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Mind-Body Interactions and Health Program

Outcome Evaluation Feasibility Study

Final Report

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by

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Office of Behavioral and Social Sciences Research: Mind-Body Interactions and Health Program Feasibility Study

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1. Introduction

Under a contract awarded in September 2007 by the Office of Behavioral and Social Sciences Research (OBSSR), National Institutes of Health (NIH), to MasiMax Resources, Inc., The Madrillon Group Inc. conducted a feasibility study to determine whether an outcome evaluation of the Mind-Body Interactions and Health (MBIH) Program is warranted and to provide recommendations for its design. This report presents findings from the feasibility study and recommendations for an outcome evaluation. Following this introduction, **Section 2** describes the history of the program, with a particular emphasis on what Congress intended the program to accomplish, the purpose of the evaluation, and the structure of the MBIH Program. **Section 3** describes the Outcome Evaluation Feasibility Study questions, methods, sources of data, and data collection approaches used. **Section 4** presents the results from the Feasibility Study. **Section 5** discusses the implications of these findings for the design of an outcome evaluation. **Section 6** presents recommendations for the design of an outcome evaluation of the MBIH Program, including evaluation questions, a conceptual framework, proposed comparison strategies, key variables, data collection methods and draft instruments, and an analysis plan.

2. Background

2.1. History of the Mind-Body Interactions and Health Program

The belief that the mind and the body influence each other has deep historical roots (See Harrington [2008] for an extensive historical overview.) Although this belief has enjoyed widespread acceptance among the general public, for many years it met with considerable skepticism, resistance, and even opposition on the part of many medical practitioners and researchers. In her historical overview of the responses of the professional community to mind-body medicine, Winnick (2005) noted that the practitioner and research communities moved from an initial period of active opposition and condemnation during the 1960s and early 1970s to a period of reassessment during the mid-1970s through the early 1990s as practitioners reflected on the increased public criticism of medicine and the health care system and on reports of high levels of public interest in and the use of complementary and alternative medicine (CAM). Since that time, the professional and research communities have sought to build an evidence-based approach to mind-body medicine, and the larger CAM field, of which it is sometimes considered to be a part.

2.1.1. Mind-Body Research Prior To the MBIH Program

Despite the early unfavorable responses by the medical community, public acceptance of mind-body approaches has been more favorable. In the first national survey of the utilization of unconventional therapies in the United States, Eisenberg and colleagues (1992) investigated the patterns of utilization and costs for 16 commonly used “unconventional therapies,” which were defined as “medical interventions not taught widely at U.S. medical schools or generally available at U.S. hospitals.” Included among these unconventional therapies were the use of acupuncture, chiropractic, herbal medicines, massage, megavitamins, self-help groups, folk remedies, energy healing, homeopathy, and others. About one-third (34 percent) of the respondents reported using at least one of these unconventional therapies in the past 12 months, primarily for chronic rather than life-threatening conditions. Extrapolating from the survey results on utilization to the general population, the authors estimated that in 1990, Americans made 425 million visits to providers of unconventional therapies, a number that exceeds the number of visits to all U.S. primary care physicians (388 million) during that year. Americans spent an estimated \$13.7 billion on unconventional therapies, of which 75 percent was paid out of pocket. A subsequent study in 1997 (Eisenberg et al., 1998), using the same definition and set of techniques and practices, showed that their use within the past 12 months had increased to that of 42 percent of the general public. Later studies,

using different definitions of CAM, have reported rates of 12-month utilization at about 36 percent (Barnes, et al., 2004.)

Research on various CAM approaches grew slowly from the 1960s through the early 1990s. Barnes and colleagues (1999) found that the number of peer-reviewed articles listed on Medline concerning CAM topics published between 1966 and 1996 increased steadily from about 423 articles per year in 1972 to about 1,847 articles per year in 1986; thereafter, the average number of CAM articles per year leveled off at approximately 1,500 articles per year between 1986 and 1996. The proportion of articles published between 1972 and 1986 reporting results from clinical trials was initially low (about 2.3 percent for this period), but it increased to about 10 percent during the 1987–1996 period. As a result, an initial base of research emerged that documented the central role that social, behavioral, and lifestyle factors play in the causation of morbidity and mortality. Psychological stress became a focus of this research, as several studies linked it to increased heart disease and decreased immune system functioning. Other studies showed that cognitions (attitudes, beliefs, and values), social support, prayer, and meditation could reduce psychological stress and could improve health outcomes.

Recognition of the extent of the public use of (and expenditures on) these practices led to a series of congressional hearings and the subsequent creation of the Office of Alternative Medicine (OAM) at the National Institutes of Health in 1991 to investigate and evaluate promising unconventional medical practices. The OAM later became the National Center for Complementary and Alternative Medicine (NCCAM) in 1999.

2.1.2. Congressional Mandate for the Mind-Body Interactions and Health Program

On September 22, 1998, the U.S. Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies held a hearing on mind-body medicine. Recognizing the important role that psychological stress was seen to play in causing and exacerbating morbidity and mortality, the hearing was convened to hear testimony on the status and results of the current research on mind-body interventions from leading researchers and to solicit scientific advice on ways of strengthening research on the relationship of stress to health and on interventions for reducing stress through interventions involving cognitions, social support, prayer, meditation, and other potential techniques. The Subcommittee had already advocated successfully for the introduction of provisions within the Omnibus Appropriations Bill for fiscal year (FY) 1999 to establish a mind-body research center program to investigate the benefits and application of mind-body interventions and approaches, with a specific focus on stress-related illness and the elimination of stress. These provisions were the genesis of the Mind-Body Interactions and Health Program.

In his testimony before this Subcommittee, Herbert Benson, M.D., presented the rationale for establishing a program of research on mind-body medicine and for locating it within OBSSR. He noted that mind-body therapies faced four barriers to integration into mainstream medicine: (1) the lack of awareness of existing scientific data supporting these techniques among health care providers, researchers in a variety of relevant fields, patients, and policymakers in government and industry; (2) a bias against mind-body interventions in medical care as reflecting “soft science;” (3) inadequate insurance payments for these treatments; and (4) a bias against shifting away from the overwhelming use of pharmaceuticals, surgeries, and other medical procedures. Dr. Benson then presented the following statement:

One way to overcome these barriers is the establishment of mind-body medical centers. They will make the benefits of mind-body medicine, specifically those of the relaxation response and those related to utilizing the beliefs of patients, more visible. Mind-body medical centers would also markedly expand the “hard” science base of mind-body interventions. It could be argued that the NIH already has the mechanisms to review mind-body proposals, and some might ask, “Why then the need for new centers?” NIH study sections do skillfully assess and perform reviews of quite

circumscribed research. Unfortunately, a striking paucity of study sections are equipped to adequately review proposals that investigate the simultaneously occurring multiple mind-body linkages that involve human physiochemistry, biology, psychology, social behavior, and belief-related phenomena such as spirituality. Mind-body medical centers under the auspices of the Office of Behavioral and Social Sciences Research at NIH would be a meaningful step toward overcoming narrowly focused, exclusively reductionist research. Understanding the inter-relatedness of different systems should be carried out in already-existing organizations that are experienced in mind-body research and treatments. It might be advisable to encourage the new centers to work collaboratively on joint projects. The centers would also teach and train healthcare professionals in mind-body approaches and promote responsible education to the public about mind-body mechanisms and treatments. Finally, these NIH-supported centers could markedly expand studies of the cost-effectiveness of mind-body interventions and provide data for new reimbursement strategies for Medicare and Medicaid as well as private insurers (U.S. Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies [1998, p.14]).

With the key support of Senators Arlen Specter and Tom Harkin, the same legislation that authorized the creation of NCCAM contained a specific mandate and funding for a new program of mind-body interactions and health research at NIH. The Mind-Body Interactions and Health Program would be led by the Office of Behavioral and Social Sciences Research, with 12 NIH Institutes and Centers (ICs) named as cosponsors. The MBIH Program was launched in 1999 with \$10 million in 1st-year funding for five major university-based research centers charged with investigating the relationships among cognitions, emotions, personality, social relationships, and health.

2.2. Purpose of the Outcome Evaluation Feasibility Study

Since its inception in 1999, the MBIH Program has grown to include funding for 6 R21 grants, 7 R24 grants, 16 R01 grants in 2004, 3 additional R24 grants in 2007, and an ongoing Program Announcement (PA) soliciting additional R01 applications. Although it is believed that the MBIH Program has significantly enhanced research in this area, the broader outcomes and impact of the program have not been evaluated. Evaluation of this program would enable NIH to document the major accomplishments of the program (including the emergence of new fields of research, development of new methodologies, and priorities for future research). A program evaluation would also highlight important lessons learned about the administration, conduct, and dissemination of mind-body research within the research community. An evaluation could also provide important information about the recruitment and retention of new investigators to this field. Developing better evidence through program evaluation will help enhance the dialog with researchers and practitioners and will ultimately support the case for future investment and new directions in mind-body research. As the MBIH Program approaches its 10th year of research activity, OBSSR and supporting ICs are interested in determining what the program has accomplished and whether it has met its initial program goals. The purpose of the MBIH Program Outcome Evaluation Feasibility Study, therefore, is to determine whether the program warrants a full-scale evaluation and to determine the most appropriate evaluation methodologies, techniques, and tools to measure the relevance, effectiveness, and impact of the MBIH Program at NIH.

2.3. Use of the Outcome Evaluation Feasibility Study Results

The findings from this feasibility study will be used to inform the full-scale evaluation of the MBIH Program at NIH. The main product of the feasibility study is a report whose audiences will include Federal policymakers within NIH and its Institutes, Centers, and Offices participating in mind-body research. The results will be used in three ways. They will provide important information about the scope and influence of NIH's mind-body programs and will inform future research in this area. Results from the study will also offer valuable insight into how to integrate a biobehavioral interdisciplinary perspective

into other NIH research areas. Finally, the results will contribute to the understanding of useful approaches for other NIH research center evaluation efforts.

2.4. Structure of the Mind-Body Interactions and Health Program

Given its organizational placement within OBSSR, mind-body research as defined by the MBIH Program takes a more behavioral and social sciences perspective than is typically used by the CAM published literature generally. The MBIH Program defined mind-body and health research as research that addressed “relationships among cognitions, emotions, personality, social relationships, and health.” OBSSR emphasized three topical areas within this broad definition: (1) the effects of emotions, personality, or cognitions (e.g., beliefs, attitudes, values, modes of thinking, decisionmaking styles) on physical health; (2) the determinants or antecedents of health-related cognitions and how these are formed, maintained, and/or changed; and (3) the mechanisms through which stress influences physical health. The MBIH Program has two broad goals: (1) to expand knowledge and understanding about mind-body relationships and their influences on health outcomes through basic, clinical, and health services research and (2) to translate this knowledge into effective interventions that improve health and functioning. Three programmatic objectives supported the accomplishment of these goals:

1. To facilitate interdisciplinary collaboration and innovation in mind-body research
2. To build the capacity for conducting and sustaining programs in mind-body research by providing cost-effective core services in support of the development, conduct, and translation into practice of mind-body and health research that is based in centers or comparable administrative units
3. To facilitate interaction among multidisciplinary teams of scientists throughout the United States to contribute to the integration and coordination of mind-body and health research.

At the time the MBIH Program began in 1999, staff members at OBSSR and the partnering NIH ICs sought to achieve two additional objectives. The first objective was to alert the research community that NIH was interested in funding and legitimizing research on mind-body issues and interventions and to stimulate an initial round of research by establishing five major research centers through the P50 center grants funding mechanism. The five funded P50 centers received an average of \$2 million dollars annually for 5 years to develop and sustain the necessary research infrastructure and to attract and support investigators.

Following the conclusion of the first round of research center funding (FY 1999–FY 2004), OBSSR and its partnering ICs at NIH shifted to a new objective of developing and nurturing a second generation of research centers. To accomplish this, they employed three types of funding mechanisms. The first mechanism, the R21 exploratory/developmental research award, funded institutions that could demonstrate that they had a nucleus of at least three investigators with demonstrated records in mind-body research and current research engagement. The R21 awards required institutions to develop specific core administrative and technical research services and provided funding for a 3-year period. The average annual amount of these grants was approximately \$400,000. The second mechanism was the research infrastructure award (R24 grants). These grants were awarded to institutions with a pre-existing research center whose research staff were willing to develop a program in mind-body research. These grants also required the development and/or maintenance of specific research core services. They provided funding for a 5-year period, with an average funding level of \$800,000 per year. The third mechanism was the traditional R01 investigator-initiated research grant; a total of 16 such grants were awarded. In 2007 a closed competition for three new 3-year R24 research infrastructure grants was held among the six R21 awardees; the successful awardees are funded through 2010. **Exhibit 1** contains a chart showing the institutions that received each type of grants the years in which they were funded, and the participating NIH Institute.

Exhibit 1.
Grantee Institutions, Principal Investigators, Funding Sources, and Years of Support for Mind-Body Interactions and Health Program Grantees

Institution	Principal Investigator	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Ohio State University	Ronald Glaser	NIDCR											
University of Miami	Michael Antoni	NCI											
University of Wisconsin	Richard J. Davidson	NIMH											
University of Michigan	George Kaplan	NICHHD					NICHHD						
University of Pittsburgh and Carnegie-Mellon University	Karen Matthews and Michael Scheier	NHLBI					NHLBI						
Johns Hopkins University	Jennifer Haythornthwaite						NINDS				NINDS		
New York University	Robert Cancro, then Paula McLugh						NINDS						
University of California, Berkeley	W.T. Boyce						NIMH				NIMH		
University of Rochester	Jan Moynihan						NIA				NIA		
University of Texas Medical Branch	Victor Sierpina						NIA						
University of Texas Medical Branch	Glenn Ostir						NIA						
University of Utah	Yoshi Nakamura						NCCAM						
Columbia University	Thomas Pickering						NHLBI						
Rutgers University	Howard Leventhal						NIA						
University of California, Los Angeles	Emeran Mayer						NCCAM						
University of California, Los Angeles	Andrew Leuchter						NCCAM						
University of North Carolina	William Whitehead						NIDDK						
Beth Israel Deaconess Medical Center	Russell Phillips						NCCAM						
Brigham and Women's Hospital	Sat Bir S. Khalsa						NCCAM						
Emory University	Viola Vaccarino						NIA						

Institution	Principal Investigator	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Harbor-UCLA Medical Center	Sheng-Xing Ma						NCCAM						
Indiana State University	Jean L. Kristeller						NCCAM						
Kent State University	Marianne Stephens						NIA						
RAND Corporation	Narayan Sastry						NIEHS						
Syracuse University	Joshua M. Smyth						NCCAM						
University of Maryland	Lydia Temoshok						NICHD						
University of Texas M.D. Anderson Cancer Center	Anil K. Sood						NCI						
University of Washington	Linda LeResche						NIDCR						
Virginia Commonwealth University	Nancy L. McCain						NCI						
University of California, Los Angeles	Frank Treiber						NHLBI						

Key:

- 1999 P50 Award
- 2004 R21 Award
- 2004 R24 Award
- 2004 R01 Award
- 2007 R24 Award

3. Feasibility Study Questions, Data Sources, and Data Collection Methods

This section discusses the questions examined in the feasibility study, the methods used to address these questions, and the data sources and collection approaches used to answer the questions.

3.1. Outcome Evaluation Feasibility Study Questions and Methods

The MBIH Program Outcome Evaluation Feasibility Study has three broad goals: (1) to determine whether the program is sufficiently mature and well implemented that a program evaluation is both feasible and warranted, (2) to identify the specific evaluation questions that should (and can) be investigated, and (3) to recommend the type of evaluation that is most appropriate and the type of design and measures that should be adopted. The seven questions posed for the MBIH Program Outcome Evaluation Feasibility Study are listed in **Exhibit 2**.

The MBIH Program Outcome Evaluation Feasibility Study followed a sequence of methodological steps in developing answers to the above evaluation feasibility study questions. This methodology is outlined in **Exhibit 3**.

Exhibit 2. MBIH Outcome Evaluation Feasibility Study Questions

1. What is the structure of the Mind-Body Interactions and Health Program, and how has the Program changed since its inception in 1999?
2. Is an outcome evaluation of the MBIH Program warranted and feasible at this time?
3. What conceptual frameworks or models exist in the evaluation literature to guide an evaluation of this program?
4. What evaluation methods have been used in past evaluations of research center programs, and what are their strengths and weaknesses?
5. What do major program stakeholders (e.g., OBSSR staff members, NIH program officers, center principal investigators) view as the most important questions and appropriate outcomes to include?
6. What types of data collection approaches do stakeholders view as appropriate?
7. Is a comparison group feasible for this study, and if so, what should it be?

Exhibit 3. Methodology of the MBIH Program Outcome Evaluation Feasibility Study

1. Clarification of study objectives, issues, and questions
2. Focused review of the relevant literature
3. Interviews with relevant stakeholders (OBSSR staff members, NIH program officers, Center Principal Investigators)
4. Identification of existing sources of data (e.g., annual progress reports, IMPAC II, etc.)
5. Development of a preliminary conceptual framework
6. Development of evaluation questions, variables, and indicators
7. Analysis of findings and recommendations for the outcome evaluation design

3.2. Data Sources and Data Collection Approaches

Exhibit 4 outlines the various data sources and data collection approaches used in completing each of the methodological steps in the feasibility study. The activities involved in reviewing documents, conducting the literature review, interviewing major stakeholders, and conducting site visits are discussed in subsections 3.2.1 through 3.2.4 below.

Exhibit 4.
Feasibility Study Questions, Data Sources, and Data Collection Approaches

Feasibility Study Questions	Data Source	Data Collection Approach
1. What is the structure of the Mind-Body Interactions and Health Program, and how has it changed since its inception in 1999?	<ul style="list-style-type: none"> • Meetings with OBSSR staff • Review of Requests for Applications and Program Announcements • OBSSR administrative records 	<ul style="list-style-type: none"> • Document review
2. Is an outcome evaluation of the MBIH Program warranted and feasible at this time?	<ul style="list-style-type: none"> • Opinions of primary stakeholders • Professional judgment 	<ul style="list-style-type: none"> • Meetings and discussions with OBSSR staff • Interviews with NIH program officers and principal investigators • Site visits
3. What conceptual frameworks or models exist in the evaluation literature to guide an evaluation of this program?	<ul style="list-style-type: none"> • Review of published and unpublished literature 	<ul style="list-style-type: none"> • Literature searches on Medline and via the Internet • Review of bibliographies from published or unpublished reports
4. What evaluation methods have been used in past evaluations of research center programs, and what are their strengths and weaknesses?	<ul style="list-style-type: none"> • Review of past reports and studies from the evaluations of NIH research centers • Review of published and unpublished literature 	<ul style="list-style-type: none"> • Literature searches on Medline and via the Internet • Review of bibliographies from published or unpublished reports • Retrieval of NIH study reports
5. What do major program stakeholders (e.g., OBSSR staff members, NIH program officers, center principal investigators) view as the most important questions and appropriate outcomes to include?	<ul style="list-style-type: none"> • Opinions of primary stakeholders • Professional judgment 	<ul style="list-style-type: none"> • Interviews with NIH program officers and center principal investigators • Site visits
6. What types of data collection approaches do stakeholders view as appropriate?	<ul style="list-style-type: none"> • Opinions of primary stakeholders 	<ul style="list-style-type: none"> • Interviews with NIH program officers and center principal investigators • Site visits
7. Is a comparison group feasible for this study, and if so, what should it be?	<ul style="list-style-type: none"> • Opinions of primary stakeholders • Review of past reports and studies from the evaluations of NIH research center programs 	<ul style="list-style-type: none"> • Interviews with NIH program officers and center principal investigators • Retrieval of NIH study reports

3.2.1. Review of Documents and Administrative Records

To gain a broad understanding of the MBIH Program, a comprehensive review was conducted of existing administrative documents and records, including solicitations (Requests for Applications [RFAs] and PAs), the grants management databases IMPAC II and Research, Condition, and Disease Classification (RCDC); annual progress reports submitted by each funded center; and several other administrative records maintained by OBSSR staff identifying the principal investigators, institutions, and type of funding mechanism used for the grants awarded in 1999 and 2004. These sources provided several types of information for the feasibility study.

The review of RFAs and PAs provided useful information on partnering NIH ICs and their interests in specific facets of mind-body research, the requirements that each grant applicant had to meet to be eligible to apply for funding under a specific funding mechanism, and the tasks that each grantee had to perform as a condition of award.

The NIH RCDC reporting system was used to examine the “fingerprint” for mind-body research for FY 2007. The “fingerprint” includes the activity code (type of funding mechanism), name of the Principal Investigator, institution, and award amount.

Copies of annual progress reports from each of the six 2004 R21 centers and seven R24 centers were obtained from IMPAC II for the most recent year available (usually 2006–2007). These reports were assessed for their value in providing information on research center personnel and publications as well as providing data on the status of existing administrative and technical core services. This assessment included the development and completion of a brief abstracting protocol for each of the two types of centers (R21 and R24).

Information was also obtained from OBSSR administrative records on the NIH program officers assigned to each of the 2004 R21 and R24 grants. This information was used to identify potential interviewees for stakeholder interviews.

3.2.2. Review of the Literature

As part of the feasibility study, a review of the published and unpublished literature on the evaluation of biomedical research and development (R&D) programs was conducted. The literature on the evaluation of R&D programs is fragmented and difficult to search by conventional means. Furthermore, the published literature on the evaluation of biomedical R&D programs remains rather small. Five strategies were used to overcome these challenges. First, searches of major publication databases, including PubMed and Scopus, were conducted using such terms as the evaluation of research and development programs, evaluation of R&D programs, research payback, and the evaluation of science and technology programs. Keywords were refined based on clusters of papers within the literature. For example, additional terms such as research value mapping, scientific and technical human capital, research environment, and transdisciplinary research programs, were used, as these emerged from successful searches. The literature was also searched by specific authors, as their names were identified in the literature. Second, the references and bibliographies of relevant articles were examined, and many additional articles, papers, reports, and presentations were identified. Third, several journals that have published a number of papers on the evaluations of R&D programs were searched manually; the Contents for these journals were reviewed for all available issues dating back to the 1980s. Among these journals were *Research Policy*, *Research Evaluation*, *Evaluation and Program Planning*, and *Evaluation Review*. Fourth, NIH program staff members who are particularly interested in program evaluation and in the evaluation of biomedical R&D programs were contacted and asked for copies of any available reports that they had. This process yielded several examples of NIH evaluations of research center programs that would not have otherwise been available. Finally, an Internet search was conducted using Google and applying the same types of search terms used in the published literature databases. This search led to the Web sites of several organizations that were actively pursuing evaluation studies on a variety of biomedical and other types of R&D programs; many of these Web sites contained unpublished reports and papers that also would not have been available through typical searches.

3.2.3. Interviews With Major Stakeholders

An important part of data collection for the feasibility study involved interviews conducted with major program stakeholders. Two stakeholder groups were identified: (1) NIH program officers who administered the different MBIH research grants and (2) principal investigators associated with the 2004 R21 and R24 research centers. The MBIH Program represented a partnership between OBSSR and other NIH ICs. Therefore, the views of program officers from other ICs were important to the design of an outcome evaluation. Structured interviews were conducted in January 2008 with 9 of the 10 program officers (representing eight ICs). The interview protocol included questions about the specific research grants administered by the program officers as well as questions about the feasibility of conducting an evaluation of the MBIH Program (including the types of questions that should be asked, data collection approaches, and desirability and feasibility of establishing a comparison group for the study). Interviews were conducted either in person or by telephone and required between 45 and 90 minutes to complete, with an average length of about 60 minutes. Summaries of the responses to each question were drafted

from handwritten notes and were content-analyzed to tabulate responses. A copy of the structured protocol is provided in Appendix 1.

The second group of stakeholders was the principal investigators of the 2004 R21 and R24 centers. No attempt was made to interview the principal investigators from the original five P50 grants because the funding for these had long since ended. The interview protocol was constructed in two parts. Part One contained several questions about the nature of the research centers' activities and the extent to which the principal investigators believed that they had met their own internal goals. Part Two included questions about an evaluation of the MBIH Program as a whole, such as the types of evaluation questions that should be asked, the types of data collection approaches that would be most useful, and whether a comparison group could be constructed. These interviews were conducted exclusively by telephone in late April and early May 2008. All 13 principal investigators were interviewed; the calls averaged about 60 minutes in length. A copy of the protocol is provided in Appendix 1.

3.2.4. Site Visits

Although much can be learned about the activities of research centers from reports and discussions with principal investigators, there is no substitute for firsthand observation. One-day visits were conducted at two research centers during the summer 2008. The centers were selected to represent an R21 center and an R24 center. The visits were deliberately informal in nature and provided an opportunity for two members of the evaluation team to meet with the principal investigator and key research staff members (e.g., leaders of core services, research team leaders) to gain an overview of the origin and history of each center, its research focus, and its major accomplishments. The meeting also provided an opportunity to discuss in more detail ideas about the design of an outcome evaluation, data collection approaches, and possible comparison strategies.

4. Findings From the Feasibility Study

This section summarizes findings from the review of documents and administrative records, review of evaluation literature and reports, stakeholder interviews, and site visits to MBIH centers.

4.1. Review of Documents and Administrative Records

The evaluation team reviewed three sets of documents and administrative records: (1) the Requests for Applications and Program Announcements issued for each phase of the MBIH Program, (2) the 2007 RCDC mind-body research “fingerprint,” and (3) the grant applications and annual progress reports for the 2004 R21 and R24 research centers. This review was conducted to identify the types of programmatic information that each source provided and to assess the feasibility of using each type of document or record as a data source for the outcome evaluation. In addressing the latter aim, the team investigated the range of information provided and the consistency of its presentation in the data source. The results from this review are presented below.

4.1.1. Review of Requests for Applications and Program Announcements

RFAs and PAs provide important information on the aims of the research initiative, involvement (if any) of partnering NIH ICs, types of research grants supported by the RFA or PA (e.g., grant activity codes), examples of the types of research questions that would be considered appropriate by the sponsoring IC (and by partnering ICs, if any), eligibility for awards, and administrative information. RFAs and PAs also include background information that describes why there is NIH interest in soliciting applications on the designated topics and that positions the current initiative in a brief history of inquiry into the topic. For the feasibility study, the main value of an examination of the RFAs and PAs was to identify the specific ICs participating in the MBIH Program at any point in time. This information is summarized in **Exhibit 5**.

Exhibit 5.
NIH Institutes and Centers Participating in the MBIH Program: 1999–2010

NIH Institute Or Center	1999 P50	2004 R21	2004 R24	2004 R01	2005 PA 05-027 (R01)	2007 R24	2007 PA 07-046 (R01)
NCI							
NCCAM							
NHLBI							
NIA							
NIAAA							
NICHD							
NIDA							
NIDCR							
NIDDK							
NIEHS							
NINDS							
NIMH							
Total ICs	5	5	5	7	10	3	9

4.1.2. Review of RCDC 2007 Mind-Body Research “Fingerprint”

The NIH RCDC system was searched for mind-body research funded in 2007. The results showed that NIH funded 456 grant applications pertaining to mind-body research in FY 2007. Because the RCDC is a new system, it was not feasible to obtain data from an earlier fiscal year at the time that this report was being prepared. A total of 32 types of grant mechanisms (activity codes) were represented among the funded grants; the largest grant category was the investigator-initiated R01 grants (n=195, or 42 percent of the total grants funded.) Three ICs collectively accounted for 78 of the 195 R01 grants, or 40 percent of the total: the National Institute of Mental Health (NIMH) (32), National Cancer Institute (NCI) (25), and National Institute on Drug Abuse (NIDA) (21). There were also 52 R21 grants funded during FY 2007. Of these, 27 R21 grants (52 percent) were funded by NCCAM.

4.1.3. Review of Grant Applications and Annual Progress Reports

The evaluation team reviewed the grant applications and annual progress reports for information on each of the six 2004 R21 grants and the seven 2004 R24 grants. The grant applications are a rich source of data on the specific goals and objectives of each center, process of how and why the centers developed, initial resources and core services, proposed research foci, and staffing and personnel. Annual progress reports also provide an update on the implementation process for and the accomplishments and challenges faced by these centers over the course of the grant period. From past experience, however, we believed that some annual progress reports would provide a richer and more detailed picture of the changes over time than others and that the level of detail for most of the centers’ reports would decrease with time. Moreover, the annual progress reports required from the R21 exploratory/developmental grants used a more abbreviated format than that used by the R24 research infrastructure programs, raising questions about the content, level of consistency, and detail that we might be able to derive from relying on these reports.

To explore the latter set of issues, we reviewed the annual progress reports for the most recently available year for each of the 2004 R21 and R24 grants. Using a data abstraction form, information was recorded from the R21 grants on the following elements: names and levels of support for research staff supported under the R21 grant, recent publications, and active grants. Sketchy information was available related to grant accomplishments in particular areas, but this was highly variable in the level of detail and content. We sought similar information from the R24 grant reports. These annual progress reports contained information on the names and levels of support for individuals supported under the R24 grant; names of

students and fellows, recent publications, active NIH grants, current pilot studies funded by the center, and detailed accomplishments and plans for each of the various core service areas supported by the grants. Overall, the data abstraction confirmed the initial concerns about variability in content and the level of consistency and detail in the information provided. Although the grant applications would be an important source of baseline information about each center, the annual progress reports provide useful information on a few elements (e.g., name and level of support of research staff, recent publications, and active grants.)

4.2. Review of Evaluation Literature and NIH Program Reports

The evaluation team conducted a review of the evaluation literature to identify the evaluation models and methods that have been used in the evaluations of R&D programs in the United States and in the United Kingdom and Canada. The review was supplemented by examining reports on the evaluations of research center programs within NIH.

4.2.1. Findings From the Review of Evaluation Literature

The literature on evaluations of research, technology, and development programs has emphasized research and development in the fields of science, engineering, and national defense, with a lesser focus on biomedical R&D programs. Several source documents provided useful entry points into this literature. A book by Bozeman and Melkers (1993), *Evaluating R&D Impacts: Methods and Practices*, collected a series of papers that reviewed the use of major evaluation approaches through the early 1990s. More recent collections of papers include a report from the Management Benchmarking study (Washington Research Evaluation Network [2002]) and a report published by the National Institute of Standards and Technology (Ruegg and Feller, 2003). Among the evaluation approaches discussed in these publications are peer reviews, case studies, historical tracing methods, content analyses, surveys, bibliometric analyses, cost-benefit analyses and return-on-investment methods, benchmarking, input-output analyses, systems models, performance indicators, and social network analyses.

4.2.1.1. Early History of Evaluation of Public Research and Development

Evaluation of publicly funded R&D programs has occurred within a more fragmented context in the United States than in the European Union. Cozzens (2000) offers several reasons for this: (1) the U.S. R&D system is far larger than that of other nations (accounting for approximately one-third of the total world effort); (2) there is no central national system of universities in the United States, so questions about how to evaluate R&D programs have not arisen here in the same manner as in other nations; and (3) there is no central research council or group of councils in the United States to clearly distinguish basic from applied research. As a consequence, U.S. Federal agencies supporting research have followed two paths. Fundamental research organizations, such as the National Science Foundation and NIH, have tended to commission formal program evaluations outside their core research activities. By contrast, mission-oriented agencies, such as the Office of Naval Research and the U.S. Department of Energy, have utilized systems of regular program review in which panels of outside experts are asked to provide assessments of agency research based on data provided to them by the agency.

Georghiou and Roessner (2000) traced the history of the evaluation of R&D programs in the United States back to early studies by economists during the 1960s and 1970s. These economic studies developed estimates of the rate of economic returns from investment in R&D and explored the costs and benefits of supporting basic versus applied research. However, few studies at that time examined the social (or noneconomic) benefits resulting from changes in technology. By the late 1970s and early 1980s, a second wave of evaluations began to explore the use of a broader range of evaluation approaches, especially bibliometric analyses. During the 1980s, NIH in particular promoted the development of bibliometric tools and methods of analysis (Hicks et al., 2004, and Michelson, 2006.)

There was also increased interest in noneconomic benefits and outcomes resulting from research programs. Dominant methodological approaches utilized during this period included expert peer-review panels, case studies, bibliometric analyses, and surveys. In the early 1980s, the journal *Research Evaluation* emerged as a focal point for published evaluations on R&D programs. By the 1990s a community of evaluators with interests in the evaluation of these programs had begun to coalesce, and in 1994 *Evaluation Review* published an entire issue that addressed the state of the art in evaluations of R&D programs.

Much of this early, pre-1990s research focused on outputs from R&D programs. Examples of commonly assessed outputs during this period included the quantity of knowledge produced (e.g., publications, invitations to speak at conferences and professional meetings, awards, honors, positions in professional societies) and the numbers of patents and devices produced. One exception to this early focus on outputs was the widespread use of peer review to assess the quality of research that had been conducted. Apart from this notion of the quality of research, the conceptualization of noneconomic outcomes did not progress far during this period.

4.2.1.2. Evaluation of Publicly Funded Research and Development Programs Since the 1990s

In 1993 Congress passed the Government Performance and Results Act of 1993 (GPRA). GPRA's requirements that agencies establish measurable goals and report their progress toward achieving them posed a serious challenge for agencies that funded R&D activities. The historical emphasis on short-term (and readily measurable) processes, such as publication counts, would no longer provide sufficient and acceptable evidence of goal attainment under GPRA. However, the longer term outcomes that resulted from research would be more challenging to measure, take longer to accumulate, and were more difficult to attribute directly to a particular research project or program. This dilemma prompted considerably greater interest in the identification and measurement of noneconomic outcomes from R&D programs.

The search for measurable noneconomic outcomes led to the development of conceptual frameworks for the evaluation of publicly funded R&D programs in both the United States and European Union. In the United States, for example, Altschuld and Zheng (1995) published an influential paper that explored the application of the construct of organizational effectiveness to the evaluation of R&D programs. Their paper compared four theoretical perspectives on organizational effectiveness and suggested how they might be applied in evaluating R&D programs. Stryer and colleagues (2000) described an empirically derived outcomes framework that emerged from an evaluation of the Agency for Healthcare Research and Quality's (AHRQ) outcomes and effectiveness research program. Its framework included four levels of potential benefit or payback from outcomes and effectiveness research, including research findings, impacts on policies, impacts on clinical practice, and impacts on health care outcomes. AHRQ emphasized that considerable periods of time might pass between conducting specific research studies and achieving impacts in the latter levels of their framework.

In the United Kingdom, a similar framework had emerged from a series of health-related evaluation studies of National Health Service programs conducted during the early 1990s by members of the Health Economics Research Group at Brunel University. This framework (the research payback framework) included a multidimensional categorization of five types of potential benefits produced from research projects and programs. The five categories included knowledge production, research targeting and capacity-building, informing policy and clinical practice, health and public health effects, and social and economic benefits at the societal level (see **Exhibit 6.**) This outcome categorization schema has been adopted widely in a series of subsequent evaluations of programs within the National Health Service (Buxton et al., 2000), Arthritis Research Campaign (Wooding et al., 2005), Alberta Heritage Foundation for Medical Research (Buxton and Schneider, 1998), and Health and Health Services Research Fund of Hong Kong (Kwan et al., 2007). The framework has been applied successfully both internationally and by researchers independent of the original research team that developed it. The framework's developers have

developed a basic methodological approach involving the use of investigator surveys at the level of individual research projects (Hanney et al., 2000, and Kwan et al., 2007). Benefits are recorded for each category of outcome for individual projects and can then be aggregated to apply to the activities of a research center portfolio.

Exhibit 6. Categorization of Research Benefits	
Knowledge Production	
Journal articles, presentations, monographs, book chapters, books, research reports, and patents	
Research Targeting and Capacity-Building	
Better targeting of future grants (e.g., spinoff grants), the development of research skills among faculty members and trainees; the training of students and fellows, the mentoring of new faculty, outreach to community organizations	
Informing Policy and Clinical Practice	
Inclusion of studies in systematic reviews, meta-analyses, clinical guidelines, improved informational base for policy decisions, and the adoption of clinical protocols in clinical practice	
Health and Public Health Effects	
Improved health of research participants and improvements in community health	
Social and Economic Benefits	
Broader social and economic impacts at societal levels	

4.2.1.3. Evaluations of Research Centers

An important issue that has not been addressed well in the previous evaluations of R&D programs is that of differentiation among individual projects (some of which may be quite large), research centers (which typically include several projects), and research programs (which may include both centers and individual projects.) The evaluation literature lacks a single, agreed-on definition of what is meant by the term “research center.”

Research centers in the United States grew out of the academic setting. Historically, research activities within American universities have followed one of two models (Geiger, 1990.) *Departmental research* represents the traditional expectation for and facilitation of the formal

scholarship associated with a faculty position. However, there are certain types of research that do not mesh well with departmental structure or the traditional annual academic cycle. These projects may be larger in scale, longer in duration, and/or more costly and/or may necessitate multiple disciplinary perspectives to complete. They may also require specific equipment or laboratory facilities that may not be practical for a single department to maintain. To attract and support these research activities, universities developed *organized research units*, or research centers and institutes that could operate quasi-independently from traditional academic departments.

The terms “research center” and “institute” have tended to become increasingly synonymous in recent years. Although both share a common primary mission of research activities, they vary considerably in size and organizational characteristics. Geiger (1990) distinguished between research centers and institutes by noting that research centers are generally intended to promote multidisciplinary research, although research investigators typically continue to identify with their individual departments. By contrast, institutes are often tied more closely to the research missions and priorities of their principal funding agencies or benefactors. Gray (2000) described one type of research center, which he termed “cooperative research centers,” as semiautonomous research units within a university that operate independently of academic departments and include a multidisciplinary team of researchers who span two or more departments or divisions and a portfolio of research projects that may be organized into distinct program areas. Cooperative research centers also include an organizational structure with a management team and often develop around shared access to a facility, laboratory, specialized equipment, or specific expertise. Over the past 35 years, the number of research centers and institutes in academic settings has grown considerably; NIH reported funding 1,137 research center grants in FY 2002 (Institute of Medicine, 2004), and its funding for center grants has typically ranged between 8 to 9 percent of the total NIH budget since FY 1990.

In its 2004 review of NIH’s center grants programs, the Institute of Medicine (IOM) approached the problem of defining research centers by focusing on the types of grant mechanisms that purportedly fund them. After conducting a review of all RFAs and PAs for research centers issued by NIH between 2001

and 2003, IOM found that some programs that were supported by these mechanisms were not actually centers, while other projects funded under noncenter grant-funding mechanisms supported projects that closely resembled research centers. In its effort to steer through this confusion, IOM defined research centers in terms of what is funded by the research center grants. “Research center grants are awarded to extramural research institutions to provide support for long-term, multidisciplinary programs of medical research. They also support the development of research resources; aim to integrate basic research with applied research and transfer activities; and promote research in areas of clinical applications, with an emphasis on intervention, including prototype development and the refinement of products, techniques, processes, methods, and practices.”

Using this definition of research center grants, IOM identified three types of center grants. *Center infrastructure* grants (also called “core” grants) support a research center’s director and several core administrative and technical services utilized by a group of investigators whose research is funded by independently obtained research grants. A primary goal of these grants is to facilitate interactions and collaborations among investigators whose research focuses on a particular disease or scientific problem while increasing efficiency in the provision of common and often expensive research tools and services. Common activity codes (types of grants) include P30 core grants and, more recently, R24 resource-related research project grants. *Research center* awards fund core administrative and technical services and individual research projects as well. These grants sometimes support additional activities including community education, screening and counseling programs, and the education of medical and allied health professionals about state-of-the-art diagnostic, prevention, and treatment techniques. Research center awards are designed to encourage multidisciplinary or clinical research that has not been addressed by investigator-initiated projects; examples include many of the disease-specific centers that Congress has mandated in recent years (e.g., centers on Parkinson’s disease, autism, and muscular dystrophy). Typical activity codes associated with these grants include P50 and P60 center grants, U54 cooperative agreements, and some P30 grants. Occasionally, U19 cooperative agreement and P01 program project grants have also been used to fund these centers. *Research resource center* awards develop and disseminate research resources and tools to any researcher in the Nation; many of these awards have been made by the National Center for Research Resources, using P40, P41, U41, and U42 center awards.

As a major strategy for stimulating research, research centers are believed to confer several advantages over the funding of individual, investigator-initiated research (Institute of Medicine, 2004). Because research centers can provide access to shared and often costly resources and services, it is believed that they can enhance the quality, productivity, and cost-effectiveness of externally supported research projects. By providing limited amounts of funding for preliminary data collection or pilot or developmental projects, research centers can support the entry of new investigators into a specific field of research and can provide more opportunities for exploratory or innovative research than the more conservative proposal/peer-review process might permit. A third potential advantage is that research centers can foster an environment that supports multidisciplinary collaboration and interaction to a greater degree than an isolated, noncenter-affiliated investigator would be likely to experience. However, there is a limited base of evaluation research that supports these arguments. For example, using a representative sample survey of academic scientists affiliated with Carnegie Research Extensive universities, Corley and Gaughan (2005) showed that center affiliation was associated with an increase in researchers’ research-related activity compared with teaching or service obligations over that reported by scientists who were not affiliated with research centers. In a recent study of cooperative reproductive health centers funded by the National Institute of Child Health and Human Development, Gaughan and Ponomariov (2008) concluded that center affiliation produced higher rates of collaboration through coauthorship than nonaffiliation.

4.2.1.4. Recent Developments in Methodology

There have been several important developments in methodology worth noting. The first is the emergence of social network analysis (SNA) as an approach for examining the patterns of growth and collaboration among researchers. It has long been recognized that the networks of researchers play an important part in the conduct of research. The development of SNA has led to insights about the role that specific network characteristics play in promoting productivity and collaboration (Mote et al., 2007.) For example, SNA studies have shown that network characteristics, such as centrality, diversity, density, and heterogeneity, are associated with greater productivity; network position (i.e., centrality) may in fact be a stronger predictor of performance than individual investigator characteristics. Another important finding is the role played by individuals who serve as connections between two separate groups of individuals. These individuals, often termed gatekeepers or boundary-spanners, play an important function in sharing information external to a group with other members, and the role of gatekeeper (or boundary-spanner) is important because individuals who are connected to two different groups frequently act as a bridge for sharing information external to these groups (Mote et al., 2007.) Recent applications of SNA as an evaluation approach include a longitudinal study of the patterns of growth and multidisciplinary activity at the Center for Interdisciplinary Research on Antimicrobial Research at Columbia University (Aboela et al., 2007), and an evaluation of the extent of transdisciplinary collaborations among tobacco researchers (Provan et al., 2008). Heinze and Bauer (2007) recently demonstrated the use of a new measure called the Network Brokerage Index, which assesses the extent to which individuals play boundary-spanning roles within their publication networks. The use of SNA as an evaluation approach has been greatly facilitated by the availability of specific software packages, such as UCINET 6, which can visually display network linkages and can calculate a variety of measures of network characteristics (including the Network Brokerage Index.)

Another evaluation approach in which new developments are occurring is bibliometrics. Although bibliometrics has traditionally focused on publication counts and on the analysis of citations, newer measures are emerging that extend the range of potential analyses. One example noted by Heinze and Bauer (2007) is an index of “thematic breadth,” which combines the number of journals in which a scientist publishes with the concentration of publications within these journals. The index of thematic breadth amounts to a measure of multidisciplinaryity.

4.2.2. Past Evaluations of Research Center Programs at NIH

A summary of 21 evaluation studies on research center programs at NIH between 1978 and 2008 can be found in **Exhibit 7**. These studies were identified from several sources, including Rowe (1994), Gallup Organization (2002), our own records, and discussions with evaluation contacts within NIH. Although the list may not be comprehensive, it is representative of evaluations for which reports are available. **Exhibit 7** shows the Institute within which each research center program was based, author(s) and year of the report, type of large grant mechanism, nature of any comparison groups used in the evaluation, and types of output and/or outcome measures that were used in the study.

Few of these studies have appeared in published form outside NIH. Most of the studies focused on large research centers funded as P50 grants (10 of 21), P30 grants (3) and/or P60 or P20 grants. A total of 14 of the 21 studies utilized some type (or types) of comparison strategy. These strategies tended to fall into four categories: (1) matched comparisons with similar institutions not funded under the target program, (2) unsuccessful center grant applicants, (3) the comparison of centers with R01 investigators, and (4) historical comparisons of the grantees prior to receipt of the award. From a methodological perspective, the evaluation studies utilized a variety of approaches, including program reviews, bibliometric analyses, and case studies. Analyses of the publication counts and grant activity were the two most frequent outcome measures examined.

Exhibit 7.
Summary of NIH Research Center Evaluations

NIH Institute or Center	Author and Year of Report	Type of Large Grant	Comparison Group(s)	Output and/or Outcome Measures Used
Trans-NIH	Carter, Lai, and Lee (1978) RAND Corporation	P01, P30, and P50 grants funded in FY 1974–FY 1973	R01 grants matched for Institute (sometimes research program within Institute), total amount of funding, and duration	<ul style="list-style-type: none"> Investigator approval rates and priority scores Citation counts Fields of publications Interdisciplinary research Backgrounds investigators
NIDR (now NIDCR)	Brodsky et al. (1982)	P50 Dental Research Institutes and Centers (DRICs)	No comparison group	<ul style="list-style-type: none"> Total number of publications Number of publications per research investigator Number of collaborative publications with researchers at same DRIC or at other universities
NIDR (now NIDCR)	Reisher and Namin (1984)	P50 Dental Research Institutes and Centers	Entire NIDR R01 portfolio	<ul style="list-style-type: none"> Publication frequency Impact Authorship Support Author background Types of journals where publications appeared Recruitment of scientists to dental research
NHLBI	Roth (2000)	P01 (Programs of Excellence in Molecular Biology [POEMBI])	Unsuccessful P01 grant applicants	<ul style="list-style-type: none"> Grant activity Publications Interviews with PIs Career trajectories of trainees
NCRR	James Bell Associates (1996)	M01 General Clinical Research Centers (GCRCs)	(1) Clinical investigators at GCRCs who used or did not use GCRC resources (2) CAP versus K08 awardees (training grants)	<ul style="list-style-type: none"> Publications Time spent on research Grant activity Resource and facility utilization
NIAMS	Rich (1996)	P60 NIAMS Centers	Noncenter-affiliated investigators with more than \$500,000 funding per year	<ul style="list-style-type: none"> Qualitative survey of center affiliation advantages and disadvantages Grant activity
NCRR	QRC Macro (1999)	G12 Research Centers in Minority Institutions	Matched institutions with similar PHS research funding, public/private assets, and location	<ul style="list-style-type: none"> Publications and citations Grant activity Graduates and fellows Knowledge transfer (educational outreach to professionals and the community) Resources and facilities

NIH Institute or Center	Author and Year of Report	Type of Large Grant	Comparison Group(s)	Output and/or Outcome Measures Used
NCRR	Wells et al. (2000)	P20 Research Infrastructure in Minority Institutions	Matched institutions with similar PHS research funding, Carnegie classification, and census region	<ul style="list-style-type: none"> • Publications • Grant activity • Majors and graduates • Collaborative activities • Utilization of core resources
NCRR	James Bell Associates (2000)	P51 Regional Primate Research Centers	(1) Center-center comparisons (2) Other researchers publishing on nonhuman primates	<ul style="list-style-type: none"> • Publications and citations • Trainees • Animal production and income generated • Cost-effectiveness • Utilization of core resources
NIAMS	NIAMS (1997)	P30, P50, and P60 Centers (Multipurpose Arthritis and Musculoskeletal Diseases Centers; Specialized Centers of Research; Skin Disease Research Centers)	Investigators who were affiliated with centers versus those not affiliated	<ul style="list-style-type: none"> • Survey of center directors and noncenter-affiliated directors • Peer review of background documents and materials
NICHD	NICHD (1999)	P30 Population Research Centers Program	Historical comparison and comparison with nonfunded applicants for P30 grants	<ul style="list-style-type: none"> • Program review (peer review plus interviews with key constituencies) • Grant activity • Publications
Trans-NIH	NIH OAR (1999)	Centers for AIDS Research Program	No comparison group	• Program review
NHLBI	NHLBI (2001)	P50 Specialized Centers of Research	No comparison group	• Program review
NCCAM	NCCAM (2002)	P50 Research Centers	No comparison group (program review)	• Program review
NIA	NIA (2002)	Alzheimer's Disease Centers	No comparison group (program review)	• Program review
NCI	National Cancer Advisory Board (2003)	P30 and P50 Cancer Centers Program and Specialized Programs of Research Excellence	No comparison group	<ul style="list-style-type: none"> • Publications • Grant activity
NINDS	NINDS (2007)	P50 Udoil Parkinson's Disease Research Centers	R01 investigators	<ul style="list-style-type: none"> • Publications • Grant activity
NICHD	Gaughan and Ponomarev (2008)	Specialized Cooperative Centers Program in Reproductive Research	Group of research investigators matched on field and level of training	<ul style="list-style-type: none"> • Grant rate • Collaboration rate • Publication rate
NICHD	Youlie et al. (2006)	National Cooperative Program in Infertility Research	Multiple case study of three research centers	<ul style="list-style-type: none"> • Publications • Grant activity • Training activities
NIDCR	Glavin (2007)	Centers for Research to Reduce Oral Health Disparities	No comparison group	<ul style="list-style-type: none"> • Grant activity • Publications

Exhibit 7 also shows the common methodological approaches and outcomes used in previous evaluations of NIH research center programs. Among the most commonly used approaches are program reviews (expert panels comprising IC staff members and sometimes outside scientists or other content experts), bibliometric methods, case studies, and surveys. These approaches are often employed in combination. Michelson (2006) notes that over the years, NIH has developed a hybrid assessment approach based on a combination of bibliometric analysis, case study analysis, and an expert review of program performance.

Four types of outputs and outcomes are commonly examined in these studies. The most frequent type of indicator is the number of publications as well as more sophisticated analyses of citation patterns, the types of journals in which the publications appear, journal impact factors, and coauthorship (collaboration) patterns. Grant activity as assessed by the number of research grants and follow-on grants obtained, degree to which researchers collaborating on grants are interdisciplinary, and approval (or “success”) rate constitute a second common type of indicator. A third set of indicators includes measures of the number of trainees trained, fellows recruited and mentored, and new investigators either recruited or groomed from within the centers. A fourth set of indicators involves the development and use of various core administrative and technical research services and facilities.

4.3. Stakeholder Interviews

The evaluation team conducted interviews with 9 NIH program officers and 13 principal investigators (6 from the 2004 R21 grants and 7 from the R24 grants). The results from the program officer and principal investigator interviews are generally consistent and demonstrate a high level of agreement, so they have been combined here for ease of presentation. The findings from these interviews are presented for three sets of topical issues: (1) the feasibility of conducting an outcome evaluation of the MBIH Program at this time, (2) the types of outcome evaluation questions that should be included in an outcome evaluation, and (3) the types of methodological approaches that should be used in an outcome evaluation.

4.3.1. Stakeholders’ Views on the Feasibility of Evaluating the MBIH Program

Both the NIH program officers and principal investigators agreed strongly that the MBIH Program has played an important role in stimulating mind-body research in general and that an evaluation of the program is clearly indicated. However, several program officers and principal investigators noted that the program has not concluded. They pointed out that the 2004 R24 grants were awarded for 5 years and are not due to end until August and September 2009 and that several of the R21 grantees continue to operate under no-cost extensions until fall 2008. Moreover, three new R24 awards were just issued in October 2007 and will continue until 2010, and the R01 investigator-initiated grants can be awarded under the current PA (07-046) until January 2010. They cautioned that a final “sunset” evaluation of the program would miss the remaining contributions that could yet arise from these continuing efforts. For that reason, they suggested that the outcome evaluation be conducted in two phases, a first phase that would focus on the accomplishments and achievements for the centers and investigator-initiated R01 grants funded in 2004 and a second phase that would address the long-range effects of these centers and the research funded under the two PAs issued after that year. This latter effort would necessarily focus on the short-term and intermediate effects of those grants.

4.3.2. Evaluation Questions and Outcomes To Include in the Outcome Evaluation

Few stakeholders had difficulty in identifying one or more questions that they believed should be included in an evaluation of the MBIH Program. In examining the types of outcomes that stakeholders identified, we found that they clustered into several categories, which are generally sequential in nature and build on one another. The first outcome category reflected the conventional notion of publications, presentations, and awards and honors accorded to research center staff. It also included new research grants that developed as “spinoffs” from the pilot work funded by the centers or through earlier mind-

body research grants. We grouped these under the heading “knowledge production.” A second outcome category included the potential effects of the research center on students, fellows, and new investigators as well as the new research collaborations within the scientific community and the partnerships with the local community. We called this category “human resource and research capacity development.” The third category reflected evidence of the diffusion of the results to the research community, clinical practitioners, policymakers, and educators. Examples of outcome measures suggested within this category included the citation of center publications by other researchers not connected with the centers, evidence that other noncenter-affiliated investigators were studying and testing hypotheses and models identified by center-affiliated researchers, the adoption of clinical protocols by clinical practitioners, and the inclusion of units and even courses on mind-body research in medical school curricula. The fourth outcome category represented the effects that the use of mind-body research findings had on community health or public health. Although most stakeholders believed that this outcome category was arguably the most important to examine, there was consistent agreement that many years would be required for most biomedical research to produce this type of effect and that evidence of this effect from centers’ activities was not likely to be detected at this point in the MBIH Program’s history. The fifth outcome category included broader social and economic impacts that would occur as a result of the health and training effects that had appeared earlier. These categories generally parallel the outcome categories proposed earlier by Buxton and Hanney (1996) and Hanney and colleagues (2000) as part of their research payback framework.

The stakeholders also suggested three additional questions that fall outside this framework. The first question concerned the sustainability of the mind-body research centers funded through the MBIH Program. How successful have the research centers been in locating additional sources of funding to support the research cores that they have developed? Have they been able to interest their home institutions in providing support for some or all of these cores? Have they established connections with other Federal agencies or with private foundations or companies that would enable them to continue to operate after their current R21 or R24 funding ends? Interviews with principal investigators suggested that there has been considerable variability in the types of strategies pursued to sustain the center programs, ranging from active collaboration with the pharmaceutical industry to efforts to persuade various academic departments within their institutions to “own” some of the developed core services.

A second question concerned the effect that the research centers have had on legitimizing mind-body research within their medical schools. Are the medical schools more willing to tolerate or encourage research activities on mind-body research issues and topics as a result of the activities of their own research centers?

The third question concerned the effect that the research and scholarship activities of the research centers have had on science in general. What particular contributions have MBIH researchers made in terms of new hypotheses and research directions, new tools or measurement approaches, and new ways of understanding earlier observations and findings through model or theory development?

4.3.3. Stakeholders’ Views Concerning Methodological Approaches

In the interviews conducted with principal investigators, we asked for their perspectives on the strengths and limitations of several types of methodologies commonly used in the evaluations of research programs. The methods examined included reviews of program documents, bibliometric analyses, social network analyses, case studies of research centers, and site visits to research centers. The results from this question are shown below in **Exhibit 8**. The strengths and limitations reported are those identified by the principal investigators.

Exhibit 8.
Strengths and Limitations of Several Methodological Approaches

Methodological Approach	Strengths of Approach	Limitations of Approach
Reviews of Existing Documents (Including grant applications, integrated review groups summary statements, advisory board minutes, and annual progress reports)	<ul style="list-style-type: none"> • Easiest and highest level of feasibility. • Annual progress reports would provide a good measure of the accomplishments of each center. • Should definitely be done. 	<ul style="list-style-type: none"> • These documents do not give good insight into how each center really worked or the effect the work has had on outcomes. • Different format for R21 and R24 centers. • Not much depth.
Bibliometric Analyses (Counts of the number of peer-reviewed publications, types of journals in which the papers have been published, journal impact factors, citation analysis, and fields where the publications appear)	<ul style="list-style-type: none"> • These are highly feasible, and they are an obvious benchmark that people would expect. • Highly feasible but need to take into account how long the center has been active. 	<ul style="list-style-type: none"> • Does not really give insight into how each center really worked. • Simple counts of publications would not tell the whole story—a lot of mind-body research does not lend itself well to high-impact journals.
Social Network Analyses (Collection of data on individuals with whom research investigators collaborated on projects and papers and the nature of the collaborative activities)	<ul style="list-style-type: none"> • Excellent and potentially valuable. • Exciting approach, but challenging to collect data. • Definitely feasible—need several data points to demonstrate how the focus of the center has grown. 	<ul style="list-style-type: none"> • These are feasible, but what is being measured? Networking can exist on many levels, and one would need to be clear about the levels being measured. • Need to make sure that data collection takes place with a full range of staff.
Case Studies of Research Centers (Detailed narrative following a common structured template and integrating the quantitative and qualitative data from multiple sources)	<ul style="list-style-type: none"> • This could be informative. • Good way to deal with different centers having different approaches. You could get more detail and look at the more successful centers versus less successful centers. • Definitely valuable. • Potentially interesting. Treat each center differently because of different focus areas. Maybe a template could work if adjusted for each center. You cannot necessarily compare one with another, or you risk drawing the wrong conclusion if all one looks at is, for example, the number of publications. Case study might be better because it is more descriptive and captures unique features at each center. 	<ul style="list-style-type: none"> • How would this be done? Even if you standardize as much as possible, there is no guarantee of comparable information across the centers. Sometimes you lose a lot through the use of templates because of important differences between the sites (e.g., purpose, size). • Less interesting—not useful if each center submits its own case study.
Site Visits to Research Centers (Visit to each research center to interview research investigators and staff members using structured protocols and other data collection procedures)	<ul style="list-style-type: none"> • Site visits are an important component to research. This type of research needs face time. Face-to-face meetings force researchers to keep things tidy and facilitate communication and understanding. • This could be informative, although some centers actually have a center, whereas others just have collaborators all over the place. If one came to see a center, what would one see? • Good—the process of going in and talking with investigators might also be of benefit to them in helping them know where to go in the next 12 months. • Reasonable—need to make sure that the interviews are done with several different people representing different perspectives. • Useful if done with a small team of 2 to 3 site visitors. 	<ul style="list-style-type: none"> • Too hard to get people together. Site visits are demanding on centers' time—it takes considerable effort to prepare. • Probably time-consuming and not too useful, depending on what is covered in the site visit. • Not useful—would be all right to assess how the program is running, but not the impact of the program. • NIH used to do a lot of site visits, but they have gone out of favor because they are expensive and hard to organize on the ground. A meeting of investigators at NIH would be more productive. • Holding another directors meeting, such as the one held by OBSSR on the NIH campus a few years ago, would provide the necessary information—wish there had been more of these.

Additional Suggestions	
Success Stories	Personal stories could be used that concern particular research breakthroughs or projects and qualitative interviews with patients who have had a positive experience.
Online Survey	An electronic survey could be developed to ask the principal investigator from each research center to encourage research investigators at his or her site to participate.
Expert Panel	OBSSR would convene a workshop to which the center principal investigators would be invited to review the contributions of the program.
Hold Another Meeting of the Principal Investigators	<ul style="list-style-type: none"> At a meeting OBSSR sponsored a few years ago, the directors from each of the centers talked about what they were doing. The directors learned how each center was organized and had developed. The convening of a meeting of principal investigators would allow for a lot of useful exchanges—what worked, what differed in grants and centers. Write up the meeting report as an evaluation document.

As **Exhibit 8** indicates, two methodological approaches were generally considered highly feasible with few serious concerns. These included (1) reviews of existing documents and (2) bibliometric analyses. Three other approaches produced more divergence of opinion among the principal investigators. Social network analyses were viewed as an intriguing approach that could produce useful information about the patterns of collaboration and growth over time. However, respondents also noted the challenges of collecting data on these networks. Case studies prompted strong positive and negative opinions. Some principal investigators viewed them as a way of identifying what is unique about each center and of providing a detailed description about the center’s characteristics. Other respondents questioned whether case studies that followed a common structure could adequately represent the differences thought to exist among the centers. Site visits represented an unusual category because they have been employed as both a methodology and data collection approach. Although several principal investigators argued that site visits are highly important ways of gathering information about a research center, others argued that they are burdensome for the research center staff in terms of the time spent preparing for them and perhaps were not as productive as convening a meeting of the principal investigators.

Respondents offered several additional suggestions for methods and/or data collection approaches—for example, the use of success stories and surveys. One suggestion advocated by four of the principal investigators was a meeting or workshop for principal investigators, at which they could reflect on what had and had not worked for their centers and for the program.

4.4. R21 and R24 Research Center Site Visits

As part of the data collection process, 1-day site visits were conducted at two of the research centers (one R21 and one R24 center.) The goal of these visits was to learn about the origin of each center, scientific scope of activity, and plan for sustainability. The visits were also used as an opportunity to explore and discuss various approaches to the evaluation of the MBIH Program and as an opportunity to meet with research investigators and staff members from the centers. Using existing documents (including the most recent annual progress reports) and the interviews conducted with the principal investigators at each center, information was obtained that both confirmed and expanded on previously available information.

The site visits provided valuable information about the advisability of using the site visits as a data collection approach in the full-scale outcome evaluation of the MBIH Program:

- Site visits provide an opportunity to meet and talk with members of the research staff (including core leaders and administrative personnel) on a face-to-face basis that would be difficult to replicate by a telephone interview or written survey.

- Site visits provide an opportunity for a structured conversation with the principal investigator and other key research investigators, which allows a richer exposure to information about the current center activities and future plans than would be obtained by either a telephone interview or a written survey. This is in part because the face-to-face nature of the meetings over an extended period allows for additional probing of and reaction to the information shared by these individuals. In the space of 1 or 2 days, it becomes possible to approach complex issues and subjects from different perspectives.
- Although it requires an investment of time and effort by research center staff to prepare for and schedule a site visit, research investigators and staff members appeared to find the occasion useful as a way of obtaining an outside perspective on their activities. There are ways that the burden of preparation time can be managed efficiently (for example, appointing a liaison person from the staff to serve as a “point person” in negotiating the dates and agenda), with less impact on the principal investigator.
- Reading information about the physical plant of a center (or hearing it described over a telephone) is a poor substitute for the firsthand observation of facilities and resources.
- Certain types of data are more easily collected face to face (for example, data on social network activities), although this can be conducted by telephone when necessary.

5. Implications of the Findings for the Outcome Study

This section discusses the challenges involved in evaluating publicly funded R&D programs in general and research centers in particular and the implications of the findings from the feasibility study for an outcome evaluation of the MBIH Program. We consider whether an outcome evaluation study of the MBIH Program is feasible and warranted and how such a study could be staged, present a definition of research centers and an outcomes framework for the study, and review several comparison strategies that could be incorporated into the study.

5.1. Challenges in Evaluating Research and Development Programs

As shown in **Exhibit 9**, the evaluation of research center programs is a complex undertaking that presents many kinds of challenges. Some of these challenges arise in any evaluation of a research center, and some are more specific to the MBIH Program. These issues underscore the importance of developing a sound conceptual framework that includes a variety of output and short-term and intermediate outcome measures.

Evaluation of the MBIH Program is further complicated by two additional issues. First, the MBIH Program consists of different types of grants that were phased in over different points in time. The funding history for this program is complex. For example, of the five original P50 research centers funded in 1999, two centers went on to secure 5-year R24 grants in 2004. The remaining three centers did not obtain further funding under the MBIH Program, yet each continues to conduct mind-body research. Of the six R21 grantees in 2004, three successfully obtained R24 funding in 2007, whereas the other three did not. In one sense, these centers appear to have sorted themselves out into natural comparison groups, yet the number of centers in each of these groups is too small to compare in a quantitative manner. The second issue is the problem of the ‘counterfactual’—what would have happened to these centers and to the mind-body research field had the MBIH Program not existed? Although there is a clear recognition that research centers can play a valuable role in “kick-starting” a new research field,

Exhibit 9. Challenges in Evaluating Research Centers

- The results from projects take many years to materialize.
- There can be some difficulty in assessing “credit” for potential center outcomes when investigators may have generated ideas through a noncenter project.
- Centers pursue multiple aims and therefore need to be assessed with multiple metrics.
- The process of measuring the “value added” by centers is complex.
- The appropriate comparison groups should be determined.
- “What would have happened in the absence of the center funding?”

some opponents argue that research centers take valuable research funding away from investigator-initiated grants, which might be stimulated through a specific RFA or PA. Determining what might have occurred in a research field in the absence of funded centers is difficult to assess with any certainty, but it is often possible to obtain at least impressionistic data from investigators who have been supported by centers and their resources.

5.2. Conclusions and Implications From the Feasibility Study

5.2.1. An Outcome Evaluation of the MBIH Program Is Both Feasible and Warranted at This Time

Based on the review of administrative and program documents, recommendations presented by IOM in its recent review of the evaluation of extramural research center programs at NIH, and perceptions of MBIH Program stakeholders, we conclude that an outcome evaluation of the MBIH Program is both feasible and warranted at the present time. Since its inception in 1999, the program has not received a formal evaluation. IOM has recommended that NIH extramural research center programs should receive a formal external retrospective evaluation on a regular basis—at least every 5 to 7 years. After 10 years of providing funding and coordinating support among other NIH ICs, OBSSR is ending its direct role in the program and is transferring the charge for continued research activity to the ICs. For these reasons, it is an especially appropriate moment to assess what the MBIH Program has accomplished and whether it has met its original objectives.

5.2.2. The MBIH Outcome Evaluation Should Be Conducted in Two Distinct Phases

Although OBSSR's role in the program is in its sunset phase, a review of the administrative and program records of the MBIH Program shows that it is continuing to operate. The five original 1999 P50 research centers ended their funding in 2004. At that time, six 3-year R21 exploratory/developmental program grants were funded; three of these received new 3-year R24 research infrastructure awards in October 2007 and will continue in that capacity until 2010. The remaining three 2004 R21 centers are concluding their research activities during this year and the first part of 2009. Also in 2004, seven R24 research infrastructure center programs were funded for 5 years, and their activities will continue until August and September 2009. With no-cost extensions, it is conceivable that at least some of these programs may continue for approximately 1 year beyond that date. Sixteen R01 investigator-initiated research projects were funded in 2004 as well; given an average duration of 3 years, these individual projects are just concluding at the present time. In 2005 a standing PA for R01 investigator-initiated research was issued and was renewed in late 2006 until January 2010.

Because these activities are continuing over the next 3 years and because it can take a minimum of 3–5 years for short-term and intermediate outcomes to be observed (and as much as 20 years for long-term outcomes to appear), conducting a full-scale summative evaluation of the MBIH Program would understate its full range of effects. Program stakeholders suggested that the evaluation be conducted in two phases, with an initial phase that would focus on the short-term and intermediate outcomes achieved by the 2004 centers and R01 projects and a second phase that would examine the longer range effects of these programs as well as the short-term and intermediate effects of the R01 grants funded under the PAs.

5.2.3. A Definition of Research Centers

The sheer diversity of research centers in terms of their organizational and operational characteristics is probably a major reason that no single definition of “research centers” has emerged from the evaluation literature. However, the literature suggests elements that could be combined to construct a definition that would be applicable for university-based research centers, such as those funded by the NIH R21 and R24 mechanisms under the MBIH Program. (See **Exhibit 10**.)

Our definition describes five major elements that together constitute a university-based research center. The first element is that members of the center share a common research and educational mission. The training of students, fellows, and new investigators is an important part of this shared mission. The second element is a distinct research infrastructure; that is, there are distinct core services or facilities that are developed for the center. There is also an organizational structure and management team. Typically, there is also an advisory group of some type, whether internal or external to the university. The third element is the existence of research personnel, who receive support from center funds. They will typically be drawn from two or more departments, schools, or other organizational units within the university. The fourth element is a research portfolio of two or more research projects. These may be federally grant-funded projects, projects funded by foundations or other non-governmental sources, pilot studies funded by the center, or some combination of all three. Finally, there is a fifth element, which we have termed “synergy.” This construct is our attempt to acknowledge that the combination of the preceding elements in conjunction with strong leadership leads to a milieu or environment that is something greater than the mere sum of its parts. This environment promotes innovation, creativity, and active collaboration outside the disciplines of the members. Synergy also includes activities designed to promote these behaviors, such as frequent meetings and opportunities for center staff to spend informal time together to exchange ideas and “brainstorm.”

Exhibit 10. Definition of a Research Center

A **university-based research center** is an organizational unit located within an academic institution that includes the following basic components:

- **Organization** based on a shared **research and educational mission**, goals, and objectives
- A **research infrastructure** (affiliation with a specific academic department or departments, a distinct organizational structure and management team, one or more shared core administrative and technical services, and usually at least one advisory group)
- **Research personnel**, which include a principal investigator, a multidisciplinary group of research investigators, fellows, staff members, and trainees, often organized into one or more distinct research teams)
- **Research projects** (a research portfolio that includes pilot or developmental studies and funded grants and contracts, often from Federal and non-Federal funding sources)
- **Synergy**, which involves the combination and interaction of these four components to produce a milieu that is greater than the sum of its parts. This milieu may emphasize multidisciplinary collaboration, community outreach, and the promotion of dissemination activities beyond scientific publications and presentations.

5.2.4. Outcomes of Research Center Activities

The review of the evaluation literature and responses from the program stakeholders indicate that the multidimensional categories of potential benefits and/or outcomes from the research programs developed by the Health Economics Research Group presents a well-supported and validated framework to apply in the evaluation of the MBIH Program. In addition to its successful deployment in several studies of health and biomedical research programs in the United Kingdom, Canada, Australia, and Hong Kong, we note the strong similarity of categories in the work by Stryer and colleagues at AHRQ and our own findings that the types of outcomes nominated by MBIH Program stakeholders map neatly into the five categories proposed in the research payback framework. We also note that the current survey methodology for collecting evidence for these five categories reflects a cost-effective data collection approach that has been tested and proven in several past studies. (See especially Hanney et al., 1999, and Kwan et al., 2007.)

5.2.5. Selection of an Appropriate Comparison Strategy

A total of 14 of the 21 NIH evaluation reports included in Exhibit 7 compared research center programs with some type of quasi-experimental comparison group. The nature of the group or groups selected varied with the type of evaluation question being studied; however, several common comparison strategies can be seen in that exhibit. Consideration of these strategies highlights some of the issues that need to be addressed in selecting an appropriate comparison strategy for the MBIH Program evaluation.

Four of these comparison strategies are shown in **Exhibit 11**, together with some of their strengths and limitations.

Exhibit 11.
Strengths and Limitations of Potential MBIH Comparison Groups

Comparison Group	Strengths of Group	Limitations of Group	Nature of Comparison
External Comparison: Matched institutions	<ul style="list-style-type: none"> • There are several center programs addressing mind-body research at NCCAM over similar periods starting with 1999. • Could show whether some R21s or R24s are more productive than others. 	<ul style="list-style-type: none"> • Difficulty of coordinating an evaluation with a different NIH IC (NCCAM). • May be differences in goals of specific RFAs. • Differences may be the result of factors other than what we are examining (e.g., oversight practices). 	Are MBIH research centers more productive or effective than research centers in other programs?
Internal Comparison (a): Unsuccessful MBIH Applicants for 1999 P50 and 2004 R21s and R24s	<ul style="list-style-type: none"> • Unfunded applicants are closest to the successful applicants in the interests, goals, structure, and critical mass of investigators at the same institution. • Can provide useful evidence about whether the program met its objectives and about questions of productivity and impact. • Probably comes closest to meeting the criterion “all other things being equal.” 	<ul style="list-style-type: none"> • Depends on the number of unsuccessful applicants and their willingness to participate. • Differences in researcher quality could bias the results unless it could be shown that unsuccessful applicants were of similar quality to successful applicants. • Would have to ensure that no cases were included that had major criticisms by reviewers. 	Did the funding of the MBIH Program centers stimulate a new research field, or might the same level of productivity have been obtained without the center funding?
Internal Comparison (b): Comparison of 2004 R21s and R24s With 2004 R01s	<ul style="list-style-type: none"> • Allows us to see the “value added” of funding an R21 or R24 in terms of measures of publications, and collaborations. • Could be further enhanced by comparing the 2004 R21s with R24s with R01s. • Favorable results would be evidence that the centers are credible, given the acceptance of the R01 as supporting the most rigorous science. • Has been used in several other NIH center evaluations. 	<ul style="list-style-type: none"> • “Apples vs. oranges” comparison of centers with R01s—goals and resources may be too different. • Does not address the question of whether a grant met its objectives. • R01 investigators could be part of a center that was not funded by a mind-body program—would have to investigate this in the process of setting up comparisons. 	Is there a “value added” for funding research centers for mind-body research versus R01 funding alone?
Historical Comparison: Prefunding Comparison (3 Prior Years) of Each 2004 Research Center With the Subsequent 5 Years (2004–2009)	<ul style="list-style-type: none"> • Helps demonstrate whether center goals are being met. 	<ul style="list-style-type: none"> • Availability of records. • Differences in time may be so great that other factors are operative. 	Did the R21 or R24 award produce an improvement in productivity compared with the levels observed prior to funding?

Each of the four comparison strategies is appropriate for different evaluation questions, and it is clear that these strategies can be combined to address multiple questions. However, some of these approaches are less relevant for the proposed outcome evaluation, given its focus on whether the program met its original goals and on what has been accomplished. Because there were no other existing center programs that duplicated the MBIH Program’s focus on particular aspects of mind-body research, a matched comparison group would be difficult to construct and would be of limited value. The remaining three comparison strategies are feasible, although a comparison between funded and unfunded research centers

is less germane to the central issues of the proposed evaluation. The comparison of the 2004 R21 and R24 centers with the 2004 R01 grants offers the opportunity to examine the “value added” of research center programs over single investigator-initiated grants in terms of several short-term and intermediate outcomes that have not been examined previously. The historical comparison (before and after funding) also holds promise for demonstrating the extent to which center funding stimulated growth and capacity-building.

6. Recommendations for the Design of the Outcome Evaluation of the Mind-Body Interactions and Health Program

This section presents recommendations for the design of an outcome evaluation of the MBIH Program. The recommended design for the outcome evaluation would be conducted in two phases and includes evaluation questions, a conceptual framework, recommended comparison groups, key variables, data collection methods, and an analysis plan.

6.1. Justification for a Two-Phase Outcome Evaluation of the MBIH Program

The MBIH Program has operated for 9 years, and during this period it has not received a formal evaluation. There is strong interest in the results of an evaluation program among its major stakeholders. Moreover, the program has reached a major turning point in its maturation cycle, which makes an outcome evaluation especially timely. With the opening of a PA for R01 investigator-initiated grants, OBSSR will not be allocating additional funds to the MBIH Program to support R21 and R24 research centers in mind-body research. Further support for mind-body interactions and health research will now be borne by the nine ICs participating in the current PA. Thus, an outcome evaluation is clearly warranted.

The research activities of the R21 and R24 centers funded through the program in 2004 and 2007 have not concluded. Although the six 2004 R21 centers are in the final stages of concluding their activities using no-cost extensions, three of these centers received new 3-year R24 awards in October 2007. The seven 2004 R24 centers received 5-year awards and will not conclude their grants until August and September 2009. A final, summative evaluation of the MBIH Program conducted at this time would therefore underestimate the accomplishments of these programs. For that reason, we recommend that an outcome evaluation of the MBIH Program be conducted in two phases. As shown in **Exhibit 12** the first phase (highlighted in blue) would focus on short-term and intermediate outcomes from the research centers funded in 1999 (P50s) and in 2004 (R21s and R24s) and the R01 investigator-initiated grants funded in 2004 and 2005.

Exhibit 12.
Phase 1 and Phase 2 of MBIH Program Outcome Evaluation

Program Component	Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes
1999 P50 Research Centers	Phase I		
2004 R21 Exploratory/Developmental Centers	Phase I	Phase I	Phase II
2004 R24 Research Infrastructure Centers	Phase I	Phase I	Phase II
2004 R01 Investigator-Initiated Grants	Phase I	Phase I	Phase II
2005 R01 Grants (PA 05-027)	Phase I	Phase I	Phase II
2006 R01 Grants (PA 05-027)	Phase II	Phase II	Phase II
2007 R24 Research Infrastructure Centers (3)	Phase II	Phase II	
2007 R01 Grants (PA 07-046)	Phase II	Phase II	
2008 R01 Grants (PA 07-046)	Phase II	Phase II	
2009 R01 Grants (PA 07-046)	Phase II		

The second phase (highlighted in yellow) would examine the longer range outcomes associated with the 2004 centers and the short-term and intermediate effects of the investigator-initiated grants funded under the PAs.

6.2. Recommended Outcome Evaluation Questions

The recommended evaluation questions for the Phase I outcome evaluation are presented in **Exhibit 13**. The questions and subquestions represent a synthesis of questions suggested by the OBSSR staff members, NIH program officers administering the MBIH grants, and the principal investigators of the R21 and R24 research centers.

Exhibit 13.
Outcome Evaluation Questions for the MBIH Program Outcome Evaluation Phase I Study

Main Evaluation Questions	Evaluation Subquestions
1. Has the Mind-Body Interactions and Health Program achieved its programmatic goals and objectives?	<p>1.1. What was the relative mix of types of research funded through the program (e.g., basic, clinical, health services research, intervention efficacy and effectiveness studies)? To what extent has the research conducted through the MBIH Program been translated from basic, clinical, or health services research into effective interventions that improve health and functioning?</p> <p>1.2. Has the MBIH Program facilitated interdisciplinary collaboration and innovation in mind-body research?</p> <p>1.3. Has the MBIH Program built capacity for conducting and sustaining mind-body research by providing cost-effective core services based in research centers or comparable administrative units? How will the research activities of these centers be sustained when funding concludes?</p>
2. Has the research conducted under the MBIH Program increased scientific knowledge and understanding about mind-body relationships and their influences on health processes and outcomes?	<p>2.1. What research areas, questions, or directions were generated through the MBIH Program that would probably not have occurred (or might have taken much longer to occur) in its absence?</p> <p>2.2. To what extent are research investigators outside the MBIH Program utilizing the methods and findings from researchers affiliated with the MBIH Centers or from MBIH investigator-initiated projects?</p>
3. What has been the productivity of the mind-body research centers and investigator-initiated projects in terms of the following:	<p>3.1. Knowledge productivity (e.g., peer-reviewed publications, spinoff grants).</p> <p>3.2. Research targeting and capacity-building (e.g., the development of new concepts, methods, tools, and/or theoretical models; training and mentoring of students, fellows, and new investigators; effects on the host universities and institutions; new partnerships with community-based organizations, providers, foundations, industry)?</p> <p>3.3. Influences on clinical practice and policy (e.g., the development and adoption of new clinical protocols for new techniques; inclusion of studies in systematic reviews, clinical practice guidelines, and "best practices"; use of findings by policymakers at the local, State, and/or national level)?</p> <p>3.4. Influences on health and public health (e.g., the effects on health and functioning of research participants and the broader public)?</p> <p>3.5. To what extent did center funding stimulate additional productivity beyond what investigators at each funded center had achieved prior to the grant?</p> <p>3.6. To what extent have the MBIH-funded research centers achieved an equivalent or greater level of productivity (in terms of research publications) than other institutions conducting MBIH-related research?</p>
4. How has mind-body research grown over time as a result of the MBIH Program's centers and activities?	<p>4.1. What patterns of growth have occurred over time in terms of research collaborations among research investigators affiliated with MBIH center programs and investigator-initiated projects?</p> <p>4.2. To what extent has interdisciplinary collaboration occurred between researchers at other MBIH centers and with other institutions in the United States and other nations?</p> <p>4.3. To what extent has the growth of MBIH research over time involved community providers and community-based organizations?</p> <p>4.4. To what extent has the mind-body research community spread beyond the United States as a result of MBIH Program research activities?</p>

Main Evaluation Questions	Evaluation Subquestions
5. Has the MBIH Program increased the support for mind-body research among Federal and non-Federal funding sources?	5.1. Has the MBIH Program increased the support for mind-body research at NIH and stimulated additional research opportunities there?
	5.2. Has the MBIH Program increased the support for mind-body research at other Federal agencies, such as the Centers for Disease Control and Prevention (CDC), AHRQ, and Food and Drug Administration (FDA)?
	5.3. Has the MBIH Program increased the support for mind-body research at non-Federal funding agencies (e.g., foundations, etc.)?
6. What can be learned from evaluating the MBIH Program that could be applied to future evaluations of other NIH research center programs?	6.1. What can be learned from evaluating the MBIH Program that could be applied to the management and oversight of multi-IC research center initiatives at NIH?
	6.2. What can be learned from evaluating the MBIH Program that could be applied in conducting future evaluations of research center programs at NIH?

6.3. Recommendations for the Design of the Phase I Outcome Evaluation

This subsection includes an overview of the Phase I outcome evaluation design and methods, recommendations for a conceptual framework for the evaluation, comparison groups, the key variables and data sources, and an analysis plan.

6.3.1. Overview of Design for the Phase I Outcome Evaluation

The primary purposes of the Phase I outcome evaluation are to determine whether the MBIH Program has met its programmatic goals and objectives and the contribution that the research pursued through the program has made to the larger field of research on mind-body interactions and health. Thus, the emphasis in this evaluation is on *accountability*—what has been accomplished after 9 years of funding and to what extent are these accomplishments consistent with the original intent of the program. The design recommendations are based on several important considerations. First, the activities of the research centers and investigator-initiated grants funded by the MBIH Program have not yet concluded. For that reason, it is recommended that the evaluation be conducted in two phases, with an initial focus on short-term and intermediate outcomes in Phase I and longer range outcomes in Phase II. Second, it is important to examine the accomplishments of the program in light of multiple types of outcomes rather than using a single measure, such as publications or research grants. This emphasis on multiple metrics is reflected in the conceptual framework developed for the evaluation. The conceptual framework incorporates the research payback framework’s multidimensional categorization schema.

To fully explore the range of short-term and intermediate outcomes that the MBIH research centers may produce, the Phase I outcome evaluation design is organized around four component substudies. These include a Project-Level Survey, a Research Center Principal Investigators Survey, a social network analysis, and a bibliometric analysis. Each of these substudies is described below.

6.3.1.1. Project-Level Survey

The Project-Level Survey will answer several important questions about the research conducted within the MBIH Program, the types of outcomes produced by the research, and the utilization or adoption of findings or products from the studies. This methodological approach has been used routinely and successfully in past studies that have applied the research payback framework (e.g., Hanney et al., 1999, and Kwan et al., 2007) and is the basic mechanism by which information is built on the overall impact of the research centers within that framework.

The Project-Level Survey will target the specific funded research projects conducted within the various research centers as well as the investigator-initiated research conducted outside the centers but funded through the MBIH Program (i.e., the R01s). The Project-Level Survey will examine three aspects of each funded project. First, it will examine the basic characteristics of the research as perceived by its principal

investigator (e.g., whether it is considered to be basic research, clinical research, or health services research; whether the specific project is a spinoff of pilot or developmental work funded by the research center; the interdisciplinarity of the research team; whether additional funding separate from NIH was used in conducting the research; community involvement and participation in the research; and the use of research center core resources in submitting the grant application and conducting the work). Surveys to be completed by R01 investigators unaffiliated with one of the MBIH investigators will ask several additional questions that elicit information on whether they were affiliated with a research center at their institution and whether they were able to utilize any existing core research services in preparing their application or in conducting the study. Second, the Project-Level Survey will adapt and use the research payback framework to explore various types of short-term and intermediate outcomes arising from the research. The outcome evaluation will examine the first four categories of potential benefits (knowledge production, research targeting and capacity-building, informing policy and clinical practice, and health and public health benefits). These are considered to be plausible categories for potential outcomes within 3–5 years of funding. The categories of informing policy and clinical practice and health and public health benefits represent an innovative break with previous evaluations of NIH research center programs. It is expected that projects conducted through an MBIH research center may be more likely to have had some positive effects at the policy or clinical practice levels than individual, non-MBIH center R01s. The third aspect that will be surveyed for each funded project concerns knowledge utilization: Who outside the research community has received (or requested) information about the project's results or products, and to what degree is this information being utilized? By documenting the potential users of mind-body interactions and health research within the policy and clinical practice communities, the Phase I outcome evaluation sets the stage for a possible users survey as part of Phase II of the evaluation.

The annual progress reports from each research center and NIH databases will be used to identify all NIH-funded research projects conducted by staff members who are affiliated with each MBIH research center and all R01 investigators who were funded as part of the 2004 round of MBIH R01s. (Individuals funded as part of the two subsequent PAs will be considered in Phase II of the evaluation.) An existing questionnaire used in earlier studies applying the research payback framework will be adapted and conducted as an online, Web-based survey.

6.3.1.2. Research Center Principal Investigators Survey

The second design component is a Research Center Principal Investigators Survey. In many ways this survey will parallel the Project-Level Survey, but will entail a broader focus on the research centers as a whole. The goals of the Research Center Principal Investigators Survey are to explore mechanisms that may have contributed to each center's effectiveness (e.g., leadership style, the institution of specific communications and team-building activities, the nature and extent of community outreach activities), highlight the accomplishments and achievements of each center, examine the strategies developed for sustaining each center's core research administrative and technical services beyond the conclusion of center funding, and identify each center's unique contributions to mind-body research (and consider what might have occurred had the center not received funding.) This survey will be conducted as a telephone interview.

6.3.1.3. Social Network Analysis of Coauthorships

The MBIH Program has attempted to promote interdisciplinary research collaboration and to “grow” the field of mind-body interactions and health research. One way by which this can be demonstrated is by the use of social network analysis. SNA is an analytical technique that provides a visual picture of the interrelationships among a group of entities. These entities can be people, organizations, or collaborators on peer-reviewed publications. The social network analysis substudy will develop a series of “snapshots” of the collaborative relationships among mind-body researchers affiliated with the various research centers funded by the MBIH Program at four points in time: 1999, 2002, 2005, and 2008. The goals of

this study are to trace how the web of collaborative relationships stimulated by the MBIH Program has grown over time and to examine the patterns of collaboration as these evolved.

6.3.1.4. Bibliometric Analysis

A bibliometric analysis of the mind-body interactions and health research literature will be used as a means of addressing several questions concerning the effect of research sponsored by the MBIH Program on the field of mind-body interactions and health research. Among the questions to be addressed are those that follow: (1) Did funding for a mind-body research center stimulate greater research productivity (as measured by peer-reviewed publications) compared with the 5 years preceding the center awards? (2) Are investigators at MBIH research centers more prolific than individual R01 investigators? (3) To what extent are mind-body investigators outside MBIH research centers citing the published work of MBIH-funded investigators, and are center-affiliated MBIH investigators cited more frequently than nonaffiliated MBIH R01 investigators?

6.3.1.5. Use of a Comparison Group

The focus of the Phase I outcome evaluation is on accountability. Did the MBIH Program achieve its originally intended goals and objectives? After careful consideration of the comparison group options, two different comparison strategies are recommended, each of which addresses a different aspect of this central question.

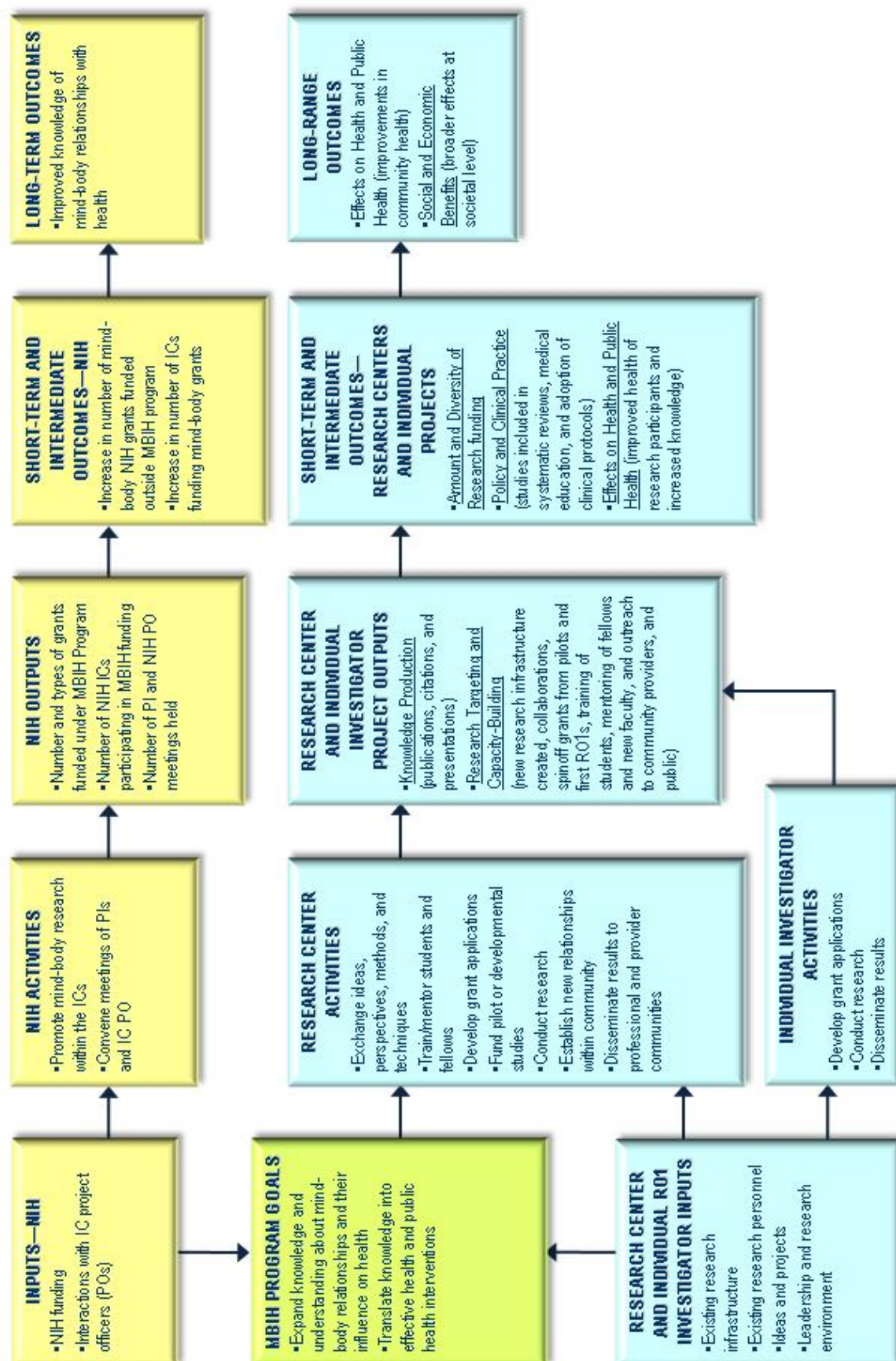
The first type of comparison strategy will entail comparisons between the outcomes achieved under the research center programs versus those achieved by the noncenter affiliated R01 investigators from 2004 and 2005. These comparisons will involve such variables as the average number of publications per investigator or the proportion of projects for which policy or clinical practice outcomes occurred among investigators within the R21 and R24 groups on the one hand and the R01 noncenter-affiliated investigators on the other hand. These comparisons will contribute to an improved understanding of the “value added” by research center funding. Data for these comparisons will be obtained from the Project-Level Surveys.

The second type of comparison strategy is the historical comparison, in which the publication and MBIH-related grant activity of the research centers is compared for a 5-year period preceding funding and the first 5 years after funding in 2004. This strategy permits an investigation of the extent to which research center funding stimulated an increase in output (publications and grant activity) among the R21 and R24 centers. Data for these comparisons will be derived from a bibliometric analysis and a review of existing NIH databases and administrative records.

6.3.2. Conceptual Framework

A conceptual framework (logic model) for the first phase of the Mind-Body Interactions and Health Program outcome evaluation is displayed in **Exhibit 14**. The conceptual framework shows the program goals and two sets of inputs, activities, outputs, short-term and intermediate outcomes, and long-term outcomes, which are shaded in two different colors. The NIH-level elements are colored yellow and represent the various inputs, activities, outputs, and outcomes associated with OBSSR and NIH. The research center and individual investigator-level inputs, activities, outputs, and outcomes are colored light blue. The outputs and outcomes at this level incorporate the research payback framework categorization of benefits. The outcomes also capture the centers’ effects on the universities (through subsequent institutional funding for the centers and through the inclusion of information from centers’ activities in the medical school or health professionals curricula.) Sustainability is also captured through the amount and diversity of subsequent funding.

Exhibit 14.
Conceptual Framework for the Mind-Body Interactions and Health Program Outcome Evaluation Phase I Study



6.3.3. Key Variables

Key variables that will be used in the outcome evaluation are listed and defined in **Exhibit 15**. This exhibit also summarizes the key variables for each evaluation question, specific indicators, and sources of data.

6.4. Data Collection and Analysis

6.4.1. Data Sources

Data for the Phase I outcome evaluation will be obtained from the following five sources:

1. Existing administrative records contained in NIH databases, including IMPAC II
2. Project-Level Survey of the principal investigators of all NIH-funded grants except the actual center grants (P50, R21, and R24)
3. Research Center Principal Investigators Survey
4. Social Network Analysis Retrospective Survey
5. Bibliometric analyses of mind-body interactions and health research.

6.4.2. Data Collection Instruments

Copies of data collection instruments are provided in **Appendix 2**. The instruments included are the Project-Level Survey and the Research Center Principal Investigators Survey.

6.4.3. Data Preparation

Data will be stored in four ACCESS databases—a project-level database, a research center-level database, a social network database, and a bibliometric database. The project-level database will contain data from the online survey of NIH-funded projects. The research center-level database will contain data from the Research Center Principal Investigators Survey as well as data that are aggregated to the center level from the online Project-Level Survey, such as the total number of peer-reviewed publications per year, the average number of peer-reviewed publications per investigator per year, and the number of trainees per year. A third social network database will house the social network data by year. The bibliographic database will include data on publications, authors, and journals that will be required for the bibliometric analysis. The Phase I evaluation plan will describe a plan for storing and retrieving these data and for ensuring their confidentiality. The plan will also discuss arrangements for ensuring the confidentiality of the institutions and investigators.

6.4.4. Data Analysis

There are four distinct sets of data that will be analyzed for the outcome evaluation. These include the Project-Level Survey, Research Center Principal Investigators Survey, social network analysis, and bibliometric analysis. Plans for these analyses are described below.

6.4.4.1. Project-Level Survey

Key variables for the Project-Level Survey will include both quantitative and qualitative variables, and standard quantitative and qualitative data analysis methods will be used for data analysis. The initial step will be the construction of the key variables at the research project level. It will then be necessary to aggregate or “roll up” these variables for each research center (P50, R21 or R24) to obtain a center-level measure. Thus, if the key variable is the number of project-level publications in peer-reviewed journals, this variable will be constructed for each project conducted within a center, and the average value will be

calculated across the projects conducted by a center. Standard quantitative analyses will include descriptive statistics (e.g., means, standard deviations, medians, frequencies or percentages). In the case of the R01 investigator-initiated grants, a similar process will be followed. Statistical comparisons of the various types of centers with the R01 grants will take the form of analyses of variance or chi-squared tests of association. In the case of qualitative variables (e.g., responses to open-ended survey items), standard content analysis methods will be used (Boyatzis, 1998.)

6.4.4.2. Research Center Principal Investigators Survey

Similar types of quantitative and qualitative analyses will be used to analyze the data from the Research Center Principal Investigators Survey.

6.4.4.3. Social Network Analysis

The social network analysis will examine the patterns of growth and the level of multidisciplinary occurring among the researchers at each center (and among the R01 investigators) at four points in time based on an analysis of coauthorships. The analyses will be conducted using UCINET 6, a software package that includes tools for constructing visual displays of network nodes and linkages and analytic features for calculating a variety of network characteristics, including measures of centrality and diversity and the Network Brokerage Index discussed previously. These measures will be examined for and compared across each of the P50 and 2004 R21 and R24 research centers.

6.4.4.4. Bibliometric Analysis

The bibliometric analysis of the mind-body research literature will include publication counts, citation analysis, journal rankings, and the use of the index of thematic breadth methods discussed earlier.

Exhibit 15.
Evaluation Questions, Key Variables and Their Definitions, and Data Sources for the MBIH Program Outcome Evaluation Study

Evaluation Questions and Subquestions	Key Variables	Key Variable Definitions	Data Sources
1. Has the Mind-Body Interactions and Health Program achieved its programmatic goals and objectives?			
1.1. What was the relative mix of types of research funded by the program (e.g., basic, clinical, health services research; intervention efficacy or effectiveness studies?) To what extent has the research conducted through the program been translated from basic, clinical, or health services research into effective interventions that improve health and functioning?	NIH MBIH grant funding	Amounts and types of grant funding provided to individual investigators and to research centers <ul style="list-style-type: none"> Number and category (activity codes) of grants awarded to MBIH-funded investigators and MBIH-funded institutions Source (Institute, Center, or Office) funding the grant(s) Total dollar amounts of MBIH funding provided to MBIH investigators and to MBIH-funded institutions 	NIH administrative records
	Types of MBIH Research Funded	Whether research is considered basic, clinical, or health services research <ul style="list-style-type: none"> Classification of research project as basic, clinical, or health services research, or a combination Classification of research project as a clinical trial Classification of research project as containing a cost or economic analysis (cost-benefit, cost-effectiveness, cost utility analysis) Classification of research project as translational research 	Project-Level survey
1.2. Has the MBIH Program facilitated interdisciplinary research collaboration and innovation in mind-body research?	Interdisciplinarity of Research Teams	Degree to which project's research team includes participation by multiple disciplines <ul style="list-style-type: none"> Number of different disciplines from within the PI's institution represented among the research investigators/co-investigators on the project's research 	NIH administrative records

Evaluation Questions and Subquestions	Key Variables	Key Variable Definitions	Data Sources
		<ul style="list-style-type: none"> team Whether the research project involves one or more additional institutions beyond that of the PI 	
	Community Collaboration within Research Team	Degree to which the project's research team includes community providers as investigators/co-investigators <ul style="list-style-type: none"> Whether the research project includes one or more community providers participating as co-investigators Nature of the role of the community provider co-investigator 	Project-level survey
	Patterns of co-authorship growth	Increased growth of mind-body research over time <ul style="list-style-type: none"> Co-authorship networks at four points in time Network size and density Multidisciplinarity of co-authorships over time (network brokerage index) 	Social network co-authorship analysis
1.3. Has the MBIH Program built capacity for conducting and sustaining mind-body research by providing cost-effective core services based in research centers or comparable administrative units?	Research Infrastructure Core Services	Description of specific research infrastructure core services created/maintained at research centers <ul style="list-style-type: none"> Description of specific research core services Number and level of personnel assigned to each core service Annual and total dollar costs associated with each core service 	NIH administrative records
	Principal Investigator use of Research Infrastructure Core Services	Whether and how much a Principal Investigator used research center infrastructure core services <ul style="list-style-type: none"> Specific research infrastructure service cores used by Principal Investigator in developing grant application Specific research infrastructure service cores used by Principal Investigator in conducting research 	Project-Level Survey
	Research Personnel affiliated with P50, R21 and R24 centers	Research personnel who received some financial support from a 1999 P50, 2004 R21, or 2004 R24 research center <ul style="list-style-type: none"> Categories of personnel supported at research centers Amount of dollars/percentage of time supported Number of fellows in training Number of students in training 	NIH administrative records
1.4. How will the research activities of these centers be sustained when funding concludes?	Sustainability of Centers	Evidence that MBIH research centers have planned for and are able to remain operational after conclusion of NIH center grants expire <ul style="list-style-type: none"> Strategies for maintaining center research infrastructure core services beyond end of center NIH grant Number and types of sources of funding (and amounts of funding) for research center activities during final year of NIH grant Whether there was a decrease in available funds for the center after the NIH center grant ended, the percentage decrease in funds, and what was reduced or cut in order to continue operating 	Research Center Principal Investigators survey
	Effects of Center activities on sponsoring institution	Short-term/intermediate outcome reflecting evidence that the Center's activities have produced a positive effect on the institution sponsoring it: <ul style="list-style-type: none"> Department/Division/School/University has agreed to provide continuing funding for one or more research infrastructure core services Department/Division/School/University has provide additional resources (new or newly renovated space, equipment, funds) for Center research activities Department/Division/School/University has added mind-body content to an existing course, or established a new course on mind-body research/medicine 	Research Center Principal Investigator survey

Evaluation Questions and Subquestions	Key Variables	Key Variable Definitions	Data Sources
1.5. Have the MBIH research centers created a research environment that supports creativity and innovation? How has this been done?	Center Activities Designed to Promote Sharing of Ideas and Collaboration	Activities that contribute to creating a research environment that fosters creative thought and innovative methods <ul style="list-style-type: none"> Formal activities or mechanisms instituted as part of the center's shared activities that are designed to encourage informal intellectual contact among individuals affiliated with the center 	Research Center Principal Investigator Survey
	Mentoring Practices	Description of mentoring strategies and practices for fellows, students, and new junior faculty <ul style="list-style-type: none"> Description of mentoring programs Estimated frequency of mentoring meetings 	Research Center Principal Investigators Survey
	Pilot Project Funding	Whether and how the center provides funding for pilot studies, developmental studies, or data collection intended to support a grant application <ul style="list-style-type: none"> Description of pilot study funding mechanism Number of pilot studies funded Number of pilot studies subsequently used as a basis for a formal grant application Amount of funding provided (average, minimum and maximum amounts) 	Project level survey Research Center Principal Investigator Survey
	Origin of Research Project	How the idea for the research project originated <ul style="list-style-type: none"> Whether the research project originated from pilot or developmental work funded all or largely by the research center Whether the idea for the research project originated during or as a result of center activities designed to promote collaboration and sharing of ideas 	Project-level survey
2. Has the research conducted within the MBIH Program increased scientific knowledge and understanding about mind-body relationships and their influences on health processes and outcomes?			
2.1. What research areas, questions, or directions were generated by the MBIH Program that would probably not have occurred (or might have taken much longer to occur) in its absence?	Research Center-level Knowledge Production	Immediate outputs of scientific activity at the level of the Research Center <ul style="list-style-type: none"> Number and listing of monographs or reports for which the Center is the author Number of sessions at scientific conferences or professional meetings organized by the Center to showcase its work New and important research hypotheses, theories or conceptual frameworks, analytic approaches and tools, tests and diagnostic procedures, and/or health interventions developed by the Center 	Research Center Principal Investigators survey
2.2. To what extent are research investigators utilizing the methods and findings from researchers affiliated with the MBIH Centers or from MBIH investigator-initiated projects?	Uptake of Project-level methods, tools, or results by others in the scientific community	Short-term/intermediate outcome reflecting the citation of peer-reviewed publications by the wider scientific community <ul style="list-style-type: none"> Citation analysis at investigator level 	Bibliometric analysis
2.3. In what respects has the MBIH Program led to an increase in knowledge about mind-body relationships and influences on health?	Improved Knowledge of Mind-Body Relationships with Health and Functioning	Contribution of MBIH-sponsored research to mind-body research and science <ul style="list-style-type: none"> Increased Journal Impact Factors over time Thematic breadth index Citation rates of MBIH-investigators compared with unaffiliated investigators 	Bibliometric analysis

Evaluation Questions and Subquestions	Key Variables	Key Variable Definitions	Data Sources
3. How productive have the mind-body research centers and investigator-initiated projects been in terms of the following:			
3.1. Knowledge productivity (e.g., peer-reviewed publications, spin-off grants)?	Project-level Knowledge Production	Immediate outputs of scientific activity at the level of the individual research project <ul style="list-style-type: none"> • Number (and listing) of peer-reviewed publications resulting from this research project • Number of presentations at scientific conferences and professional associations resulting from this research project • Number of book chapters, books or monographs resulting from this project • Number of patents filed resulting from this project 	Project-level survey
	Center-level Knowledge Production	Tacit knowledge gained from research activities about how to conduct this type of research, new methods and tools developed for use within the Center	PI Survey
3.2. Research targeting and capacity-building (development of new concepts, methods, tools, and/or theoretical models; training and mentoring of students, fellows, and new investigators; effects on host universities and institutions; new partnerships with community-based organizations, provider groups, foundations, industry, etc.)?	Project-level Research Capacity Building	Extent to which the individual project has contributed to building research capacity within the center/institution <ul style="list-style-type: none"> • Types and extent of outreach activities targeting community providers, industry • Number of students trained • Number of fellows trained • Number and types of new collaborative relationships established with community organizations 	Project-level survey
	Center-level Research Capacity Building	Extent to which multiple projects within the research center have contributed to: <ul style="list-style-type: none"> • Theses and dissertations by students participating in center activities • Number of new faculty recruited to the center • Number of first-time investigators who have successfully completed funded research at the center • Number of faculty receiving promotions largely due to research activities at the center • Attraction of research funding from private foundations as a result of center efforts (enhanced reputation) • Attraction of research funding from private companies and corporations (e.g., pharma) • Awards and honors received by center-affiliated researchers due to work conducted at center 	Research Center Principal Investigators survey
3.3. Influences on clinical practice and policy (e.g., development and adoption of new clinical protocols for the use of mind-body techniques and interventions; inclusion of studies in systematic reviews, clinical practice guidelines and “best practices”; use of findings by policy makers at local, state, and/or national level)?	Project-level Effects on Policy and Clinical Practice	Short-term/intermediate outcome reflecting evidence that results from the project are being used at the policy level and/or by clinical providers <ul style="list-style-type: none"> • Requests from policy makers (community, state, national) for more information about results from study or for presentations or speaking engagements on the study • Requests from provider organizations for more information about the results from the project, or for presentations or speaking engagements on the project • Inclusion of a project-related peer-reviewed publication in a systematic review, clinical practice guideline, or national treatment recommendations • Adoption of clinical protocols developed for or from the project by providers in other areas • Results from the project have been used by policy makers to promote, change, or establish a policy decision • Invitation to PI or co-PI from policy or provider organizations to consult or advise on issues related to the project 	Project-level survey

Evaluation Questions and Subquestions	Key Variables	Key Variable Definitions	Data Sources
	Center-level Effects on Policy and Clinical Practice	<p>Evidence that the work of the Center is recognized by policy-making, provider and/or community organizations and that the Center is sought out for engagement in policy or clinical issues</p> <ul style="list-style-type: none"> • Evidence that policy-making, provider, or community organizations are bringing research opportunities to the Center • Evidence that policy-making, provider, or community organizations are providing resources to the Center to support work on shared issues • Evidence that policy-making, provider, or community organizations are contributing to or shaping the Center's research agenda 	Center PI survey
3.4. Influences on health and public health (e.g., improved health and functioning of research participants and the general public)?	Project-level Effects on Health and Public Health	<p>Intermediate/long-term outcome reflecting improvement in health and public health attributable to the project</p> <ul style="list-style-type: none"> • Improved health of research participants • Potential or actual effect on health if findings are adopted at community level 	Project-level survey
	Center-level Effects on Health and Public Health	<p>Intermediate/long-term outcome reflecting improvement in health and public health attributable to the Center</p> <ul style="list-style-type: none"> • Evidence that work from multiple Center affiliated projects is being implemented in other jurisdictions and producing measurable improvements in health and public health 	Research Center Principal Investigator survey
3.5. To what extent did MBIH Center funding stimulate additional productivity beyond what investigators at each funded center had achieved prior to the grant?	Project-level Knowledge Production	<p>Immediate outputs of scientific activity at the level of the individual research project</p> <ul style="list-style-type: none"> • Number (and listing) of peer-reviewed publications resulting from this research project • Number of presentations at scientific conferences and professional associations resulting from this research project • Number of book chapters, books or monographs resulting from this project • Number of patents filed resulting from this project 	Project-level survey
3.6. To what extent have the MBIH-funded research centers achieved an equivalent or greater level of productivity (peer-reviewed publications) than other R01 investigators conducting MBIH-related research not affiliated with MBIH research centers?	Affiliation with a Research Center	<p>Whether a Principal Investigator was affiliated with a research center during the development of a grant application and during the research project (R01 investigators)</p> <ul style="list-style-type: none"> • Did Principal Investigator receive support from a research center during preparation of a grant application • Did Principal Investigator receive support from a research center during the time research was conducted • Name (and Institution) of research center 	Project-level Survey
	Project-level Knowledge Production	<p>Immediate outputs of scientific activity at the level of the individual research project</p> <ul style="list-style-type: none"> • Number (and listing) of peer-reviewed publications resulting from this research project • Number of presentations at scientific conferences and professional associations resulting from this research project • Number of book chapters, books or monographs resulting from this project • Number of patents filed resulting from this project 	Project-level survey
	Project-level Research Capacity Building	<p>Extent to which the individual project has contributed to building research capacity within the center/institution</p> <ul style="list-style-type: none"> • Types and extent of outreach activities targeting community providers, industry • Number of students trained • Number of fellows trained • Number and types of new collaborative relationships established with community organizations 	Project-level survey

Evaluation Questions and Subquestions	Key Variables	Key Variable Definitions	Data Sources
	Project-level Effects on Policy and Clinical Practice	<p>Short-term/intermediate outcome reflecting evidence that results from the project are being used at the policy level and/or by clinical providers</p> <ul style="list-style-type: none"> • Requests from policy makers (community, state, national) for more information about results from study or for presentations or speaking engagements on the study • Requests from provider organizations for more information about the results from the project, or for presentations or speaking engagements on the project • Inclusion of a project-related peer-reviewed publication in a systematic review, clinical practice guideline, or national treatment recommendations • Adoption of clinical protocols developed for or from the project by providers in other areas • Results from the project have been used by policy makers to promote, change, or establish a policy decision • Invitation to PI or co-PI from policy or provider organizations to consult or advise on issues related to the project 	Project-level survey
4. How has mind-body research grown over time as a result of the MBIH Program's centers, grants, and research activities?			
4.1. What patterns of growth have occurred over time in terms of research collaborations among research investigators affiliated with MBIH Centers and investigator-initiated projects?	Patterns of co-authorship growth	<p>Increased growth of mind-body research over time</p> <ul style="list-style-type: none"> • Co-authorship networks at four points in time • Network size and density • Multidisciplinarity of co-authorships over time (network brokerage index) 	Social network co-authorship analysis
4.2. To what extent has interdisciplinary collaboration occurred between researchers at other MBIH centers, and with other institutions in the United States and in other nations?	Patterns of co-authorship growth	<p>Increased growth of mind-body research over time</p> <ul style="list-style-type: none"> • Co-authorship networks at four points in time • Network size and density • Multidisciplinarity of co-authorships over time (network brokerage index) 	Social network co-authorship analysis
4.3. To what extent has the growth of mind-body research over time involved community providers and community-based organizations?	Community Collaboration within Research Team	<p>Degree to which the project's research team includes community providers as investigators/co-investigators</p> <ul style="list-style-type: none"> • Whether the research project includes one or more community providers participating as co-investigators • Nature of the role of the community provider co-investigator 	Project-level survey
5. Has the MBIH Program increased the support for mind-body research among federal and non-federal funding sources?			
5.1. Has the MBIH Program increased the support for mind-body research at the NIH and stimulated additional research opportunities there?	NIH MBIH grant funding	<p>Amounts and types of grant funding provided to individual investigators and to research centers</p> <ul style="list-style-type: none"> • Number and category (activity codes) of grants awarded to MBIH-funded investigators and MBIH-funded institutions • Source (Institute, Center, or Office) funding the grant(s) • Total dollar amounts of MBIH funding provided to MBIH investigators and to MBIH-funded institutions 	NIH administrative records
5.2. Has the MBIH Program increased the support for mind-body research at other federal agencies such as CDCP, AHRQ, FDA, etc.?	Other Federal MBIH Research Funding	<p>Amounts, types, and funding sources for other (non-NIH) Federal mind-body research grants obtained by research center</p> <ul style="list-style-type: none"> • Dollar amounts, period of grant, type of grant, and Federal agency funding mind-body research at research center 	Research Center PI survey
5.3. Has the MBIH Program increased the support for mind-body research at non-	Non-Federal MBIH Research Funding	<p>Amounts, types, and funding sources for non-Federal mind-body research grants obtained by research center</p> <ul style="list-style-type: none"> • Dollar amounts, period of grant, type of grant, and agency 	Research Center PI survey

Evaluation Questions and Subquestions	Key Variables	Key Variable Definitions	Data Sources
federal funding organizations and agencies?		funding mind-body research at research center	
6. What can be learned from evaluating the MBIH Program that could be applied to future evaluations of other NIH research center programs?			
6.1. What can be learned from evaluating the MBIH Program that could be applied to the management and oversight of other multi-IC research center initiatives at NIH?	Interactions with NIH Project Officer	Formal and informal interactions between the Principal Investigator and NIH Project Officer <ul style="list-style-type: none"> • Whether any interactions with NIH Project Officer occurred during preparation of grant application and during the period of the grant itself • Whether amount of contact between PI and NIH Project Officer was too little, too much, or just right • Whether contact with NIH Project Officer led to new ideas or identification of new funding opportunities for the Principal Investigator • Whether the contacts with NIH Project Officer were helpful 	Project-Level Survey Research Center Directors Survey
6.2. What can be learned from evaluating the MBIH Program that could be applied in conducting future evaluations of research center programs at NIH?	Lessons Learned	Observations and lessons learned in conducting the MBIH Phase I Outcome study	

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APPENDIX 1

NIH Project Officers Stakeholder Interview Protocol

Office of Behavioral and Social Sciences Research:
Mind-Body Interactions and Health Program Outcome Evaluation Feasibility Study

Mind-Body Interactions and Health Program:
R21 Data Abstraction Template

Mind-Body Interactions and Health Program:
R24 Data Abstraction Template

NIH Project Officers Stakeholder Interview Protocol

Interview: Jared Jobe, NHLBI, January 17 at 10 a.m., (301) 435-0407

Introduction

As you know, the Office of Behavioral and Social Sciences Research (OBSSR) plans to conduct an outcome evaluation of its *Mind-Body Interactions and Health (MBIH) Program*. This program began in 1999 with the funding for five Mind-Body Interactions and Health research centers. In 2004 seven institutions received funding to operate MBIH research centers, and six other institutions received developmental funding intended to assist them in developing research centers. Three of these centers were awarded an additional 5 years of funding in September 2007. In addition to funding the development of these centers, the MBIH Program also awarded 10 R01 grants in 2004 to investigators conducting specific research projects on mind-body and health issues.

OBSSR has contracted with The Madrillon Group Inc. to conduct a feasibility study to determine the need and the optimal approach for evaluating the MBIH Program and to develop an outcome framework and an evaluation design for the MBIH Outcome Evaluation Feasibility Study. We would like to talk with you about your perceptions of and experiences with this program and your ideas concerning an appropriate evaluation design.

Thank you for your willingness to meet with us today.

To begin, we'd like to ask you some questions about your perceptions concerning the specific *research center(s)* for which you served as the Project Officer. Our records indicate that you were the Project Officer for the following grant(s) (list title and grant number[s]).

R24—UNIVERSITY OF PITTSBURGH, KAREN MATTHEWS (WITH CARNEGIE-MELLON)
R24—Columbia University, Thomas Pickering
R01—University of California, Los Angeles, Frank Trelber

1. First, how long were you the Project Officer for this grant?

[Ask separately for each grant.]

2. What were the goals of this research center? To what extent do you feel that this center accomplished these goals?
3. Were there any goals that this center did not accomplish (or accomplished only partially)? What factors (either within the institution or outside of it) do you believe accounted for this?
4. In what ways do you believe that this center was productive?

Now we'd like to ask you some questions about the MBIH Program *as a whole*.

5. One of the broad programmatic goals of the MBIH Program was to stimulate mind-body research across the Institutes and Centers of NIH. In what ways do you believe that the *program* has stimulated mind-body research within this Institute?
 - a. Which of the following MBIH activities did you attend? If you attended, did you find the meetings helpful and educational? What would have made the meetings more useful for you?
 - (1) MBIH Grantees Meeting, 2001
 - (2) MBIH Grantees Meeting, 2004
 - b. Has this Institute developed and funded any specific Requests for Applications (RFAs) as a result of the MBIH Program? Why (or why not)?
 - c. What level of priority does mind-body interactions and health research have within your Institute? In what ways has the MBIH Program contributed to this level of prioritization?
6. In thinking about the MBIH Program in its entirety, what *specific outcomes and outcome measures* do you believe are the most critical ones to examine? What would you most like to learn from an outcome evaluation of this program?
7. What type(s) of evidence do you believe that senior NIH management and Congress would want to see to persuade them of this program's *effectiveness* (or lack of effectiveness)?
8. In thinking about the evaluation of the MBIH Program, what do you believe would be the possible comparison groups to consider?
9. Do you believe that the MBIH Program has been effective? Why (or why not)?
 - a. What do you think have been the most successful aspects of the program? Why?
 - b. If the program model used for the MBIH Program were to be carried out for a different topical area, are there any activities you would recommend adding to it (or removing from it) to increase its impact?
 - c. Are there any plans to continue this initiative within your Institute after the current grants end?
10. Is there anyone else at your Institute to whom you think we should talk to better understand this program and its evaluation?

**Office of Behavioral and Social Sciences Research:
Mind-Body Interactions and Health Program Outcome Evaluation Feasibility Study
R21 and R24 Principal Investigators Interview Protocol**

NAME OF INSTITUTION:	
Name of Center	
Type of Grant: R-2	Name of Principal Investigator:

DATE OF INTERVIEW:	LENGTH OF INTERVIEW (MINUTES):
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NAME OF INTERVIEWER:

Introduction

The Office of Behavioral and Social Sciences Research (OBSSR) has coordinated and overseen the Mind-Body Interactions and Health (MBIH) Program since its inception in 1999. After 9 years of active program funding, OBSSR is planning to conduct an outcome evaluation of the MBIH Program and has retained The Madrillon Group Inc. to conduct a feasibility study to develop an evaluation framework and to determine the most appropriate design, methods, and sources of data to use in conducting this outcome study. As a Principal Investigator for one of the R21/R24 center grants, your views about your experiences with the program and its results would be helpful to us in identifying the evaluation questions, potential outcomes, appropriate methods, and sources of data for this outcome evaluation.

Thank you for your willingness to talk with us today.

This interview contains two sections. The first section includes questions about your research center. The second section contains questions pertaining to the MBIH Program as a whole and how it may best be evaluated.

Section I. Research Center

1. First, how long have you been the Principal Investigator for this grant? With which academic department(s) are you affiliated at _____?

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2. What is the current funding status of this grant (e.g., continuing under original funding until month/year, under a no-cost extension until month/year, or concluded as of month/year)?

Check the appropriate box and fill in the month and year as indicated.

		MONTH AND YEAR
<input type="checkbox"/>	Currently active—continuing under original funding	
<input type="checkbox"/>	Currently active—continuing under a no-cost extension	
<input type="checkbox"/>	Grant concluded	

3. In preparing for this interview, I reviewed some descriptive materials about your center that described its goals and objectives in general terms. Can you tell me about the goals that *you* had for this center? What led you to develop and submit this application, and what were you hoping to build or develop through this R21/R24 center grant?

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4. In thinking about the goals of a research center, some observers have suggested that there are two directions a center might take. The first is to study a particular area in great depth (specialization). The second is to focus broadly on many areas (generalist). Which of these two directions do you feel best describes your center's activities? Why?

5. *Within your university*, how actively did your center reach out to and engage with other research and training centers and activities? How successful were you in doing this?

6. *Outside your university*, how actively did your center reach out to and engage with other researchers at other institutions? How successful were you in doing this?

Probe for:

- Contact and collaboration with other MBIH center investigators
- Contact and collaboration with investigators from other institutions apart from the MBIH Program

7. I'd like to ask you for your views on the overall success of your project and the factors that helped you or hindered you in your progress.
- a. To what extent do you believe that your center has met or exceeded the goals that you set for it? Were there any goals that you think you did not achieve in the way you would have liked?

- b. What factors or reasons do you believe were important in helping you meet or exceed these center goals?

- c. What factors hindered you in achieving what you wanted to accomplish?

8. As part of your center's activities, did you conduct any type of formal or informal program evaluation or assessment of the center (independent of preparing the annual progress reports for NIH)?

Circle one:

YES	NO
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If yes: Would you describe this assessment for me—who conducted it, what kind of questions did you seek to answer, what outcome measures did you use, what sources of data did you use, to whom were the results reported, and how were they used?

WHO CONDUCTED THE EVALUATION?	
What evaluation questions were asked?	
What outcome measures were used?	
What were the sources of data?	
How were the results used?	

Can we get copies of any reports?

9. One of the major goals of the MBIH Program was to promote multidisciplinary and transdisciplinary research. What strategies and mechanisms did your center use to promote research collaboration across disciplines within your institution or outside your institution?

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10. Do you envision that this center will continue after its current R21 or R24 funding concludes? *If yes:* What developments have made or will make that continuation possible?

Section II. The MBIH Program and Its Evaluation

Now we'd like to shift our focus from your specific research center to the MBIH Program as a whole.

11. Let's begin with your perception about the larger MBIH Program. Besides the funding of the various research centers, what did you see as the main program components of the MBIH Program?

12. What *evaluation questions* do you think we should be asking about the MBIH Program that would help us measure the overall success or impact of the program?

13. In thinking about the MBIH Program in its entirety, what are the most important outcomes you think we should examine?

- a. Do you believe that your center and this program have had any effects on policy or on decisionmaking within health care organizations? How would you suggest we assess that?

- b. Do you believe that your center and the MBIH Program have had any effects on health or public health? How would you suggest we assess that?

- c. Do you believe that your center and the MBIH Program have had any broader economic or social effects or benefits? How would you suggest we assess that?

- d. What effects do you think that your center and this program have had on science, and how would you suggest we assess that?

14. Clearly, gauging the effectiveness of a broad program such as the Mind-Body Interactions and Health Program is likely to require several different research methods within a single study. I'm going to name some methods we have been considering, and I'd like to ask you for your thoughts about the feasibility of the method for this evaluation and how difficult it might be to carry out.

EVALUATION METHOD	BRIEF DESCRIPTION	COMMENTS ON FEASIBILITY AND DIFFICULTY
Review of program documents	Review of existing documents such as grant applications, integrated review group summary statements, and annual progress reports	
Interviews with research staff and with potential users of research from this program	Interviews with research investigators and with individuals who have been involved in applying the results from the research completed through this program	
Bibliometric analysis	Counts of the numbers of peer-reviewed journal publications, types of journals in which these were published, and citation analyses (number of times cited within a specific timeframe)	

EVALUATION METHOD	BRIEF DESCRIPTION	COMMENTS ON FEASIBILITY AND DIFFICULTY
Social network analysis	Collection of data on individuals with whom center staff members collaborated on research activities and the nature of the collaborative activities	
Case studies of research centers	Structured case studies of each research center, following a common template and integrating data from multiple sources	
Site visits to research centers	Visit to each research center using a structured protocol to guide the interview and other data collection procedures	

15. Are there other approaches that you believe would be more appropriate for examining the effectiveness of the MBIH Program? What do you suggest?

Mind-Body Interactions and Health Program: R21 Data Abstraction Template

This Data Abstraction template was designed for use with the 2004 R21 Developmental Infrastructure Grant *Annual Progress Reports*. This template was developed to enable us to determine the extent to which an annual progress report represents a useful source of data and the types of data that we might be able to extract from it. The format for the R21 Annual Progress Report is rather abbreviated when compared with the R24 Annual Progress Report, so I have drafted a slightly different form for the R24 center grants.

There were six R21 Developmental Infrastructure Grants awarded in 2004. These included the following universities:

- Johns Hopkins University*
- New York University
- University of California, Berkeley*
- University of Rochester*
- University of Texas Medical Branch
- University of Utah.

The three grants that have asterisks (*) are the three projects that successfully competed for the 2007 R24 awards. In developing this template for the R21 infrastructure grants, I have identified several types of quantitative and qualitative data elements that I would like you to abstract from the six sample annual progress reports. Please make notes on any problems or difficulties that you encounter in abstracting and compiling the requested information.

The university and the name of the center whose report you are abstracting:

The grant number for this center:

Period covered by this report:

1. Number of publications in peer-reviewed journals during this reporting period:

2. Citations for each publication (add extra rows to the table if needed):

3. Personnel associated with this center during this reporting period (from the personnel report) (add additional rows if necessary):

Name	Degree(s)	Role on Project	Annual % Effort
		Principal Investigator	

4. Accomplishments (from narrative). Please abstract a short summary of the accomplishments identified, if any, in the following general topical areas. If there is no information provided in the report, state “No information provided.”

- a. Relationships and/or partnerships established or maintained with local community-based organizations, health care providers, and/or patient advocacy groups (including the provision of training to community groups as well as the partnerships established to facilitate research activities):

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- b. Relationships and/or partnerships established or maintained with State or national associations, professional groups, or disease-oriented advocacy groups:

- c. Research collaborations within this university (e.g., individuals, departments):

- d. Research collaborations with other universities (e.g., individuals, departments) within the United States:

- e. Research collaborations with other universities (e.g., individuals, departments) outside the United States:

- f. Training and faculty recruitment and development (e.g., the types of training provided and to whom, number of faculty members recruited, number of faculty members receiving promotions and/or tenure, number of students mentored):

- g. Dissemination activities (e.g., presentations within the university, presentations to community groups, presentations before national and professional associations, presentations at international meetings, testimony before policymaking groups or meetings):

- h. Planning for the future of the center after the current R21 award ends (including the funding obtained from private foundations or organizations, donations, and discussions with university officials concerning university funding of center staff and activities):

5. Pilot projects funded by this center (include the title of the project and any indication from the narrative that this pilot project has successfully “spun off” a Federal or non-Federal research grant):

Title of Pilot Project	Indication of Successful “Spinoff”?

6. Active research grants (please complete the following table):

Grant Type	NIH Institute (or Other Funding Source)	Dates Active	Title of Grant and Grant Number

Mind-Body Interactions and Health Program R24 Data Abstraction Template

This Data Abstraction Template was designed for use with the 2004 R24 Research Center Grant *Annual Progress Reports*. This template was developed to enable us to determine the extent to which an annual progress report represents a useful source of data and the types of data that we might be able to extract from it. There were a total of seven R24 Developmental Infrastructure Grants awarded in 2004; however, two of these operate as a single large combined center, as noted below. The 2004 R24 centers included the following universities:

- Columbia University
- Rutgers University
- University of California, Los Angeles
- University of Michigan
- University of North Carolina
- University of Pittsburgh and Carnegie-Mellon University.

In developing this template for the R24 center grants, I have identified several types of quantitative and qualitative data elements that I would like you to abstract from the six sample annual progress reports. Please make notes on any problems or difficulties that you encounter in abstracting and compiling the requested information.

1. The university and the name of the center whose report you are abstracting:

2. The grant number for this center:

3. Period covered by this report:

4. Number of publications in peer-reviewed journals during this reporting period:

5. Citations for each publication (add extra rows to the table if needed):

6. Personnel associated with this center during this reporting period (from the personnel report) (add additional rows if necessary):

Name	Degree(s)	Role on Project	Annual % Effort
		Principal Investigator	

7. Accomplishments (from narrative). Please abstract a short summary of the accomplishments identified, if any, in the following general topical areas. If there is no information provided in the report, state “No information provided.”

- a. Relationships and/or partnerships established or maintained with local community-based organizations, health care providers, and/or patient advocacy groups (including the provision of training to community groups as well as the partnerships established to facilitate the research activities):

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- b. Relationships and/or partnerships established or maintained with State or national associations, professional groups, or disease-oriented advocacy groups:

- c. Research collaborations within this university (e.g., individuals, departments):

- d. Research collaborations with other universities (e.g., individuals, departments) within the United States:

- e. Research collaborations with other universities (e.g., individuals, departments) outside the United States or with other international organizations and groups:

- f. Training and faculty recruitment and development (e.g., the types of training provided and to whom, number of faculty members recruited, number of faculty members receiving promotions and/or tenure, number of students mentored):

- g. Dissemination activities (e.g., presentations within the university, presentations to community groups, presentations before national and professional associations, presentations at international meetings, testimony before policymaking groups or meetings):

- h. Planning for the future of the center after the current R24 award ends (including the funding obtained from private foundations or organizations, donations, and discussions with university officials concerning university funding of center staff and activities):

- i. Please describe in detail any special training programs or formal outreach efforts that the center conducts (e.g., summer institutes, special workshops, visiting scholar or faculty exchange programs, colloquia, workshops, other formal activities in which individuals from within the host university and outside the host university are invited or encouraged to attend). (Note any partnering departments or organizations that assist in these activities.)

8. Pilot projects funded by this center. Include the title of the project and any indication from the narrative that this pilot project has successfully “spun off” a subsequent Federal or non-Federal research grant. Also note by using an asterisk (*) any pilot projects that receive funding from non-NIH grant sources and identify those sources beneath the following chart:

Title of Pilot Project	Indication of Successful “Spinoff”?

9. Patents or inventions:

Title of Pilot Project	Indication of Successful “Spinoff”?

10. Active research grants (please complete the following table):

Grant Type	NIH Institute (or Other Funding Source)	Dates Active	Title of Grant and Grant Number

APPENDIX 2

Project-Level Survey

Research Center Principal Investigators Survey

Project-Level Survey

The Project-Level Survey will be administered to each funded research project's principal investigator. Where an individual has held several grants at a research center, we will ask that that individual fill out a separate questionnaire for each project. The purpose of the Project-Level Survey is to collect data on several aspects of the research project's aims, the type of research conducted, the origin of the idea for the project, and the research team and to ascertain the potential effects of the findings of the project in terms of the outcome framework discussed in the Outcome Evaluation Feasibility Study. To facilitate the data collection process, we are proposing to conduct the survey using an online format.

The approach we have chosen has been used in several studies that utilize the research payback framework. The survey will include the following general categories of variables.

Variable Category	Description
Project Identification Information	Information identifying the specific research grant (prepopulate if funded by the National Institutes of Health [NIH]) <ul style="list-style-type: none"> • Title of grant • Principal investigator • Institution • Grant number (including activity code) • NIH Institute or Center funding the grant • Dollar amount of grant • Period of grant
Type of MBIH Research Funded	Whether the research is considered basic, clinical, or health services research <ul style="list-style-type: none"> • Classification of the research project as basic, clinical, or health services research or a combination of them • Classification of the research project as a clinical trial • Classification of the research project as containing a cost or economic analysis (e.g., cost-benefit, cost-effectiveness, cost-utility analysis) • Classification of the research project as translational research
Affiliation With a Research Center	Whether a principal investigator was affiliated with a research center during the development of a grant application and during the research project (e.g., R01 investigators) <ul style="list-style-type: none"> • Amount of support, if any, that the principal investigator received from a research center during the preparation of a grant application • Amount of support, if any, that the principal investigator received from a research center during the time that the research was conducted • Name (and institution) of the research center
Interactions With NIH Project Officer	Formal and informal interactions between the principal investigator and NIH project officer <ul style="list-style-type: none"> • Whether any interactions with the NIH project officer occurred during the preparation of the grant application and during the period of the grant • Whether the amount of contact between the principal investigator and NIH project officer was too little, too much, or just right • Whether the contact with the NIH project officer led to new ideas or the identification of new funding opportunities for the principal investigator • Whether the contacts with the NIH project officer were helpful
Origin of Research Project	How the idea for the research project originated <ul style="list-style-type: none"> • Whether the research project originated from pilot or developmental work funded all or largely by the research center • Whether the idea for the research project originated during or as a result of center activities designed to promote collaboration and the sharing of ideas
Principal Investigator Use of Research Infrastructure Core Services (if applicable)	Whether and how much a principal investigator used the research center infrastructure core services <ul style="list-style-type: none"> • Specific research infrastructure service cores used by the principal investigator in developing the grant application • Specific research infrastructure service cores used by the principal investigator in conducting the research

Variable Category	Description
Community Collaboration Within Research Team	<p>Degree to which the project's research team includes community providers as investigators/co-investigators</p> <ul style="list-style-type: none"> • Whether the research project includes one or more community providers participating as co-investigators • Nature of the role of the community provider/co-investigator
Project-Level Knowledge Production	<p>Immediate output of scientific activity at the level of the individual research project</p> <ul style="list-style-type: none"> • Number (and listing) of peer-reviewed publications resulting from this research project • Number of presentations at scientific conferences and professional associations resulting from this research project • Number of book chapters, books, or monographs resulting from this project • Number of patents filed resulting from this project
Project-Level Research Capacity-Building	<p>Extent to which the individual project has contributed to build research capacity within the center and/or institution</p> <ul style="list-style-type: none"> • Types and extent of outreach activities targeting community providers or industry • Number of students trained • Number of fellows trained • Number and types of new collaborative relationships established with community organizations
Project-Level Effects on Policy and Clinical Practice	<p>Short-term or intermediate outcomes reflecting evidence that the results from the project are being used at the policy level and/or by clinical providers</p> <ul style="list-style-type: none"> • Requests from policymakers (community, State, or national) for more information about the study results or for presentations or speaking engagements on the study • Requests from provider organizations for more information about the results from the project or for presentations or speaking engagements on the project • Inclusion of a project-related, peer-reviewed publication in a systematic review, clinical practice guideline, or national treatment recommendations • Adoption of the clinical protocols developed for or from the project by providers in other areas • Results from the project being used by policymakers to promote, change, or establish a policy decision • Invitation to the principal investigator or co-principal investigator from policy or provider organizations to consult or advise on issues related to the project
Project-Level Effects on Health and Public Health	<p>Intermediate or long-term outcomes reflecting improvement in health and public health attributable to the project</p> <ul style="list-style-type: none"> • Improved health of research participants • Potential or actual effect on health if the findings are adopted at the community level

Research Center Principal Investigators Survey

The following listing provides a general idea of what will be included as part of the Research Center Principal Investigators Survey.

Item	Description
Center Identification	Description of the research center, including <ul style="list-style-type: none"> • Name of research center • Type of grant funding (e.g., P50, R21, R24) • Institution • Department and school in which the center is organizationally located • Partnering departments (if any) • Partnering organizations outside the sponsoring university (if any) • Date that the center was established
Interactions With NIH Project Officer(s)	Formal and informal interactions between the principal investigator and NIH project officer <ul style="list-style-type: none"> • Whether any interactions with the NIH project officer occurred during the preparation of the grant application and during the period of the grant • Whether the amount of contact between the principal investigator and NIH project officer was too little, too much, or just right • Whether the amount of contact with the NIH project officer led to new ideas or to the identification of new funding opportunities for the principal investigator • Whether the contacts with the NIH project officer were helpful
Center Activities Designed To Promote Sharing of Ideas and Collaborations	Activities that contribute to creating a research environment that fosters creative thought and innovative methods <ul style="list-style-type: none"> • Formal activities or mechanisms instituted as part of the center's shared activities that are designed to encourage informal intellectual contact among individuals affiliated with the center
Mentoring Practices	Description of mentoring strategies and practices for fellows, students, and new junior faculty <ul style="list-style-type: none"> • Description of mentoring programs • Estimated frequency of mentoring meetings
Pilot Project Funding	Whether and how the center provides funding for pilot studies, developmental studies, or data collection intended to support a grant application <ul style="list-style-type: none"> • Description of the pilot study funding mechanism • Number of pilot studies funded • Number of pilot studies subsequently used as a basis for a formal grant application • Amount of funding provided (average, minimum, and maximum amounts)
Community Collaborations	Engagement with community providers, disease treatment advocacy organizations, other community-based organizations, and the general public <ul style="list-style-type: none"> • Number and types of outreach activities conducted with community providers, disease treatment advocacy organizations, other community-based organizations, and the general public • Number of research partnerships established with community organizations and groups
Research Center-Level Knowledge Production	Immediate outputs of scientific activity at the level of the research center <ul style="list-style-type: none"> • Number and listing of monographs or reports for which the center is the author • Number of sessions at scientific conferences or professional meetings organized by the center to showcase its work • New and important research hypotheses, theories or conceptual frameworks, analytic approaches and tools, tests and diagnostic procedures, and/or health interventions developed by the center

Item	Description
Research Center-Level Research Capacity-Building	<p>Extent to which multiple projects within the research center have contributed to</p> <ul style="list-style-type: none"> • Theses and dissertations by students participating in center activities • Number of new faculty recruited to the center • Number of first-time investigators who have successfully completed funded research at the center • Number of faculty receiving promotions largely due to the research activities at the center • Attraction of research funding from private foundations as a result of center efforts (enhanced reputation) • Attraction of research funding from private companies and corporations (e.g., pharmaceutical companies) • Awards and honors received by center-affiliated researchers due to the work conducted at the center
Research Center-Level Effects on Policy and Clinical Practice	<p>Evidence that the work of the center is recognized by policymaking, provider, and/or community organizations and that the center is sought out for engagement in policy or clinical issues</p> <ul style="list-style-type: none"> • Evidence that policymaking, provider, or community organizations are bringing research opportunities to the center • Evidence that policymaking, provider, or community organizations are providing resources to the center to support work on shared issues • Evidence that policymaking, provider, or community organizations are contributing to or shaping the center's research agenda
Research Center-Level Effects on Health and Public Health	<p>Intermediate or long-term outcomes reflecting improvement in health and public health attributable to the center</p> <ul style="list-style-type: none"> • Evidence that work from multiple center-affiliated projects is being implemented in other jurisdictions and is producing measurable improvements in health and public health
Research Center-Level Effects on Activities on Sponsoring Institution	<p>Short-term or intermediate outcomes reflecting evidence that the center's activities have produced a positive effect on the institution sponsoring it:</p> <ul style="list-style-type: none"> • Department, division, school, and/or university has agreed to provide continuing funding for one or more research infrastructure core services • Department, division, school, and/or university has provide additional resources (e.g., new or newly renovated space, equipment, funds) for center research activities • Department, division, school, and/or university has added mind-body content to an existing course or has established a new course on mind-body research or medicine
Sustainability of Center	<p>Evidence that MBIH research centers have planned for and are able to remain operational after the conclusion of NIH center grants</p> <ul style="list-style-type: none"> • Strategies for maintaining center research infrastructure core services beyond the end of center NIH grant • Number and types of sources of funding (and amounts of funding) for research center activities during final year of the NIH grant • Whether there was a decrease in available funds for the center after the NIH center grant ended, what the percentage decrease in funds was, and what was reduced or cut to continue operating
Other Federal MBIH Research Funding	<p>Amounts, types, and funding sources for other (non-NIH) Federal mind-body research grants obtained by the research center</p> <ul style="list-style-type: none"> • Dollar amount of, period of grant for, type of grant for, and Federal agency funding the mind-body research at the research center
Non-Federal MBIH Research Funding	<p>Amounts, types, and funding sources for non-Federal mind-body research grants obtained by the research center</p> <ul style="list-style-type: none"> • Dollar amount of, period of grant for, type of grant for, and Federal agency funding the mind-body research at the research center
Most Important Successes and Accomplishments	<p>Listing of up to five of the most important accomplishments and contributions of the center</p>
Lessons Learned—Advice for Future Research Center Directors and for NIH	<p>Most important lessons learned from managing a research center and advice for NIH</p>