
Harvard Medical School  
Boston, Massachusetts

David L. Felten, M.D., Ph.D.  
Executive Director  
Susan Samueli Center for Complementary  
and Alternative Medicine  
Professor, Anatomy and Neurobiology  
University of California, Irvine  
Irvine, California

Susan Folkman, Ph.D.  
Director  
Osher Center for Integrative Medicine  
Professor of Medicine  
University of California, San Francisco  
San Francisco, California

Scott Haldeman, D.C., M.D., Ph.D.  
Clinical Professor  
Department of Neurology  
University of California, Irvine  
Adjunct Professor, Research Division,  
Southern California University of Health  
Sciences  
Santa Ana, California

Ji-Sheng Han, M.D.  
Professor and Director  
Neuroscience Research Institute  
Beijing Medical University  
Beijing  
People's Republic of China

John J. McGowan, Ph.D.  
Director, Division of Extramural  
Activities  
National Institute of Allergy and  
Infectious Diseases  
National Institutes of Health  
Bethesda, Maryland

Irwin Rosenberg, M.D.  
Dean, School of Nutrition  
Senior Scientist, USDA Human  
Nutrition Research Center on Aging  
Tufts University  
Boston, Massachusetts

#### Representative to the National Advisory Council for Complementary and Alternative Medicine

Haile Debas, M.D.  
Dean, School of Medicine  
Vice Chancellor, Medical Affairs  
University of California, San Francisco  
San Francisco, California

Guests

Brian Berman, M.D.  
Professor of Family Medicine  
Director, Complementary Medicine  
Program  
University of Maryland School of  
Medicine  
Baltimore, Maryland

Steven Bolling, M.D.  
Professor of Surgery  
Director, Complementary and  
Alternative Medicine Research Center  
University of Michigan School of  
Medicine  
Ann Arbor, Michigan

William Meeker, D.C., M.P.H.  
Director of Research  
Palmer Center for Chiropractic Research  
Palmer Chiropractic University  
Foundation  
Davenport, Iowa

NIH Staff

Paul Coates, Ph.D.  
Director  
Office of Dietary Supplements  
Office of the Director  
National Institutes of Health  
Bethesda, Maryland

NCCAM Staff

Christine Goertz, D.C., Ph.D.  
Program Officer  
Division of Extramural Research and  
Training  
National Center for Complementary and  
Alternative Medicine  
National Institutes of Health  
Bethesda, Maryland

Richard Nahin, Ph.D., M.P.H.  
Senior Advisor for Scientific  
Coordination and Outreach  
National Center for Complementary and  
Alternative Medicine  
National Institutes of Health  
Bethesda, Maryland

Stephen E. Straus, M.D.  
Director  
National Center for Complementary and  
Alternative Medicine  
National Institutes of Health  
Bethesda, Maryland

Jennifer Sutton, M.S.  
Evaluation Officer  
Office of Science Policy and Operations  
National Center for Complementary and  
Alternative Medicine  
National Institutes of Health  
Bethesda, Maryland

## **Appendix B**

### **Report Reviewers**

Ted J. Kaptchuk, O.M.D.  
Assistant Professor of Medicine  
Harvard Medical School  
HMS-Osher Institute  
Boston, Massachusetts

Arthur H. Rubenstein, M.B.B.Ch.  
Executive Vice President  
University of Pennsylvania for the Health System  
Dean, University of Pennsylvania School of Medicine  
Philadelphia, Pennsylvania

Leanna J. Standish, N.D., Ph.D.  
Senior Research Scientist  
Bastyr University Research Institute  
Kenmore, Washington

## **Appendix C Meeting Agenda**

### **National Center for Complementary and Alternative Medicine Research Centers Assessment June 18, 2002**

8:30 a.m.	Continental Breakfast	
9:00 a.m.	Welcome and Introductions	Ralph Snyderman, M.D.
9:10 a.m.	Charge to Committee	Stephen E. Straus, M.D.
9:30 a.m.	Overview and Perspective on NCCAM Research Centers	Richard Nahin, Ph.D., M.P.H.
9:55 a.m.	Office of Dietary Supplements/NCCAM Botanical Research Centers	Paul Coates, Ph.D.
10:20 a.m.	Break	
10:45 a.m.	Center Directors' Perspective	Brian Berman, M.D. Steven Bolling, M.D. William Meeker, D.C., M.P.H.
12:00 p.m.	Break	
12:15 p.m.	Working Lunch: NIH Approaches to Funding Research Centers	John J. McGowan, Ph.D.
12:45 p.m.	Consideration of Questions and Discussion	Ralph Snyderman, M.D.
2:30 p.m.	Break	
2:45 p.m.	Further Consideration and Discussion	Ralph Snyderman, M.D.
4:30 p.m.	Adjourn	

## Appendix D

### Questions to Consider

1. Should NCCAM continue to require its research centers to be “multipurpose” centers, incorporating both basic and clinical research, pilot research projects, and career development?
2. What particular role(s) should the Research Centers Program play in furthering NCCAM’s overall mission?

For example, should NCCAM centers be structured to foster:

- Research in specific disease areas, such as cancer? If so, what criteria should be used to select areas of research interest?
  - Specific research goals, such as multidisciplinary or translational research?
  - Particular groups of investigators, such as CAM professionals or scientists who have already established themselves in conventional research?
3. Given NCCAM’s developing portfolio of research, research training, and other activities, in what ways might centers make a special contribution in:
    - Developmental research?
    - Research career development?
    - Outreach to the CAM community?
    - Building research infrastructure?
  4. Considering the current state of complementary and alternative medicine research, would NCCAM centers benefit more from funding mechanisms that provide:
    - More staff involvement and oversight (e.g., cooperative agreements)?
    - Greater autonomy to investigators (e.g., P01s)?
  5. Of the existing NIH funding mechanisms for research centers (P01s, P20s, P30s, P50s, U19s, R24s), which could most successfully be used by:
    - Academic medical centers and research universities?
    - CAM institutions?
    - CAM and conventional institutions conducting joint projects?