The Mind-Body Interactions and Health Program Outcome Evaluation

Final Report

Prepared for

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Table of Contents

Acknowledgements viii
Executive Summary ix
1. Background and Introduction 1
1.1 Origins of the Mind-Body Interactions and Health Program 1
1.2 Goals and Objectives of the Mind-Body Interactions and Health Program 3
1.3 Structural Elements and Components of the MBIH Program 3
1.4 Organization of this Report 4
2. The Mind-Body Interactions and Health Program Outcome Evaluation 5
2.1 Purposes of the MBIH Program Outcome Evaluation 5
2.2 Considerations Shaping the Design of the MBIH Program Outcome Evaluation 5
2.3 The Payback Framework 7
2.4 MBIH Program Outcome Evaluation Questions and Sub-Questions 8
2.5 Design of the MBIH Program Outcome Evaluation 10
2.6. Data Collection Approaches 10
2.6.1 Document Review 10
2.6.2 Research Center Principal Investigator Interview 11
2.6.3 Research Center Pilot Study and Sub-project Data Table 11
2.6.4 Research Project Principal Investigator Interview 12
2.6.5 Bibliometric Analysis 12
3. Attainment of MBIH Program Goals and Objectives 14
3.1 An Overview of the MBIH Research Centers 15
3.2 Overview of the MBIH Investigator-Initiated Research Projects 16
3.3 Relative Mix of Research Funded Under the MBIH Program (1.1 & 1.3) 17
3.4 Innovation and Interdisciplinary Collaboration in the MBIH Centers and Projects (1.2) 19
3.4.1 Innovation in the MBIH Research Centers 19
3.4.2 Interdisciplinary Collaboration in the MBIH Research Centers and Projects 20
3.5 Capacity for Conducting and Sustaining MBIH Research (1.4 & 1.5) 21
3.5.1 P50 Comprehensive Research Centers 22
3.5.2 R21 Exploratory/Developmental Centers 22
3.5.3 R24 Research Infrastructure Centers (2004) 23
3.5.4 R24 Research Infrastructure Centers (2007) 23
3.6 Research Center Sustainability—A Preliminary Model (1.6) 24
4. Effects of the MBIH Program on Scientific Knowledge and Understanding 25
4.1 Most Significant Scientific Achievements of MBIH Research Centers (2.1) 25
4.2 How MBIH Research Has Gained Respectability and Acceptance Over the Past Decade 27

4.3 Use of Tools, Methods, Instruments, or Measures from MBIH-funded Research by Other Investigators ..28
5. Research Payback from the MBIH Program ..30
5.1 Research Payback from the MBIH Program Research Centers ..30
5.1.1 Research Centers—Inputs ..30
5.1.2 Research Centers—Research Activities (Processes) ..32
5.1.3 Research Centers—Knowledge Productivity (3.1) ..35
5.1.4 Research Centers—Research Targeting (3.2) ..38
5.1.5 Research Centers—Capacity Development (3.2) ..41
5.1.6 Research Centers—Influencing Clinical & Administrative Policy and Product Development (3.3) ..45
5.1.7 Research Centers—Health Outcomes and Healthcare Service Delivery (3.4) ..49
5.1.8 Research Centers—Broader Economic and Social Impacts (3.5) ..51
5.1.9 Scoring the Research Centers on Payback Framework Benefit Categories ..52
5.2 Research Payback from the MBIH Research Projects ..57
5.2.1 Research Projects—Knowledge Productivity (3.1 and 3.6) ..58
5.2.2 Research Projects—Research Targeting (3.2) ..59
5.2.3 Research Projects—Capacity Development (3.2) ..60
5.2.4 Research Projects—Informing Clinical and Administrative Policy and Product Development (3.3) ..62
5.2.5 Research Projects—Effects on Health Outcomes and Healthcare Service Delivery (3.4) ..63
5.2.6 Research Projects—Broader Economic and Social Impacts (3.5) ..64
5.3 Comparing the Payback Framework Results for the MBIH Research Centers and Projects ..65
6. Growth of the Mind-Body Research Field and MBIH Program Contributions to It ..69
6.1 MBIH Bibliometric Analysis Methods ..69
6.2 MBIH Research Center and Project Partnerships with External Universities (4.2) ..83
6.3 MBIH Program Component Involvement with Community-based Organizations (4.3) ..83
7. Program Effects on Federal and Non-federal Funding for MBIH Research ..84
8. Lessons Learned from the Mind-Body Interactions and Health Program Outcome Evaluation ..86
8.1 Innovative Features of the MBIH Program Outcome Evaluation ..86
8.2 Summary of Main Findings from the MBIH Program Outcome Evaluation ..86
8.2.1 Has the MBIH Program achieved its programmatic goals and objectives? ..87
8.2.2 Has the research conducted through the MBIH Program increased scientific knowledge and understanding about mind-body relationships and their influences on health processes and outcomes? ..88
8.2.3 How productive have the MBIH research centers and projects been in terms of the Payback Framework research benefit categories? ..89
8.2.4 How has the field of mind-body research grown over time and what contributions have the MBIH investigators made to it? ..91

8.2.5 Has the MBIH Program increased financial support for mind-body research among federal and non-federal funding sources? 93
8.3 Strengths and Limitations of the MBIH Program Outcome Evaluation 94
8.3.1 Strengths of the MBIH Program Outcome Evaluation 94
8.3.2 Limitations of the MBIH Program Outcome Evaluation 94
8.4 Lessons Learned for Future NIH Research Center Programs 94
8.4.1 The Payback Framework provides a useful conceptual model for evaluating research center programs. 95
8.4.2 Annual investigator meetings are an important element for NIH research center programs. 95
8.4.3 Research center sustainability deserves greater programmatic attention than it typically receives. 95
8.4.4 Annual Progress Reports should be modified to capture meaningful information on potential research benefits. 96
8.5 Lessons learned for future applications of the Payback Framework 97
8.6 Conclusion 98
References 99
Appendix 1 Conceptual Model for Evaluation A-1
Appendix 2 MBIH Research Center Radar Graphs B-1

List of Exhibits

Exhibit 1. Landmarks in the Establishment of the Mind-Body Interactions and Health Program....1
Exhibit 2. Mind-Body Interactions and Health Research....3
Exhibit 3. MBIH Program Funding Chronology....3
Exhibit 4. MBIH Program Feasibility Study Process....5
Exhibit 5. Payback Framework Categorization of Benefits from Research Programs....7
Exhibit 6. MBIH Program Outcome Evaluation Evaluation Questions and Sub-questions....9
Exhibit 7. Definitions and Parameters of e-SPA Indicators Collected for Each MBIH Publication....13
Exhibit 8. Types and Frequencies of MBIH Non-Research Articles....13
Exhibit 9. MBIH Program Goals and Objectives....14
Exhibit 10. MBIH Program Funding Shares by Participating NIH Institutes and Centers, 2000-2009....14
Exhibit 11. MBIH Research Center Funding Mechanisms....15
Exhibit 12. Eligibility Requirements for Three MBIH Research Center Funding Mechanisms....16
Exhibit 13. Themes of Research Conducted at MBIH Research Centers....17
Exhibit 14. Types of Research Conducted as Sub-projects and Pilot Studies at MBIH Research Centers....18
Exhibit 15. Research Themes in the 44 MBIH Research Projects....18
Exhibit 16. Research Themes Associated with Peer Reviewers' Comments on Innovation in MBIH Research Center Grants....19
Exhibit 17. Interdisciplinarity in the MBIH Research Centers by Funding Mechanism....21
Exhibit 18. Interdisciplinary Index by Principal Investigator Experience and Center Affiliation....22
Exhibit 19. MBIH Research Center End-States....24
Exhibit 20. Scientific Accomplishments of MBIH Research Centers....25
Exhibit 21. Evidence of Increased Acceptability of Mind-Body Research....27
Exhibit 22. Development and Use of New Tools, Methods, Instruments or Measures by MBIH Research Projects....28
Exhibit 23. Factors Affecting External Use of New Research Tools, Methods, Instruments or Measures....29
Exhibit 24. Payback Framework Logic Model....30
Exhibit 25. Input Characteristics of the MBIH Research Centers....31
Exhibit 26. MBIH Research Funding for Early and Late-Stage Research Centers....32
Exhibit 27. Center Activities Promoting Interdisciplinary Collaboration....33
Exhibit 28. Pilot Studies at the MBIH Research Centers....34
Exhibit 29. Numbers and Proportions of Sub-projects and Pilot Studies Resulting in an Oral Presentation or Publication by Center....36
Exhibit 31. Publications, Funding and Dollars per Publication for the MBIH Research Centers....37
Exhibit 30. Knowledge Productivity in the MBIH Research Centers....37
Exhibit 32. Number and Total Dollar Value of NIH Spin-off Grants by MBIH Center....39
Exhibit 33. Number and Total Dollar Value of NIH SPIN-Off Grants by NIH IC....40
Exhibit 34. Number and Total Dollar Value of NIH Spin-off Grants by Type of Grant....40

Exhibit 35. Non-federal Funding Sources for the MBIH Research Centers....40
Exhibit 36. Summary of Findings; 41
Exhibit 37. Research Staff Development at MBIH Research Centers....42
Exhibit 38. Types of New Research Collaborations by MBIH Center....42
Exhibit 39. New Tools, Instruments and Infrastructure at MBIH Centers 44
Exhibit 40. Summary of Findings: 45
Exhibit 41. Influencing Clinical and Administrative Policy and Product Development....46
Exhibit 42. Examples of Centers' Influence on Policy 47
Exhibit 43. Examples of Centers' Influence on Education and Training....48
Exhibit 44. Examples of Centers' Influence on Clinical Guidelines 48
Exhibit 45. Summary of Findings: 49
Exhibit 46. Influencing Health and Healthcare Service Delivery 50
Exhibit 47. Summary of Findings: 51
Exhibit 48. Selected Research Payback Benefit Categories and Indicators 53
Exhibit 49. Scoring Scales for Research Targeting....53
Exhibit 50. Scoring Scales for Capacity Development 54
Exhibit 51. Scoring Scales for Informing Policy....55
Exhibit 52. Adoption by Clinical Practitioners....55
Exhibit 53. Final MBIH Center Scores on Indicators 56
Exhibit 54. Radar-graph for Center A....56
Exhibit 55. Radar-graph for Center J 57
Exhibit 56. Radar-graph for Center H....57
Exhibit 57. Summary of MBIH Research Project Characteristics....57
Exhibit 58. Research Projects with Research Publications by Center Affiliation, PI Experience, and Timing of Funding 59
Exhibit 59. NIH Research Spin-off Grants and Center Affiliation, PI Experience, and Funding Round....60
Exhibit 60. Career Development and the MBIH Research Projects 60
Exhibit 61. Effects of Center Affiliation on Faculty Promotions, Faculty Recruitment, and Special Honors and Awards....61
Exhibit 62. Effects of PI Experience on Faculty Promotions, Faculty Recruitment, and Special Honors and Awards....61
Exhibit 63. Types of New Collaborations Resulting from MBIH Research Projects 62
Exhibit 64. Examples of Effects on Clinical and Administrative Policies 63
Exhibit 65. Examples of New Product Development....64
Exhibit 66. Summary of Research Payback Framework Benefits and Indicators for MBIH Centers & Projects....65
Exhibit 67. Summary of Effects of Center Affiliation on Academic Impacts....66
Exhibit 68. Comparison of Payback Framework Results for the MBIH Program with Other Research Payback Studies 67

Exhibit 69. Number of Total MBIH Articles, Research and Non-Research Articles by Web of Science (WoS) Subject Category (SC) by Time Period (2000-2004 and 2005-2009) with Duplicate Articles Removed 69

Exhibit 70. Top10 WoS Categories by Number of Articles, Percent of Articles and Time Period (2000-2004 and 2005-2009) 72

Exhibit 71. Selected Web of Science (WoS) Subject Categories (SCs) and Macro-Disciplines for the 527 MBIH Research Articles 72

Exhibit 72. Macro-disciplines, Number of Articles and WoS Subject Categories by Macro-disciplines for the 527 MBIH Research Articles 74

Exhibit 73. WoS Categories in Each Macro-Discipline and the Number of Scopus Review Articles and MBIH Articles in each Macro-discipline and WoS Category 76

Exhibit 74. Percentage of MBIH Research Articles and Scopus Review Articles by Macro-discipline 79

Exhibit 75. Comparison of the Top WoS Categories (Percentages) within the Macro-discipline of Clinical Medicine for the MBIH Research Articles with the Distribution of the Same Categories in the Scopus Review Articles 80

Exhibit 76. Comparison of the Top WoS Categories (Percentages) within the Macro-discipline of Clinical Medicine for the Scopus Review Articles with the Distribution of the Same Categories in the MBIH Research Articles 80

Exhibit 77. Distribution of WoS Subject Categories (Percentage) within the Macro-discipline of Psychology for MBIH Research Articles and Scopus Review Articles. 81

Exhibit 78. Top Five Macro-disciplines by Number of Articles by year 2000-2009 for MBIH Research Articles 82

Exhibit 79. Top Five Macro-disciplines by Number of Articles by Year 1999-2009 for Scopus Review Articles 82

Exhibit 80. NIH Institutes, Centers, and Offices Participating in the MBIH Research Centers, Research Projects, and Center Spin-off Grants 84

Exhibit 81. Summary of Evaluation Findings for MBIH Program Evaluation Question 1 87

Exhibit 82. Summary of Evaluation Findings for MBIH Program Evaluation Question 2 88

Exhibit 83. Summary of Evaluation Findings for MBIH Program Evaluation Question 3 89

Exhibit 84. Summary of Evaluation Findings for MBIH Program Evaluation Question 4 92

Exhibit 85. Summary of Evaluation Findings for MBIH Program Evaluation Question 5 93

Exhibit 86. Lessons Learned for Future NIH Research Center Programs 94

Map of MBIH Program Outcome Evaluation Sub-Questions and Relevant Sections Within This Report			
#	MBIH PROGRAM EVALUATION SUB-QUESTIONS	Report Section(s)	
1. Has the Mind-Body Interactions and Health (MBIH) Program achieved its programmatic goals and objectives?		MBIH RESEARCH CENTERS	MBIH RESEARCH PROJECTS
1.1	What was the relative mix of research funded by the MBIH Program?	3.3	
1.2	Has the MBIH Program facilitated interdisciplinary collaboration and innovation in MBIH research?	3.4	
1.3	To what extent has the research conducted by the program been translated from basic, clinical, or health services research into effective interventions that improve health and functioning?	3.3	
1.4	Has the MBIH Program built capacity for conducting and sustaining mind-body research?	3.5	
1.5	Has the MBIH Program built capacity for conducting and sustaining MBIH research by creating cost-effective research core services?	3.5	
1.6	How will the research activities of these centers be sustained when funding concludes?	3.6	
2. Has the research conducted through the MBIH Program increased scientific knowledge and understanding about mind-body relationships and their influence on health processes and outcomes?			
2.1	What research advances and directions have been generated by the MBIH Program that would not have occurred (or might have taken much longer to occur) in its absence?	4.1	
2.2	To what extent are other research investigators using the methods, tools, and results of MBIH-funded research?		4.3
3. How productive have the MBIH research centers and investigator-initiated projects been in terms of the following Research Payback Framework benefit categories:			
3.1	Knowledge productivity?	5.1.3	5.2.1
3.2	Research targeting and capacity building?	5.1.4 & 5.1.5	5.2.2 & 5.2.3
3.3	Influence on policy and clinical practice?	5.1.6	5.2.4
3.4	Influence on health, public health, and health care services?	5.1.7	5.2.5
3.5	Influence on broader economic and social gains?	5.1.8	5.2.6
3.6	Do center-affiliated investigators exhibit an increase in productivity compared with MBIH-funded investigators not affiliated with centers?		5.2.1 & 5.3
4. How has the field of mind-body research grown over time and what contributions have the MBIH investigators made to it?			
4.1	What were the main MBIH research areas in FY 1999 and how did these change over time?	6.1	
4.2	To what extent has interdisciplinary collaboration occurred between researchers at various MBIH centers, at other US institutions, and at foreign institutions?	6.2	
4.3	To what extent has the involvement of community-based organizations and providers in MBIH research increased over time?	6.3	
5. Has the MBIH Program increased financial support for mind-body research among federal and non-federal funding sources?			
5.1	Has the MBIH Program increased support for mind-body research at NIH and stimulated additional research opportunities there?	7	
5.2	Has the MBIH Program increased support for MBIH research at other non-NIH federal agencies?		
5.3	Has the MBIH Program increased support for MBIH research at non-federal agencies?		
6. What can be learned from evaluating the MBIH Program that can be applied to future evaluations of other NIH research center programs?		8	

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Executive Summary

Introduction

The *Mind-Body Interactions and Health (MBIH) Program* was a ten-year trans-NIH program established by Congressional mandate in 1999. Administered by the Office of Behavioral and Social Sciences Research (OBSSR) with participation by twelve partnering NIH Institutes, the MBIH Program was created to expand current research on interactions among the brain, mind, body and behavior and on the mechanisms by which factors such as the emotions, cognitions and attitudes, and social and behavioral phenomena directly affect physical and mental health. The program had two basic goals: the expansion of scientific knowledge about the nature and underlying mechanisms of these interactions, and the translation of this knowledge into new kinds of health care interventions. To accomplish these goals, OBSSR and its partnering NIH institutes developed the MBIH Program's activities around three objectives: promotion of interdisciplinary collaboration and innovation; development of ongoing capacity to conduct and pursue mind-body research at participating institutions; and facilitation of scientific interaction among the funded programs. Over the ten-year period spanning 1999 through 2009, OBSSR and its partnering institutes provided nearly $175 million in research support, which funded a total of 15 MBIH research centers and 44 investigator-initiated research projects.

Design and Methodology

Planning for the MBIH Program Outcome Evaluation began in September 2007 when OBSSR commissioned The Madrillon Group Inc. to conduct a feasibility study to determine whether an outcome evaluation of the MBIH Program was both feasible and warranted, and, if so, how the evaluation should be designed. The study concluded that the MBIH Program had operated for nearly 10 years without an evaluation of its outcomes, and that the program had reached a stage of sufficient developmental maturity that an outcome evaluation was both feasible and warranted. Based upon interviews and discussions with OBSSR and other NIH program staff and the Principal Investigators (PIs) for the 15 funded research centers, the evaluation team identified a set of six evaluation questions and numerous sub-questions. The evaluation team also determined that the Payback Framework would provide the most suitable conceptual framework for examining the outputs and outcomes of the MBIH Program.

The Research Payback Framework (Payback Framework) is both a model of and an approach for examining the economic and non-economic benefits (payback) from health research expenditures. Developed during the mid-1990s by the Health Economics Research Group (HERG) at Brunel University in England, the Payback Framework consists of two components: a multidimensional categorization of five types of research benefits that accrue from research activities, and an input-output type logic model that captures the flow of the research process over time, relating the various types of research benefits in the form of outputs and outcomes to research inputs and activities. The Payback Framework typically employs a case study methodology that uses the logic model as an organizing template for the structure of the case studies; this approach has been modified in more recent work to include a survey approach. The framework has been widely used in evaluations of health, biomedical, and social sciences research programs in England, Ireland, the Netherlands, Canada, Australia, and Hong Kong. As far as can be determined, the MBIH Program Outcome Evaluation is the first formal application of the Payback Framework in the United States (US).

The design of the MBIH Program Outcome Evaluation is a mixed-methods cross-sectional evaluation design. This type of design uses both qualitative and quantitative data to build a single cumulative "snapshot" of a program and its outcomes at a single point in time (2010-2011). In this instance, the evaluation design consists of three "snapshots"—the program as a whole, the research centers, and the research projects.

Within these cumulative "snapshots" four types of comparisons were conducted to clarify certain relationships. First, within the research centers, the structural characteristics of centers that achieved different types of end-states were compared. Second, outputs and outcomes for the research centers as a group were compared with the research projects as a group. Third, the outputs and outcomes of research projects conducted by investigators who were affiliated with a research center were compared with projects conducted by investigators who were not affiliated with a research center. Finally, the results for the research centers and projects were compared with several other published studies that used the Payback Framework.

Five data collection approaches were used to gather data for the MBIH Program Outcome Evaluation: document review; Research Center PI semi-structured interviews; Research Center Pilot Study and Sub-project Data Tables; Research Project PI semi-structured interviews; and bibliometric analyses. The evaluation was conducted between October 2009 and September 2011.

Findings

The main findings from the MBIH Program Outcome Evaluation are summarized below for each of the six evaluation questions.

Question 1: Has the Mind-Body Interactions and Health Program achieved its programmatic goals and objectives?

The results from the MBIH Program Outcome Evaluation indicate that the program did achieve its two main program goals (expansion of scientific knowledge about mind-body relationships and the mechanisms by which they influence health and health outcomes, and translation of this knowledge into health interventions). The evaluation also provided clear evidence that two of the three programmatic research objectives were accomplished (facilitating interdisciplinary collaboration and innovation in research ideas, and building a capacity for mind-body research through cultivation and development of research personnel and funding of research core services). The latter objective highlights a problem that is endemic to research center programs in general: it is very difficult to sustain the operation of research core services without the specific infrastructure funding that is provided through research center programs. This was a point noted by several of the research center PIs during interviews with them, and is also illustrated by the closure of the six research centers that ended after their MBIH funding concluded. The availability of core services is often described as a major advantage of research centers, and is a critical resource in generating new research projects and pilot research activities.

The third programmatic objective called for the promotion of regular interactions among interdisciplinary research teams across the US. In other research center programs this is often accomplished by convening the investigators for an annual research meeting, at which the various investigators can exchange information on their current projects and identify other investigators with whom they might collaborate on areas of common interest. Two such meetings were held for the MBIH research center investigators. Center investigators reported that they also maintained informal communications with each other through participation in various scientific and professional meetings, and they reported a general awareness of other centers' research activities. The Research Center PI interviews and the analyses of research publications indicated that some research collaborations occurred among the MBIH research centers (i.e., five co-authored publications), but overall there was not a high level of interaction that resulted in tangible collaborations across the MBIH research centers.

Specific findings associated with this evaluation question included the following:

- Research centers and investigator-initiated research projects addressed all three of the original thematic areas identified in the Program's Requests for Applications.

- Research centers and projects included both basic and clinical research, and investigated a number of topics new to mind-body research, including health disparities, population research, and effects of environmental factors on health.
- Research centers and projects exhibited a high degree of interdisciplinarity on an Index of Interdisciplinarity developed for the evaluation.
- Innovation was an important element of applications for research centers' grants, and included the use of interdisciplinary conceptual frameworks to guide research; fielding of interdisciplinary research teams; the development of novel types of research activities; utilization of basic science and clinical research approaches to investigate common research problems; creation of novel research measures; and the development of new research products.
- Within the research centers, almost 19 percent of the subprojects and pilot studies involved the evaluation of mind-body interventions and 80 percent of the centers developed and evaluated at least one mind-body intervention. For the 44 investigator-initiated research projects, 43 percent of the projects involved an evaluation of a mind-body intervention.
- Research centers were highly successful in promoting career development and training opportunities for research staff.
- By the time their research funding concluded, four research centers had evolved into new centers with a shift in research focus, and five centers had been wholly or partially absorbed by a separate research center within their host institutions; thus 60 percent of the centers continued in some form after MBIH funding concluded.

Question 2: Has the research conducted through the MBIH Program increased scientific knowledge and understanding about mind-body relationships and their influences on health processes and outcomes?

The MBIH research centers clearly contributed to scientific knowledge and understanding about mind-body relationships and the mechanisms by which they affect health and well-being.

Specific findings associated with this question included the following:

- Major scientific accomplishments of the research centers could be characterized in terms of five themes: stress mechanisms and stress reduction interventions; the development of important new conceptual approaches and frameworks; the creation or application of new tools and instruments; new findings; and education and training in mind-body medicine.
- 70 percent of the research projects and 80 percent of the research centers reported developing new research tools, methods, instruments or measures; 55 percent of the projects and 58 percent of the centers reported some use of these new products by investigators at external academic institutions.

Question 3: How productive have the MBIH research centers and projects been in terms of the Payback Framework benefit categories?

The MBIH Program research centers and research projects achieved outputs and outcomes across the five Payback Framework benefit categories. A particularly noteworthy aspect of this accomplishment is that achievement of the more distal outcomes occurred despite the fact that such accomplishments often require as much as 10-15 years to occur in biomedical research programs. Research centers were more likely to demonstrate effects on policy, health outcomes, and service delivery and even broader economic

impacts at a national or international level, while the results of research projects were more likely to be noted at a community or national level.

Specific findings associated with this question included the following:

- MBIH research centers as a group generated 429 unduplicated peer-reviewed research publications; MBIH research projects produced a total of 129 peer-reviewed research publications.
- MBIH research centers obtained 100 new NIH-funded spin-off grants based on their sub-projects and pilot studies, or about $1.95 for every NIH dollar spent funding the MBIH research centers.
- Eleven of the 15 centers obtained research funds from non-federal sources excluding their host institutions.
- Forty-three percent of the MBIH research projects obtained new NIH-funded spin-off grant funding, and 27 percent of the projects generated non-federal research spin-off funding.
- Between 50 and 67 percent of the centers reported mentoring post-doctoral fellows and junior faculty, recruiting new faculty, supporting the promotions of existing faculty, and enabling doctoral students to obtain advanced degrees.
- Almost half of the centers (47 percent) promoted international research collaborations, often through Visiting Scientist programs.
- About 40 percent of the centers reported contributions to clinical guidelines, 60 percent reported an impact on policy, and 87 percent reported an impact on medical or healthcare professional education.
- Slightly over half of the research centers and the research projects reported some effect on clinical practice or provider behavior.
- About 27 percent of the centers and 9 percent of the projects reported that they anticipated broader economic or social impacts.

Question 4: How has the field of mind-body research grown over time and what contributions have MBIH investigators made to it?

The field of mind-body research continued to expand throughout the 2000-2009 period examined. In order to trace the growth and directions of mind-body publications (and the contributions MBIH Program investigators made to this literature), a bibliometric analysis was performed based on the Web of Science subject categories assigned to journals in which the articles appeared. These analyses supported the conclusion that mind-body research is appearing more regularly in mainstream medical journals, an indication of the growing acceptance of this field within the scientific community; this acceptance was further corroborated in several of the Research Center PI interviews.

Specific findings associated with this question included the following:

- There has been a steady growth over the past decade in published research articles on mind-body interactions and health research.
- MBIH investigators published more frequently in macro-disciplines such as oncology, gastroenterology and hepatology, and peripheral vascular disease than the field as a whole.
- Forty-seven percent of the MBIH research centers involved partnerships with other US academic institutions, with the number of partnering institutions ranging from 1 to 8.

- Research teams for 5 percent of the MBIH research projects involved investigators from other US academic institutions with the number of partnering institutions ranging from 2 to 7.

Question 5: Has the MBIH Program increased financial support for mind-body research among federal and non-federal funding sources?

MBIH Program grantees were successful in obtaining funding for new spin-off research projects from NIH, other federal agencies, and non-federal agencies and organizations.

Specific findings associated with this question include the following:

- MBIH research centers obtained 100 new NIH research spin-off grants totaling $184,781,090.
- The number of NIH institutes funding MBIH research center spin-off grants grew over the ten years of program funding, suggesting that other NIH institutes are becoming more receptive to mind-body interactions and health research.
- MBIH research centers and projects reported obtaining funding for mind-body research projects from other federal agencies such as the Agency for Healthcare Research and Quality and the Department of Veterans Affairs.

Question 6: What can be learned from evaluating the MBIH Program that can be applied to future evaluations of other NIH research center programs?

The MBIH Program Outcome Evaluation discussed four recommendations for future evaluations of NIH research center programs. These included:

- The Payback Framework provided a highly useful conceptual framework for evaluating research center and other biomedical research programs at NIH.
- Annual investigator meetings are an important element for promoting communication and collaboration for NIH research center programs.
- Research center sustainability deserves greater programmatic attention and emphasis than it typically receives.
- Annual Progress Reports should be modified to capture meaningful information on potential research benefits such as those identified by the Payback Framework.

Conclusions

The MBIH Program was a ten-year program designed to promote an emerging field of research that was perceived to be under-developed at the time the program was initiated. During the ten years from 2000 through 2009, a trans-NIH partnership provided nearly $175 million in research funding to support 15 research centers and 44 investigator-initiated research projects. The goals of the program included the expansion of scientific knowledge about mind-body relationships and how they affect health and illness, and the translation of this knowledge into health interventions. The program was evaluated using the Payback Framework, a conceptual model that identifies five categories of research benefits (knowledge productivity; research targeting and capacity development; influence on policy; influence on health outcomes and healthcare service delivery; and broader economic and social impacts). The evaluation showed that the MBIH program met its original programmatic goals and most of its objectives, and that the 15 research centers and 44 research projects produced clear and positive effects across all five of the Payback Framework research benefit categories.

Several aspects of the MBIH Program Outcome Evaluation were innovative in terms of approaches used in past evaluations of research programs at NIH. The foremost aspect was the successful application of the Payback Framework as a conceptual model for this outcome evaluation. The Payback Framework represents an important advance because it focuses on research *outcomes* as well as traditional *outputs* such as numbers of publications. By examining domains such as impacts on policies, clinical practice, health outcomes and service delivery, and even more distal economic and social effects, the Payback Framework highlights not only what biomedical research programs produce, but the monetary and non-monetary value that results from this productivity. The MBIH Program Outcome Evaluation was the first evaluation in the US to apply the Payback Framework, and this evaluation showed that it could be successfully adapted for a US context. In terms of previous Payback Framework studies, the MBIH evaluation was also unique in its inclusion of all of the centers and investigator-initiated projects funded by the program, rather than a sample as has been the case in previous applications. The MBIH Program Outcome Evaluation clearly demonstrated that the Payback Framework provides a valuable tool for the evaluation of biomedical research programs at NIH.

Two other aspects of this evaluation are also noteworthy. The first was the use of a new approach for examining the distribution of research literature based on Web of Science journal subject categories. This approach was based on bibliometric science-mapping approaches developed by Alan Porter and Ismael Rafols. While the number of mind-body research articles produced by the MBIH research centers was too small to permit the use of the visual mapping approach described by these investigators (see Porter and Rafols, 2009), the MBIH evaluation was able to apply the journal subject category classification approach they proposed, leading to evidence of greater acceptance of mind-body research based on its increasing likelihood of publication in mainstream medical journals. The second aspect was the development of a measure of research targeting based upon the number of new spin-off research funding dollars generated per dollar of research center funding. In this evaluation, the measure was constructed based on new NIH-funded spin-off grants. The decision to restrict the measure to NIH-funded spin-off grants was made because both the grants and the amounts of research funding could be verified using NIH databases. In the future, this measure should be expanded to include non-NIH grant and contract funding, which could be collected routinely from annual progress reports if the information was explicitly requested and reported. A measure of this type would be valuable as another means of demonstrating the potential return on investment from funding research programs.

1. Background and Introduction

The idea that the human mind and body interact to influence physical and mental health is not new; the notion was discussed by the ancient Greeks and has been a part of the ongoing dialog about medicine and health ever since that time. As noted by Pelletier (2004, p.26), until 300 years ago, "…virtually all philosophy and medicine treated body and mind as an integral whole." A comprehensive history of the evolution of mind-body medicine was recently published by Harrington (2008).

Mind-body medicine (MBM) explores the interactions among the brain, mind, body, and behavior, and on the various ways by which emotional, mental, social and behavioral factors directly affect physical and mental health. Research on MBM dates back at least to the nineteenth century. During the past seventy years, however, studies began to show linkages between psychological characteristics, behaviors and emotions and the phenomena of disease onset and progression, with particular emphasis on diseases such as allergies, asthma, peptic ulcers, cancer, autoimmune diseases, and infectious diseases (Kiecolt-Glaser *et al.,* 2002). Several key events during this period included the introduction of a new medical framework called the biopsychosocial model of medicine (Engel, 1977; Schwartz, 1982), and the publication of papers by Solomon and Moos (1964)—who first coined the term *psycho-immunology*—and Ader and Cohen (1975). Six years later, Ader, Cohen, and Felton (1981) published their landmark book entitled *Psychoneuroimmunology*, which summarized research on the interactions among the nervous system, immune system, and the onset and progression of disease, launching a new sub-field of research.

Since that time, researchers have worked to establish a firmer evidentiary basis for MBM. By the end of the 1990s, an initial body of research on the effects of psychological characteristics, behavior, emotion and stress on morbidity and mortality had appeared in the scientific literature. By the early 2000s, separate reviews of randomized controlled trials and meta-analyses by Astin *et al*. (2003) and Pelletier (2004) were able to conclude that strong evidence existed to support the use of some mind-body interventions as part of the treatment for chronic low back pain, coronary artery disease, hypertension, headache, insomnia, general pain syndromes, preparation for surgery, and in the management of disease-related symptoms in cancer, arthritis, and urinary incontinence. At the same time, there was also promising evidence of possible effects of mind-body interventions for diseases such as asthma, dermatological disorders, diabetes, HIV progression, irritable bowel syndrome, post-stroke recovery, peptic ulcers, pregnancy outcomes, and chronic obstructive pulmonary disease, but further research was needed. In particular, further research was necessary to examine the mechanisms underlying the relationships between mind-body processes and disease onset, progression, and recovery.

1.1 Origins of the Mind-Body Interactions and Health Program

Recognition of the extent of public interest in and expenditure on MBM practices and the need for research to identify effective MBM interventions led to a series of Congressional hearings and actions during the 1990s (see **Exhibit 1**). The background and rationale for these Congressional actions has been described in some detail by Boyle (2010). A consistent theme unifying these different actions is Congressional intent to push NIH toward taking a stronger role in supporting research in this area, a stance that NIH appeared initially reluctant to embrace. In part, this reflected a lingering medical skepticism about mind-body research. It also

Exhibit 1. Landmarks in the Establishment of the Mind-Body Interactions and Health Program

1991—Congress directs NIH to establish the Office for the Study of Unconventional Medical Practices;

1992—The NIH Ad-Hoc Alternative Medicine Program Advisory Committee holds panel meetings and an Open Forum on Unconventional Medical Practices, whose proceedings were published as the Chantilly Report;

1992—Congress renames the Office for the Study of Unconventional Medical Practices the Office of Alternative Medicine;

1998—The Office of Alternative Medicine is expanded and renamed the National Center for Complementary and Alternative Medicine;

1999—Congress authorizes the Mind-Body Interactions and Health Program

reflected a structural problem—mind-body research did not fit conveniently within the purview of any one Institute at NIH. Mind-body research often required the participation of interdisciplinary research teams and frequently involved research fields that cut across the domains of several Institutes.

While research by the late 1990s had successfully demonstrated that mind body medicine could affect physical and mental health, far less was known about why, how, and for whom these interventions worked. On September 22, 1998, the US 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 Senate convened to hear testimony on the status of current research on mind-body interventions and to solicit advice from leading researchers on how best to strengthen research on the relationship of stress to physical and mental health, and on interventions for reducing stress via techniques involving cognitions, social support, prayer, meditation, and other approaches.

One of the researchers who testified on that date was Herbert Benson, M.D, from Harvard University. In his testimony, he noted that mind-body interventions faced four formidable barriers to integration in mainstream medicine: (1) the lack of awareness by physicians and other health care practitioners of existing scientific data supporting the efficacy and effectiveness of these techniques; (2) a bias against mind-body interventions in medical care as reflecting 'soft science;' (3) the lack of third-party insurance reimbursement for the application of mind-body interventions; and (4) a bias against moving away from the use of pharmaceuticals, surgery, and other mainstream medical procedures.

Dr. Benson then read the following statement into the record, which is quoted here at length because it states a clear rationale for the subsequent Congressional recommendation to fund the Mind-Body Interactions and Health Program. In his statement, Dr. Benson said:

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. 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 treatment. It might be advisable to encourage the new centers to work collaboratively on joint projects. The centers would also train health care 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. (US Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, 1998; p.14).

With the key support of Senators Arlen Spector and Tom Harkin, the same legislation that authorized the creation of NCCAM incorporated a specific and separate mandate and special funding for a new program of mind-body interactions and health research at NIH. The program was formally launched in 1999 with $10 million in first-year funding to establish five university-based research centers, charged with the task of investigating relationships among cognitions, emotions, personality, social relationships, stress, and health.

1.2 Goals and Objectives of the Mind-Body Interactions and Health Program

Congress assigned responsibility for organizing the *Mind-Body Interactions and Health Program* (hereafter called the MBIH Program) to the Office of Behavioral and Social Sciences Research (OBSSR), a programmatic unit within the Office of the NIH Director. OBSSR coordinates and promotes behavioral and social sciences research across NIH through partnerships with other Institutes and Centers. To implement the MBIH Program, OBSSR issued an initial *Request for Applications* (*RFA OD-99-005*) with 12 NIH Institutes and Centers as co-sponsors. This initial *RFA* outlined three topical areas that would define mind-body interactions and health research in each of the successive *RFA*s and *Program Announcements (PAs)* issued under the *MBIH Program* (see **Exhibit 2**).

The MBIH Program officially began in 1999 and ended its last year of new funding in 2009. Over this ten-year period, the program sought to achieve two broad goals: to expand scientific knowledge about mind-body relationships and the mechanisms by which they influence health outcomes, and to translate this knowledge into effective health interventions. To accomplish these goals, OBSSR established three objectives:

- To facilitate interdisciplinary collaboration and innovation in research ideas;
- To build capacity for conducting and sustaining continuing research in mind-body interactions and health by funding research core services at established and nascent research centers; and
- To promote regular interaction among interdisciplinary research teams across the US.

Exhibit 2. Mind-Body Interactions and Health Research

Topical Research Areas

- Effects of emotions, personality, or cognitions (e.g., beliefs, attitudes, values, modes of thinking, decision-making styles) on physical health;
- Determinants or antecedents of health-related cognitions and how these are formed, maintained, or changed; and
- Mechanisms by which stress affects physical health.

1.3 Structural Elements and Components of the MBIH Program

To grow this interdisciplinary research community and field, OBSSR and its partnering Institutes and Centers (ICs) funded both research centers and investigator-initiated research projects (see **Exhibit 3**). The partnering ICs used three different funding mechanisms to fund research centers: P50 comprehensive research center grants (average annual funding nearly $2 million for five years); R24 research infrastructure awards (average annual funding of $800,000 for five years); and R21 exploratory-developmental research awards (average annual funding of about $400,000 for three years). In 2007, a special restricted competition was held to fund 3 additional R24 research infrastructure awards; the competition was limited to the 6 previously funded R21 exploratory-developmental awardees. The three types of funding mechanisms have different eligibility requirements, a factor which will be discussed in further detail in Section 5.

Exhibit 3. MBIH Program Funding Chronology

2000: Funded 5 P50 Comprehensive Research Centers (2000-2004);

2004: Funded 7 R24 Research Infrastructure Centers (2004-2009);

2004: Funded 6 R21 Exploratory-Develop-mental Centers (2004-2007);

2005: Funded 15 R01/U01 Investigator-initiated Research Projects;

2006: Funded 7 R01 Investigator-initiated Research Projects;

2007: Funded 3 Research Infrastructure Centers in a Special Restricted Competition (2007-2010);

2007: Funded 22 R01/U01 Investigator-initiated Research Projects.

1.4 Organization of this Report

This report presents the design, methods, and results from an outcome evaluation of the *Mind-Body Interactions and Health Program.* **Section 2** presents an overview of the design and methodology of the MBIH Program Outcome Evaluation. This section summarizes the earlier Feasibility Study (The Madrillon Group, Inc., 2008) from which the outcome evaluation design was developed and the conceptual framework employed for the study. The conceptual framework is unique, since it represents the first application of an internationally-tested research impact assessment model with a US biomedical research program. This framework is known as the Payback Framework and will be described further in Section 2. This section also includes a discussion of the evaluation questions and sub-questions, and the data sources and data collection approaches applied in this evaluation.

Sections 3-7 present the results for the first five general evaluation questions for the study. **Section 3** examines the extent to which the MBIH Program has met its two broad goals and three programmatic objectives. This section considers the types of research funded by the MBIH Program, what reviewers found innovative from the research center applications, the level of interdisciplinary staffing present among the key personnel listed for both the centers and the investigator-initiated projects, and the types of research cores fielded by the research centers. The section closes by considering the issue of research center sustainability, and introduces a typology based on the final "ending states" of the 15 funded research centers.

Section 4 considers the MBIH Program's effects on scientific knowledge and understanding, focusing on two areas: the most important research advances and directions generated by the research centers as perceived by their PIs, and the tools, methods, models and measures developed by the centers.

Section 5 uses the Payback Framework to examine and compare the outputs and outcomes of the research centers and the investigator-initiated research projects. Two types of program outputs (knowledge production, and research targeting and capacity-building), and three types of outcomes (impact on clinical and administrative policy, improved health outcomes and service delivery, and broader economic and social impacts) are considered. This section examines two additional issues: types of center structural characteristics associated with various end-states, and a comparison of effects of research center affiliation on outputs of the investigator-initiated research projects.

Section 6 presents the main results from the outcome evaluation's bibliometric analyses, examining how the mind-body research field has grown and developed between 1999 and 2009, and how MBIH-sponsored research has contributed to that growth.

Section 7 considers how the MBIH Program has affected research funding for mind-body research at NIH by examining funding for new NIH spin-off research generated from the research centers and the extent to which NIH ICs (that were not part of the original MBIH Program IC partners) have begun to fund new projects from these centers.

Section 8 concludes the report by discussing several lessons learned from the MBIH Program Outcome Evaluation, with specific reference to two areas: the evaluation of future NIH research center programs and the utility of the Payback Framework as a conceptual model for assessing the impacts of NIH biomedical research programs.

2. The Mind-Body Interactions and Health Program Outcome Evaluation

Planning for the MBIH Program Outcome Evaluation began in September 2007 when OBSSR commissioned The Madrillon Group Inc. to conduct a feasibility study to determine whether an outcome evaluation of the MBIH Program was both feasible and warranted, and, if so, how the evaluation should be designed. Over the course of the following year, the Madrillon Group evaluation team conducted a feasibility study that included seven sets of activities (see **Exhibit 4)**. The study concluded that the MBIH Program had operated for nearly 10 years without an evaluation of its outcomes, and that the program had reached a stage of sufficient developmental maturity that an outcome evaluation was both feasible and warranted. Based upon interviews and discussions with OBSSR and other NIH program staff and the Principal Investigators (PIs) for the 15 funded research centers, the evaluation team identified a set of six evaluation questions and numerous sub-questions. The evaluation team also determined that the Payback Framework would provide the most suitable conceptual framework for examining the outputs and outcomes of the MBIH Program. The rationale for the selection of this framework is described in greater detail in Scott et al. (2011) as well as the final report from the Feasibility Study (The Madrillon Group, Inc., 2008).

Exhibit 4. MBIH Program Feasibility Study Process

- Clarification of study objectives, issues, and questions;
- Focused review of literature on research impact assessment (including past evaluations of NIH research center programs);
- Interviews with relevant OBSSR program staff and partnering NIH IC stakeholders and Principal Investigators of research centers;
- Identification and review of existing sources of data;
- Development of a preliminary conceptual framework;
- Identification of appropriate evaluation questions, variables and measures; and
- Analysis of information and development of recommendations for an outcome evaluation.

2.1 Purposes of the MBIH Program Outcome Evaluation

OBSSR commissioned the Madrillon Group to conduct the MBIH Program Outcome Evaluation over a two-year period beginning in September 2009. During the program's 10-year lifetime, OBSSR and its partnering NIH ICs invested a total of $174,608,014 in program funding for 15 research centers and 44 investigator-initiated research projects. The MBIH Program had reached its sunset stage in 2009, which seemed an appropriate time to determine what the program had accomplished and whether it had met its original stated goals. Thus, the purposes of the outcome evaluation were identified as determining whether the MBIH Program had met its programmatic goals and objectives, and assessing the contributions the program had made to the broader field of mind-body interactions and health research. As stated in the OBSSR Statement of Work (2009), "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".

2.2 Considerations Shaping the Design of the MBIH Program Outcome Evaluation

Several aspects of the MBIH Program shaped the evaluation design of the MBIH Program Outcome Evaluation. These included the general structure of program (a mixture of research centers and investigator-initiated research projects), the latency of program outcomes, and the problem of outcome attribution.

Unlike many NIH research center programs that fund only research centers or networks, the MBIH Program consists of both research centers and investigator-initiated research projects. Within the scientific community, there has sometimes been a tension over the funding of centers *versus* investigator-

initiated research projects, with center proponents arguing that research center funding can accomplish a broad range of results including funding for pilot research projects, training for post-doctoral and junior investigators, the development of core research services that can serve as important resources for other researchers, and dissemination and community outreach activities. Opponents of research center funding have argued that the larger expenditures of limited research funds might better be put to use in funding additional investigator-initiated research projects, and that research centers, once funded, seem to persist forever. The structure of the MBIH Program provided the Madrillon evaluation team with an important opportunity to examine the outputs and outcomes of both centers and investigator-initiated research projects using the same framework and metrics. While the outcome evaluation does not provide a conclusive test of the policy question "Which is it better to fund—research centers or investigator-initiated projects," it does permit some comparisons that could provide useful insights for the future. Moreover, the number of investigator-initiated research projects funded under the MBIH Program provides an opportunity to examine a second and related question, namely, whether affiliation with a research center confers any advantage to individual investigators compared with investigators lacking a research center affiliation. Participation in a research center should confer certain advantages, such as access to important research resources, mentoring, and the opportunity for discussion and collaboration with colleagues who share a similar scientific interest. To test this idea, it was included as a specific sub-question within the set of evaluation questions.

A second important consideration concerns the latency of program outcomes. One of the findings from the feasibility study was that relatively few prior NIH program evaluations of research center programs included outcomes of the program; most used measures of a variety of types of program outputs, such as publications, or numbers of trainees. In some cases, these measures were mislabeled by the program evaluators as outcomes. However, measuring true program outcomes can be difficult because it can take many years for the results of research centers or individual research projects to emerge. One assessment of basic medical research discoveries found that it can take as many as 20 years or more from the time a discovery is made until it is translated into an effective clinical application (Contopoulos-Ionnidas *et al.*, 2008). Evaluations that are conducted at the conclusion of a single (five-year) program cycle are therefore apt to fail to detect some of the longer-range outcomes that could result from adoption of the research findings in the practitioner or policy communities.

This is a particular problem in the case of the MBIH Program, in which centers and projects were funded in cohorts that started in different years over the course of the program. In the case of the research centers, the first wave of five comprehensive centers (P50s) was funded starting in 2000 for a five year period, and at the time of the outcome evaluation data collection activities had seven years for results to develop; other centers were just concluding their final activities under No-Cost Extensions at the time semi-structured interviews were conducted. The investigator-initiated research projects were also funded in three waves, with the first wave beginning in 2004; those projects had been mostly completed by the time the investigators were approached, in contrast to the second two cohorts of projects which were frequently near the mid-point of their research funding. Time therefore introduced two challenges for this evaluation; on the one hand, some centers and projects are still conducting (or have just completed) their activities, while others have concluded their activities several years earlier. On the other hand, not enough time may have elapsed from the conclusion of research activities for some of the longer range outcomes to appear. This is an unavoidable challenge in evaluating research programs generally. An alternative would be to evaluate such programs 5-10 years after they have ended, but evaluation research funds are rarely available to pursue such evaluations.

A third issue that shaped this evaluation is attribution—to what extent can it be said that a research project (or program) "caused" an outcome, particularly when the outcome may occur several years after the program has ended? This is a common challenge in evaluating research programs. The approach used in this evaluation is to argue that rather than attributing a specific outcome to research activities or findings, it can be argued that the program or project has contributed to that outcome.

2.3 The Payback Framework

The conceptual framework around which the MBIH Program Outcome Evaluation is organized is the Payback Framework. The Madrillon evaluation team selected this framework after a careful analysis of the literature on research impact assessment and comparisons with other potential frameworks (e.g., Brutscher *et al*., 2008).

During the early 1990s, members of the Health Economics Research Group (HERG) at Brunel University, London, England conducted a series of evaluation studies of National Health Service programs. During the course of these early studies, Martin Buxton, Stephen Hanney, and HERG colleagues developed what they called the Payback Framework as a model of and an approach for examining the economic and non-economic benefits (payback) from health research expenditures. The model consists of two components: a multidimensional categorization of several types of research benefits that accrue from research activities, and an input-output type logic model that captures the flow of the research process over time, relating the various types of research benefits in the form of outputs and outcomes to research inputs and activities. The Payback Framework utilizes a case study methodology (which has subsequently been modified to include a survey approach) that uses the logic model as an organizing template for the structure of the case studies. The first published paper describing the application of the Payback Framework to an evaluation of National Health Service programs was co-authored by Martin Buxton and Stephen Hanney (Buxton and Hanney, 1996). The framework has been widely used in evaluations of health, biomedical, and social sciences research programs in England, Ireland, the Netherlands, Canada, Australia, and Hong Kong. As far as can be determined, the MBIH Program Outcome Evaluation is the first such US application of the Payback Framework.

The multidimensional benefits categorization schema includes five categories of potential benefits. The first three categories represent primary and secondary research program outputs, while the remaining categories are outcomes arising from research programs. These five categories are listed in **Exhibit 5**. Knowledge productivity includes publications, presentations and patents and licenses. A second type of primary output is improved research targeting and capacity-building. Improved research targeting refers to the development of more focused hypotheses and represents new spin-off research grants that result from the research activities of a center or research project. Capacity-building includes career development and training, honors or awards conferred upon the PI or research team that enhance its professional prestige, the formation of new research collaborations, the creation of new research infrastructure and new research tools, methods, instruments and models created through research activities or projects. It also includes effects on the host institution, such as the stimulation of new centers or programs that arise from the center or project. These are usually the most immediate products generated by a research program or project and as such are considered primary outputs. Secondary outputs include informing policy and clinical practice. This can include several types of indicators, such as the inclusion of study findings in policy briefs or white papers, the citation of publications as part of the rationale for a change in clinical practice guidelines, and the inclusion of study findings in medical or other health professional curricula or continuing education programs. Together, these two categories are sometimes called academic impacts in the Payback Framework.

Exhibit 5. Payback Framework Categorization of Benefits from Research Programs

Primary Outputs:

- Knowledge productivity; and
- Research targeting and capacity-building

Secondary Outputs:

- Informing policy and clinical practice;

Outcomes:

- Effects on health and healthcare service delivery; and
- Broader economic and social impacts on society.

The Payback Framework also identifies several types of research outcomes, or wider impacts. The first type of outcome is an impact on health outcomes and healthcare service delivery. The most immediate example of this is the improved health or quality of life of subjects participating in the research center activity or project, but this outcome category also includes changes in practitioner behavior or in how healthcare services are organized or delivered as a result of the study. The final outcome category consists of broader economic or social impacts on society, for example, dollar valuations of reductions in disability or mortality attributable to the research project. Clearly, this is a category that is more difficult to assess than the others, since these types of benefits may require many years to occur, economic studies that could document them are harder to locate, and many of these benefits are difficult to quantify.

The second component of the Payback Framework model is an input-process-output-outcome logic model that consists of nine steps (seven stages and two intervening interfaces). The model is a simplified attempt to depict the research process from the initial identification of a research question or problem (Stage 0), project specification and development (Interface A), inputs to the research (Stage 1), research processes (Stage 2), research outputs (Stage 3) which include both the primary (knowledge productivity) and secondary (research targeting and capacity-building) outputs, dissemination beyond the scientific community (Interface B), political and administrative benefits including informing policy and clinical practice (Stage 4), adoption by clinical practitioners and the public (Stage 5), and health sector and broader economic and social benefits (Stage 6).

The Payback Framework usually entails the preparation of multiple case studies of individual research projects or centers, using the logic model as an organizational template. The case studies are compiled from multiple sources, including document reviews and interviews with one or more researchers from each project. In some applications, additional interviews have been conducted with potential 'users' of the findings or products of the research. A typical Payback Framework evaluation includes multiple case studies, with the individual cases selected on a purposive sampling basis (i.e., selecting for specific types of research projects). Cross-case analysis is conducted by means of ratings for various outcomes across projects. This involves the development of a series of rating scales for each domain. Members of the evaluation team meet as a group to rate each case and discuss their ratings (in some more recent applications of the framework, independent content experts have also been included). Reasons underlying differences in ratings are discussed and the team members can change their ratings based on this discussion. This scoring system has been idiosyncratic for each application, and necessarily subjective. The final ratings may be displayed in the form of a radar graph (also called a "spider graph" due to its resemblance to a web) which allows a visual comparison between centers, projects or programs.

One criticism of the Payback Framework has been that case studies are labor and time-intensive to conduct. There has been some effort to explore whether a survey-based approach based on questionnaires could be used instead. Hanney et al. (1999) compared both approaches with a sub-sample of projects as part of a larger evaluation project and found that a carefully constructed questionnaire could provide results of comparable validity to a case study, although the latter approach provided richer detail. The questionnaire approach has been used successfully in several studies, notably Kwan et al. (2007) and Kalucy et al. (2009).

Because the MBIH Program involves both research centers and research projects, the outcome evaluation design applied the case study approach with the research centers and used semi-structured interviews with the research projects.

2.4 MBIH Program Outcome Evaluation Questions and Sub-Questions

As noted earlier, the MBIH Program Evaluation Feasibility Study included a series of semi-structured interviews with OBSSR program staff, NIH program officers who had overseen and monitored the various MBIH research center and project grants, and the 15 PIs (and an additional Co-Principal Investigator (Co-PI)). One objective of these interviews was to solicit perspectives on the types of

evaluation questions that should be included in the outcome evaluation. The final set of evaluation questions (with multiple sub-questions) is shown in **Exhibit 6.**

Exhibit 6. MBIH Program Outcome Evaluation Evaluation Questions and Sub-questions

Evaluation Question	Evaluation Sub-Questions
1. Has the Mind-Body Interactions and Health (MBIH) Program achieved its programmatic goals and objectives?	1.1 What was the relative mix of research funded by the MBIH Program?
	1.2 Has the MBIH Program facilitated interdisciplinary collaboration and innovation in MBIH research?
	1.3 To what extent has the research conducted by the program been translated from basic, clinical, or health services research into effective interventions that improve health and functioning?
	1.4 Has the MBIH Program built capacity for conducting and sustaining mind-body research?
	1.5 Has the MBIH Program built capacity for conducting and sustaining MBIH research by creating cost-effective research core services?
	1.6 How will the research activities of these centers be sustained when funding concludes?
2. Has the research conducted through the MBIH Program increased scientific knowledge and understanding about mind-body relationships and their influence on health processes and outcomes?	2.1 What research advances and directions have been generated by the MBIH Program that would not have occurred (or might have taken much longer to occur) in its absence?
	2.2 To what extent are other research investigators using the methods, tools, and results of MBIH-funded research?
3. How productive e have the MBIH research centers and investigator-initiated projects been in terms of the following Research Payback domains:	3.1 Knowledge productivity?
	3.2 Research targeting and capacity building?
	3.3 Influence on policy and clinical practice?
	3.4 Influence on health, public health, and health care services?
	3.5 Influence on broader economic and social gains?
	3.6 Do center-affiliated investigators exhibit an increase in productivity compared with MBIH-funded investigators not affiliated with centers?
4. How has the field of mind-body research grown over time and what contributions have the MBIH investigators made to it?	4.1 What were the main MBIH research areas in FY 1999 and how did these change over time?
	4.2 To what extent has interdisciplinary collaboration occurred between researchers at various MBIH centers, at other US institutions, and at foreign institutions?
	4.3 To what extent has the involvement of community-based organizations and providers in MBIH research increased over time?
5. Has the MBIH Program increased financial support for mind-body research among federal and non-federal funding sources?	5.1 Has the MBIH Program increased support for mind-body research at NIH and stimulated additional research opportunities there?
	5.2 Has the MBIH Program increased support for MBIH research at other non-NIH federal agencies?
	5.3 Has the MBIH Program increased support for MBIH research at non-federal agencies?
6. What can be learned from evaluating the MBIH Program that can be applied to future evaluations of other NIH research center programs?	

2.5 Design of the MBIH Program Outcome Evaluation

The design of the MBIH Program Outcome Evaluation is a mixed-methods cross-sectional evaluation design. This type of design uses both qualitative and quantitative data to build a single cumulative "snapshot" of a program and its outcomes at a single point in time (2010-2011). In this instance, the evaluation design consists of three "snapshots"—the program as a whole, the research centers, and the research projects.

Within these cumulative "snapshots," however, four types of comparisons are utilized to clarify certain relationships. First, within the research centers, the structural characteristics of centers that achieved different types of end-states were compared. Second, outputs and outcomes for the research centers as a group were compared with the research projects as a group. Third, the outputs and outcomes of research projects conducted by investigators who were affiliated with a research center were compared with projects conducted by investigators who were not affiliated with a research center. Finally, the results for the research centers and projects were compared with several other published studies that used the Payback Framework.

A conceptual framework for the MBIH Program Outcome Evaluation is included as **Appendix 1.**

2.6. Data Collection Approaches

Five data collection approaches were used to gather data for the MBIH Program Outcome Evaluation: document review; Research Center PI semi-structured interviews; Research Center Pilot Study and Sub-project Data Tables; Research Project PI semi-structured interviews; and bibliometric analyses. The approaches and the sources of data informing them are discussed below.

2.6.1 Document Review

Considerable data for each research center and research project already existed in the form of program documents, including grant applications, reviewers' Summary Statements, and Annual Progress Reports. These are stored electronically by grant number in pdf format within the QVR application of the NIH IMPAC II database. For the most part, these records were relatively complete from 1999 onward, although the grant applications, Summary Statements and some Annual Progress Reports for two of the original five comprehensive centers could not be located. In addition, Annual Progress Reports for the most recent years (2008 and 2009) were available in only some cases.

The information provided by these documents was extensive, and in order to collect relevant data in a systematic fashion, two Data Abstraction forms were developed—one for the Research Centers and one for the Research Projects. The Research Center Data Abstract (RCDA) form contained sections that corresponded to the major stages within the Payback Framework, and integrated information from each of the three types of source documents (grant applications, Summary Statements, and Annual Progress Reports). The RCDA form included information on center structure and organization, center origins and aims, reviewer reactions and comments (including assessments of what was considered innovative about the center), the development of the center's research agenda, types of research inputs, research activities (including subprojects and pilot studies, research cores, career development and training activities, efforts to promote interdisciplinary interaction, and research translation activities), dissemination activities other than scientific papers, primary and secondary outputs, and outcomes (including policy impacts, health and healthcare service delivery, and broader economic and social impacts). Five centers were funded under two separate grant mechanisms. Two of the five P50 comprehensive centers obtained R24 grants in 2004, and three of the R21 grantees obtained R24 grants in 2007. The RCDA form was designed so that all relevant information from both sets of grants could be captured on the same form, either by direct entry or by cutting and pasting from original documents. Data entered into the RCDA forms were subsequently coded and entered into an Excel spreadsheet for analysis.

The Research Projects Data Abstract (RPDA) form followed a similar organizational format, with some variation in content to reflect research projects rather than centers. Because there were 44 investigator-initiated research projects, an ACCESS database was developed and the RPDA form data were coded directly into the database.

2.6.2 Research Center Principal Investigator Interview

In addition to the document review and data abstraction for each MBIH research center, semi-structured interviews were conducted with each of the 15 PIs and 1 Co-PI for the research centers (one research center included two neighboring academic institutions with a PI at one and a Co-PI at the other). The interview protocol contained a total of 16 questions, addressing topics such as the most significant scientific advances or accomplishments achieved by the center, perceived changes in scientific acceptance and respectability of the mind-body interactions and health research field over the past ten years, effects of the center on the host institution and partnering organizations, the development of research capacity, effects of the center's research on clinical practice and healthcare service delivery, effects on health outcomes and quality of life, effects on health or social policy, broader economic and social impacts, and the sustainability of the center in the future.

An initial email invitation was sent to each investigator, explaining the purpose of the MBIH Program Outcome Evaluation and the interview, asking for their participation, and explaining that a member of the Madrillon evaluation team would be contacting them to schedule the interviews. The interviews were conducted with all 16 PIs and Co-PI between December 2010 and January 2011 for a 100 percent response rate. In two cases, interviews were interrupted. In one case, a second interview was scheduled. In the other case, the interviewee asked that the remaining questions be sent to her and she completed them in writing within one week. The interview required an average of 77 minutes (range of 50-136 minutes). Data from the interviews were coded and entered into the same Excel spreadsheet used for the RCDA form data.

2.6.3 Research Center Pilot Study and Sub-project Data Table

Most of the MBIH research centers operated some type of program for funding pilot studies or sub-projects (while both terms were used, there appeared to be little difference overall in the scope of the scientific activities subsumed under either label, and so they are referred to collectively as pilot studies.) These programs provided graduate students, post-doctoral fellows, junior faculty, and sometimes even senior faculty with seed funding, to collect pilot data that could be used to support a formal NIH or other type of grant application. Descriptions and updates on the status of these pilot studies over time were to be reported as part of Annual Progress Reports, but the consistency and quality of this reporting varied considerably across research centers and even within the same center for different years. In order to explore the types of pilot research conducted in these studies and the extent to which these pilot studies actually resulted in a funded research NIH grant, a customized Data Table was constructed for each research center.

Using each center's grant application and Annual Progress Reports, the various pilot or sub-projects reported were identified. A table was constructed that included: project title; lead investigator(s); whether study was a sub-project or pilot study; year begun; scientific focus (basic science, clinical research, or both); status of the project on December 1, 2010 (completed, discontinued, or in progress); whether the study resulted in one or more oral presentations, peer-reviewed publications, or both); and whether the study led to a funded grant. At the completion of the Research Center PI interview, the Data Table was described and sent to the PI to forward to his administrative staff to complete. Completed Data Tables were returned in February and March 2011 by 15 of the 16 PIs and Co-PI. The remaining investigator was no longer an active faculty member with her university, and verified in the interview that none of their projects had led to subsequent funding. Instead the data compiled from that center's grant application and Annual Progress Reports were utilized to complete the Data Table for that center.

Information from the completed Data Tables was entered into the Excel spreadsheet containing the RCDA forms and the Research Center PI Interviews.

2.6.4 Research Project Principal Investigator Interview

While the Research Project Data Abstract (RPDA) form captured information pertaining to the background and aims of the 44 investigator-initiated research projects, existing source documents (including Annual Progress Reports) did not provide much information addressing project outputs and outcomes. Therefore a brief semi-structured Research Project PI Interview Protocol was developed to gather this information directly from the projects' PIs. The interview protocol contained 16 questions, addressing the following topical areas: receipt of additional project funding from NIH (i.e., supplements, ARRA funds) or non-federal sources; research capacity development (including graduate degrees, academic and non-academic promotions, honors or awards, faculty recruitment, creation of new research infrastructure, development of new tools, instruments, methods, new research collaborations, etc.); spin-off grants (either NIH, other federal, or other non-federal); effects on policy formulation; effects on clinical practice or behavior; changes in healthcare service delivery; effects on medical or professional curricula or continuing education; effects on individual or community health; and broader economic and social impacts.

The same procedures were used for contacting the investigators and explaining the purpose of the study. The interviews were conducted between April and May, 2011. Of 41 eligible PIs (3 PIs each had two projects), all 41 interviews were completed. Interviews averaged about 35 minutes in length.

2.6.5 Bibliometric Analysis

Scientific publications are strong and readily accessible indicators of research productivity and scientific direction. The **e**lectronic **S**cientific **P**ortfolio **A**ssistant (e-SPA), a Web-based application that allows users to search for NIH-funded research grants, build portfolios, and analyze individual grant and portfolio outputs and outcomes, was utilized to develop a list of the scientific publications generated by each of the MBIH grants. A separate e-SPA portfolio was created for the grants supported through each Funding Opportunity Announcement (FOA) and funding mechanism (P50, R21, R24, and R01/U01).

In e-SPA the Scientific Publication Information Retrieval and Evaluation System (SPIRES) links National Library of Medicine (NLM) PubMed data to NIH Grant Data via explicit NIH grant acknowledgements. Publication data also include articles distributed by NLM to MEDLINE/PubMed licensees. Therefore, only those articles that directly acknowledge an NIH grant are linked to grants in e-SPA. In addition to the publication date, article title, journal, authors, and the article abstract, at the time the portfolios for this evaluation were created, the e-SPA indicators shown in **Exhibit 7** were reported for each article. Since the first MBIH grants were funded in 1999, papers published between January 1, 1999 and December 31, 2009 were selected for inclusion in the analyses; however, no papers published in 1999 were found in the e-SPA portfolios. Therefore the articles included in the analyses were published between January 1, 2000 and December 31, 2009. December 31, 2009 was selected as the cutoff date in order to capture 10 full years of publications. The publications retrieved in the three R01/U01 FOA portfolios were subsequently combined as were those retrieved in the two R21 portfolios.

Exhibit 7. Definitions and Parameters of e-SPA Indicators Collected for Each MBIH Publication

e-SPA Indicator	Definition and Parameters
PubMed Identifier (PMID)	A unique number assigned to each PubMed citation
Impact Factor	Impact Factor (as defined by ISI) is a journal-based indicator based on the average citation rate for articles in a given journal. The indicator is recalculated on an annual basis; for example, articles published in *Cell* in 1998 will have a different impact factor than articles published in *Cell* in 2006.
Times cited with self	The number of times an article is referenced by other articles, including citations by the lead author.
Times cited without self	The number of times an article is referenced by other articles, excluding self-citations.
Research article	e-SPA defines a "research article" as a publication that has at least one of 26 possible National Library of Medicine Medical Subject Heading publication tags. For articles with multiple publication tags, the article is considered "non-research" if any of the tags belongs to the non-research category.
Author count	The number of authors listed for a given article.
Bibliography count	The number of articles listed as references by a publication.
Portfolio Projects	The grant number of all the grants in the portfolio acknowledged in the article.
All projects	The grant numbers of all grants acknowledged in the article.

This search strategy yielded 675 MBIH publications including 560 research articles and 115 non-research articles, 91 of which were review articles. Following the removal of duplicate articles[1], 527 research articles and 113 non-research articles remained. In e-SPA a "Research Article" is defined as a publication that has at least one of 26 possible NLM Medical Subject Heading (MeSH) publication type tags. For articles with more than one type tag, the article is considered non-research if any of the types belongs to the non-research category. The distribution of types of non-research articles is shown in **Exhibit 8.** Literature reviews of various types comprised the single largest category of non-research articles (n=89). Analyses of number of research articles by centers and research projects are presented in section 5. The methods for categorizing MBIH publications by scientific discipline and the related bibliometric analyses are presented in section 6.

Exhibit 8. Types and Frequencies of MBIH Non-Research Articles

Types of Non-Research Articles	Frequency
Review article	89
Comment, Editorial	5
Comment, Letter	4
Letter	4
Comment	4
Editorial, Review	2
Comment, Review	2
Editorial	1
Addresses	1
Lectures	1
TOTAL	113

[1] Duplicates of the same article appeared when more than one MBIH grant was acknowledged for that article. For some analyses the duplicate articles were retained but for total counts they were removed.

3. Attainment of MBIH Program Goals and Objectives

The following six sections present the results from the Mind-Body Interaction and Health Program Outcome Evaluation. In this section, a general overview of the MBIH Program as a whole and its two principal components, the Research Centers and the investigator-initiated Research Projects is provided followed by the evaluation results addressing the first evaluation question ("Has the MBIH Program achieved its programmatic goals and objectives?") The two program goals and three program objectives are repeated in **Exhibit 9.**

Exhibit 9. MBIH Program Goals and Objectives

Goal 1: Expand scientific knowledge about mind-body relationships and the mechanisms by which they influence health outcomes;

Goal 2: Translate this knowledge into effective health interventions;

Objective 1: Facilitate interdisciplinary collaboration and innovation in research ideas;

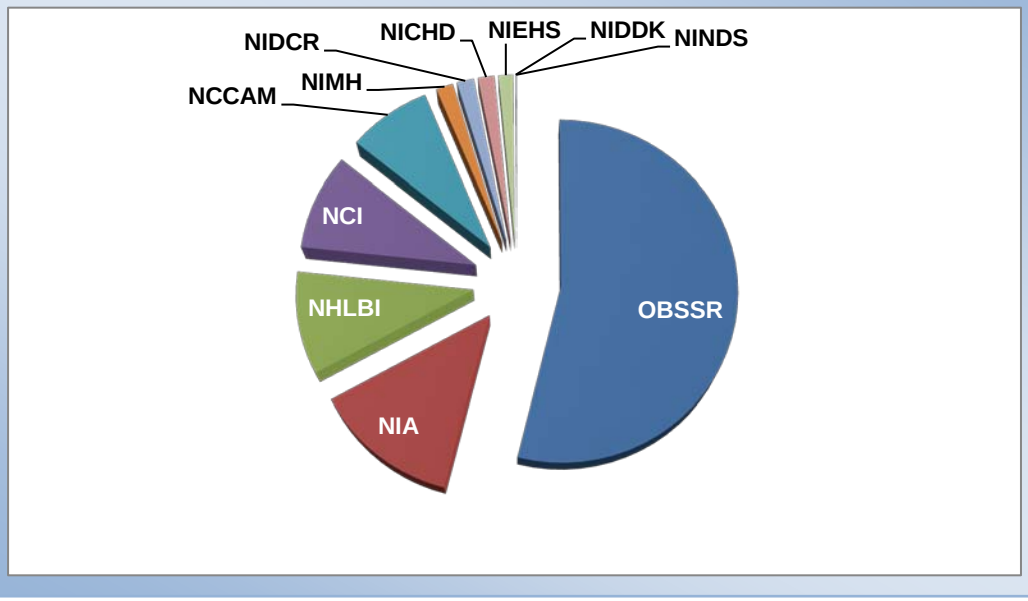
Objective 2: Build a capacity for research in mind-body interactions and health by funding research core services at established and nascent research centers; and

Objective 3: Promote regular interactions among interdisciplinary research teams across the US.

Because each evaluation question contains multiple sub-questions, the titles for specific sub-sections within this report that address a particular sub-question will include the number for that sub-question in the title in parentheses.

As noted previously, the MBIH Program received a total of $174,608,014 in research funding between 2000 and 2009. Of these total research dollars, $94,713,359 (or 54 percent) funded the15 MBIH research centers, and the remaining $79,894,655 (46 percent) funded the 44 investigator-initiated research projects. OBSSR and 11 other NIH ICs provided this funding (see **Exhibit 10**). Almost all of the funding provided by the partnering ICs supported research projects, while OBSSR provided the bulk of the funding for the research centers.

Exhibit 10. MBIH Program Funding Shares by Participating NIH Institutes and Centers, 2000-2009



3.1 An Overview of the MBIH Research Centers

The 15 MBIH Program Research Centers were funded under three separate grant funding mechanisms as shown in **Exhibit 11**.

Exhibit 11. MBIH Research Center Funding Mechanisms

Institution	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Ohio State University	P50										
University of Miami	P50										
University of Wisconsin	P50										
University of Pittsburgh & Carnegie Mellon University	P50					R24					
University of Michigan	P50					R24					
Columbia University						R24					
Rutgers University						R24					
University of California, Los Angeles						R24					
University of North Carolina						R24					
Johns Hopkins University						R21			R24		
University of California, Berkeley						R21			R24		
University of Rochester						R21			R24		
New York University						R21					
University of Texas, Medical Branch						R21					
University of Utah						R21					

As **Exhibit 11** shows, the funding history for the MBIH research centers was complex. Five P50 comprehensive research centers were funded for a period of five years from the initial non-renewable 1999 solicitation. In 2004, OBSSR issued two new solicitations, the first for R24 Research Infrastructure grants and the second for R21 Exploratory/Developmental grants. The R24 solicitation funded six research centers (the University of Pittsburgh and Carnegie Mellon University operated as a single center) for five years, ending in 2009. The R21 solicitation funded six Exploratory/Developmental grants for a three year period ending in 2007. In 2007, OBSSR announced a restricted competition among the six R21 grantees for three R24 Research Infrastructure awards, which provided an additional three years of funding through 2009 and into 2010. Thus, there were five different funding mechanism combinations represented among the 15 research centers: P50 only (three centers); P50 and R24 (two centers); R24 only (four centers); R21 and R24 (three centers); and R21 only (three centers).

As mentioned earlier, the three funding mechanisms were associated with different levels of annual funding. In addition, the three funding mechanisms differed in terms of requirements for the level of research structure and development that needed to be in place at competing institutions. Discussions with OBSSR program staff indicated that the decision to stop funding the more costly P50 comprehensive center grants after five years and to employ the R21 and R24 funding mechanisms was driven largely by cost considerations, rather than a specific attempt to use the latter two mechanisms in a systematic effort to grow and evolve targeted research centers. Nonetheless, there is a distinct trajectory that can be seen from comparing the eligibility requirements for these mechanisms (see **Exhibit 12)**. For example, an institution could obtain an R21 Exploratory/ Developmental grant that would enable three or more investigators who had independently pursued mind-body research with only informal contact to establish themselves as a mind-body research team, with jointly authored publications and research grants. The grant would provide funds that enabled this new research team to develop some initial research infrastructure in the form of new research collaborations and specific research core services that would support their research activities. At the conclusion of the R21 grant, this slightly expanded research team could apply for R24 Research Infrastructure funding, which would enable the team to develop its research core services more extensively, offering some career development activities and evolving into a research center. At the conclusion of this funding, this center would then have established a track record of research activities that would enable it to be competitive for a P50 (or P60) comprehensive center grant. While this evolutionary strategy was not the specific intention of OBSSR and its partners when the funding mechanisms were selected, it can be seen that three of the MBIH research centers received both R21 and R24 awards, and their trajectories can be examined in light of this model.

Exhibit 12. Eligibility Requirements for Three MBIH Research Center Funding Mechanisms

P50 Comprehensive Research Center:

- A pre-existing research center that has been conducting research on mind-body research topics for at least the past five years;
- Expected result of funding: Move existing mind-body research activities and infrastructure in a direction new to the center.

R21 Exploratory/Developmental Grant:

- Institution must have at least three researchers with a history of research activity related to mind-body research that meets both of the following criteria:
  - Externally funded research grants during the preceding 36 months, and
  - One or more publications in peer-reviewed journals during the preceding 36 months.
- Expected result of funding: Operate as a productive research team with one or more new joint mind-body research activities and preliminary infrastructure.

R24 Research Infrastructure Grant:

- Institution must have at least five researchers with a history of research activity related to mind-body research that meets both of the following criteria:
  - Externally funded research grants during the preceding 36 months, and
  - One or more publications in peer-reviewed journals during the preceding 36 months.
- Expected result of funding: Pursue new mind-body research activities, build new research infrastructure to support them, and develop to the level of a full fledged research center.

3.2 Overview of the MBIH Investigator-Initiated Research Projects

The MBIH Program funded a total of 44 investigator-initiated research projects under three separate solicitations. Fifteen research projects (14 R01s and one U01) were awarded under the first solicitation (OB-03-008). Seven research projects (six R01s and one U01) were awarded under the second solicitation (PA-05-027), and 22 R01 projects were funded under the third and final solicitation (PA-07-046). Investigators from 30 different institutions received awards. Three investigators received two awards each; thus, there were a total of 41 PIs for the 44 grants. One institution (UCLA) received five awards, one institution received four awards (Emory), one institution received three awards (University of

Pittsburgh), and four institutions received two awards each (Kent State University; University of Texas, Medical Branch; Boston University Medical Campus; and Yale University). Awards ranged in size from $692,585 to $4,788,620, with an average award of $1,815,787.

At the time they were conducting these research projects, 25 PIs reported an affiliation with one or more research centers, while 16 (representing 19 grants) were not affiliated with any type of research center at their universities. Of the 25 affiliated PIs, only 3 were affiliated with an MBIH research center, while 6 PIs were affiliated with a cancer clinical and research center, and the remaining 16 investigators were affiliated with other academic research centers. In terms of NIH research grant experience, seven PIs obtained their first NIH grant through the MBIH program, 11 were considered early-stage investigators, and the remaining 23 were considered established researchers.

3.3 Relative Mix of Research Funded Under the MBIH Program (1.1 & 1.3[2])

To examine the relative mix of research conducted by the MBIH research centers and research projects, the application abstract for each center and research project was reviewed and a series of codes were developed to capture the general themes of the research. Results for the MBIH research centers are presented in **Exhibit 13**. The three central topical areas outlined in the various solicitations were well represented in the research themes of the 15 MBIH research centers. All but one of the centers explicitly described stress and stress reduction as a general research theme, and nine of the 15 centers stated their intentions to investigate beliefs and cognitive processes and emotional processes and their influence on physical health. In addition, 12 of the 15 centers included evaluating the efficacy and/or effectiveness of mind-body interventions among their research activities. Types of mind-body interventions evaluated included mindfulness-based stress reduction, cognitive-behavioral stress reduction, yoga, acupuncture, music therapy, meditation, and other interventions.

Exhibit 13. Themes of Research Conducted at MBIH Research Centers

Research Theme	Number of 15 Centers Reporting This
Stress and Stress Reduction	14
Efficacy and Effectiveness of MB Interventions	12
Beliefs and Cognitive Processes	9
Emotional Processes	9
Psychoneuroimmunology	9
Basic Research	8
Developmental Psychobiology	6
Population Studies	4
Health Disparities	4
Aging	4

In addition to these thematic areas, the centers introduced additional research themes. Not surprisingly, nine of the 15 research centers expressed intentions to investigate various aspects of psychoneuroimmunology. Eight of the 15 centers conducted basic research studies as part of their research activities. Six centers intended to conduct studies on developmental psychobiology, four centers identified a special focus on aging, four centers intended to build upon ongoing population studies into which they would add various biological measures, and four centers planned to address health disparities in specific populations such as Hispanics or African Americans with low incomes.

A second way to examine the relative mix of types of research conducted at the MBIH research centers is to examine the various sub-projects and pilot studies that each center funded. Many of the centers (particularly those funded by P50 and R24 grants) proposed sub-projects as part of their applications. These studies were intended to be research projects that were comparable in scope to an R01 investigator-initiated research grant. In addition to these sub-projects, each center provided some type of pilot-study funding. Pilot study funds were generally limited to one or two years and were allocated within the centers to post-doctoral fellows or junior investigators following a competitive review. While a

[2] These numbers represent the evaluation sub-questions in Exhibit 6

few centers allowed more senior level investigators to apply for these funds, most centers sought to use these funds to enable new or early-stage investigators to gather preliminary data that would support a larger investigator-initiated research grant application.

A special data collection form (the Research Center Data Table) was developed to gather information on these projects. One item on the Data Table asked the PI (or someone on his or her staff) to indicate whether each sub-project or pilot study could be considered basic research, clinical research, or both basic and clinical research. The 15 MBIH research centers conducted a total of 287 sub-projects and pilot studies; of these, 77 were sub-projects and 209 were pilot-studies. The distribution of these studies over the three research categories is shown in **Exhibit 14**. A total of 53 sub-projects and pilot studies were evaluations of specific interventions, or about 18.5 percent of the total.

Exhibit 14. Types of Research Conducted as Sub-projects and Pilot Studies at MBIH Research Centers

Type of Research	Sub-Project	Pilot Studies	Total
Basic Research	25	24	49
Clinical Research	38	165	204
Basic & Clinical Research	14	20	34
TOTAL	77	209	287

For the 44 investigator-initiated research projects, each project's abstract was reviewed and codes developed for the major research themes. Frequencies for the primary codes are shown in **Exhibit 15.** Note that there is overlap between themes.

Exhibit 15. Research Themes in the 44 MBIH Research Projects

Research Theme	Number of 44 Projects With This Theme
Program Topical Areas	
Stress and Stress Reduction	20
Beliefs and Cognitive Processes	10
Emotional Processes	4
Research Topics	
Efficacy and Effectiveness of Interventions	19
Population Studies	7
Family Caregivers	6
Role of Environmental Stressors	5
Health Disparities	3
Aging	2
Basic Research	2
Cost Analyses	2

Twenty of the 44 research projects examined some aspect of stress and/or stress reduction. Ten projects investigated the effects of beliefs and cognitive process on health, while only four projects examined the effects of emotional processes or expression on health. Altogether, 28 of the 44 projects examined one or more of these three topical areas listed in the solicitations. The second largest thematic category after solicitation topics was evaluations of mind-body interventions, for which there were 19 projects. The types of interventions investigated in these studies included mindfulness-based stress reduction, cognitive-behavioral stress management models, tai chi, yoga, acupuncture, expressive writing, and others. Several themes similar to those identified for the research centers appeared in a smaller number of studies, including population studies, health disparities, aging, and basic research. Two themes not examined in the research centers included burden in family caregivers, and cost analyses.

Studies conducted by the MBIH research centers and research projects investigated a broad range of phenomena, and ran the gamut from basic research studies to population studies. Studies from both MBIH program components addressed the three topical areas that were outlined in the various MBIH solicitations, and expanded the range of research questions to include several additional topical areas. One important type of study conducted by both the centers and the research projects involved evaluations of mind-body interventions. About 80 percent of the research centers conducted at least one intervention study, and among the 287 sub-projects and pilot studies, intervention studies comprised about 18.5

percent of the total. For the research projects, 19 of 44 projects (43 percent) evaluated one or more mind-body interventions.

3.4 Innovation and Interdisciplinary Collaboration in the MBIH Centers and Projects (1.2)

In addition to a common set of research topical areas, the research solicitations issued for MBIH research centers and investigator-initiated projects share two other aspects: a stated expectation that proposals would be "innovative," and a strong emphasis on interdisciplinary collaboration, both at centers and within individual projects. These two aspects are considered in the following two sub-sections.

3.4.1 Innovation in the MBIH Research Centers

Innovation was highlighted in the research solicitations by establishing it as one of several criteria on which each grant application would be reviewed. This meant that reviewers needed to address specific comments on the degree to which innovation was evident in each proposal. However, innovation is difficult to define clearly, and therefore is highly subjective—one reviewer may see a proposed component within a center as being highly innovative while another may not. This left each reviewer (and panel) to reach an independent judgment of what aspects of each proposal would be considered "innovative."

As part of the MBIH research center data abstraction process, the Madrillon evaluation team reviewed the Summary Statement for each funded grant application. Among the types of information abstracted from the grant reviews, the evaluation team captured reviewers' comments on what they viewed as innovative about each grant. The intention was to conduct thematic coding on these comments and identify a smaller set of general ideas about innovation within a research field that was by definition innovative. The results from this qualitative analysis are shown in **Exhibit 16.** Looking across the 15 research centers, peer reviewers' comments about innovation in the grant applications could be summarized in terms of seven basic themes; these are briefly discussed below.

Exhibit 16. Research Themes Associated with Peer Reviewers' Comments on Innovation in MBIH Research Center Grants

- Interdisciplinary conceptual frameworks;
- New ideas about how researchers can work together;
- New types of research activities;
- Integrating basic and clinical research;
- Addressing a new research problem or question;
- Development of new measures or measurement approaches; and
- Development of novel research tools or products

The central theme that emerged from the reviewers' comments was recognition of an interdisciplinary conceptual framework. Three characteristics caught the reviewers' attention: frameworks that involved several levels of measurement of a phenomenon (for example, genetic and biological measures combined with psychological and social measures); frameworks that synthesized theoretical insights from multiple disciplines; and research plans that applied the same framework across several types of diseases or health conditions. While reviewers tended not to describe these conceptual frameworks as 'transdisciplinary,' these characteristics have been associated with transdisciplinary frameworks by some authors (Rosenfield, 1992). Closely related to this theme of transdisciplinarity was a second idea concerning the bringing together of a group of research scientists who would not normally have joined forces in the past, and providing them with a new way of working together by means of common study protocols that would be applied across several proposed studies.

A third element that reviewers described as innovative in some proposals was the idea of new types of research activities. Two examples of center activities that were called out as "innovative" by reviewers included the formation of a Cochrane Behavioral Medicine Field at one center and the Summer Mind-Body Institute sponsored by two centers. The Cochrane Behavioral Medicine Field was viewed as

an especially exciting development because as one reviewer stated, “Cochrane is the gold standard within the medical community and studies that meet this criterion will be more readily accepted and are more likely to break down barriers within the medical community.” The reviewers thought that the Summer Institute program could be a powerful approach for training current mind-body researchers and stimulating the interest of biomedical researchers less familiar with the mind-body research field.

A fourth theme mentioned in several center applications was an effort to bring basic science and clinical research to focus on the same research areas. The involvement of animal researchers, biomedical researchers, and behavioral scientists working together on a core theme was seen as highly innovative and an important strength of three funded centers.

Addressing a new (or under-studied) research problem was also identified by some reviewers as innovative. An example here was one center, which proposed a developmental project focusing on identifying and surmounting barriers to acceptance of mind-body medicine within the medical community. Extending an existing research field by bringing in new types of measures was also associated with innovation. Several research centers introduced biological measures to ongoing psychosocial studies. The development of novel research products, such as center databases that drew upon a battery of core biological and psychosocial measures was also innovative, and was praised as developing a resource that could provide valuable research opportunities for postdoctoral fellows and junior faculty for years to come. One example of this was a center that tested a specific mindfulness-based stress reduction intervention across patients with several specific types of cancer.

3.4.2 Interdisciplinary Collaboration in the MBIH Research Centers and Projects

Three indicators were used to assess the extent of interdisciplinary collaboration evident in the MBIH research centers and projects. The indicators were the number of individuals listed as *Key Personnel* in the center and project grant applications, and the number of degree disciplines represented among these Key Personnel, which was determined by examining their NIH curricula vitae forms in the grant application. Key Personnel were considered important because they represented individuals who either led project cores or subprojects at research centers or otherwise played a significant role in the center or research project. Degree discipline rather than departmental discipline was utilized because individuals from multiple disciplines could be employed in the same academic department. These data were available for all of the research centers and funding mechanisms except the P50 grant applications for the University of Miami and the University of Michigan which could not be located despite an extensive search. The third indicator represents a rough index of interdisciplinarity, calculated by dividing the number of disciplines by the number of Key Personnel; this produced a proportion that ranged from 0 to 1, with higher values representing a greater degree of interdisciplinarity.

The results for these measures are shown in **Exhibit 17**. The values for the index of interdisciplinarity ranged from .42 to .90; with one exception (the Pittsburgh/CMU R24 in 2004), the index for each center exceeded .50, indicating that there appeared to be a concerted effort on the part of grantees to propose interdisciplinary teams. The average index for the P50 grantees (based on three available grants) was .62; for the R21 grantees it was .71. The 2004 R24 grantees had an average index value of .56 and the 2007 R24 grantees averaged .84. It is interesting to note that each of the three centers that started as R21 grantees and subsequently obtained an R24 grant increased its interdisciplinary index value for their second grant applications.

Exhibit 17. Interdisciplinarity in the MBIH Research Centers by Funding Mechanism

P50	Key Personnel	Degree Disciplines	Interdisciplinarity Index
Ohio State	14	10	.71
Miami	n.a.	n.a.	--
Michigan	n.a.	n.a.	--
Pittsburgh/ CMU	7	4	.57
Wisconsin	17	10	.59
Average			.62

R21	Key Personnel	Degree Disciplines	Interdisciplinarity Index
Johns Hopkins	6	4	.67
Berkeley	9	6	.67
Rochester	25	13	.52
New York	14	11	.79
Texas	7	6	.86
Utah	13	10	.77
Average			.71

R24--2004	Key Personnel	Degree Disciplines	Interdisciplinarity Index
Pittsburgh/CMU	19	8	.42
Michigan	20	12	.60
Columbia	22	11	.50
Rutgers	10	5	.50
UCLA	42	27	.64
North Carolina	11	8	.73
Average			.56

R24--2007	Key Personnel	Degree Disciplines	Interdisciplinarity Index
Johns Hopkins	11	8	.73
Berkeley	16	14	.88
Rochester	10	9	.90
Average			.84

For the 44 MBIH research projects, the number of Key Personnel per project ranged from 4 to 16 individuals with an average of 7.98. The number of degree disciplines ranged from 1 to 8, with an average of 4.32 disciplines. The index of interdisciplinarity ranged from 0.08 to 1.00 (three projects), with an average value of .58. This value appears comparable to the MBIH research centers. **Exhibit 18** shows that overall, projects that were conducted by PIs who were affiliated with a research center did not differ in their interdisciplinary index values from projects conducted by investigators without a center affiliation. Early stage investigators tended to have higher average interdisciplinary index values than either new or established investigators; however, affiliation with a research center does appear to help new investigators field more interdisciplinary research teams than new investigators without a research center affiliation.

3.5 Capacity for Conducting and Sustaining MBIH Research (1.4 & 1.5)

The two principle approaches for building the capacity to conduct and sustain MBIH research at the MBIH research centers involve the cultivation of research personnel and the development of research infrastructure through the creation of research core services. Efforts to promote training and career development are discussed briefly in this section but considered in more detail in Section 5. This section will describe the types of research core services that MBIH research centers provided.

3.5.1 P50 Comprehensive Research Centers

Exhibit 18. Interdisciplinary Index by Principal Investigator Experience and Center Affiliation

Principal Investigator Experience	Affiliated With a Center	Unaffiliated	Total
New	.54	.45	.50
Early Stage	.68	.65	.66
Established	.58	.55	.57
TOTAL	.59	.57	.58

In considering the research core services proposed by the five original P50 MBIH research centers, it is important to keep in mind that the grant requirements stipulated that eligible applicants were restricted to pre-existing, actively functioning mind-body research centers. Thus, it is likely that some level of research infrastructure already existed among the five P50 research centers. At the same time, however, support for research infrastructure is difficult to find. Individual R01-type research grants do not provide support for research infrastructure and maintaining continuity in funding for these services is an ongoing challenge in most research centers. Thus, the opportunity to obtain research infrastructure support as part of the P50 comprehensive center grant mechanism was a welcome development for the original MBIH PIs.

The five original P50 MBIH research centers followed a similar pattern in terms of the types of research core services they proposed. All five centers created an Administrative and Planning core, which oversaw the operation of the centers, and in some cases maintained a training and career development function as well. Similarly, the five centers each proposed some type of Statistics and Data Management core. While there was some slight variability, in general the Statistics and Data Management core performed three important functions: statistical consultation on the design and analysis of research studies at both the pilot and the sub-project level within each center; management of the centers' databases and files; and conduct of statistical analyses for centers' studies. In most cases, this core also provided occasional individual or group tutorials for affiliated center investigators.

The centers also proposed research core services for specific types of measures. This reflected an important theme that prevailed across the majority of MBIH research centers, regardless of funding mechanism; namely, centers attempted to develop one or more sets of core instrument batteries that would be used across multiple center studies. To that end, two of the P50 centers established specific Psychosocial Instrument research cores, which were responsible for identifying the instruments that would be part of the battery, ensuring that research staff members were trained in their use, and scoring those instruments that included scoring elements. The same two centers also created Biological Measures research cores, which performed the same functions for various biological measures. Two other centers established research cores that had an even narrower focus. One center operated separate Immunohistopathology and Neuroendocrinology research cores. A second center operated a similar Endocrinology and Immunology research core. In each case, these core services identified common sets of assays, oversaw their collection, analysis and storage, and provided consultation to investigators concerning their interpretation.

3.5.2 R21 Exploratory/Developmental Centers

The six 2004 R21 awardees presumably started at a less-developed level than the P50 grantees, given that this award was aimed at promoting and developing promising research units that had not held a P50 or P30 research grant during the past five years. Given that there was an assumption that the three or more investigators proposing each application were probably at least partially supported by their own research grants at the time they applied, the annual average funding of $400,000 could support some initial infrastructure development, and that is what occurred based upon the data. All six of the R21 grantees established some form of Administrative and Planning core. An important function for some of the Administrative and Planning core services was supervision of an internal pilot studies program, unless that function was placed under a different core service. Four of the six grantees also created a Statistics

and Data Management core, which performed similar functions as those described above. An additional function performed by some of these research cores was the development of a common instrument battery. Four of the six grantees also established a specific Training or Faculty Development core that handled training and mentoring efforts for graduate students, post-doctoral fellows, and junior faculty. In some cases this core also coordinated various internal seminar programs or Visiting Scholar programs in which outside researchers presented seminars on their current mind-body research work. One center created a specific Mind-Body Intervention Development research core which provided assistance in developing specific intervention activities for the center.

3.5.3 R24 Research Infrastructure Centers (2004)

The centers or research units applying for the 2004 R24 Research Infrastructure awards were expected to display a stronger track record and a somewhat higher level of development than the R21 applicants. This is reflected in both the number and types of research core services that were proposed by the six center applications. In fact, two of the six awardees were previous holders of MBIH P50 awards who had previously had an opportunity to develop their internal research infrastructure. Compared with the research cores proposed by the R21 awardees, the research cores proposed by the R24 awardees were considerably more specialized. Again, all six R24 awardees proposed Administrative and Planning research cores, and four also created Statistical and Data Management research cores. Three centers created research cores that focused on the development of shared instruments and measures across studies within their respective centers. Two centers established specific types of assessment cores, including research cores that addressed Sleep Assessment, Neuroimaging, Psychophysiology and Pain Assessment, and Animal Research Models. Three centers established Faculty Development and Training research core services. Three other centers proposed unique research core services: a Minority Health Oversight core, a Dissemination core (which focused on creating a Cochrane Behavioral Medicine Field), a core that was created to manage the large research network the research center had established, a Spatial Analysis and GIS research core that was established to link this emerging technology with mind-body research, a Gene-Environment Interaction core, and later, a Complex Systems research core.

3.5.4 R24 Research Infrastructure Centers (2007)

The three research centers in this group had each been the recipient of an earlier R21 MBIH award in 2004. In terms of the research center development model outlined previously, it is interesting to note what the 2007 R24 grantees added on to the initial infrastructure they developed as part of the earlier R21 award. One of the centers did not propose any additional infrastructure in its 2007 application, an omission that was noted in the reviewer comments. The circumstances of this application were unusual, however, in that the PI had recently received an appointment to an endowed chair at a second university, and the two institutions were bringing their considerable internal resources to bear on the R24 project. For both of the remaining two centers, the 2007 R24 award provided an opportunity to expand existing work into new areas, as well as developing important new resources that would facilitate their continued growth. Thus one center added both a Psychophysics core and a Clinical Research Implementation core to its previous infrastructure, while the second center added two new scientific areas (Animal Research and Human Aging) and a new Community Relations and Recruitment core.

In considering how the 15 MBIH research centers used their MBIH funding to develop internal research infrastructure, it is clear that they used several strategies. All of the centers used funding to support Administrative and Planning research core services, a research core that is necessary but difficult to support financially. All but four of the 15 centers established or supported some type of Statistics and Data Management research core. This is a critical resource needed to support the design and analysis of research studies, and its functions require technically trained and experienced personnel to perform. It is sometimes possible to establish some form of cost center for such services, under which service fees can be charged that can defray some operating costs, but it is clear that infrastructure funding can provide much needed support for these activities. Beyond these two basic areas, research core services addressed

a number of specialized scientific and logistic areas that included specialized assessment services, animal research, the application of new technologies, and functions such as community relations and recruitment, minority health oversight, dissemination, intervention development, and research network management.

3.6 Research Center Sustainability—A Preliminary Model (1.6)

The issue of whether and how research centers can sustain themselves once their initial funding has ended has not received the research attention it deserves, in part because many research center programs seem to continue receiving funds indefinitely. In the case of the MBIH Program, a definite end to the funding was clear from the outset. Each research solicitation was clearly described as not renewable, and it was therefore incumbent on the center staff members to formulate some type of plan for the continuation of the research centers.

Interviews with MBIH Research Center PIs were conducted during January and February 2011. By that time, several research centers had already concluded their funding, while others were operating under No-Cost Extensions that would end by the summer of 2011. It was a good opportunity to ask each PI about the final "end-state" of his or her research center. Based upon their responses, the following typology of MBIH research center "end-states" was compiled (see **Exhibit 19**.)

Exhibit 19. MBIH Research Center End-States

Type of End-State	Description	Number of Centers
Center Ended	Research center no longer operates; Individual researchers are supported from their own grants	6
Absorption into Separate Center	Research center cores and staff have been partially or wholly absorbed by another research center	5
Evolved into New Center	Research center cores and staff are operating as a new center within which they have maintained their identity as a unit	4

As shown, there were three types of final "end-states" among the 15 MBIH research centers. The most common was that the center ended as a center, and the individual research investigators who had worked within it were now supported from their own research grants. In the most extreme case, the former PI was now occupying an adjunct faculty appointment and the other investigators had returned to their original departments. In other cases, the investigators continued some joint activities but these were not covered by any revenues. This outcome occurred in six of the 15 cases. All four of the research centers that had received 2004 R24 awards only were in this category, as well as one of the 2004 R21 only group and one of the P50-R24 grantees.

The second end-state category could be considered 'partially sustained' in that an academic department or another research center absorbed some or all of the research cores and research staff. Within this new organizational home, the research staff from the former center might continue some low level of their original activities, or alternatively, redirect their efforts toward new objectives. One example was an R21 research center that had successfully obtained funding to redirect its effort toward cancer prevention, and had been "picked up" by a new cancer center. Five of the original 15 centers achieved end-states consistent with this category, including two of the R21-R24 centers, one of the original P50-only centers, and two of the R21-only group.

The final category consisted of four MBIH research centers that were able to obtain sufficient research funding to evolve into a new and larger center operation, continuing in the same scientific direction with expanded resources. Two of the original P50-only centers, one of the P50-R24 centers and one of the R21-R24 centers finished in this category. Further consideration of this typology will be discussed in Section 5.

4. Effects of the MBIH Program on Scientific Knowledge and Understanding

One of the two program goals of the MBIH Program was to expand scientific knowledge about mind-body relationships and their influences on health. At the time the MBIH Program was created, there already existed a research base showing that stress was linked to a variety of diseases and disease processes, and that stress reduction interventions could reduce stress and improve physical and psychological outcomes for certain diseases. This previous research also showed that emotional states and processes (especially several negative emotions such as depression, anxiety, and anger or hostility) could influence health, and that some cognitive beliefs and attitudes could also affect health. The MBIH Program was created in part to generate further research on these topics and to provide resources that could "grow the field" of mind-body research.

This section examines the impact of research conducted at the MBIH research centers on scientific knowledge and understanding of mind-body interactions and health (Evaluation Question #2) from the perspectives of the PIs of the centers. The research centers rather than the research projects were the focus for this question because many of the research projects were still in progress at the time these data were collected, whereas the research centers had already completed their funding (or were operating on No-Cost Extensions). This section draws upon responses to three of the questions from the Research Center PI semi-structured interviews. The first question asked respondents to identify the most significant scientific achievements accomplished by their research centers. The second and third questions explored their perceptions about whether and how the mind-body research field has gained acceptability and respectability during the past ten years and ways in which the MBIH Program contributed to the field.

4.1 Most Significant Scientific Achievements of MBIH Research Centers (2.1)

PIs identified several major accomplishments (scientific and non-scientific) in response to this question. In their discussions of their centers' accomplishments, the PIs frequently alluded to parallel research activities that had been conducted at other MBIH research centers, and an important insight about these accomplishments is that in most instances, the investigators were aware of others' scientific work and occasionally communicated with each other about their research activities. For example, four research centers conducted studies with stress-reduction interventions that involved similar elements. Unfortunately, their communications about these interventions did not lead to any coordinated cross-center research efforts.

The various accomplishments PIs described could be placed in five thematic categories as shown in **Exhibit 20**. Each of these themes is discussed further below.

Exhibit 20. Scientific Accomplishments of MBIH Research Centers

- Stress and stress reduction;
- Development of new conceptual approaches and perspectives;
- Creation or application of new tools and instruments;
- Important findings; and
- Education and training in mind-body medicine

As noted in the previous section, *stress and stress reduction* were central scientific themes of research activities at the majority of the MBIH research centers, thus it was not surprising that several investigators identified findings in these areas as among the most significant scientific accomplishments at their centers. These accomplishments were classified in two sub-categories: mechanisms of stress and how it affected health and disease, and stress reduction interventions. Among the former sub-category, PIs reported demonstrating clear linkages between stress and wound healing, breast and prostate cancers, fibromyalgia, cardiovascular disease, and several other illnesses. An especially important accomplishment was the successful development of animal models of stress and hormonal levels. Several PIs described successful tests of cognitive-based stress reduction and mindfulness-based stress reduction interventions

in individuals with various diseases such as cancer. These studies extended the variety of diseases in which these interventions had proven effective; they also documented new types of outcomes, such as improved urinary and sexual functioning in men with prostate cancer.

A second important group of accomplishments concerned the *development of new conceptual approaches and perspectives*. Several centers incorporated life-course developmental perspectives into their general research frameworks, which was a new perspective for mind-body research. Other centers augmented ongoing population research approaches by incorporating new biological measures of constructs such as allostatic load into their instrument batteries, adding new levels of analysis to existing research databases. Related to this was a new focus on the effects of powerful non-health factors such as economic events, welfare reform, and housing on health indicators and outcomes. Another new perspective involved investigation of the effect of positive emotions (e.g., well-being) on health outcomes.

Related to this was the *creation and application of new tools and instruments*. The use of neuroimaging as a tool for exploring the mechanisms of mind-body interactions is an especially important example; neuroimaging was used at four different research centers to investigate areas such as gastro-intestinal disorders, pain sensitivity, sub-clinical disease states, and others. A second important development was the introduction of new measures of neighborhood and spatial context that permitted exploration of the role these factors play in disease onset and health. Several centers developed new measures of other constructs such as positive emotion, life purpose, and cognitive measures of benefit-finding and illness representation, among others. One center advanced and promoted the application of complex system modeling approaches (such as system dynamics models) for understanding population-level phenomena.

MBIH research centers also produced a number of *important scientific findings and insights* that are prompting new studies. Work conducted at one center demonstrated that growing up in relative poverty substantially alters the biology of the frontal cortex in children, affecting critical executive functions such as decision-making and emotional regulation over the life course. Other studies at this center showed that epigenome is altered by early life experiences with adversity and stress and cross-validated this finding in a series of animal models. Work conducted at other centers showed that a cognitive-based stress management intervention could reduce stress, improve natural killer-cell activity, reduce urinary free cortisol levels in women with breast cancer, and improve quality of life and self-reported sexual functioning in men with prostate cancer. Still another research center conducted a series of studies that documented the clinical phenomenon of masked hypertension and demonstrated the value of ambulatory blood pressure monitoring for assessment and monitoring of this condition. Yet another research center conducted clinical trials that demonstrated the value of biofeedback as a treatment modality for specific forms of fecal incontinence. Other centers produced important findings about the roles of catastrophizing and sleep disturbance on inflammation, and the effects of post-traumatic stress disorder on physical health.

The fifth category of accomplishments concerned the effects of mind-body research center activities on *health professional educational and training curricula*. One center developed a national curriculum in mind-body medicine for family medicine residents that has already been adopted by nine university medical programs. Accomplishments by other centers included integration of their conceptual frameworks into professional education for nursing and psychology students in the US and in England, as well as the development of specific continuing education programs for physicians and others based upon specific research protocols such as clinical hypnosis and stress management.

4.2 How MBIH Research Has Gained Respectability and Acceptance Over the Past Decade

MBIH Research Center PIs were unanimous in their agreement that the field of mind-body interactions research has grown considerably over the past ten years. Several investigators described the difficulties they had encountered in obtaining research funding for investigations on stress, stress mechanisms, or mind-body medicine topics before the MBIH Program. One investigator, for example, commented on the degree of "eye-rolling" that used to accompany discussion of mind-body research. Two NIH institutes were identified as particular pioneers in funding this research prior to the MBIH Program: the National Institute of Mental Health (NIMH) and the National Institute of Allergy and Infectious Disease (NIAID). Both of these institutes were described as important sources of funding for studies on psychoneuroimmunology during the 1990s. However, both institutes began to "back away" from these studies by the late 1990s, and several investigators praised the MBIH Program for providing an "organizational home" for research on these issues.

In supporting their views of the mind-body research field, PIs identified several developments they deemed as important indicators (see **Exhibit 21**). Several respondents described a growing acceptance of mind-body findings and ideas within the academic medical community, a development one investigator called a "real attitudinal sea-change." Part of the increased acceptance of mind-body research is attributed to the confirmation of mind-body effects and constructs that is emerging from the neurosciences. As one investigator noted, mind-body topics are now almost a mainstream area within the field of neuroscience, and studies investigating the mechanisms or effects of interventions such as meditation or hypnosis are now viewed as worthy areas of investigation.

Exhibit 21. Evidence of Increased Acceptability of Mind-Body Research

- Acceptability of mind-body research in medicine;
- Influx of new researchers into the mind-body research field;
- Greater ease of publication; and
- Willingness of NIH to fund this research.

With growing acceptance of the scientific legitimacy of some mind-body phenomena came an increased willingness to incorporate instruction on some mind-body topics as part of the medical or health professional curricula. One respondent noted that "as professors go, so go the students," and the younger generation of medical students appear more receptive to mind-body research than their older colleagues. Mind-body relationships and research findings are being woven into the curricula for various specialties (e.g., the family medicine residency training program noted previously). Biopsychosocial etiology is now recognized as a distinct etiological factor in brain-gut dysregulation, again driven by findings from neuroimaging studies. At the same time, as the field becomes more accepted, more research investigators who would not have considered conducting research on mind-body topics are becoming interested and are entering the field.

Most PIs expressed the opinion that it has become easier to publish findings from mind-body research studies in quality journals, and that this trend has become especially noticeable during the past ten years. One investigator noted that it has become much easier to publish in journals with higher journal impact factors in medicine—such as Chest, or Diabetes, and even the New England Journal of Medicine—because the research is highly relevant to the types of problems clinicians are encountering in their practices. One investigator noted that as long as there is a biological marker associated with the study, there is certainly greater interest by journal reviewers.

Finally, several PIs commented that while competition for research grants remains keen, it is getting easier to obtain funding from NIH for mind-body research. One investigator noted that NIMH has now begun to incorporate psychoneuroimmunology and biological issues into more traditional mental health topics in its PAs and RFAs. The National Institute on Aging (NIA) was also singled out as notably

more receptive to mind-body research. This same investigator also commented that review panels are becoming more acceptant of these research concerns.

Asked how they thought the MBIH Program had contributed to these developments, most respondents were quick to praise the program as offering an important opportunity to fund needed research, but were generally unsure of what specific impacts the program had apart from the overall trajectory of the field as a whole. Several investigators commented that the fact that NIH was willing to sponsor a program for mind-body research served as an important signal that research scientists should take this research seriously.

One investigator summarized his assessment of the recent growth of the mind-body research field by noting that while there has been tremendous movement and growth over the past decade, the field at present has "hit a wall;" there has been much work accomplished in exploring different pieces of the puzzle, but insufficient progress has been made in putting the pieces together and showing how they relate to different clinical groups and populations. A new emphasis needs to be made on integrating what has been learned, in order to develop the next generation of studies.

4.3 Use of Tools, Methods, Instruments, or Measures from MBIH-funded Research by Other Investigators

Part of the MBIH Research Project PI semi-structured interviews explored whether the project research team had developed a new tool, method, instrument, or measure as part of the process of conducting their studies. For those PIs who reported having done so, the evaluation team asked whether the tool, method, instrument or measure was being used by others at their institutions, or by other investigators outside their university (see **Exhibit 22**). Of the 44 MBIH research projects, investigators from 31 projects (70 percent) reported that they had developed one or more new research tools, methods, instruments or measures. All investigators for these 31 projects reported that researchers at their own institutions were using these research products. Fifty-five percent (17/31) of these PIs reported that these research products were also being used by investigators from other external academic institutions.

Exhibit 22. Development and Use of New Tools, Methods, Instruments or Measures by MBIH Research Projects

Proportion of MBIH research projects that developed new tools, methods, instruments or measures	70%
Proportion of projects with newly developed tools, methods instruments or measures in which other investigators at same institution were using them	100%
Proportion of projects with newly developed tools, methods, instruments or measures in which investigators from other institutions were using them	55%

Three factors that could affect this utilization by external research investigators were investigated (see **Exhibit 23**). These included whether the project had been funded as one of the first round of research projects (2004-2005) versus one of the two later rounds (2006-2009), whether or not the project had produced any peer-reviewed research publications, and whether or not the project had been affiliated with a research center. The first factor represents time and the likelihood of project completion, which could reflect whether the research product had been validated or successfully demonstrated. The second factor captures whether the product might have been mentioned or described in a research publication, thereby alerting the scientific community to its existence. The third factor relates to another aspect of dissemination, whether information about the product may have been conveyed through the broader activities of a research center. The analysis was restricted to the 31 projects that reported developing a new tool, method, instrument or measure.

As **Exhibit 23** shows, those projects funded during the first round of the MBIH research solicitations were more likely than those funded in either the second or third funding round to report some external use of their newly developed tools, methods, instruments or measures (75 percent versus 42 percent). Similarly, projects that produced one or more research publications reported a higher likelihood of external utilization than those that did not (79 percent versus 35 percent). Finally, projects producing a new research product that were conducted within a research center were more likely to report external utilization of these products than those conducted by unaffiliated research investigators (63 percent versus 42 percent).

Exhibit 23. Factors Affecting External Use of New Research Tools, Methods, Instruments or Measures

MBIH Research Project Funding Start-up	External Product Use			
	No Use	Any Use	Total	% Any Use
2004-2005	3	9	12	75%
2006-2009	11	8	19	42%
TOTAL	14	17	31	

Did Project Produce Any Research Publications?	External Product Use			
	No Use	Any Use	Total	% Any Use
No	11	6	17	35%
Yes	3	11	14	79%
TOTAL	14	17	31	

Was Project Investigator Affiliated with a Research Center?	External Product Use			
	No Use	Any Use	Total	% Any Use
No	7	5	12	42%
Yes	7	12	19	63%
TOTAL	14	17	31	

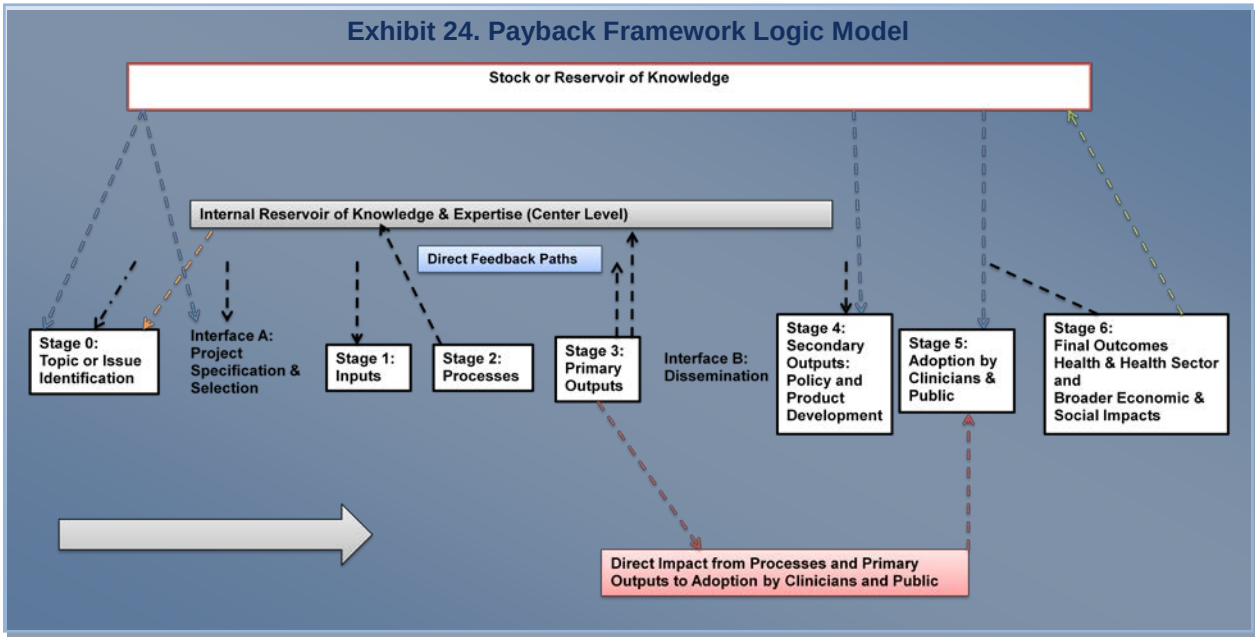
The first two results are not unexpected. Projects that were funded during the first round of solicitations are more likely to have been completed, while many of those funded during the second (and especially the third) round are still in progress. Projects that have produced one or more research publications have probably mentioned the new tools, methods, instruments or models as part of the publication, thereby increasing awareness of and interest in them within the scientific community. The third finding on affiliation with research centers is novel, however. One possible explanation is that projects conducted within research center settings may have benefitted from larger communication networks associated with centers, which may have also contributed to increased likelihood of external use.

5. Research Payback from the MBIH Program

The Payback Framework was developed to address an important gap in the assessment of impact from research programs. The costs of research have led to a growing interest in documenting the returns on investment from research spending. For a variety of reasons, it is not always possible to put a single quantitative value on this return. One of the strengths of the Payback Framework is that it brings both quantitative and qualitative benefits that may be derived from a research program together within one conceptual model.

This section presents results from the application of the Payback Framework to the evaluation of the MBIH Program. The results are presented separately, first for the 15 MBIH research centers (sub-section 5.1) and then the 44 investigator-initiated R01 and U01 research projects (sub-section 5.2). In presenting these results, the general outlines suggested by the Payback Framework logic model, which is shown in **Exhibit 24** have been followed. In both of these sub-sections, results will be presented for Stages 1 through 6 of the model. These stages include inputs, processes (activities), primary outputs (knowledge productivity), secondary outputs (research targeting and capacity development), and outcomes (informing administrative and clinical policy, adoption by clinical practitioners, health and healthcare service delivery, and broader economic and social impacts). Sub-section 5.3 compares results for the MBIH research centers and research projects and presents an additional comparison with results from other published applications of the framework.

Exhibit 24. Payback Framework Logic Model



5.1 Research Payback from the MBIH Program Research Centers

In presenting these results, the research centers and research projects will not be identified by name. Research centers will be identified by a letter (**A-O**), and the results for the research projects will be presented in aggregate form. These steps have been taken to provide some level of confidentiality for the research investigators involved.

5.1.1 Research Centers—Inputs

Exhibit 25 describes several input characteristics of the MBIH research centers. Eight of the MBIH research center grantees had an existing research center already in place at the time they received their initial MBIH research center grant. In three of these cases, a group of research investigators from a

larger research center sought to develop a separate free-standing center that would reflect their research interests. Three of these eight pre-existing centers had operated as centers for at least 10 years prior to applying for an MBIH grant. Four of the centers had been operating for a much shorter period (between two and four years). Six of the eight pre-existing research centers were located in Schools (or Colleges) of Medicine. The other two centers were located in a larger Institute and in a School of Public Health.

Seven MBIH research center grantees did not start from a previously existing research center. These grantees formed research centers as a result of receiving their MBIH grant. Each of these grantees proposed a research team that had a history of shared research collaborations for at least 18 months; key personnel from four of these teams had collaborated for at least 10 years. Four of these new centers were located within Schools of Medicine, while three of them were located in Departments of Psychology or in a School of Public Health.

Exhibit 25. Input Characteristics of the MBIH Research Centers

MBIH Center	Pre-Existing Center?	Pre-Existing Research Team?	Years of Activity	Part of A Larger Center?	Org Locus
A	Yes		2 Years		MED
B	No	Yes	At Least 10 Years		MED
C	No	Yes	18 Months		OTH
D	Yes		4 Years		MED
E	Yes		2 Years	Yes	MED
F	Yes		At Least 10 Years		MED
G	Yes		At Least 10 Years	Yes	OTH
H	No	Yes	At Least 3 Years		MED
I	Yes		3 Years		MED
J	No	Yes	4 Years		MED
K	Yes		7 Years	Yes	OTH
L	No	Yes	At Least 10 Years		MED
M	Yes		At Least 10 Years		MED
N	No	Yes	At Least 10 Years		OTH
O	No	Yes	At Least 5 Years		OTH

In an evaluation of the Health Resources and Services Administration's Rural Health Research Centers Program, the evaluation team drew a distinction between centers they described as *developmental* (those with little or no previous rural health research base) and *mature* (those with established rural health services research programs), noting that each center type faced different challenges (Board of Visitors, 1994). Developmental centers needed to develop a basic research infrastructure, an organizational structure, and a center identity. Mature centers, on the other hand, needed to develop greater depth of expertise in their established research areas and to create structures and processes that supported center growth into new research areas. Centers in each of these two groups showed different patterns of growth and required different types of assistance and institutional support. This notion is examined in greater detail throughout this sub-section, characterizing those MBIH research centers that started from a research team (without a pre-existing research center) as *early-stage* research centers, and those that started from a pre-existing research center as *later stage* centers.

Exhibit 26 shows the total amount of MBIH research center grant funding committed to the early and later stage centers as a group. As shown, roughly comparable amounts of funding were provided in total to the two groups of centers, although funding for individual MBIH research centers within each group varied considerably.

Exhibit 26. MBIH Research Funding for Early and Late-Stage Research Centers

	Early Stage Centers	Late Stage Centers
Centers in this group	B, C, H, J, L, N, O	A, D, E, F, G, I, K, M
Total MBIH Funds Awarded	$46,478,613	$48,224,747

5.1.2 Research Centers—Research Activities (Processes)

Within the Payback Framework, research processes typically refer to how the actual research was conducted, what problems if any were encountered, and how the problems were resolved. In adapting the framework for the MBIH Program Outcome Evaluation, the evaluation team identified five specific functions that were addressed in varying ways across the MBIH research centers. These included: career development activities, interdisciplinary collaboration, pilot studies, dissemination activities, and research translation.

5.1.2.1 Career Development Activities

The function of career development (which included training and mentoring for undergraduate and graduate students, post-doctoral fellows, clinical residents, and/or junior faculty) was managed in several different ways within the 15 MBIH research centers. Each MBIH research center operated within an institutional environment in which there was at least one NIH-funded training program, either for graduate students or for post-doctoral fellows or residents. In several research centers, as many as four separate training grant programs were operating and key research personnel participated in these as mentors. Three MBIH research centers served as sites for the Robert Wood Johnson Health and Society Scholars program beginning in 2003.

All 15 centers conducted some level of career development activities. Six centers established separate research cores that coordinated their career development activities. Six of the nine remaining centers explicitly assigned responsibility for managing career development activities to their Administrative Cores. In three cases, responsibility for managing these activities was not clearly described in the original grant applications. Specific career development activities ranged from minimal to elaborate. Examples of minimal career development activities included encouraging the participation of undergraduate and graduate students in research center research sub-projects, or providing funds to enable faculty members to travel to one mind-body professional meeting per year. One center annually sent clinical residents to a special week-long training program on mind-body interventions. More elaborate activities included mentoring programs for post-doctoral fellows or residents, sponsoring an annual Mind-Body Research Day to showcase graduate student and post-doctoral fellow research projects, and participation by center faculty in grand rounds programs within the host institution. One center sponsored an annual Summer Institute that brought up to 30 research scientists from the US and other nations to that institution for an intensive practicum in a particular mind-body topic or theme. Another center developed a specific curriculum to train family medicine residents in the use of mind-body interventions. Several career development activities overlapped with activities designed to promote interdisciplinary collaboration, including then use of journal clubs, seminar series, and regular meetings of center staff on a monthly or bimonthly basis.

5.1.2.2 Activities to Promote Interdisciplinary Collaboration

Promotion of interdisciplinary collaboration was one of the main programmatic objectives of the MBIH Program. The MBIH research centers used two basic strategies to promote interdisciplinary

research collaboration: bringing research investigators together to share ideas, and using common research protocols across research projects within a center. To bring investigators together, the MBIH centers engaged in several activities (see **Exhibit 27).** The most frequently described approach (eight MBIH centers) was the use of a Center-wide seminar series, usually meeting once every two weeks. Participation by all center staff (and especially by junior faculty, post-doctoral fellows or other trainees) was required.

The second most commonly employed activity was the use of Visiting Scholar or Visiting Scientist Programs, in which an outside investigator conducting mind-body research or specializing in a field where mind-body approaches might be addressed would be invited to visit the center for one or more days; at some centers, visits lasted up to two weeks. Some centers brought in experts from outside the US for these programs. The time would be used to allow the Visiting Scholar or Scientist to make a presentation on his or her current research, followed by the opportunity to meet with interested center research investigators to discuss possible collaborations. This approach was described by seven MBIH research centers. Other less frequently described approaches included journal clubs and annual research center retreats.

Exhibit 27. Center Activities Promoting Interdisciplinary Collaboration

Center	Visiting Scholar Programs	Journal Clubs	Seminar Series	Annual Center Retreats
A	✓	✓	✓	
B	✓	✓	✓	
C				
D			✓	✓
E	✓		✓	
F	✓			
G			✓	
H	✓	✓	✓	
I		✓		✓
J				
K	✓		✓	
L				
M				
N				
O	✓	✓	✓	
TOTAL	7	5	8	2

These activities provided means of formally bringing investigators together in a setting where they could meet, interact, and exchange scientific ideas. A second general strategy for promoting interdisciplinary collaboration was the use of common research protocols across research studies conducted within the centers. Four of the 15 research centers used common research protocols as a means of encouraging investigators from different disciplines to work together.

5.1.2.3 Pilot Studies

All but one of the MBIH research centers funded some type of pilot research program for post-doctoral fellows, residents, junior faculty, and less often, for senior faculty or graduate students. The fifteenth center mentioned plans to establish a pilot research program but no further activity appeared to result. The purpose of a pilot research program was to provide a modest amount of research funding for one or two years that would enable the investigator to conduct a small-scale research project and collect data that could be used in an application for NIH (or other) research funding. Typically such programs were operated by the research center in a manner analogous to the NIH research solicitation process. A call for letters of intent would be issued, and interested research investigators would submit a short description of their proposed project. A research committee within the MBIH center would review the letters and invite selected candidates to submit a full-scale research proposal. Part of the application process involved identifying a research mentor from the center's research team with whom the applicant would work on developing the proposal and conducting the study if funded. In the interest of creating an experience that resembled the actual process of grant application, the research proposal would take the form of a PHS-398 grant application. Upon receipt of the proposals, the research committee would

conduct a formal review of each application and provide a critique in the same manner as a formal Internal Review Group committee. Funded applicants would then move ahead with conducting the research project, collecting and analyzing data, and drafting both progress and final reports. Frequently the pilot studies would be featured on the center's website.

As noted previously in Section 3.3, there were a total of 209 pilot studies funded by the 14 research centers that had pilot study programs. **Exhibit 28** shows the number of pilot studies at each MBIH center and their status on December 1, 2010 as reported by the Research Center PIs on the Data Tables. The number of pilot studies at each of the 14 centers that funded one or more ranged from 2 studies to 58 studies. Of the 209 funded pilot studies, 72 percent were completed by December 1, 2010, 21 percent were in progress on that date and 7 percent had been discontinued. Early stage centers funded slightly fewer pilot studies than later stage centers, but the difference was not substantial.

Exhibit 28. Pilot Studies at the MBIH Research Centers

Center	Total Pilots	Project Status on December 1, 2010		
		Complete	In Progress	Discontinued
A	43	23	17	3
B	17	6	8	3
C	2	1	1	--
D	8	8	--	--
E	20	11	7	2
F	15	13	2	--
G	9	8	--	1
H	8	6	1	1
I	8	8	--	--
J	4	2	--	2
K	2	--	2	--
L	58	49	7	2
M	6	6	--	--
N	9	9	--	--
O	--	--	--	--
TOTAL	209	150	45	14

Stage of Center Maturity	Total Pilots	Project Status on December 1, 2010		
		Complete	In Progress	Discontinued
Early	98	73	17	8
Late	111	77	28	6
TOTAL	209	150	45	14

5.1.2.4 Dissemination Activities

While it was expected that research investigators at the MBIH research centers would pursue the conventional scientific activities of presenting at professional meetings and conferences and authoring articles for peer-review publication, there was an expectation in the R21 and R24 research center grant solicitations that the centers would also engage in some dissemination activities that were targeted to individuals outside the research community, such as policy makers, clinical practitioners, students, and the general public. Most of the MBIH research centers approached this in fairly conventional ways, through mechanisms such as maintaining a center website, publishing a quarterly newsletter, or less often, engaging in direct meetings with community groups and organizations. Nine of the 15 centers related plans for maintaining a center website in their center grant applications; two centers published quarterly newsletters that were distributed widely within their surrounding communities through the offices of local clinical practitioners and to individuals who had participated in center research projects. One center established a community relations board with which it met on an annual basis; another designated a part-time staff member to serve as a community outreach agent for the center. Four centers engaged in informal meetings with policy makers or included them in regular seminars. Ten centers operated various programs for informing local clinical practitioners about center research activities at open seminars and meetings. Four centers held regular monthly lectures to which the public was invited.

Three centers conducted activities that were considerably more complex. One research center proposed to create a Cochrane Collaborative Behavioral Medicine Field. The development of a Cochrane field involves a specific agreement with the Cochrane collaborative and a detailed set of procedures by which studies eligible for inclusion in the field are identified, reviewed, abstracted, and forwarded to the Collaborative. The creation of a Cochrane Collaborative field for behavioral medicine would be an important contribution to the legitimacy of behavioral medicine studies since systematic reviews conducted under the auspices of the Collaborative are regarded very highly within the biomedical research and practitioner communities.

A second center engaged in extensive consulting with a wide range of healthcare organizations and clinical practices. These consultations typically involved working closely with providers to train them on the use of specific mind-body interventions and approaches. A third center produced a variety of health education materials (both video and print versions) which were available through its website and its network of providers.

5.1.2.5 Research Translation Activities

Four research centers conducted activities described as oriented toward translational research. At two centers, specific research staff specialized in the development of mind-body interventions. Both of these centers had worked with a particular type of mind-body intervention for several years. At one center, this work culminated in the development and publication of three treatment manuals and packaged materials for conducting the intervention. At the second center, the intervention (clinical hypnosis) was taught to physicians and other healthcare practitioners through a special continuing education workshop; upon completion of the workshop, individuals could obtain formal certification in the use of hypnosis. Two other centers maintained close relationships with clinical practitioners in order to obtain their views on important problems to address and to inform them about center research activities.

5.1.3 Research Centers—Knowledge Productivity (3.1)

Knowledge productivity refers to the production of publications and presentations by a research program. Oral presentations and publications are generally among the first research products that emerge from research, and are therefore considered *primary outputs.* Other examples of primary outputs are patents and licenses, but none of these were generated by the MBIH research centers. Within the Payback Framework logic model, knowledge productivity fits within Stage 3.

As discussed in section 2.6.5, publications can be classified as research publications or non-research publications (predominantly review articles)[3]. The sum of these two categories reflects total publications associated with a specific research center. In their publications, investigators tend to acknowledge multiple funding sources rather than attributing a particular paper to one specific grant. For example, a publication may acknowledge a P50 and an R24 or an R24 and an R01, or two different R01s. In assessing knowledge productivity for both the MBIH research centers and research projects, duplicate publications were counted in all grants that were acknowledged. Therefore, the numbers of publications included in Section 5 should not be compared with those in Sections 2.6.5 and 6.1. Another complicating factor occurs when an investigator at one center publishes an article with an investigator at a second center. In that case, both centers have been credited with the publication, which results in a slightly inflated count of total publications. This occurred for five research publications which represented collaborations between two centers in each instance. The totals shown for research publications and total publications have been adjusted by deducting five from each total count.

[3] In e-SPA a "Research Article" is defined as a publication that has at least one of 26 possible NLM Medical Subject Heading (MeSH) publication type tags. For articles with more than one type tag, the article is considered non research if one of the types belongs to the non-research category.

The presentations and publications associated with the research centers arose from work conducted as either sub-projects or pilot studies at each of the centers, since it would be unusual for the center to present or publish apart from a specific scientific activity. As part of the Research Center Data Table the centers completed, information was collected on whether each center sub-project or pilot study produced a presentation or publication. **Exhibit 29** shows the number of sub-projects and pilot studies at each center, and the number and proportion of sub-projects and pilot studies resulting in an oral presentation or publication.

Exhibit 29. Numbers and Proportions of Sub-projects and Pilot Studies Resulting in an Oral Presentation or Publication by Center

Center	Sub-Projects					Pilot Studies				
	# of Sub-Projects	# of Sub-Projects With Oral Pres	% With Oral Pres	# of Sub-Projects With Pubs	% With Pubs	# of Pilot Studies	# of Pilots With Oral Pres	% With Oral Pres	# of Pilots With Pubs	# With Pubs
A	--	--	--	--	-	43	27	63%	27	63%
B	1	--	--	--	--	17	10	59%	4	24%
C	17	9	53%	12	71%	2	2	100%	1	50%
D	1	--	--	1	100%	8	7	88%	4	50%
E	8	5	63%	3	38%	20	15	75%	5	25%
F	--	--	--	--	--	15	14	93%	5	33%
G	3	3	100%	2	67%	9	4	44%	2	22%
H	--	--	--	--	--	8	--	--	4	50%
I	--	--	--	--	--	8	1	13%	5	63%
J	10	3	30%	5	50%	4	--	--	2	50%
K	19	--	--	16	84%	2	--	--	2	100%
L	5	5	100%	5	100%	58	44	80%	28	48%
M	4	3	75%	4	100%	6	2	33%	6	100%
N	4	3	75%	2	50%	9	8	89%	4	44%
O	6	6	100%	5	83%	--	--	--	--	--
TOTAL	78	37	47%	54	69%	209	134	64%	99	47%

Exhibit 29 reveals several aspects about the productivity of sub-projects and pilot studies within MBIH research centers which have only rarely been reported in prior evaluations of research center programs at NIH. Eleven of the 15 MBIH research centers (73 percent) conducted sub-projects, which are intended to be broader in scope and scale than pilot studies. The 11 centers conducted a total of 78 sub-projects, ranging from 1 to 19 in number. Of the 11 centers at which sub-projects were conducted, eight centers (73 percent) conducted at least one sub-project that resulted in one or more oral presentations. The total number of sub-projects resulting in one or more oral presentations was 37 (47 percent). Ten of the 11 centers (91 percent) conducting sub-projects resulted in one or more publications; only one center that funded a sub-project did not generate any publications based on that sub-project. The total number of sub-projects that led to one or more publications was 54 (or 69 percent). A higher proportion of subprojects resulted in one or more publications than oral presentations, which is understandable for two reasons. First, sub-projects are likely to be more highly funded than pilot studies and are more likely to involve more complex designs; according to the research solicitations, they are supposed to be comparable in

scope to an R01 investigator-initiated project. Second, sub-projects are more likely to be led by more senior research investigators who may be more interested in publishing than in making oral presentations.

Pilot studies, on the other hand, are more likely to be smaller in scope (1-2 years in duration) and are more likely to be led by post-doctoral fellows or junior faculty who are pursuing them in order to gather preliminary data for a grant application submission. There is often strong encouragement for more junior investigators to present their work at professional conferences and meetings as a way of building their professional experience. Fourteen of the 15 research centers (93 percent) funded at least one pilot study, and a total of 209 pilot studies received funding at these research centers. Eleven of the 14 research centers that funded pilot studies (79 percent) had at least one pilot study that resulted in one or more oral presentations, and a total of 134 pilot studies generated at least one oral presentation (64 percent). All 14 of the 14 centers had at least one pilot study that produced one or more publications; a total of 99 pilot studies led to publications (47 percent). This pattern is the reverse of the sub-projects, and again, this is probably due to the more junior status of the investigators leading pilot studies.

Exhibit 30. Knowledge Productivity in the MBIH Research Centers

- MBIH research centers conducted a total of 287 scientific studies (sub-projects and pilot studies).
- 82 percent of these studies resulted in at least one oral presentation.
- 73 percent of these studies resulted in at least one publication.
- The centers as a group produced an unduplicated total of 429 publications.

A total of 429 publications were generated by these sub-projects and pilot studies; this included five papers that were co-authored by investigators from two MBIH centers. (Two papers were co-authored by research investigators from Centers E and F, and three papers were co-authored by investigators from Centers L and N. This total has been adjusted for the doubly counted papers, and represents an unduplicated count of publications.) The 429 publications included 336 peer-reviewed research articles (78 percent of the total) and 93 non-research articles, or 22 percent of the total. **Exhibit 30** summarizes these general findings for the MBIH research centers as a whole.

One metric that has been used as a measure of the relative efficiency of publication production is the dollar cost per publication, calculated by dividing the total funding, and dollars per publication for the 15 research centers. The publication counts presented in **Exhibit 31** reflect the published articles as of December 31, 2009[4].

Exhibit 31. Publications, Funding and Dollars per Publication for the MBIH Research Centers

Center	Research Publications	Non-Research Publications	Total Publications	Total Research Funding	Dollars Per Publication
A	13	9	22	$4,443,492	$201,976.90
B	8	1	9	$4,387,994	$487,554.88
C	9	--	9	$4,145,992	$460,665.77
D	44	9	53	$3,455,692	$65,201.74
E	31	12	43	$4,638,692	$107,876.55
F	31	12	43	$4,500,579	$104,664.62
G	7	4	11	$4,329,180	$393,561.81
H	6	2	8	$1,503,221	$187,902.62
I	--	--	--	$1,334,960	---

[4] The numbers of research, non-research and total publications shown in **Exhibit 31** represent the published articles through December 31, 2009. This means that articles that were published in 2010 are not counted in this Exhibit. The data presented in **Exhibit 29** represent what was reported in the Research Center Data Tables through 2010; thus, it is possible that a center could have no articles listed in **Exhibit 31** but could have generated several articles as shown in **Exhibit 29**.

Center	Research Publications	Non-Research Publications	Total Publications	Total Research Funding	Dollars Per Publication
J	5	2	7	$1,348,350	$192,621.42
K	22	6	28	$15,111,070	$539,681.07
L	101	24	125	$14,490,469	$115,923.75
M	15	5	20	$10,421,132	$521,056.60
N	32	2	34	$10,593,644	$311,577.76
O	17	5	22	$10,009,008	$454,954.90
TOTAL	341-5=336	93	434-5=429	$94,713,359	AVG=$220,777.06

Exhibit 31 also shows that the total number of articles published through 2009 ranged from no articles to a maximum of 125 articles. Using the average dollars per publication as a general benchmark, it can be seen that six centers achieved a dollars-per-publication value below the benchmark. It is interesting to note that this higher-efficiency group included the center with the lowest total funding as well as the center with the second highest funding.

5.1.4 Research Centers—Research Targeting (3.2)

A second category of primary outputs is research targeting and capacity development, which is also considered part of Stage 3 in the Payback Framework. Research targeting refers to the degree to which a research project enables the investigator to develop new or more refined hypotheses which can be tested in subsequent studies. One measure of research targeting is whether a project leads to a subsequent funded grant. Research targeting in this evaluation was measured by determining whether a sub-project or pilot study led to a subsequent NIH-funded grant, called a "spin-off" grant. While this is not a novel idea, it is not a measure that has been commonly used in prior NIH research program evaluation studies. This measure was further extended by comparing the total value of new NIH-funded research grants derived from MBIH research center sub-projects and pilot studies with total MBIH funding provided to the research center. This led to the calculation of a measure of new NIH spin-off grant funding per dollar of MBIH research funding. The revenue achieved by NIH spin-off grant funding represents an economic benefit to the individual host institution (and the research center) but it does not reflect a wider economic benefit because NIH would have awarded the research funding to some applicant in any case; it happens to have been awarded to the investigators at this specific MBIH center at this time. That said, NIH spin-off funding is an important indicator of research targeting for the various centers.

Data on NIH spin-off funding was obtained in several steps. Research center PIs were asked to indicate for each of the specific sub-projects and pilot studies conducted by their respective centers whether the study had resulted in a funded NIH grant as part of the Research Data Table. The name of each lead investigator for these scientific studies was also identified. Following receipt of the completed Data Table from each center, QVR was searched to identify the specific research grant that had been awarded. In some cases this required some additional communications with the research center PI (for example, the lead investigator might not have been the PI of record for the submitted grant). In searching for funded NIH grants in QVR, applications that were described as "under review" (several remained in this category for long periods of time) as well as those that had not been formally awarded (awaiting Council approval) were excluded.

Of the 287 research center sub-projects and pilot studies conducted by the MBIH research centers, a total of 140 were reported as leading to funded NIH research grants. Upon review in QVR, a grant number, title, and funding amount were verified for 100 grants. Of the 40 projects that were not verified, 29 projects were described as under review at the time of data collection (April-May 2011), and the remaining 11 grants fell into a miscellaneous category that included long-standing 'awaiting Council

action' or the PI could not be identified. Based upon these numbers, 100 of the 287 scientific studies (35 percent) conducted by the MBIH research centers resulted in a newly funded NIH spin-off grant.

Exhibit 32 presents data on the number of NIH spin-off grants obtained by each MBIH research center and the total dollar value of NIH spin-off research funding. Of the 15 MBIH research centers, 13 (87 percent) obtained at least one NIH spin-off grant. The number of grants per center ranged from one to 31; three centers obtained ten or more grants. The total dollar value for the 100 NIH spin-off grants was $184,781,090, which represents almost twice ($1.95) the total of original MBIH research center funding over the ten years of the program. Center O obtained the highest total dollar amount of NIH spin-off funding, but center D achieved the highest NIH spin-off dollars to center funding ratio. Using $1.00 as a break-even point in terms of NIH spin-off funding, eight centers (53 percent) brought in as much new NIH research funding as had been spent on funding the original MBIH research center.

Exhibit 32. Number and Total Dollar Value of NIH Spin-off Grants by MBIH Center

Center	Number of NIH Spin-Off Grants	Total Dollar Value of NIH Spin-Off Grants	NIH Spin-Off Dollars Per Dollar of MBIH Research Center Funding
A	10	$10,280,485	$2.31
B	5	$7,283,121	$1.70
C	1	$279,780	$0.07
D	9	$27,415,026	$7.93
E	6	$9,428,250	$2.03
F	3	$2,443,087	$0.54
G	2	$308,750	$0.07
H	--	--	--
I	2	$1,483,362	$1.11
J	--	--	--
K	15	$31,564,073	$2.09
L	31	$34,312,277	$2.37
M	4	$7,449,165	$0.71
N	7	$10,375,270	$0.98
O	5	$42,158,444	$4.21
TOTAL	100	$184,781,090	$1.95

Exhibit 33 presents data on the number of spin-off grants and their total dollar value by NIH IC. A total of 18 NIH ICs funded spin-off grants for the MBIH research centers; this number included six ICs that had not previously funded MBIH research. NIA, NHLBI, and NIMH collectively funded a total of $115,465,877, or 62 percent of the spin-off funding total dollars. Eight ICs that had not previously funded MBIH Program centers or projects provided funding for spin-off grants, including NIAAA, NIAMS, NIDA, NIGMS, NCMHD, NINR, NCRR and the Fogarty International Center.

Data on the types of grants funded are presented in **Exhibit 34**. As the Exhibit shows, one award was a contract, while the remaining 99 awards were project grants. The R01 investigator-initiated grant was the most common type of grant awarded and accounted for 48 percent of the total spin-off grant funds awarded. A total of 17 R21 Exploratory-Developmental grants were awarded to MBIH investigators.

Exhibit 33. Number and Total Dollar Value of NIH SPIN-Off Grants by NIH IC

Funding IC	Number of Spin-Off Grants	Total Dollar Value
NIAAA	1	$279,780
NIA	13	$45,646,208
NIAMS	4	$5,144,889
NCCAM	8	$9,335,045
NCI	7	$7,412,267
NIDA	7	$12,463,421
NIDDK	4	$8,340,175
NIEHS	1	$393,947
NIGMS	1	$1,868,750
NICHD	6	$4,660,565
NHLBI	18	$41,085,559
NCMHD	1	$6,944,209
NIMH	16	$28,734,110
NINR	5	$3,448,949
NINDS	4	$4,303,202
OBSSR	1	$3,292,418
NCRR	2	$1,316,336
FOGARTY	1	$111,260
TOTAL	100	$184,781,090

Exhibit 34. Number and Total Dollar Value of NIH Spin-off Grants by Type of Grant

Type of Grant	Number of Grants Awarded	Total Dollar Value of Spin-Off Grants
Contract	1	$3,292,418
F32	3	$276,045
K01	9	$5,948,673
K07	1	$756,744
K08	2	$1,282,483
K23	7	$4,470,828
K99	1	$701,281
P01	2	$36,584,165
P50	1	$10,850,797
P60	1	$6,944,209
R01	44	$88,824,143
R03	6	$838,858
R21	17	$8,293,063
R37	1	$3,716,420
RC1	2	$6,516,003
S10	1	$500,000
U01	1	$4,984,960
TOTAL	100	$184,781,090

While comprehensive data on the amount of funding received by various non-federal sources were not obtained, information about the types of sources from which such funding was obtained was gathered (see **Exhibit 35)**. Non-federal funding sources included intramural support from host institutions (universities), foundations, state or provincial funding, contracts with local pharmaceutical and biomedical research companies, contracts with local city departments and agencies, and other sources (included one contract with the US Army and one grant from the Agency for Healthcare Research and Quality.

Exhibit 35. Non-federal Funding Sources for the MBIH Research Centers

Center	Host Instit	Foundations	States or Provinces	Pharma & Biomed	City Depts	Other
A	YES	--	--	--	--	--
B	--	YES	--	--	--	--
C	--	YES	YES	--	--	--
D	YES	YES	--	--	--	--
E	--	YES	--	YES	--	--
F	YES	YES	--	YES	--	YES
G	--	YES	YES	YES	--	--
H	--	--	--	--	--	--
I	YES	YES	--	--	YES	--
J	YES	--	YES	--	--	--

Center	Host Instit	Foundations	States or Provinces	Pharma & Biomed	City Depts	Other
K	YES	YES	--	--	--	YES
L	YES	YES	--	--	--	--
M	--	--	--	--	--	--
N	YES	--	--	--	--	--
O	YES	YES	--	--	YES	-
TOTAL	9	10	3	3	2	2

All but two of the 15 centers (87 percent) obtained additional funding from at least one of six non-federal sources. If the host institution is excluded as a possible revenue source, four centers received no outside funding. The largest amount was more than $15 million in grant money from a private foundation. In the few instances where PIs reported funding, most awards tended to be less than $100,000. Several professional organizations such as the American Heart Association, the National Alliance for Research on Schizophrenia and Depression, and the American College of Gastroenterology awarded funds to MBIH research centers (these were counted among the foundations in **Exhibit 35**).

Exhibit 36. Summary of Findings;

Research Targeting

- MBIH research investigators obtained a total of 100 new NIH spin-off grants based on MBIH scientific studies.
- NIH spin-off funding totaled $184,781,090 or about $1.95 for every NIH dollar spent funding the MBIH research centers.
- Eight MBIH research centers obtained new funding that totaled as much or more than the amount of original center funding.
- Three NIH institutes (NIA, NHLBI and NIMH) collectively funded about 62 percent of the new spin-off grants.
- R01 grants accounted for 44 percent of the new grants awarded, and 48 percent of the new funding.
- Eleven of the 15 centers received funds from non-federal funding sources (excluding their host universities).
- Foundations and professional associations were the most common source of non-federal funds, followed by the host university.

A brief summary of the main findings for research targeting is shown in **Exhibit 36**. There are several limitations and caveats that are important to consider in interpreting the NIH spin-off grant data. First, some investigators were successful in obtaining funding from non-federal funding sources based on MBIH center work. In some instances, the investigators could report the dollar amounts of this funding; in other cases it was reported that such funding had been received but not how much. In a few instances, the amount of funding was large. Because there was no way to verify the dollar amounts for non-federal funds, collection of data on funding amounts from non-federal sources was not attempted. However, the data from the research interviews with the center PIs indicated that most did not actively seek funds outside NIH, so it is likely that the new NIH spin-off funding represents the majority of spin-off funding for the MBIH centers. Second, some investigators could have submitted research grants on topics unrelated to mind-body research, or submitted grants on mind-body research issues that did not derive from their sub-projects or pilot studies. Data on those submissions were not collected.

5.1.5 Research Centers—Capacity Development (3.2)

Research capacity development is the second category of secondary outputs in the Payback Framework. Capacity development consists of research staff development (investigator honors and awards, graduate degree training, faculty promotions, new faculty recruitment, and new research collaborations) and technical capacity (the development of new research tools, methods, measures and models, and new infrastructure such as laboratories and equipment). Research staff development

represents the various ways that research centers can recruit new investigators, form new collaborations, train and mentor post-doctoral fellows and junior faculty, and build and strengthen skills and expertise within existing research staff at all levels.

Exhibit 37. Research Staff Development at MBIH Research Centers

Center	Research Staff Received Special Awards or Honors	One or More Graduate Students Earned Degrees	Mentor-Ed Post Docs & Jr Faculty	One or More Faculty Promoted Based in Part on MBIH Work	New Faculty Recruited to Join the MBIH Research Center
A	--	--	YES	YES	--
B	--	--	--		YES
C	--	--	YES	YES	YES
D	--	YES	YES	--	YES
E	--	YES	YES	--	YES
F	YES	--	YES	YES	YES
G	--	YES	--	YES	--
H	--	YES	YES	--	
I	--	--	YES	--	--
J	--	--	YES	YES	--
K	--	--	--	YES	YES
L	--	YES	--	--	YES
M	YES	YES	YES	--	YES
N	--	YES	YES	YES	YES
O	--	YES	--	YES	--
TOTAL	2	8	10	8	9

Exhibit 37 shows which centers had accomplishments in each of these areas. All of the 15 MBIH research centers reported achievements in at least one of the five research development areas examined. At two centers, investigators received significant recognition for the quality of their scientific work based at least in part on their MBIH center scientific activities; this included recognition from professional associations and in one case, election to the National Academy of Sciences' Institute of Medicine. At eight centers, graduate students who had worked on MBIH research projects completed dissertations based on MBIH research data. Two thirds of the centers reported mentoring post-doctoral fellows, clinical residents, and/or junior faculty members; in several centers, post-doctoral fellows obtained faculty appointments based in part on their research activities in MBIH studies. At over half of the centers (53 percent), one or more faculty members received academic promotions. At several centers, the PI obtained a promotion and at one center, the PI actually received two promotions (from Assistant to Associate to Full Professor) over the period of the center grant. At nine centers (60 percent), the existence of the MBIH center helped to recruit one or more new faculty members from outside institutions who came to the university in part due to an interest in mind-body research.

Exhibit 38. Types of New Research Collaborations by MBIH Center

Center	Internal (Same Institution)	External (Other Academic Institution)	National Organizations	Local Community	Int'l Collabora-tions
A	YES	YES	--	--	YES
B	YES	YES	--	--	--

Center	Internal (Same Institution)	External (Other Academic Institution)	National Organizations	Local Community	Int'l Collabora-tions
C	YES	YES	YES	--	YES
D	YES	--	--	--	--
E	YES	YES	--	--	YES
F	YES	YES	YES	YES	YES
G	YES	YES	YES	--	YES
H	YES	--	YES	YES	--
I	YES	YES	--	--	--
J	YES	YES	--	--	--
K	YES	YES	--	--	YES
L	YES	--	--	--	--
M	YES	YES	--	--	YES
N	YES	--	--	YES	--
O	YES	YES	--	--	--
TOTAL	15	11	4	3	7

New research collaborations represent an important way of building and extending research capacity within a center. Collaborations can develop with colleagues in a variety of settings, including within the same academic institution, at other (external) academic institutions, with representatives from national organizations, with representatives from the local community, and with international colleagues. **Exhibit 38** shows where these new research collaborations developed for each MBIH center.

All of the MBIH center PIs indicated that their research investigators formed new research collaborations with other research scientists at their host institutions. These collaborations could include writing papers or co-authoring grant applications. Moreover, at nearly three-quarters of the centers (73 percent), investigators entered into new research collaborations with research investigators from other institutions. At four centers, investigators began to partner with representatives from national organizations, and in three centers, research partnerships formed with local community organizations. Perhaps the most interesting pattern was in the area of international collaborations. Seven of the centers (47 percent) undertook international collaborations of various kinds. These included conducting clinical trials at universities in other countries such as England and Italy, and instances in which Visiting Scientists from other nations conducted studies in their own countries that closely coordinated with an MBIH center. Several studies took place in Canada, Mexico, Brazil and Japan based upon these Visiting Scientist programs.

Research staff development is one important avenue for the development of research capacity. Another is the creation of new research tools, instruments, methods, models and measures as well as research infrastructure (laboratories, facilities, and equipment) that are developed, purchased, or organized through the center's activities. New tools and research infrastructure are important because they can be used by other researchers at the host university or at external universities when the original research projects are completed. As part of the research center PI interview, the creation of new tools, and whether these were being used by other investigators either at their own university or at outside institutions was explored as was new research infrastructure. In **Exhibit 39** the number of MBIH centers that developed new tools and instruments and new research infrastructure is shown.

Eleven of the 15 MBIH centers reported developing one or more new research tools, instruments, methods or measures. At ten centers, these tools are being used by other investigators at the host institution, and at seven centers, the tools are also being used at external universities. New tools, instruments and measures ranged from developing new scales and instruments (e.g., the Life Purpose Inventory) to the creation of new animal models. Several centers developed research databases that consolidated data from several studies using common instruments or protocols; these databases are continuing to be used by graduate students, post-doctoral fellows and junior faculty for new analyses and publications or preliminary data for grant applications. One center developed an innovative database to simplify research participant recruitment and tracking over time and across multiple studies. Some centers developed new software that promoted electronic data collection.

Exhibit 39. New Tools, Instruments and Infrastructure at MBIH Centers

Centers	New Tools, Instruments, Methods, & Measures		New Research Infrastructure
	Internal Use	External Use	
A	YES	YES	YES
B	YES	--	--
C	--	--	YES
D	YES	--	YES
E	YES	YES	YES
F	YES	YES	YES
G	YES	--	--
H	YES	--	--
I	--	--	YES
J	--	--	--
K	YES	YES	--
L	YES	YES	YES
M	YES	--	YES
N	YES	YES	YES
O	--	YES	YES
TOTAL	10	7	10

One of the more exciting tools developed by an MBIH research center was the development of he PROCAIM (Patient-reported Outcomes—Complementary, Alternative and Integrative Medicine) atabase. The database was originally created as an in-house MBIH center tool for consolidating data rom multiple center studies using common instruments and measures. However, it quickly became opular with several local community complementary and alternative medicine clinics. As it was mplemented at these multiple sites, its value as a broader research tool became evident. It is now being sed as part of a national multi-site pilot project to construct a practice-based research network with omplementary and alternative medicine practitioners. A total of nine universities are participating in this ational pilot study, which is funded by the National Consortium of Academic Health Centers for ntegrative Medicine.

In addition to the creation of new research tools and instruments, the MBIH centers also eveloped new research infrastructure, either through the purchase of new equipment or the creation of ew laboratories. PIs from ten of the centers (67 percent) reported that their research investigators had reated new infrastructure. The most frequently cited examples were the purchase of specialized quipment that enabled new types of studies or analyses to be performed. A number of the centers that nvestigated stress mechanisms, for example, reported developing new biochemical assays that could be sed to explore specific biological interactions. One of the centers that conducted neuroimaging studies eveloped new procedures and algorithms for imaging specific types of biologic events. Investigators at ultiple centers were active in exploring the use of electronic diaries that enabled research participants to ecord their activities at specific times of the day or in relation to specific stimuli. One PI expressed a egret that it had not been possible to meet together as a full group more often in order to share xperiences and ideas about how to further refine existing equipment.

Exhibit 40. Summary of Findings:

Research Capacity Development

- The 15 MBIH centers achieved considerable progress in developing and strengthening their research capacity in terms of research staff development and the creation of new tools and infrastructure to support future research activities.
- Between 50-67 percent of the centers reported mentoring post-doctoral fellows and junior faculty, recruiting new faculty to pursue mind-body research activities, supporting the promotion of faculty members, and enabling doctoral students to complete dissertations and obtain advanced degrees.
- The MBIH centers were very effective in promoting new research collaborations with center investigators and other researchers at host universities and at other academic institutions. Almost half (47 percent) of the centers also promoted international collaborations, often through Visiting Scientist programs that brought foreign researchers to MBIH centers. These programs often led to future research partnerships and joint studies.
- Almost three-quarters (73 percent) of the centers developed one or more new research tools, methods, models or measures that were then used by researchers at host universities and at external academic institutions. Ten of the centers reported developing new research infrastructure through center activities.

In summary (see **Exhibit 40)** the MBIH centers achieved considerable progress in developing their capacity to pursue mind-body research. This progress was notable in two areas: research staff development and the creation of new research tools and infrastructure. In terms of research staff development, the centers successfully pursued training and mentoring activities, recruited new faculty members to their host universities who were specifically interested in conducting mind-body research, obtained recognition for faculty members affiliated with the centers who subsequently qualified for promotions (including several of the center PIs), and helped their investigators to expand their network of research collaborators, both within their host universities as well as at external academic institutions, national organizations and local organizations. One of the more interesting accomplishments in this area concerned international research collaborations, many of which originated from local Visiting Scientist programs in which foreign scientists participated, then returned to their native countries to pursue additional mind-body research, sometimes in direct collaboration with MBIH research investigators.

The MBIH centers also developed a variety of new research tools, instruments, methods, models and measures as well as new research infrastructure. Some of these tools (such as the PROCAIM database discussed earlier) have achieved national prominence and recognition. In other cases, research investigators from the MBIH centers developed new assays, algorithms, and software that have expanded the range of mind-body phenomena that can be investigated.

5.1.6 Research Centers—Influencing Clinical & Administrative Policy and Product Development (3.3)

A secondary category of research outputs that is often not addressed in evaluations of NIH research programs is policy and product development. This is represented as Stage 4 of the Payback Framework logic model. Research can be used to inform policy and clinical practice in a variety of ways and at a variety of levels. Policy as used within the framework is broadly defined. As discussed in Hanney et al. (2004; p. 6), policy making refers "…not just to national policies of the government, but also includes: policies made by managers at many levels within a health service; policies agreed at national or local levels by groups of practitioners in the form of clinical or local guidelines; policies developed by those responsible for training/education/inspection in various forms including training packages, curricula and audit and evaluative criteria; and policies about media campaigns run by healthcare providers." In operationalizing this stage of the framework, the evaluation team focused on gathering evidence of the effects of MBIH research center scientific studies and research activities on three indicators: influence on medical or healthcare professional education and continuing education training; influence on policy development; and influence on treatment guidelines or recommendations. To gather this evidence, the center PIs were asked about each of these four areas as well as whether and to what extent their centers' activities had influenced these indicators, and when a center PI stated that there had been an effect, details

were probed for. Thus the information used to examine this area was based on self-report, which is subject to a number of limitations. While it would have been desirable to have investigated each claim in greater detail, resources did not allow this.

In **Exhibit 41**, data showing which centers reported that their activities influenced each of these four indicators are presented.

These data suggest that the MBIH centers contributed substantially to clinical and administrative policy and practice in several ways. From 40-87 percent of the centers claimed some degree of influence for the three indicators examined. The indicator most frequently endorsed by the center PIs involved medical or healthcare education or training (87 percent), followed by influence on policy (60 percent), contributing to clinical guideline development (40 percent).

Examples of each of these are considered below. An important dimension across each of the three indicators is the level (i.e., international or national, state or province, community, or institutional) at which the influence occurred; when possible, examples for various levels are provided.

Exhibit 41. Influencing Clinical and Administrative Policy and Product Development

Center	Influenced Policy	Influenced Medical or Healthcare Education or Training	Contributed to Clinical Guideline Development
A	YES	YES	YES
B	--	YES	YES
C	YES	YES	--
D	YES	YES	YES
E	--	YES	--
F	YES	YES	YES
G	--	YES	YES
H	YES	YES	--
I	YES	--	--
J	--	YES	YES
K	YES	YES	--
L	--	YES	--
M	YES	YES	--
N	YES	YES	--
O	--	--	--
TOTAL	9	13	6
PERCENT	60%	87%	40%

Clinical & Administrative Policy: **Exhibit 42** lists several examples of instances where MBIH research center scientific studies and activities have influenced clinical or administrative policies at several system levels. Four examples are provided that illustrate the types of effects that MBIH center studies have had on policy formulation and development. In the first example, results from studies performed at an MBIH center contributed to an earlier set of studies by this team that demonstrated the existence of a new medical condition, termed “white coat hypertension.” Patients with this condition have elevated blood pressure in the clinical setting and normal blood pressure in other settings such as the home. These individuals have lower morbidity and mortality and less end organ damage than patients with sustained (chronic) hypertension and require different treatment. By obtaining readings of their patients’ blood pressure outside the clinic, the research team demonstrated that these patients were indeed normotensive in nonmedical settings. The quality of the evidence this group assembled was so compelling that the Center for Medicare and Medicaid Services now provides reimbursement for patients with this disorder for home-based ambulatory blood pressure monitoring. In the second example, the MBIH-funded research investigator planned and conducted a clinical trial of biofeedback in Italy for patients with a specific type of fecal incontinence. This trial provided strong evidence for the efficacy of biofeedback as a treatment intervention for these patients. A subsequent clinical trial in Iowa by investigators not associated with MBIH obtained similar results, and the studies now support offering this low-cost intervention to patients who might otherwise have been institutionalized. Clinical treatment guidelines are

being revised to include this recommendation; a member of the MBIH research team serves as part of the group revising the recommendations.

The third example illustrates a different type of influence on policy which is more indirect than the first two examples. The PI and his research team had conducted a series of studies that documented that poverty and certain types of adverse stressful events in childhood produce actual changes in the size and functioning of the prefrontal cortex area of the brain, leading to impairments in several types of executive functions including decision-making as well as the ability to regulate emotion. These changes persist over the life course. Based upon this work, the PI was asked to join a national scientific advisory group called the National Scientific Council on the Developing Child. This organization provides briefings and scientific support to several key executive and legislative organizations. The MBIH-supported research by this investigator and his team have been included as part of the scientific recommendations promoted by the Council.

Exhibit 42. Examples of Centers' Influence on Policy

National or International Level

- Demonstrated the medical condition of "white coat" hypertension and the value of ambulatory home-based blood pressure monitoring. As a direct result of this work, the US Center for Medicare and Medicaid Services agreed to reimburse ambulatory blood pressure monitoring in patients suspected of suffering from "white coat hypertension".
- Demonstrated that a specific biofeedback intervention was efficacious in patients with a specific form of fecal incontinence. As a result, treatment guidelines for management of this problem are being revised to incorporate a recommendation that this intervention be offered as a preferred form of treatment.
- Based on research funded under the MBIH center program, the PI conducted several studies demonstrating the poverty and early adverse stressful events have important and long-lasting effects on brain development and executive function in children. As a result of this work, he was invited to join the National Scientific Council on the Developing Child, a national scientific advisory group that advises US governors and state legislators on best science and best practices in child development. The research is also being cited and used by the Canadian Ministry for Children and Youth.
- Established a Cochrane Collaborative Behavioral Medicine Field. Identified clinical trials of various behavioral medicine interventions, abstracted the data from more than 10,000 publications from these trials in accordance with Cochrane Collaborative procedures and created a resource that now exists for others to conduct systematic reviews.

In the fourth example, a research center established a Cochrane Collaborative Behavioral Medicine Field, and located and abstracted information from more than 10,000 behavioral medicine clinical trials. This activity has increased the scientific legitimacy of the behavioral medicine field by providing an important resource for the scientific community to use in conducting systematic reviews on behavioral medicine interventions. While this does not create an immediate impact on policy, it will provide a resource that can have an impact in the future.

Medical or Healthcare Professional Education and Continuing Education: The second indicator examined ways that MBIH research center activities and studies influenced medical or healthcare professional education and/or continuing education training. **Exhibit 43** highlights several examples of the influence of MBIH research activities on medical and healthcare professional education and training. In general, influence on professional education and/or training occurred at either a national or international level or at a local institutional level. Examples of national or international influence included the development of entire educational curricula or educational or training materials that could be used in existing courses. The Summer Institute example is significant because it was an internationally renowned program that provided training to researchers and clinical practitioners from across the US and several other countries. The Institute operated over a five year period.

Other types of impacts on professional education and training took place within specific academic institutions. Several centers described the development of specific courses that drew upon MBIH center research activities; examples included the development of a course on health disparities at one university, and several courses that addressed statistical advances and refinements that resulted from MBIH projects and cores. The Research Center PIs at most of the centers noted that mind-body issues were now being addressed in Grand Rounds presentations.

Contributions to Clinical Guideline Development: **Exhibit 44** shows several examples of the influence MBIH centers have had on the development of clinical treatment guidelines and recommendations. It is interesting to note that the MBIH centers have had a significant impact on the management of several chronic illnesses (asthma, HIV/AIDS, and hypertension) in countries outside the US.

As is evident from this discussion, the MBIH research centers have influenced administrative and clinical policy formulation and development in several key areas. What is especially interesting about this influence is the degree to which it has taken place at the national and international level. **Exhibit 45** highlights the key findings. Influence on administrative and clinical policy appears to occur in several ways. Research findings can have a direct influence on policy, as illustrated by the citation of research findings on ambulatory blood pressure monitoring in documents supporting the change in reimbursement for ambulatory blood pressure monitoring by the US Center for Medicare and Medicaid Services, or in supporting documentation for new treatment guidelines. Research findings can also shape professional education and training, as seen in the development of the family medicine residency curriculum, but these changes are likely to require longer time to take effect. The results also show that research findings (and particularly those from a body of work) can elevate an investigator to an advisory position from

Exhibit 43. Examples of Centers' Influence on Education and Training

National or International Level

- One center developed a 200-hour Integrative Medicine for Residents curriculum for family medicine residents. The curriculum was pilot-tested at nine academic institutions in the US and has since been adopted by six additional institutions.
- An MBIH research center investigator who conducted pilot studies on methamphetamine abuse and social cognitions in gay/bisexual men was invited to edit the first comprehensive textbook on methamphetamine abuse; this text is now widely used to train clinical practitioners.
- One center developed and demonstrated the effectiveness of a cognitive-behavioral stress management intervention for individuals with several types of cancer (breast, prostate). The center developed treatment manuals and educational materials for these interventions, and has published three of these (two by the American Psychological Association).
- The center's main conceptual framework on cognitive factors and the management of illness has been integrated into the curriculum at three Schools of Nursing in the US and on psychology training program in England.
- Center conducted an annual Summer Institute on Mind-Body medicine for continuing education credits which attracted researchers and clinical practitioners from across the US and several other countries.

Institutional Level

- Center developed a methodology for training third-year medical students to recognize and address non-adherence to medical treatment among patients with chronic illnesses.
- Several centers described specific courses built around mind-body topics that have been included in the medical school curriculum.

Exhibit 44. Examples of Centers' Influence on Clinical Guidelines

National or International Level

- Contributed to a European Consensus Statement on Ambulatory Blood Pressure Monitoring and a similar statement in Australia.
- Center's research has contributed to treatment guidelines for the management of HIV/AIDS and asthma in the United Kingdom (UK).
- Center has developed specific treatment protocols for the use of biofeedback as a preferred modality in management of fecal incontinence; treatment guide-lines for this condition are now under revision and will be recommending the use of this intervention.

Exhibit 45. Summary of Findings:

Influence on Policy

- Between 40 and 87 percent of the MBIH research centers reported an impact on administrative and/or clinical policy for the three types of indicators examined (policy formulation, medical and healthcare professional education and training, and clinical guidelines).
- The strongest area of influence was on medical and healthcare professional education and training (87 percent of centers).
- Sixty percent of centers influenced medical and healthcare professional education and training, and 40 percent influenced clinical guidelines.
- MBIH research centers influenced administrative and clinical policy at national and international levels for each of the three indicators.

which he or she can influence policy discussions and formulation within key political groups such as state governors and legislators. Each of these three pathways occurred as a result of research conducted at some MBIH research centers.

5.1.7 Research Centers—Health Outcomes and Healthcare Service Delivery (3.4)

Improvements in health and quality of life and changes to the healthcare service delivery system that facilitate or support these improvements are the fourth major category of benefits from health and biomedical research in the Payback Framework. Before these changes can occur, there must be some degree of adoption of new practices and behaviors by clinical practitioners and the general public (Stage 5 in the Payback Framework logic model). As a result of this adoption, there can then be changes in individual and community level health outcomes and quality of life, and changes in healthcare service delivery (Stage 6 of the logic model).

This sub-section examines the effects the MBIH research centers had in three areas: the extent to which practitioners have begun to implement or adopt research findings and interventions investigated by the MBIH centers, the effects that center findings and interventions have had on health outcomes and quality of life, and the extent to which center findings and interventions have led to actual changes in healthcare service delivery. These outcomes tend to be more intermediate in nature and do not occur quickly. In exploring these indicators with the center PIs, the investigators reported that while they could describe activities by which they disseminated information about center findings or interventions to clinical practitioners, they did not have any systematic means of tracking the extent to which this information was applied (and whether it was applied appropriately). It was especially difficult for these university-based researchers to appraise the effects of their work beyond the immediate university clinic populations with which they might be familiar.

Exhibit 46 shows reports by center PIs concerning each of the three indicators examined. Overall, between 53 and 60 percent of the MBIH centers reported some type of effect for each of the three areas investigated. In terms of the adoption of mind-body research findings and interventions by clinical practitioners, nine of the 15 center PIs reported some indication that clinical practitioners were adopting center findings and interventions. The most common response for this indicator was that individual clinical practitioners who had worked with these investigators were continuing to use these interventions (or recommended their use) for their patients after the original research study had concluded, or had begun to inquire about mind-body issues such as levels of stress when examining patients. In one case, a research center team had developed and tested a specific stress management intervention for arthritis. They subsequently developed a treatment manual and materials for this intervention. A local community arthritis patients' group obtained training in the use of this intervention from the research team, and now is continuing to provide this as a service to the local community. In a second example, following a major hurricane, a center PI wrote a news article for the local newspaper that described psychological aspects and symptoms of stress; following the publication of this article, there was a documented increase in the number of referrals to local mental health services within the community. In a third instance, members of the research center taught a continuing education course on clinical hypnosis for physicians and other interested providers; completion of the course led to certification by the American Clinical Hypnosis Society, and approximately 150 clinicians per year complete the course.

As noted earlier, the PIs had difficulty in appraising the degree to which there were individual or group-level improvements in health outcomes or quality of life. While they could talk with precision about the results from their specific scientific studies, broadening this question to consideration of changes in health outcomes or quality of life based on use of mind-body research findings or interventions by clinical practitioners who had begun to use these in their clinical practices was difficult to assess, since no one was collecting data on this. One exception was the PROCAIM database discussed earlier. Data collection instruments associated with this database have been placed on the web where they can be accessed by the general public. One study that is currently under way is collecting ongoing data about the use of mind-body practices and their outcomes over time by the general public. Those PI who gave a positive response to this question generally stated that for those patients of whom they were aware, the use of mind-body interventions and practices had led to improved health and functioning and more favorable quality of life. They also emphasized that they had no hard data to support these claims.

Exhibit 46. Influencing Health and Healthcare Service Delivery

Center	Adoption By Clinical Practitioners and the Public	Changes in Health Outcomes or Quality of Life	Changes in Healthcare Service Delivery
A	--	--	YES
B	YES	--	YES
C	--	--	--
D	YES	YES	YES
E	YES	YES	--
F	YES	YES	YES
G	--	--	--
H	YES	--	--
I	--	YES	YES
J	YES	YES	YES
K	YES	YES	--
L	YES	YES	YES
M	--	--	YES
N	YES	YES	YES
O	--	--	--
TOTAL	9	8	9
PERCENT	60%	53%	60%

Changes in healthcare service delivery were easier to track. The nine center PIs who reported these changes were able to identify examples such as the addition of new services and changes in provider behavior (e.g., inquiring about psycho-social stressors when taking patient histories). In one instance, the Chaplain's Office of a university medical center began to offer classes in mindfulness-based stress management as a service to patients attending the medical center. Another center conducted research on health beliefs in Hispanic populations and worked with local service providers to increase their cultural awareness and sensitivity. Changes in healthcare service delivery that led to increased service efficiency or reduced costs were not reported. Two centers reported conducting studies in local city school systems to assess the effectiveness of stress management interventions in helping students to increase their focus and manage stress. In one case, the initial study produced equivocal results, but the school system was sufficiently interested that it asked the research investigators to conduct a second trial.

Between one-half to two-thirds of the MBIH research centers reported some type of influence on health outcomes, quality of life, and healthcare service delivery (see **Exhibit 47).** Because the MBIH research centers do not typically track their clinical dissemination efforts, it is difficult to answer questions about how many clinical practitioners have received education on center findings or interventions, and how many of those are using them appropriately. An unexpected and interesting development is that some local school systems have been receptive to the MBIH centers' research and have teamed with center research investigators to evaluate the effectiveness of stress management interventions with school students.

5.1.8 Research Centers—Broader Economic and Social Impacts (3.5)

Exhibit 47. Summary of Findings:

Influencing Health Outcomes and Healthcare Service Delivery

- Assessing the influence of MBIH research centers' studies on health and quality of life outcomes and healthcare service delivery was more difficult for investigators to appraise because they do not collect systematic data on these issues.
- Between 53 and 60 percent of the centers reported some influence on adoption of center research findings and interventions by clinical practitioners or the public, improved health outcomes, and improved service delivery.
- Some school systems have become interested in mind-body research.

The final category of benefits from health and biomedical research posited by the Payback Framework represents broader economic and social impacts to society that result from improvements in health outcomes and healthcare service delivery. For example, if ambulatory blood pressure monitoring leads to better control and management of hypertension, this could result in fewer disability days attributable to hypertension, fewer hypertension-related episodes of hospitalization, and lower medical care costs over time, producing an economic benefit for society. This is the type of payback many policy makers are most interested in obtaining as a result of funding scientific research. It is also the most difficult to estimate or measure for several reasons. First, the types of research studies that could trace such linkages and provide estimates are simply unavailable for many types of interventions and diseases. Second, it can often take many years before these broader economic and social impacts occur. Third, it can be very difficult to attribute these types of long-range impacts to specific studies or interventions. In a few instances where the Payback Framework has been applied, there have been studies that permitted such quantification. For the most part, however, such data tend to be lacking. In thinking about these broader economic and social impacts in the cases where no firm data exist, others who have used the Payback Framework have sometimes considered what the health gain might be if the finding were to be applied.

The MBIH center PIs were asked whether their centers' research findings and/or products had led to broader societal impacts, either economically, socially, culturally, or environmentally. Eleven of the 15 PIs stated that they did not believe that their research had resulted in broader societal impacts, at least at present. Four PIs stated that they believed that some of their research activities would eventually produce this type of payback. One example is the ambulatory blood pressure monitoring example described above. At the second center, work on a biofeedback intervention for individuals with a specific type of fecal incontinence could be expected to enable older individuals who suffer from this to be treated successfully in the community, thereby avoiding costly institutional care while improving their quality of life (and that of their caregivers). This reduction in the costs of institutionalization would be a societal economic benefit. The third case involves the series of research findings produced by a MBIH research center team that addressed the deleterious effects of early adverse stressful events and poverty on brain growth and development in children; here, the argument is that improved policy concerning how society should work with children from vulnerable homes may lead to substantial economic and social cost savings in the future. The fourth center also addressed the effects of poverty in several ways. One example involved the application of geographic information systems (GIS) technology developed by this center's MBIH research core. The GIS application was used to link a mapping of grocery stores and other food stores into a broader database that contained substantial neighborhood and socioeconomic data. One study using this enhanced database demonstrated that outlets where individuals could purchase food were less available in more economically and socially distressed neighborhoods, a policy issue which is currently receiving considerable attention at the federal level. The lack of suitable food stores leads to excessive use of fast food outlets, which in turn is contributing substantively to the current obesity problem in these neighborhoods.

While firm economic arguments cannot be made yet for the direct societal economic and social benefit of the research supported by the MBIH research centers, it is possible to trace several pathways by which these benefits may someday be evident.

5.1.9 Scoring the Research Centers on Payback Framework Benefit Categories

In sub-sections 5.1.3 through 5.1.8, what the MBIH research centers have accomplished in terms of the five categories of research benefits has been described. More recent work with the Payback Framework (Wooding et al., 2011) has further refined consideration of these benefits by grouping them into two impact categories: academic impacts and wider impacts. Academic impacts include knowledge productivity and research targeting and capacity development. These are largely the benefits accruing to the academic institution where the research took place. Wider impacts include effects on administrative and clinical policy, health outcomes and healthcare service delivery system, and broader societal economic and social impacts. These benefits usually accrue to those outside the academic institution—healthcare providers, the public, and government. In considering the various benefits from the MBIH research centers, the majority of these centers produced benefits within the academic impacts category, and a smaller number of centers produced benefits from the wider impact category. This is actually further evidence that the MBIH Program is meeting its goals and objectives, since a primary aim of the program was to develop and grow the mind-body interactions research field.

To this point, the various benefit categories have been examined individually, with a focus on whether a MBIH research center did or did not claim an accomplishment for each of the various indicators. As a result, the proportion of centers that claimed an accomplishment for a given indicator could be described which made it possible to focus on the accomplishments of the MBIH research center component of the program without distinguishing between the general level or magnitude of the accomplishment. The common practice in Payback Framework studies is to develop and apply a scoring system that allows the evaluation team to consider the scope of a claimed accomplishment in terms of dimensions such as the organizational level or the number of people affected by an accomplishment for each case. In this sub-section the development and application of a series of scoring scales for seven indicators is described.

5.1.9.1 Developing the MBIH Research Center Scoring Methodology

The Payback Framework methodology evolved from the earliest studies conducted by the Health Economics Research Group team in the mid-1990s. Whether the focus of the evaluation (the evaluand) is individual research projects or research centers, the evaluation team selected a sample of the evaluands and compiled case studies on each one, using the Payback Framework logic model as a template for organizing the information. Members of the evaluation team then developed a scoring scale for each of the major benefit categories. The evaluation team then scored each case on each scale. Upon completion of their individual scoring, the team met as a group to discuss their ratings. The purpose of the meeting was not necessarily to derive a consensus, but to explore where different perceptions of the evidence led to different scores; team members then re-scored categories and cases for which there were scoring differences.

The scoring approach developed by the Madrillon evaluation team was informed by discussions with Dr. Stephen Hanney (co-developer of the Payback Framework and a consultant to this study), and a review of several prior Health Economics Research Group reports. The approach was based in part on one described in Hanney et al. (2007), an evaluation of the National Health Service Health Technology Assessment program and uses scales that were scored from 0 to 5 points, with descriptors for each scoring level. Scorers (the Madrillon evaluation team) could use 0.5 points in between levels. A description of the scales used in scoring the MBIH research centers is presented below.

Exhibit 48 shows the seven indicators for which scoring scales were developed. The seven indicators represent those for which the available evidence from the center PIs provided the clearest evidence that would permit appraisal of the qualitative differences across the centers. Research targeting and capacity development represent primary outputs that are also considered academic impacts in terms of the Payback Framework. It was necessary to include two indicators for each of these two primary outputs. In the case of research targeting, both NIH research spin-off funding, and the *sources* of non-federal spin-off funding were included. Because detailed and verified amounts for the non-federal funding sources were not available, the number of sources served as a rough proxy measure.

Exhibit 48. Selected Research Payback Benefit Categories and Indicators

Research Payback Domain	Impact Category	Indicator
Research Targeting	Academic Impacts	NIH Research Spin-off Funding
		Non-federal Research Spin-off Funding
Capacity Development		Career Advancement
		University Contribution to Center Research Infrastructure
Informing Policy	Wider Impacts	Effects on Medical or Healthcare Professional Education or Training
		Effects on Clinical or Administrative Policy
Health Outcomes and Healthcare Service Delivery		Adoption by Clinical Practitioners

The scoring scales devised for these first two indicators are shown in **Exhibit 49**. In constructing these scales, the range of responses for each indicator was examined and levels that would include at least one center for each score within the scale was created. Two conventions were observed. First, a score of 0 was reserved for those centers for which there was no evidence of the specific indicator, while a score of 5 represented the highest level of attainment by the MBIH research centers. And second, in order to obtain a single rating, a weighting scheme for the Research Targeting domain was developed in which the NIH research spin-off funding score was weighted twice as much as the score for the non-NIH funding sources because it was possible to verify the NIH research funds.

Exhibit 49. Scoring Scales for Research Targeting

NIH Research Spin-off Funding	
5	Center obtained more than $40 million in NIH research spin-off funding
4	Center obtained more than $30 million but less than $40 million in NIH research spin-off funding
3	Center obtained more than $10 million but less than $30 million in NIH research spin-off funding
2	Center obtained more than $5 million but less than $10 million in NIH research spin-off funding
1	Center obtained no more than $5 million in NIH research spin-off funding
0	No evidence of subsequent NIH research spin-off funding

Non-NIH Research Spin-off Funding Sources	
5	Center obtained research funding from 5 or more non-NIH sources
4	Center obtained research funding from 4 non-NIH sources
3	Center obtained research funding from 3 non-NIH sources
2	Center obtained research funding from 2 non-NIH sources
1	Center obtained research funding from 1 non-NIH source
0	No evidence of subsequent non-NIH research funding

Capacity development posed a similar challenge. **Exhibit 50** shows the scoring scales devised for these indicators. Two indicators were selected to represent this domain: career advancement (the number of graduate degrees earned, faculty promotions, and/or faculty recruitments) and host university contributions to center research infrastructure. Career advancement included three elements—graduate student degrees at the doctoral level, faculty promotions, and new faculty recruitments. In devising this

scale, the numbers of degrees, promotions and recruitments reported were examined and a simple gradient was developed to score on this indicator. In many cases, the MBIH center PIs were able to report the exact number for each of these; in others they used words such as 'several' or 'numerous.' Therefore, 'several' was defined as three or more, and 'numerous' as five or more.

Exhibit 50. Scoring Scales for Capacity Development

Career Advancement	
5	Center contributed to 5 or more graduate degrees, 5 or more faculty promotions AND/OR 5 or more faculty recruitments
4	Center contributed to 4 graduate degrees, 4 faculty promotions AND/OR 4 faculty recruitments
3	Center contributed to 3 graduate degrees, 3 faculty promotions AND/OR 3 faculty recruitments
2	Center contributed to 2 graduate degrees, 2 faculty promotions AND/OR 2 faculty recruitments
1	Center contributed to 1 graduate degree, 1 faculty promotion AND/OR 1 faculty recruitment
0	No evidence of Center contribution to career advancement

University Contribution to Center Research Infrastructure	
5	Host university built a new clinical and research center or new laboratory which houses the research center
4	Host university provided a seed grant or cost-sharing arrangement that enabled expansion of the Center's research activities
3	Host university provided the Center with its own cost code and budget line (independent of the grant)
2	Host university provided renovated office and/or lab space within an existing building for the Center's use
1	Host university provided financial coverage of up to one salaried position that enabled the Center to redirect its funds for other purposes
0	No evidence of host university contribution to Center research infrastructure

University Contributions to Center Research Infrastructure represents several types of possible contributions from the host university, including provision of newly renovated office and lab space for the use of MBIH center personnel, provision of a cost center and budget from indirect funds, appointment of the PI to an endowed chair within his or her department, provision of partial support for one or more faculty positions, and provision of pilot grant funds or other forms of center-related cost-sharing. This indicator proved the most difficult to score for two reasons. First, in some cases these contributions occurred at the time the center started (which would make it more similar to an input) while in others the contribution occurred in direct response to the activities and accomplishments of the center. Second, it was difficult to assess the monetary value of certain types of contributions. In combining them for a single Capacity Development score, they were weighted them equally.

For the third domain (informing policy) two indicators were also selected: effects on medical or healthcare professional education or training and informing administrative or clinical policy. These indicators were treated as conceptually separate because they reflected important types of benefits which were desirable to highlight.

Exhibit 51 shows the two scales developed for these indicators. As Exhibit 51 shows, higher scores were assigned to effects that occurred at a national or international level and lower scores at local or host university levels.

Exhibit 51. Scoring Scales for Informing Policy

Effects on Medical or Healthcare Professional Education and Training	
5	Center research findings have contributed substantively to the development of a new training program or curriculum that has been adopted by 5 or more institutions in the US or internationally
4	Center research findings have contributed substantively to the development of a new training program or curriculum that has been adopted by up to four (4) institutions in the US or internationally
3	Center research findings have been integrated into the course content for several courses in a medical or healthcare professional curriculum OR are being taught as part of a continuing education workshop that leads to certification
2	Center research findings have led to the development of a single course within an existing curriculum OR are offered for continuing education credits at a workshop
1	Center research findings have been presented in individual lectures or at Grand Rounds at medical or other health professional schools
0	No evidence of an effect on education or training

Effects on Administrative or Clinical Policy	
5	Research activities have contributed to clinical or administrative policy at a national or international level in at least two countries
4	Research activities have contributed to clinical or administrative policy at a national level in one country
3	Research activities have contributed to clinical or administrative policy at a state or regional level or at three or more institutions, but not at a national level
2	Research activities have contributed to administrative or clinical policy at a local level (city, neighborhood)
1	A claim for an effect on policy has been made, but there is no real evidence substantiating it, or an effect is expected but has not yet occurred
0	No evidence of an effect on administrative or clinical policy

The final domain for which a scoring scale was developed was the extent to which the research centers' findings or interventions were adopted by clinical practitioners. Some credit was given for research that identified important clinical risk factors that could be explored in future studies on the grounds that this represents a pre-intervention stage of development. Progressively greater credit was assigned for dissemination and practitioner uptake that extended beyond the host university setting. **Exhibit 52** shows the final scale for this domain.

Exhibit 52. Adoption by Clinical Practitioners

5	At least one treatment manual for an effective treatment intervention has been published and is distributed nationally
4	A treatment manual has been developed for an efficacious intervention but dissemination has been limited
3	Mind-body interventions are being used locally by clinicians who have attended Center lectures or participated in Center research activities
2	Research activities have identified important clinical risk factors that should be explored in future studies
1	A claim for an effect has been made but there is no evidence to support it
0	No evidence of adoption by clinical practitioners

5.1.9.2 Results of the Scoring Process for MBIH Research Centers

Three members of the Madrillon evaluation team individually scored each case on the seven indicators and then met to discuss their scores and specific instances where there were differences. The three members agreed on 86 of the 105 specific scores; for the remaining 19 specific scores, the members

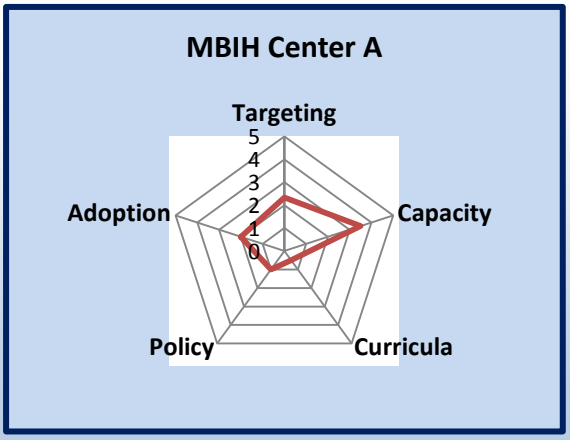
discussed their reasons for assigning the scores and reached a consensus. The scale prompting the greatest number of disagreements (5) was the University Contribution to Center Research Infrastructure. **Exhibit 53** shows the final scores for the seven indicators.

Exhibit 53. Final MBIH Center Scores on Indicators

Center	NIH Research Spin-Off Funding	Non-NIH Research Spin-Off Funding Sources	Career Advancement	University Contribution to Research Center Infra-Structure	Medical or Healthcare Professional Education & Training	Effects on Administrative or Clinical Policy	Adoption by Clinical Practitioners
A	3	1	5	2	.5	1	2
B	2	1	3	4	2	1	3
C	1	3	4	1	1.5	5	2
D	3	3	5	3	3	5	5
E	2	4	5	4	3	1	3
F	1	4	3	1	3	1	5
G	1	4	5	2	4	4	3
H	0	0	5	0	1	1	3
I	1	3	2	4	1	2	3
J	0	2	5	0	5	4	2
K	4	5	4	4	2	5	3
L	4	4	5	4	5	0	4
M	2	0	5	5	1	1	3
N	3	1	5	2	2.5	1	5
O	5	3	5	2.5	0	0	0

Exhibit 53 also emphasizes a second point—when multiple indicators are scored, presenting the results in tabular form may make it more difficult to perceive variations in scores for a center. In a payback report by HERG and RAND Europe (Wooding et al., 2005), the authors used a graphic display known as a radar-graph or spider-gram to display these scores. An example of a radar-graph is shown in **Exhibit 54**. The value of the radar-graph display is that it visually highlights the indicators on which a center scored higher or lower, thereby illustrating the major accomplishments of the MBIH centers. For example, based on these data, the biggest area of achievement for Center A has been the expansion of its research capacity. In large part, this was due to its performance in the area of career development. A second area of achievement was in research targeting. Both of these were primary outputs that represented academic impacts. It is interesting to note that the final end-state for Center A was that it evolved into a new research center. By contrast, Center J achieved less in terms of academic impacts, but clearly demonstrated several areas of wider impacts, including effects on policy and on medical curricula (see **Exhibit 55).** Based in part on these

Exhibit 54. Radar-graph for Center A



accomplishments, Center J was partially absorbed by a new cancer center on the campus of its host university.

Exhibit 56 provides a third example. In this example, the MBIH center did not continue beyond the conclusion of its MBIH funding; when the center grant ended, its investigators supported themselves from their own research grants. This center is an example in which primary outputs (research targeting and capacity development) were low and wider impacts (curricula, policy and adoption by clinical practitioners) were also low.

Radar-graphs for the remaining centers are displayed in **Appendix 2**.

Exhibit 55. Radar-graph for Center J

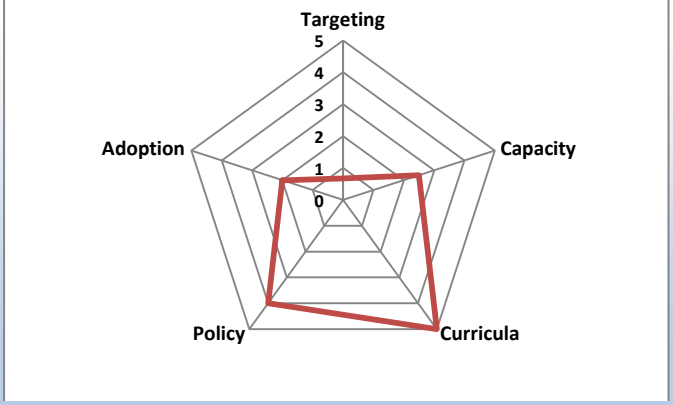
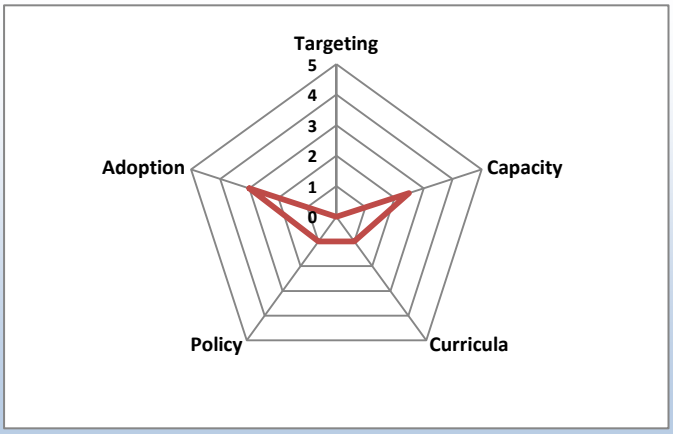


Exhibit 56. Radar-graph for Center H



5.2 Research Payback from the MBIH Research Projects

The second component of the MBIH Program consisted of the 44 investigator-initiated research projects. Some characteristic of these projects were presented earlier in sub-sections 3.2 and 3.3; this information is summarized in **Exhibit 57**. In addition to these data, 15 of the 44 projects (34 percent) received additional funding. In 13 cases, these funds were federal, and 7 of the 13 projects received ARRA stimulus funds. Three projects (including one of the federally supplemented projects) received additional funds from non-federal sources (e.g., intramural university funds). Twenty of the 44 projects (45 percent) involved a single university; the remainder included between two and seven universities.

Data on the research payback outputs and outcomes were gathered by means of semi-structured interviews conducted with each of the 41 PIs: all investigators agreed to be interviewed. For three PIs, the interview explored two research projects; for all others the interview covered one project.

The data in the following sub-sections are presented for the 44 research

Exhibit 57. Summary of MBIH Research Project Characteristics

- 44 research projects (42 R01s and 2 U01s) funded under three under three separate announcements;
- 15 projects were funded from the first announcement, 7 projects from the second announcement, and 22 projects from the third announcement;
- Total of 41 investigators at 30 institutions received MBIH research project funding;
- Awards ranged from $692,585 to $4,788,620;
- 25 PIs were affiliated with a research center at the time they were funded; 16 were not affiliated with a center; and
- 8 new PIs, 12 early-stage PIs, and 24 established PIs.
- 15 projects (34 percent) received some type of supplemental funding.
- 20 of the 44 projects (45 percent) were conducted by a single university; the other 55 percent were conducted by two or more universities.

projects as a group. In addition the 44 projects are compared on three variables. The first variable is center affiliation. Twenty-five PIs (57 percent) were affiliated with a research center when they received their MBIH funding; in three cases these centers were MBIH research centers, while the remaining 22 centers included cancer centers and a variety of NIH-funded research centers. Since center affiliation can confer a number of advantages, the effects of affiliation on the various Payback Framework outputs and outcomes were examined for these investigator-initiated projects.

The second variable is PI experience, which is classified as new, early-stage, and established. New PIs are those for whom the MBIH research grant is their first NIH-funded research project. Early-stage PIs are defined as individuals with at least one previous NIH research grant for whom fewer than ten years since receiving their highest academic degree (doctorate or medical) have elapsed. Established investigators are those with more than ten years since attaining their highest academic degree. It is anticipated that level of experience will influence investigators' motivations and activities in ways that may create differences across the three groups. For example, new investigators may be more highly motivated to publish more quickly than more established investigators.

The third variable concerns the timing of the grant funding. The 44 MBIH projects were funded under three separate announcements: OD-03-008 (15 projects); PA-05-027 (7 projects) and PA-07-046 (22 projects). Because many of the projects funded under the second and third announcements were not completed by the time of the interviews (April and May 2011), it is possible that some of the earlier projects would be more likely to produce some of the outputs and outcomes being examined. To investigate this variable as a potential check on project completion, projects were grouped in terms of whether they were funded during the first announcement (n=15) or during the second two announcements (n=29).

5.2.1 Research Projects—Knowledge Productivity (3.1 and 3.6)

Publications examined in this section were published through December 31, 2009. Eighteen MBIH research projects (41 percent) generated at least one publication (either research or non-research publications), and nine projects (20 percent) yielded at least one oral presentation. Seventeen projects reported at least one research publication. The total number of publications reported for the 18 research projects was 140, of which 129 articles (92 percent) were considered research articles and the remaining 11 articles were classified as non-research. For the 18 projects with at least one publication of either type, the number of total publications per project ranged from 1 to 29 articles. The distribution of the number of articles published was highly skewed; three projects generated 29, 23 and 22 articles respectively, accounting for more than half of the total number of articles.

Research publications, considered more prestigious than non-research publications, are focused on next. **Exhibit 58** compares this variable with center affiliation, PI experience, and timing of funding. Slightly fewer of the PIs who were affiliated with a research center reported one or more research publications versus those who were not affiliated (32 versus 47 percent), thus research center affiliation did not appear to influence research productivity in this instance. New PIs were more likely than early-stage or established investigators to report one or more research publications (63 percent versus 42 percent versus 29 percent). More than half (53 percent) of the investigators funded during the first round of MBIH research projects reported one or more research publications, versus 45 percent of those funded during the second or third funding rounds.

Exhibit 58. Research Projects with Research Publications by Center Affiliation, PI Experience, and Timing of Funding

Variable & Category		Projects With Research Publications			
		Any Res Pubs	No Res Pubs	Total	% Any
Center Affiliation	Affiliated	8	17	25	32%
	Not Affiliated	9	10	19	47%
	TOTAL	17	27	44	
PI Experience	New	5	3	8	63%
	Early	5	7	12	42%
	Established	7	17	24	29%
	TOTAL	17	27	44	
Timing of Funding	First Round	8	7	15	53%
	Second & Third Rounds	9	20	29	45%
	TOTAL	17	27	44	

5.2.2 Research Projects—Research Targeting (3.2)

The PIs were asked whether their projects had led to any new spin-off funding and if so, whether this funding was NIH or non-NIH. Information was not collected on how much research funding was received. Also, the evaluation team did we attempt to verify the reported NIH research spin-off grants as they did for the research centers.

Few PIs reported receiving funding from a non-NIH federal funding agency such as the Agency for Healthcare Research and Quality or the Department of Veterans Affairs. Based on the 44 research projects, a total of 19 projects (43 percent) obtained new NIH research spin-off funding. Twelve projects generated new non-federal research spin-off funds, of which seven projects also received federal spin-off funds. Therefore, a total of 24 projects received either NIH or non-federal research spin-off funds (56 percent).

The relationship of NIH research spin-off funding to center affiliation, PI experience, and funding round are shown in **Exhibit 59**. Center affiliation does not appear to affect the likelihood of obtaining NIH research spin-off funding; center-affiliated investigators' projects were slightly less likely to lead to NIH research spin-off funding than non-affiliated investigators (40 versus 47 percent). PI experience also did not seem to affect NIH research spin-off funding, with new investigators only slightly more likely than early-stage or established investigators to obtain additional NIH spin-off funding. Investigators with projects funded during the first round were more likely to obtain spin-off funding than those funded during the second or third funding rounds (60 versus 34 percent). This finding makes sense since a higher proportion of first found grantees would have completed their research projects than those funded more recently.

Exhibit 59. NIH Research Spin-off Grants and Center Affiliation, PI Experience, and Funding Round

Variable & Category		NIH Research Spin-Off Funding			
		Yes	No	Total	%
Center Affiliation	Affiliated	10	15	25	40%
	Not Affiliated	9	10	19	47%
	TOTAL	19	25	44	
PI Experience	New	4	4	8	50%
	Early Stage	5	7	12	42%
	Established	10	14	24	42%
	TOTAL	19	25	44	
Funding Round	First Round	9	6	15	60%
	Second & Third Round	10	19	29	34%
	TOTAL				

5.2.3 Research Projects—Capacity Development (3.2)

5.2.3.1 Career Development

Capacity development includes three areas—career development, new collaborations, and new tools and infrastructure. The MBIH investigator-initiated research projects provided an important avenue for career development for the PI and his or her research team. The PIs were asked about several aspects of career development, including: whether any graduate students earned advanced degrees (masters or doctorates), whether any faculty received promotions through their work on the projects, whether a member of the research team earned a special award or received recognition from the university or a professional group, and whether the project had led to recruitment of a new faculty member from outside the institution. A summary of findings for the 44 MBIH projects as a group is shown in **Exhibit 60**. All MBIH PIs reported that they mentored graduate students, post-doctoral fellows, and/or junior faculty as part of their research activities. In almost three-quarters of the projects, graduate students worked as research assistants and through their project work they completed dissertations or theses and earned (or were about to earn) advanced degrees. The MBIH projects also led to a high level of faculty promotions, particularly attainment of tenure. Almost ninety percent of the projects led to a faculty promotion for one or more members of the research team. In nearly one-half of the projects, a member of the research team (usually but not always the PI) received some form of special honor or recognition, either from the host university or from a professional association. MBIH projects were also instrumental in recruiting new faculty from outside the host university; almost one-third of the projects contributed substantially to the recruitment of new faculty

Exhibit 60. Career Development and the MBIH Research Projects

Indicator	Number of Projects (n=44)	% of Projects
Advanced degrees were earned	32	73%
Faculty promotions	39	89%
Special honors and awards	21	48%
New faculty recruitment	14	32%
Appointment to advisory groups, committees, task forces	18	41%

members. Finally, involvement in an MBIH research project frequently led to appointment to some form of advisory committee or group, or task force, either inside the host university or outside.

Affiliation with a research center may have contributed to some of these career advancement indicators, and the effect of center affiliation on three of these was investigated: promotions, new faculty recruitment, and special honors and awards (see **Exhibit 61**).

Exhibit 61. Effects of Center Affiliation on Faculty Promotions, Faculty Recruitment, and Special Honors and Awards

Center Affiliation	Faculty Promotions				Faculty Recruitment				Special Honors & Awards			
	Yes	No	Total	%	Yes	No	Total	%	Yes	No	Total	%
Affiliated	20	5	25	80%	7	18	25	72%	13	12	25	52%
Not Affiliated	19	--	19	100%	7	12	19	63%	8	11	19	42%
Total	39	5	44		14	30	44		21	23	44	

All of the projects conducted by investigators who were not affiliated with a research center led to a faculty promotion, compared with 80 percent of those conducted by investigators who were affiliated with a center. Research centers did have a small effect on faculty recruitments and special honors and awards since they were slightly higher among projects with investigators who were affiliated with a research center than among projects whose PI was not affiliated with a research center.

Stage in career (PI Experience) may also influence several career advancement indicators. **Exhibit 62** shows results from these analyses. PI experience did not have much effect on the likelihood of faculty promotion. The results for special honors and awards, and appointment to advisory committees and groups or task forces suggest that more established PIs were more likely than new investigators to receive these accolades.

Exhibit 62. Effects of PI Experience on Faculty Promotions, Faculty Recruitment, and Special Honors and Awards

PI Experience	Faculty Promotions				Special Honors & Awards				Appointment To Advisory Committees & Groups and Task Forces			
	Yes	No	Total	%	Yes	No	Total	%	Yes	No	Total	%
New	7	1	8	88%	3	5	8	38%	2	6	8	25%
Early Stage	10	2	12	83%	5	7	12	42%	4	8	12	33%
Established	22	2	24	92%	13	11	24	54%	12	12	24	50%
Total	39	5	44		21	23	44					

5.2.3.2 New Collaborations

The second avenue by which research projects can contribute to capacity development is through the formation of new collaborations. All but one of the MBIH project investigators reported forming new collaborations as a result of their work on their MBIH research project. **Exhibit 63** shows several types of new collaborations emerging from their MBIH research activities. The most common type of new collaboration was with other researchers from one's own university, which was reported in 73 percent of the projects. New collaborations with researchers from other academic institutions were almost as frequent (64 percent). These new collaborations were about equally as likely to occur in projects conducted at a single university as in projects involving multiple universities. New collaborations with researchers at other academic institutions were more likely to occur in projects where the investigator was not affiliated with a research center (79 percent) than projects where the investigator was affiliated with a research center, and more likely to occur when the investigator was new (63 percent) or early stage (83 percent) than established (54 percent). Thirty percent of the projects led to new collaborations with community organizations, while 18 percent led to new research collaborations with national organizations. Two projects resulted in new international collaborations.

Exhibit 63. Types of New Collaborations Resulting from MBIH Research Projects

New Collaborations With Others From:	Projects Reporting (n=44)	
	Number	Percent
Host Institution	32	73%
Other Academic Institutions	28	64%
Community Organizations	13	30%
National Organizations	8	18%
International Institutions	2	5%

5.2.3.3 New Research Tools and Methods and Research Infrastructure

The third avenue for the development of research capacity is the creation of new research tools and methods and new research infrastructure through project activities. These can include the development of new scales or tests, statistical methods or analytic approaches, animal models, or the purchase or construction of new equipment or facilities that will be available for others to use after the project has concluded. Investigators from 31 projects (70 percent) reported developing new research tools, instruments, methods, models, or measures through their MBIH research activities. In all of these cases, PIs reported that the new tools were being used internally by others within their host university; moreover, in 52 percent of these cases, the new tools were also being used by other researchers outside the host university. Investigators affiliated with a research center were somewhat more likely than those not affiliated with a research center to report the development of new tools or instruments, and also more likely to report that the new tools or instruments were being used by others outside their host institution (48 percent versus 26 percent).

Slightly more than half of the projects (52 percent) led to the purchasing or creation of new research infrastructure. In many instances, the type of research infrastructure was small and represented purchases of new equipment such as refrigerators for specimen storage, or specialized equipment for conducting assays or other biologic tests.

5.2.4 Research Projects—Informing Clinical and Administrative Policy and Product Development (3.3)

In the semi-structured interviews with the Research Project PIs, three indicators were investigated for this research benefit category: influencing clinical or administrative policy, influencing medical or healthcare professional curricula, and informing product development. Fifteen of the 44 projects (34 percent) resulted in some form of influence on clinical or administrative policy, 18 projects (41 percent) led to influence on medical or healthcare curricula, and 11 of the projects (25 percent) led to new product development. Each of these indicators is described in further detail below.

Exhibit 64 shows several examples of the types of influences MBIH research projects have had on administrative and clinical policies. Several projects have led to inclusion as supporting research for national organizations' position papers. In two other cases, research findings are influencing training standards and diagnostic criteria. In contrast to the effects from the MBIH research centers, eight projects described effects at the local (community) level, where the collaboration of community organizations with the researcher has led to new policy directions and adoption of research findings in local programs. One project PI described changes in policies within a local cancer center that resulted from the PI's research activities. These examples suggest two differences between the types of effects on policy from research centers and research projects. First, MBIH research centers had a number of effects on administrative policy formulation and direction, while the types of effects reported by research project PI's tended to be more clinical in nature. Second, more of the effects reported by the research project PIs tended to occur at the local community level which did not seem to be the case for the research centers.

Exhibit 64. Examples of Effects on Clinical and Administrative Policies

National Level:

- PI's research on effects of ecological factors in heart disease has been cited in several major position papers by the American Heart Association;
- PI's research on adherence to medication regimens in HIV/AIDS demonstrated that a broad drug company strategy of higher doses in fewer pills not only made no difference to patient adherence, but actually led to increased incidence of side effects and drug resistance for some patients; recommendations against this practice have now been included in CDC prevention guidelines; and
- PI's research findings on clinical hypnosis have been incorporated into the American Society for Clinical Hypnosis training standards and guidelines.

Local/Community Level:

- Several community organizations involved with family caregivers of persons with Alzheimer's disease are incorporating PI's research into their activities;
- Several community organizations that collaborated with PI's research have decided to focus on reducing minority health disparities; a local church secured a grant from the American Cancer Society to this end.

A second trend is evident from consideration of the effects of the MBIH research projects on medical and healthcare curricula and training. The 18 PIs who reported effects on medical and healthcare curricula described inclusion of their findings in courses offered at their host universities, or in continuing education workshops that were conducted locally or regionally, rather than nationally. PIs who were affiliated with research centers were more likely to report these effects than PIs who were not affiliated with research centers (48 percent versus 31 percent).

The Payback Framework includes the effects of research on the development of new products as part of the Informing Policy and product Development category. New product development differs from the development of new research tools or methods or the creation of new infrastructure in that new product development is commercially oriented. As noted earlier, 11 of the 44 projects reported that their research was leading to new product development. Some examples of these new products are listed in **Exhibit 65**. In several examples, the PI is currently developing a *Small-Business Innovation Research (SBIR)* grant application to continue development and testing of the new product. Patent applications have been filed for several of these new products.

5.2.5 Research Projects—Effects on Health Outcomes and Healthcare Service Delivery (3.4)

Three indicators were examined for this fourth category of research benefits: effects on clinical practice or provider behavior, effects on health outcomes and quality of life, and changes in healthcare service delivery systems. Twenty-three of the 44 MBIH research project PIs (52 percent) reported some effects on clinical practice or provider behavior. Twenty-one PIs' (48 percent) reported some effects on health outcomes and quality of life, and five PIs (11 percent) reported changes in healthcare service delivery. Effects on clinical practice or provider behavior ranged from identification of important new

risk factors that clinical practitioners could now address through further research and in practice (e.g., depression in heart disease, ecological factors, and diabetes management), the packaging and dissemination of effective treatment interventions (with treatment manuals and relevant educational and instructional materials) that can be used in practice settings, and actual changes in provider behavior (use of cognitive screening in heart rehabilitation, and discussions with patients about relevant psychosocial factors that might affect the management of chronic illnesses such as diabetes and stroke. These effects were reported more often by PIs who were not affiliated with research centers versus those who were (63 percent versus 44 percent), and were particularly associated with projects that involved cancer or heart disease. Improvements in health outcomes or quality of life were slightly more likely to be reported by PIs affiliated with research centers than those who were not (52 percent versus 42 percent). Changes in healthcare service delivery were rare, and usually involved adoption of screening protocols in local clinics or cancer centers, or provision of certain mind-body interventions.

Exhibit 65. Examples of New Product Development

- A smart-phone enabled heart-rate monitor;
- A smart-phone application for measurement of stress levels and stress reduction;
- Technology that has been shown to be effective in detecting placebo response;
- Hardware and software for a computer application for measurement of medication adherence;
- Computer application for a memory impairment test;
- Laptop diary software for use by older research participants for data collection; and
- Tai-chi instructional package (trademarked and registered to the university).

5.2.6 Research Projects—Broader Economic and Social Impacts (3.5)

Four of the 44 MBIH research project PIs reported broader economic and social effects from their projects. While measurable economic and social effects are not yet evident from these four projects, a plausible argument can be made for each of them. The first case involved a controlled trial of a mindfulness-based cognitive therapy intervention for individuals with treatment-resistant depression. The trial demonstrated the efficacy of the intervention over a pharmacotherapy control group. Based on the data from the study, the PI argued that there should be a trend toward less relapse and more rapid return to full function and resumption of work. This would yield economic and social benefits to the larger society.

A second project involved a clinical trial of mindfulness-based stress reduction in women. The trial was listed on clinicaltrials.gov, a national website. Based upon publications from the study and its listing on the website, the PI has received telephone calls from women from across the country who are interested in taking part in a mindfulness-based stress reduction program and are looking for available opportunities in their communities. The PI noted that women are assuming greater control and responsibility for their health, and that interventions such as this that can promote greater health and well-being are seen by some women as empowering.

A third project which examined behavioral and social factors affecting health received considerable publicity within its local metropolitan region. As a result of the findings and the interest the study generated, a broad-based community coalition of organizations and individuals formed a non-profit organization to pursue better health for their region by acting upon findings from this and similar studies. The non-profit has been successful in launching several ongoing initiatives.

A fourth project involved the development and evaluation of a clinical hypnosis intervention for women with hot flashes. The intervention, which is designed to be provided in an inexpensive, four-session format by nurses, represents a low-cost and effective alternative to hormonal replacement therapy and is generating considerable interest. By reducing the costs and avoiding complications and side-effects that could result from hormonal replacement therapy, considerable societal economic benefit is possible.

5.3 Comparing the Payback Framework Results for the MBIH Research Centers and Projects

Sections 5.1 and 5.2 examined whether and to what extent the MBIH Program research centers and research projects produced benefits across the five Payback Framework benefit categories. In this first application of the framework in an evaluation of a biomedical research program in the US, the results from sections 5.1 and 5.2 show that the MBIH Program as a whole and each of its two major components (the research centers and the investigator-initiated research projects) produced benefits across all of the five benefit categories in the framework. In this section, several findings that emerge from comparing the two program components are provided. **Exhibit 66** provides a summary by benefit category for the MBIH research centers and investigator-initiated research projects.

Exhibit 66. Summary of Research Payback Framework Benefits and Indicators for MBIH Centers & Projects

Research Payback Framework Benefit Categories	MBIH Research Centers (n=15)	MBIH Research Projects (n=44)
KNOWLEDGE PRODUCTIVITY		
Number of total publications	429	140
Number of research publications	336	129
Percentage with one or more research publications	93%	39%
RESEARCH TARGETING & CAPACITY DEVELOPMENT		
Percentage with one or more NIH research spin-off grants	87%	43%
Percentage with non-NIH research spin-off funding	87%	27%
Percentage in which graduate students earned advanced degrees	53%	73%
Percentage in which one or more faculty received promotions	53%	89%
Percentage in which one or more new faculty were recruited	60%	32%
Percentage which led to new collaborations with researchers from host university	100%	73%
New collaborations researchers from other academic institutions	73%	64%
New collaborations with national organizations	27%	18%
New collaborations in local community	20%	30%
New international collaborations	47%	5%
New research tools, instruments, methods and measures	73%	70%
New research infrastructure	67%	52%
INFORMING POLICY & NEW PRODUCT DEVELOPMENT		
Influenced clinical or administrative policy	60%	34%
Influenced medical or healthcare professional education or training	93%	41%
Contributed to clinical guideline development	40%	
Contributed to new product development	33%	25%
HEALTH OUTCOMES & HEALTHCARE SERVICE DELIVERY		
Adoption by clinical practitioners and the public	60%	
Influenced health outcomes and quality of life	53%	48%
Changes in healthcare service delivery	60%	11%
BROADER ECONOMIC & SOCIAL BENEFITS		
Percentage claiming effect on broader economic and social benefits	36%	9%

First, it is important to emphasize that both program components produced benefits in all of the five categories. These include both the academic impact categories (knowledge productivity and research targeting and capacity development) and the wider impacts (effects on policy formulation and development, health outcomes, and broader economic and social impacts). As noted earlier, achievements in the academic impact categories are important because they contribute to building a research community and strengthening its capacity to continue to conduct research in the future. While both program components were expected to demonstrate strong levels of achievement in terms of these academic impacts, the degree to which each component produced benefits in the wider impacts categories was impressive. Prior evaluations of NIH research programs frequently do not include the wider impact categories examined here. One major reason for this omission is that it may take many years for the full effects of biomedical research programs to emerge. While this may also hold true for the MBIH Program, evidence of some effects in each of these categories has been found.

Within the wider impact benefit categories, the MBIH research centers have tended to produce greater effects at the national and/or international levels, while the research projects have tended to produce more effects at the community level. Several factors could contribute to this result. Research centers may have a greater number of connections at the national or international levels than individual research projects. Research centers may engage in activities that are broader in scope than those of individual research projects. Many of the research projects are still under way, and their results may yet lead to more national or international effects by the time they are completed.

As discussed earlier, research centers confer several advantages for investigators who are affiliated with them such as access to a larger, interdisciplinary group of research colleagues with common research interests in a given field or problem area; access to research core services that can provide expertise and technical infrastructure that an individual investigator may not be able to obtain on his or her own; and a synergy that results from these elements that can stimulate creativity and innovation to a greater extent than an individual unaffiliated investigator may be able to find. The 44 MBIH research projects were divided into projects led by an investigator who was affiliated with a research center (n=25) and projects led by investigators who were unaffiliated with research centers (n=19), to examine whether center affiliation actually influenced some of the academic and wider impacts in the Payback Framework. It is important to note that only three of the 25 research projects were conducted within MBIH research centers; thus this comparison does not reveal anything about the effects of the MBIH centers on the academic impact indicators examined. These results are summarized in **Exhibit 67**.

For the five indicators of academic impacts examined, investigators who were affiliated with research centers reported a slightly greater proportion of new faculty recruitments and special honors and awards than unaffiliated investigators. On the other hand, unaffiliated investigators reported a slightly higher proportion of projects resulting in research publications, NIH research spin-off funding, and faculty promotions than affiliated investigators.

Exhibit 68 compares results from the current study with those from four other Research Payback studies conducted in England (Buxton et al., 1999; Hanney et al., 2007), Hong Kong (Kwan et al. 2007) and Australia (Kalucy et al., 2009).

Exhibit 67. Summary of Effects of Center Affiliation on Academic Impacts

Academic Impact Indicators	Affiliated With a Center (n=25)	Not Affiliated With a Center (n=19)
Projects with research publications	32%	47%
Projects with NIH research spin-off funding	40%	47%
Projects leading to faculty promotions	80%	100%
Projects leading to faculty recruitment	72%	63%
Projects leading to special awards and honors	52%	42%

Exhibit 68. Comparison of Payback Framework Results for the MBIH Program with Other Research Payback Studies

Indicator	MBIH Program	Buxton et al. (1999)	Hanney et al. (2007)	Kwan et al. (2007)	Kalucy et al. (2009)
Sample	Mind-body research centers and projects	Health service and mental health projects funded by North Thames NHS	Projects from the NHS Health Technology Assessment Program	Health and health services research fund projects	Primary health care research projects
Methods	Semi--structured interview	Questionnaire	Questionnaire	Questionnaire	On-line Questionnaire
Sample Size and Response Rate	15 Center PIs; 44 Project PIs; 100% response rate	115 projects 70% response rate	204 projects 65% response rate	187 projects 87% response rate	17 projects 29% response rate
Knowledge Productivity Peer-reviewed publications	93% of centers had research pubs 39% of projects had research pubs;	47% of projects resulted in journal articles	73% of projects resulted in journal publications or books	70.8% of projects had peer-reviewed publications	76% of projects had journal articles
Research Targeting & Capacity Develop-ment Research spin-off grants	87% of centers had one or more NIH spin-off grants; 43% of projects had one or more NIH spin-off grants	>66%	46% led to further funding	44.9% led to further funding	64% led to further funding
Graduate degrees	53% of centers led to graduate degrees 73% of projects led to graduate degrees	>25% of projects led to graduate degrees	21% led to graduate degrees	38.2% of projects led to post-graduate degrees	58% of projects led to at least 1 PhD
Informing Policy & Product Development Influenced policy making	60% of centers influenced policy 34% of projects influenced policy	35.6% influenced policy	73% influenced policy		23% influenced policy
Influenced medical or healthcare curricula	93% of centers influenced curricula 41% of projects influenced curricula				52% influenced medical or healthcare curricula
New product development	33% of centers 25% of projects				11% of projects

Indicator	MBIH Program	Buxton et al. (1999)	Hanney et al. (2007)	Kwan et al. (2007)	Kalucy et al. (2009)
Health Outcomes & Healthcare Service Delivery: Used in Clinical Practice	60% of centers		42% of projects	42% had at least one impact over these indictors	41% of projects
Led to improved health outcomes	53% of centers 48% of projects				
Led to changes in service delivery	60% of centers 11% of projects				41% of projects
Broader Economic and Social Impacts	36% of centers 9% of projects				5% of projects

Buxton et al. (1999) was a study conducted by the Health Economics Research Group for the National Health Service in England. It investigated the payback from health and mental health research projects funded by the North Thames Research and Development Centre. Hanney et al. (2007) describes the results of an evaluation of the NHS Health Technology Assessment Program. Kwan et al. (2007) was one of the earliest independent applications of the payback framework, and describes an evaluation of the Health and Health Services Research Fund of Hong Kong. Kalucy et al. (2009) describes the final results from an evaluation of primary health care research in Australia.

The 44 MBIH research projects produced results across all five benefit categories that were at least comparable to or in some cases greater than those produced by the four earlier payback studies. On four indicators, the MBIH projects actually exceed the results from these other studies; the indicators included the proportion of projects leading to graduate degrees (Research Targeting and Capacity Development); the proportion of projects leading to new product development (Informing Policy and Product Development); the proportion of projects leading to improved health outcomes (Health Outcomes and Healthcare Service Delivery); and Broader Economic and Social Impacts. The latter three indicators are considered wider impacts. When the results from the MBIH research centers are compared with these other studies, the centers exhibited stronger performance on most of the indicators and in most benefit categories than the projects examined in the other four studies.

6. Growth of the Mind-Body Research Field and MBIH Program Contributions to It

Evaluation Question 4 asks "How has the field of mind-body research grown over time and what contributions have the MBIH investigators made to it?" In order to answer this question, it is necessary to characterize mind-body research in general and research conducted by the MBIH program in particular.

6.1 MBIH Bibliometric Analysis Methods

Research publications were selected as the research outputs to be examined. Researchers have utilized a number of methods for assigning scientific disciplines to research articles. After investigation of the options, the methodology of Porter and Rafols (2009) which utilizes the Thompson Reuters Web of Science (WoS) as the primary data source was employed. The WoS, which contains over 10,000 journals, provides substantial coverage of science, medicine and engineering and categorizes research areas into Subject Categories (SCs) that correspond to disciplines. Although the bibliometric community has noted some weaknesses, the SCs offer the most widely available categorization resource available. In this method categorization of articles is based upon the SC (or SCs[5]) into which the WoS places the journal in which the article was published rather than individual article content analysis.

Each of the 640 MBIH publications (527 research publications and 113 non-research publications) identified from the e-SPA MBIH portfolios discussed in Section 2.6.5 was assigned to one or more SCs based on the journal in which it was published. A total of 272 articles were published in journals classified to more than one SC. Based on decision rules developed by the research team, two team members independently reviewed the titles and abstracts of the articles and, if necessary, the full text of the articles, and placed each article in a single category. Both team members agreed on the categorization of 177 articles. The remaining articles were discussed and a consensus reached regarding the SC to be assigned to each article. The decision rules for coding were then revised to reflect the discussion. To examine changes over time in the SCs of MBIH research papers, WoS SCs were tabulated for two time periods—2000-2004 and 2005-2009. Small numbers per SC precluded an analysis by single years. The total number of MBIH articles as well as the numbers of research and non-research articles by WoS SC for the time periods 2000-2004 and 2005-2009 are shown in **Exhibit 69**.

Exhibit 69. Number of Total MBIH Articles, Research and Non-Research Articles by Web of Science (WoS) Subject Category (SC) by Time Period (2000-2004 and 2005-2009) with Duplicate Articles Removed[6]

Selected WoS Category	Total Appearances 2000-2004	Total Appearances 2000-2004 Research Articles	Total Appearances 2000-2004 Non-Research Articles	Total Appearances 2005-2009	Total Appearances 2005-2009 Research Articles	Total Appearances 2005-2009 Non-Research Articles
Behavioral Sciences	2	1	1	2	2	-
Biochemistry and Molecular Biology	-	-	-	3	3	-
Biology	2	1	1	1	1	-

[5] In 2010, approximately 43% of journals were categorized into more than one SC.
[6] There were no duplicate articles for 2000-2004 and 39 duplicate articles for 2005-2009.

Selected WoS Category	Total Appearances 2000-2004	Total Appearances 2000-2004 Research Articles	Total Appearances 2000-2004 Non-Research Articles	Total Appearances 2005-2009	Total Appearances 2005-2009 Research Articles	Total Appearances 2005-2009 Non-Research Articles
Cardiac and Cardiovascular System	2	2	-	25	18	7
Cell Biology	2	2	-	-	-	-
Chemistry, Medicinal	-	-	-	1	-	1
Clinical Neurology	-	-	-	17	13	4
Endocrinology and Metabolism	4	4	-	13	9	4
Family Studies	-	-	-	1	1	-
Gastroenterology and Hepatology	1	1	-	46	32	14
Genetics and Heredity	-	-	-	2	2	-
Geriatrics and Gerontology	7	5	2	20	15	5
Health Care Sciences and Services	-	-	-	5	3	2
Health Policy and Services	-	-	-	1	1	-
Immunology	13	10	3	20	19	1
Integrative and Complementary Medicine	-	-	-	3	3	-
Mathematics and Computational Biology	-	-	-	3	3	-
Medical Laboratory Technology	-	-	-	1	1	-
Medicine, General and Internal	3	3	-	26	18	8
Medicine, Research and Experimental	-	-	-	2	2	-
Multidisciplinary Sciences	3	3	-	4	4	-
Neuroimaging	-	-	-	8	5	3
Neurosciences	9	6	3	33	27	6
Nursing	-	-	-	1	1	-
Nutrition and Dietetics	-	-	-	2	2	-
Obstetrics and Gynecology	-	-	-	5	4	1
Oncology	4	2	2	31	28	3
Ophthalmology	-	-	-	1	1	-
Pediatrics	-	-	-	4	4	-
Peripheral Vascular Disease	3	3	-	29	28	1
Pharmacology and Pharmacy	-	-	-	8	4	4
Physiology	1	1	-	4	3	1
Psychiatry	3	2	1	32	28	4
Psychology	31	27	4	56	52	4

Selected WoS Category	Total Appearances 2000-2004	Total Appearances 2000-2004 Research Articles	Total Appearances 2000-2004 Non-Research Articles	Total Appearances 2005-2009	Total Appearances 2005-2009 Research Articles	Total Appearances 2005-2009 Non-Research Articles
Psychology, Clinical	1	1	-	20	19	1
Psychology, Developmental	2	2	-	2	1	1
Psychology, Experimental	1	1	-	3	3	-
Psychology, Multidisciplinary	7	6	1	14	11	3
Psychology, Social	7	7	-	15	13	2
Public, Environmental, and Occupational Health	7	4	3	32	27	5
Rehabilitation	1	1	-	5	5	-
Respiratory System	-	-	-	1	1	-
Rheumatology	-	-	-	1	1	-
Social Sciences	1	1	-	-	-	-
Social Sciences, Biomedical	-	-	-	4	4	-
Social Work	-	-	-	1	-	1
Statistics and Probability	-	-	-	2	2	-
Substance Abuse	-	-	-	2	2	-
Surgery	2	1	1	1	1	-
Urology and Nephrology	1	1	-	6	5	1
Virology			-	1	1	-
Zoology	1	1	-	-	-	-
Total Number of Articles (excluding duplicates)	121	99	22	519	428	91

The MBIH publications represent 52 of the SCs being utilized in 2010. The top 10 WoS SCs by number and percent of articles for 2000-2004 and 2005-2009 are shown in **Exhibit 70**. It should be noted that in the exhibit, the Psychology category is actually an aggregate category which includes the WoS SCs of Psychology; Psychology, Clinical; Psychology, Developmental; Psychology, Multidisciplinary; and Psychology, Social.

Exhibit 70. Top10 WoS Categories by Number of Articles, Percent of Articles and Time Period (2000-2004 and 2005-2009)

WoS Categories 2000-2004	Number of articles (percent)	WoS Categories 2005-2009	Number of articles (percent)
Psychology[7]	49 (40.4%)	Psychology	110 (21.2%)
Immunology	13 (10.7%)	Gastroenterology and Hepatology	46 (8.8%)
Neurosciences	9 (7.4%)	Neurosciences	33 (6.4%)
Geriatrics and Gerontology	7 (5.8%)	Public, Environmental, and Occupational Health	32 (6.2%)
Public, Environmental, and Occupational Health	7 (5.8%)	Psychiatry	32 (6.2%)
Endocrinology and Metabolism	4 (3.3%)	Oncology	31 (6.0%)
Oncology	4 (3.3%)	Peripheral Vascular Disease	29 (5.6%)
Medicine, General and Internal	3 (2.5%)	Medicine, General and Internal	26 (5.0%)
Peripheral Vascular Disease	3 (2.5%)	Cardiac and Cardiovascular System	25 (4.8%)
Psychiatry	3 (2.5%)	Geriatrics and Gerontology	20 (3.9%)

The large number of SCs and the small number of articles per SC make it difficult to assess changes in the direction of MBIH science over time. Porter and Rafols (2009) have developed a methodology for consolidating the narrow research areas of the SCs into larger categories which they call "macro-disciplines." They base their grouping of SCs on Principal Components Analysis—a type of factor analysis. Utilizing this methodology, the authors placed 221 SCs in 18 macro-disciplines. The WoS SCs and macro-disciplines of the 527 MBIH research articles are shown in **Exhibit 71**.

Exhibit 71. Selected Web of Science (WoS) Subject Categories (SCs) and Macro-Disciplines for the 527 MBIH Research Articles

Selected Web of Science Subject Category	Macro-discipline (Porter & Rafols)	Alternative Macro-discipline (Madrillon)	Number of Articles
Behavioral Sciences	Cognitive Sciences	Cognitive Sciences	3
Biochemistry & Molecular Biology	Biomedical Sciences	Biomedical Sciences	3
Biology	Biomedical Sciences	Biomedical Sciences	2
Cardiac and Cardiovascular System	Clinical Medicine	Clinical Medicine	19
Cell Biology	Biomedical Sciences	Biomedical Sciences	2
Clinical Neurology	Cognitive Sciences	Clinical Medicine	13
Endocrinology and Metabolism	Biomedical Sciences	Clinical Medicine	13
Family Studies	Social Studies	Psychology	1
Gastroenterology & Hepatology	Clinical Medicine	Clinical Medicine	33
Genetics and Heredity	Biomedical Sciences	Biomedical Sciences	2
Geriatrics and Gerontology	Cognitive Sciences	Clinical Medicine	20
Health Care Sciences and Services	Health Issues	Health Issues	3
Health Policy and Services	Health Issues	Health Issues	1

[7] For both time periods, the Psychology category includes the WoS categories Psychology; Psychology, Clinical; Psychology, Developmental; Psychology, Multidisciplinary; and Psychology, Social.

Selected Web of Science Subject Category	Macro-discipline (Porter & Rafols)	Alternative Macro-discipline (Madrillon)	Number of Articles
Immunology	Infectious Diseases	Infectious Diseases	29
Integrative and Complementary Medicine	Agricultural Sciences	Clinical Medicine	3
Mathematics and Computational Biology	Biomedical Sciences	Biomedical Sciences	3
Medical Laboratory Technology	Biomedical Sciences	Biomedical Sciences	1
Medicine, General and Internal	Clinical medicine	Clinical Medicine	21
Medicine, Research and Experimental	Biomedical Sciences	Biomedical Sciences	2
Multidisciplinary Sciences	Biomedical Sciences	Biomedical Sciences	7
Neuroimaging	Cognitive Sciences	Cognitive Sciences	5
Neurosciences	Cognitive Sciences	Cognitive Sciences	33
Nursing	Health Issues	Clinical Medicine	1
Nutrition and Dietetics	Agricultural Sciences	Health Issues	2
Obstetrics and Gynecology	Biomedical Sciences	Clinical Medicine	4
Oncology	Biomedical Sciences	Clinical Medicine	29
Opthalmology	Cognitive Sciences	Clinical Medicine	1
Pediatrics	Clinical Medicine	Clinical Medicine	4
Peripheral Vascular Disease	Clinical Medicine	Clinical Medicine	29
Pharmacology and Pharmacy	Biomedical Sciences	Biomedical Sciences	4
Physiology	Biomedical Sciences	Biomedical Sciences	4
Psychiatry	Cognitive Sciences	Cognitive Sciences	30
Psychology	Cognitive Sciences	Psychology	79
Psychology, Clinical	Psychology	Psychology	19
Psychology, Developmental	Psychology	Psychology	3
Psychology, Experimental	Psychology	Psychology	4
Psychology, Multidisciplinary	Psychology	Psychology	17
Psychology, Social	Psychology	Psychology	20
Public, Environmental and Occupational Health	Health Issues	Health Issues	31
Rehabilitation	Cognitive Sciences	Clinical Medicine	6
Respiratory System	Clinical Medicine	Clinical Medicine	1
Rheumatology	Clinical Medicine	Clinical Medicine	1
Social Sciences	Health Issues	Health Issues	1
Social Sciences, Biomedical	Health Issues	Health Issues	4
Statistics and Probability	Engineering	Health Issues	2
Substance Abuse	Cognitive Sciences	Clinical Medicine	2
Surgery	Clinical Medicine	Clinical Medicine	2
Urology and Nephrology	Clinical Medicine	Clinical Medicine	6
Virology	Infectious Diseases	Infectious Diseases	1
Zoology	Ecological Sciences	Biomedical Sciences	1

For the most part the assignments of SCs to macro-disciplines corresponded to those of Porter and Rafols; however slight modifications were made. Following an initial mapping of the 18 Porter and Rafols macro-disciplines to the SCs of the MBIH articles, it was found that the 527 articles fell into 10 of the 18 macro-disciplines; however, many of these macro-disciplines contained only a few articles (i.e., fewer than 10), and some of the classifications seemed unsuitable for this project (for example, the SC of Psychology was classified as Cognitive Science, while the categories of Psychology sub-specialties such as Clinical Psychology and Developmental Psychology were classified under Psychology). Therefore the 18 mega-disciplines identified by Porter and Rafols were utilized but some of the problematic SCs were assigned to different macro- disciplines. This revised macro-discipline categorization schema yielded a total of six macro-disciplines each with at least 30 articles which provides a better classification approach for the purposes of the MBIH project. The six macro-disciplines, the number of MBIH articles in each macro-discipline and the SCs included in the macro-discipline are shown in **Exhibit 72.**

Exhibit 72. Macro-disciplines, Number of Articles and WoS Subject Categories by Macro-disciplines for the 527 MBIH Research Articles

Macro-Discipline	Number of Articles in Macro-discipline	WoS Subject Categories (SCs)
Biomedical Sciences	31	Biochemistry & Molecular Biology
		Biology
		Cell Biology
		Genetics and Heredity
		Mathematics and Computational Biology
		Medical Laboratory Technology
		Medicine, Research and Experimental
		Multidisciplinary Sciences
		Pharmacology and Pharmacy
		Physiology
		Zoology
Clinical Medicine	208	Cardiac and Cardiovascular System
		Clinical Neurology
		Endocrinology and Metabolism
		Gastroenterology & Hepatology
		Geriatrics and Gerontology
		Integrative and Complementary Medicine
		Medicine, General and Internal
		Nursing
		Obstetrics and Gynecology
		Oncology
		Ophthalmology
		Pediatrics
		Peripheral Vascular Disease
		Rehabilitation
		Respiratory System
		Rheumatology
		Substance Abuse

Macro-Discipline	Number of Articles in Macro-discipline	WoS Subject Categories (SCs)
		Surgery
		Urology and Nephrology
Cognitive Sciences	71	Behavioral Sciences
		Neuroimaging
		Neurosciences
		Psychiatry
Health Issues	44	Health Care Sciences and Services
		Health Policy and Services
		Nutrition and Dietetics
		Public, Environmental and Occupational Health
		Social Sciences
		Social Sciences, Biomedical
		Statistics and Probability
Infectious Diseases	30	Immunology
		Virology
Psychology	143	Family Studies
		Psychology
		Psychology, Clinical
		Psychology, Developmental
		Psychology, Experimental
		Psychology, Multidisciplinary
		Psychology, Social

At the August 25, 2010 meeting of the MBIH Evaluation Advisory Committee, Committee members recommended that general mind-body literature searches be performed in order to be able to place the scientific areas addressed by the MBIH Program in a broader context. It was agreed that an examination of review articles of mind-body research over the same time period (1999-2009) would meet this need. Therefore a Scopus search was performed for review articles on mind-body interactions and health research from 1999-2009 which yielded 1,438 articles. After removal of articles not published in English, 1,274 review articles remained. Scopus (now called SciVerse Scopus) was selected because is the world's largest abstract and citation database of peer-reviewed literature and quality web sources. In addition to providing 100% Medline (PubMed) coverage, Scopus provides broader coverage of the social sciences often included in mind-body research. Following removal of articles beyond the scope of mind-body research (e.g. archeology) or which were not review articles (despite that being one of the search criteria), 694 articles remained. The process of ascertaining the WoS SCs for each journal in which the review articles were published was then completed. Although the Web of Science and its parent database the Web of Knowledge are quite inclusive, some journals in which the review articles were published were not listed and thus not assigned to WoS SCs. Staff members at Thompson Reuters Web of Knowledge were consulted to insure that the list of journals was as complete as possible. Journals not listed were assigned to WoS SCs based on their subject-matter similarity to journals included in the Web of Knowledge. Utilizing the previously described methodology, each of the 694 Scopus review articles was assigned to one of 18 Macro-disciplines based on its WoS SC. The Thompson Reuters Web of Knowledge list of WoS SCs is updated every year and new categories are often created. Examples of new

WoS categories created after Porter and Rafols produced their mapping of WoS categories onto macro-disciplines include "Cell and Tissue Engineering" and "Primary Health Care." New WoS categories were placed in Macro-disciplines containing the WoS categories most similar. Thus "Cell and Tissue Engineering" was placed in the macro-discipline "Biomedical Sciences" and "Primary Health Care" was placed in "Clinical Medicine."

The 694 Scopus review articles and the 527 research articles in the MBIH portfolio were then compared. In theory the WoS SCs encompassed by the Scopus review articles would represent the "universe" of mind-body research. In practice this was not quite the case: there were seven WoS SCs to which 16 MBIH research articles were coded but no Scopus review articles were coded. On the other hand, the "universe" was quite broad; there were 29 WoS SCs to which 74 Scopus review articles were coded but no MBIH articles were coded. The WoS categories in each macro-discipline and the numbers of Scopus review articles and MBIH research articles in each macro-discipline are shown in **Exhibit 73.**

Exhibit 73. WoS Categories in Each Macro-Discipline and the Number of Scopus Review Articles and MBIH Articles in each Macro-discipline and WoS Category

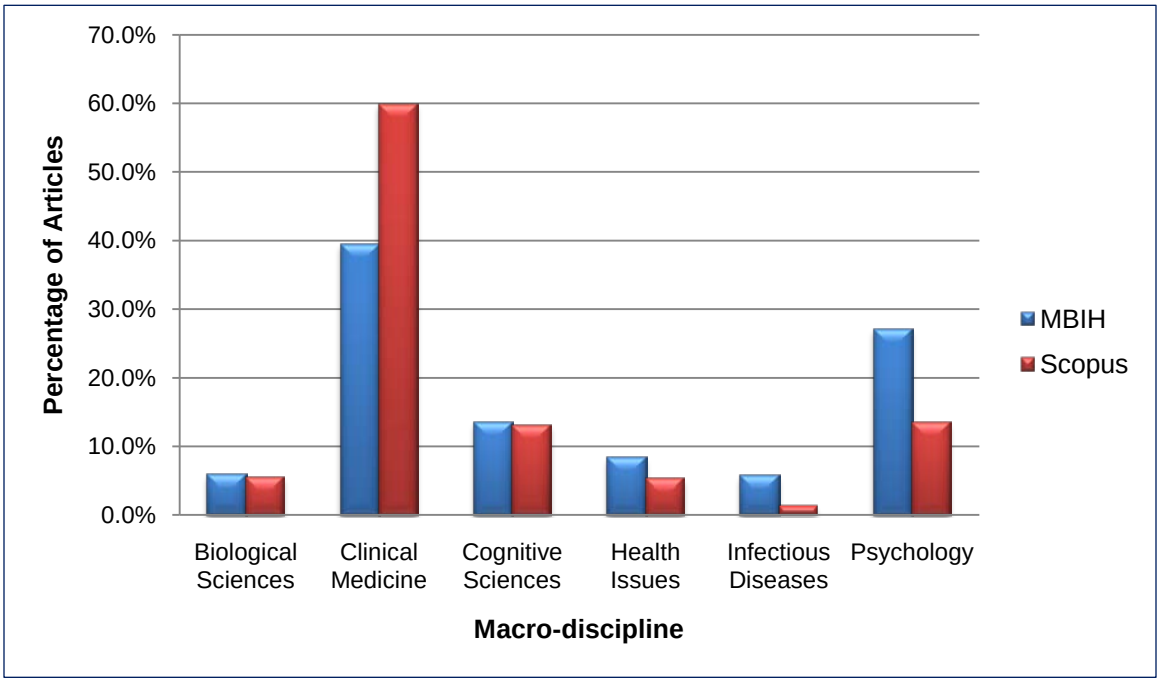
Macro-discipline	# Scopus Articles in Macro-discipline	# MBIH Articles in Macro-discipline	WoS Categories
Biomedical Sciences	38	31	Biochemistry & Molecular Biology
			Biology
			Cell Biology
			Cell & Tissue Engineering
			Genetics & Heredity
			Mathematical & Computational Biology
			Medical Laboratory Technology
			Medicine, Research & Experimental
			Multidisciplinary Sciences
			Pharmacology & Pharmacy
			Physiology
			Reproductive Biology
			Zoology
Business & Management	2	0	Management
Clinical Medicine	416	208	Anesthesiology
			Cardiac & Cardiovascular Systems
			Clinical Neurology
			Critical Care Medicine
			Dentistry, Oral Surgery & Medicine
			Dermatology
			Emergency Medicine
			Endocrinology & Metabolism
			Engineering, Biomedical
			Gastroenterology & Hepatology
			Geriatrics & Gerontology

Macro-discipline	# Scopus Articles in Macro-discipline	# MBIH Articles in Macro-discipline	WoS Categories
			Integrative & Complementary Medicine
			Medicine, General & Internal
			Nursing
			Obstetrics & Gynecology
			Oncology
			Ophthalmology
			Orthopedics
			Otorhinolaryngology
			Pediatrics
			Peripheral Vascular Disease
			Primary Health Care
			Rehabilitation
			Respiratory System
			Rheumatology
			Sports Sciences
			Substance Abuse
			Surgery
			Urology & Nephrology
Cognitive Sciences	91	71	Behavioral Sciences
			Neuroimaging
			Neurosciences
			Psychiatry
Ecological Sciences	1	0	Biodiversity Conservation
Engineering	1	0	Engineering, Mechanical
Health Issues	37	44	Health Care Sciences & Services
			Health Policy & Services
			History & Philosophy Of Science
			Medical Informatics
			Nutrition & Dietetics
			Public, Environmental & Occupational Health
			Social Sciences
			Social Sciences, Biomedical
			Statistics & Probability
Infectious Diseases	9	30	Allergy
			Immunology
			Infectious Diseases
			Virology

Macro-discipline	# Scopus Articles in Macro-discipline	# MBIH Articles in Macro-discipline	WoS Categories
Psychology	93	143	Education & Educational Research
			Family Studies
			Linguistics
			Psychology
			Psychology, Applied
			Psychology, Biological
			Psychology, Clinical
			Psychology, Developmental
			Psychology, Educational
			Psychology, Experimental
			Psychology, Multidisciplinary
			Psychology, Psychoanalysis
			Psychology, Social
			Social Work
Social Studies	6	-	Anthropology
			Humanities, Multidisciplinary
			Religion
			Social Sciences, Interdisciplinary

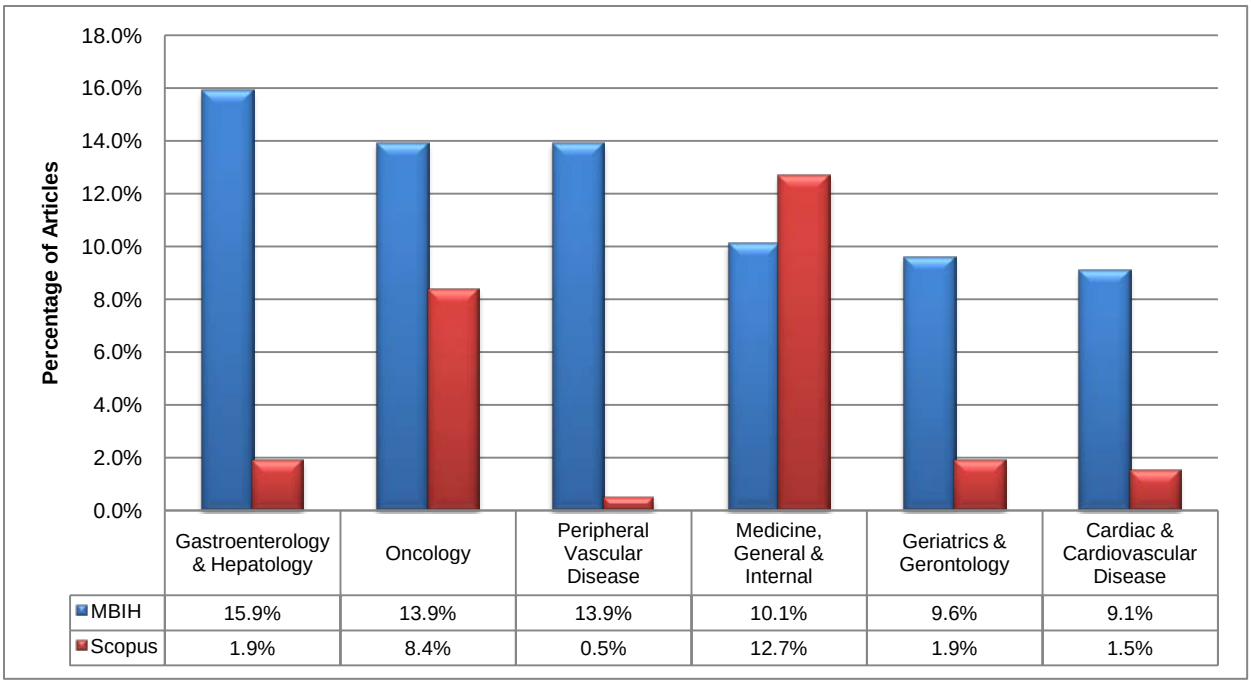
A comparison of the proportions of MBIH research articles and Scopus review articles in each macro-discipline is shown in **Exhibit 74.** Since no MBIH research papers were coded to the macro-disciplines of Business and Management, Ecological Sciences or Engineering, these macro-disciplines are not included in the exhibit.

Exhibit 74. Percentage of MBIH Research Articles and Scopus Review Articles by Macro-discipline



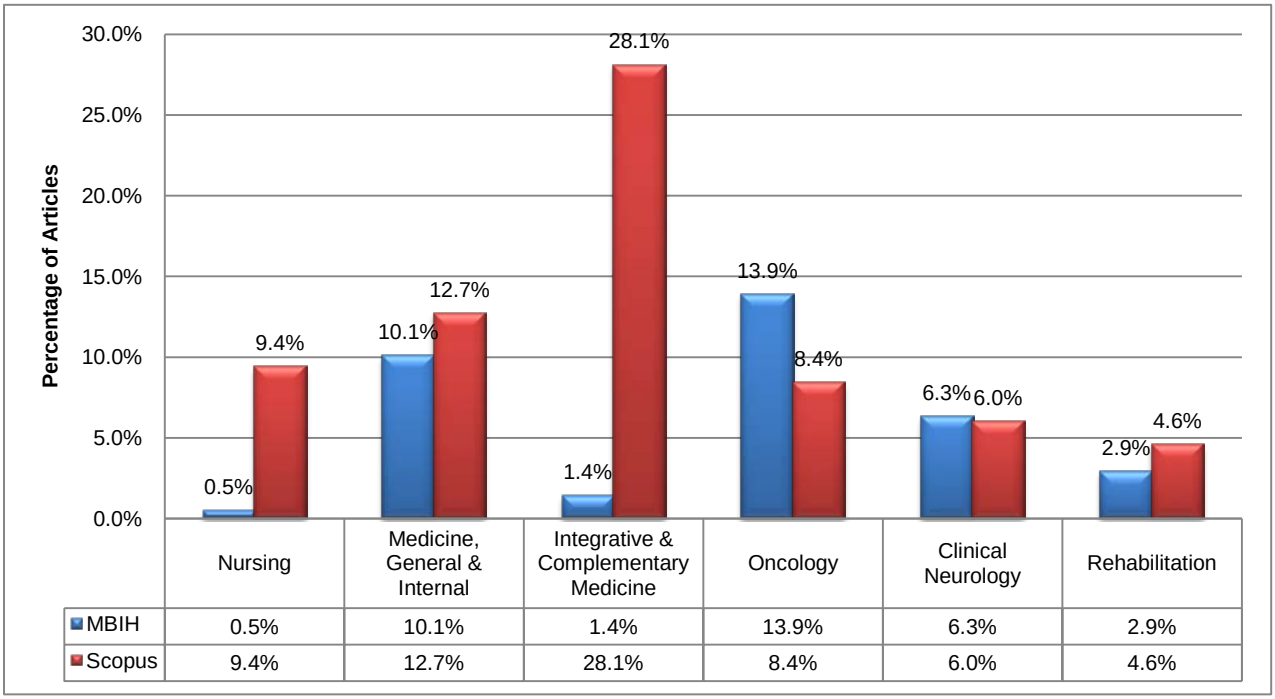
The macro-discipline of Clinical Medicine contains the largest proportion of articles--40 percent of the MBIH research articles (208 articles) and 60 percent of the Scopus review articles (416 articles). The distributions of WoS SCs within Clinical Medicine differ substantially between the two groups of articles. **Exhibit 75** shows the proportions of articles in the top WoS SCs for the MBIH research articles compared with the distribution of the same SCs for the Scopus review articles while **Exhibit 76** shows the proportions of articles in the top WoS SCs for the Scopus review articles compared with the distribution of the same SCs for the MBIH research articles. Gastroenterology and Hepatology, Oncology, and Peripheral Vascular Disease were the top three WoS categories for MBIH articles while Integrative and Complementary Medicine was the largest category in the Scopus review with nearly 30 percent of the Clinical Medicine articles.

Exhibit 75. Comparison of the Top WoS Categories (Percentages) within the Macro-discipline of Clinical Medicine for the MBIH Research Articles with the Distribution of the Same Categories in the Scopus Review Articles



	Gastroenterology & Hepatology	Oncology	Peripheral Vascular Disease	Medicine, General & Internal	Geriatrics & Gerontology	Cardiac & Cardiovascular Disease
MBIH	15.9%	13.9%	13.9%	10.1%	9.6%	9.1%
Scopus	1.9%	8.4%	0.5%	12.7%	1.9%	1.5%

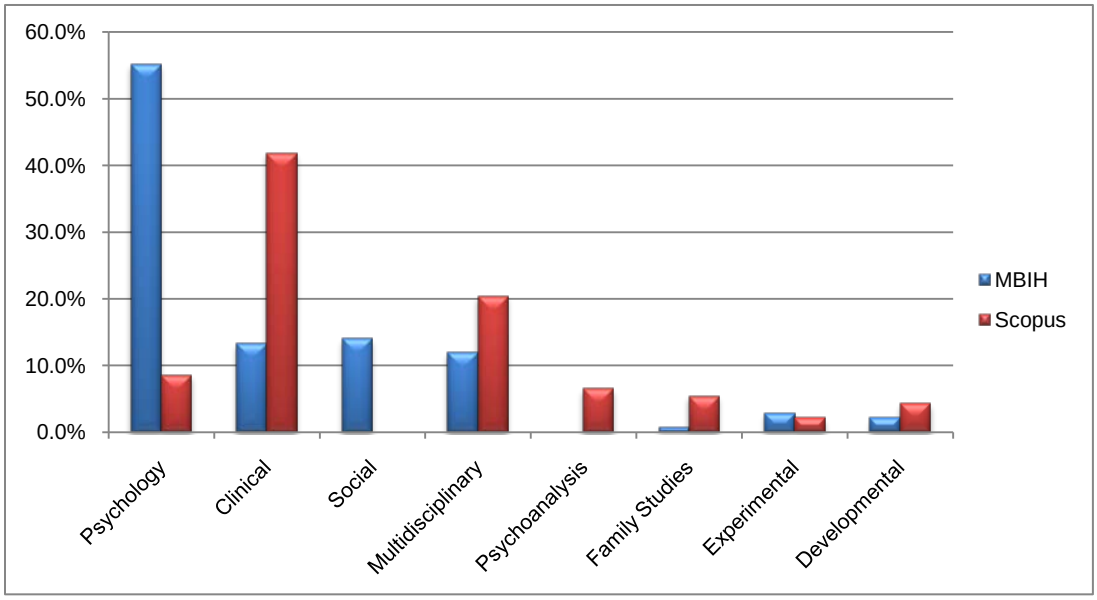
Exhibit 76. Comparison of the Top WoS Categories (Percentages) within the Macro-discipline of Clinical Medicine for the Scopus Review Articles with the Distribution of the Same Categories in the MBIH Research Articles



	Nursing	Medicine, General & Internal	Integrative & Complementary Medicine	Oncology	Clinical Neurology	Rehabilitation
MBIH	0.5%	10.1%	1.4%	13.9%	6.3%	2.9%
Scopus	9.4%	12.7%	28.1%	8.4%	6.0%	4.6%

The macro-discipline of Psychology contains the second largest proportion of articles—13.4 percent of the MBIH research articles (93 articles) and 27.1 percent of the Scopus review articles (143 articles). As shown in **Exhibit 77**, again the distribution of articles differs with 55.2 percent of the MBIH research articles in the WoS SC of Psychology and nearly 42 percent of the Scopus review articles in Clinical Psychology.

Exhibit 77. Distribution of WoS Subject Categories (Percentage) within the Macro-discipline of Psychology for MBIH Research Articles and Scopus Review Articles.



In order to access changes over time in mind-body research as a whole and the MBIH Program in particular, the top five macro-disciplines by number of articles by year were plotted for both the MBIH research articles and Scopus review articles (see **Exhibit 78** and **Exhibit 79**). Since there were no MBIH research articles published in 1999, the timeframe for **Exhibit 78** begins in 2000. The numbers of articles by macro-discipline for the MBIH articles show steady growth over time especially in Clinical Medicine. As shown in **Exhibit 75**, these articles are primarily in the SCs of Gastroenterology and Hepatology; Oncology; Peripheral Vascular Disease; Medicine, General and Internal; Geriatrics and Gerontology; and Cardiac and Cardiovascular Disease. On the other hand, the Scopus review articles do not show trends over time and fall into the SCs of Integrative and Complementary Medicine; Medicine, General and Internal; and Nursing. These findings suggest that over time MBIH research articles are increasingly being published in mainstream medical journals and being recognized as genuine scientific research. This trend substantiates the discussion in section 4.2 regarding the increasing acceptance of the scientific legitimacy of mind-body research and its increasing representation in mainstream medical disciplines and journals.

Exhibit 78. Top Five Macro-disciplines by Number of Articles by year 2000-2009 for MBIH Research Articles

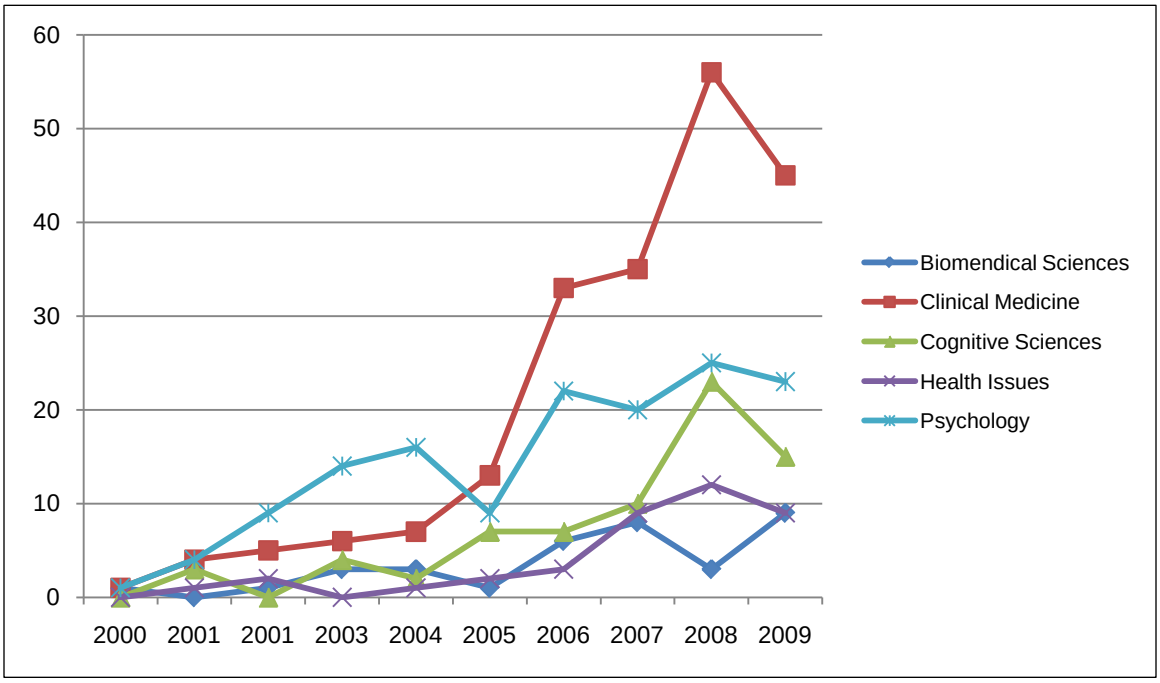
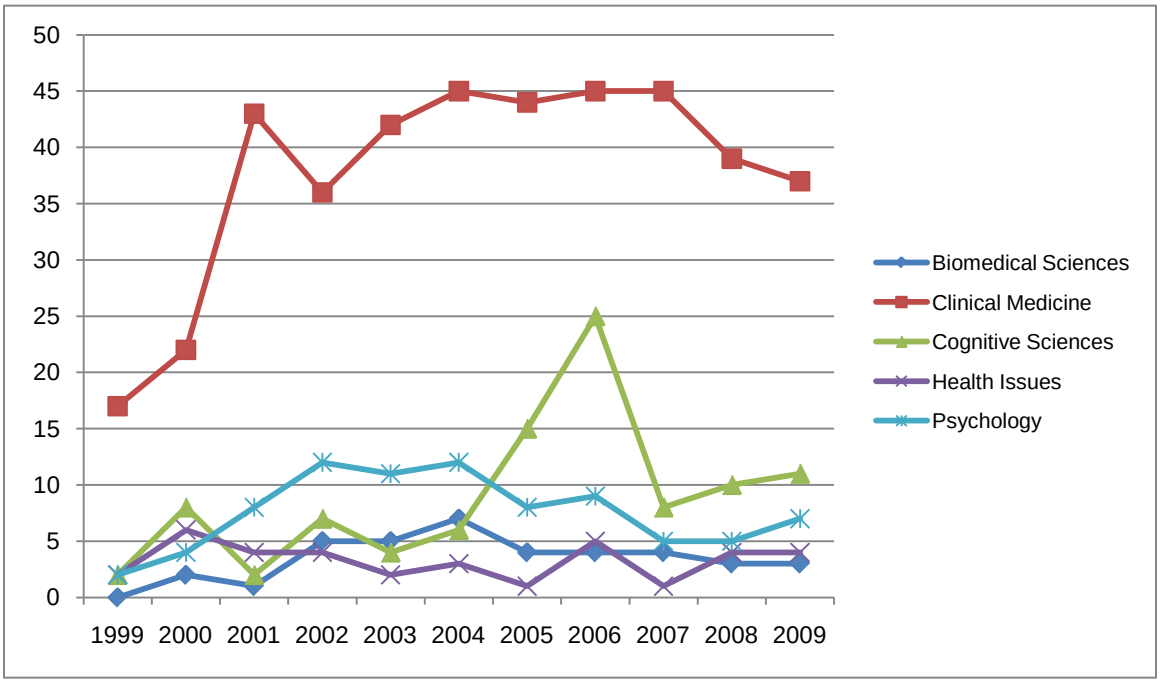


Exhibit 79. Top Five Macro-disciplines by Number of Articles by Year 1999-2009 for Scopus Review Articles



6.2 MBIH Research Center and Project Partnerships with External Universities (4.2)

Eight of the 15 MBIH research centers (53 percent) did not partner with other US universities. Of the remaining seven centers, the number of other partnering universities ranged from one to eight universities. Three of these seven centers also partnered with universities in Canada and Europe. In addition, one university conducted several pilot studies in Latin American countries, another center worked with a Visiting Scientist from Japan, and a third center conducted a clinical trial with university researchers in Italy.

The research teams for 20 of the 44 MBIH research projects (45 percent) involved investigators from a single university. The remaining 24 projects involved research teams from two to seven other universities, all of which were located in the US. None of the research projects involved studies conducted outside the US.

The average index of interdisciplinarity for the 15 MBIH research centers was 0.65 (SD=.12), compared with an index of 0.58 (SD=.25) for the 44 research projects.

6.3 MBIH Program Component Involvement with Community-based Organizations (4.3)

Involvement with community-based organizations was generally not viewed as a strong priority by the PIs from the MBIH research centers or research projects. Of the 15 MBIH centers, only seven identified any community-based organizations as partners in their grant applications. All but two of the 17 community-based organizations listed by these seven centers provided clinical or supportive services; these two organizations included a local church and a community coalition of organizations focusing on the aging. The remaining organizations included local hospitals, clinics, outreach programs, VA Medical Centers, a primary health care research network and an organization that provided personal assistance to elderly individuals. Descriptions of reasons for partnering with these organizations indicated that they were seen as assets for patient recruitment efforts. Five of the 15 centers had involved clinical providers at some level in setting their centers' research agendas. In addition, the centers' External Advisory Boards rarely contained any representation by individuals other than those from academia. This may help explain why only three of the centers reported developing new research collaborations with community-based organizations.

A similar pattern was evident for the MBIH research projects, where only eight of the 44 research projects (18 percent) had involved clinicians in planning the research study. When community-based organizations were included, they were clinical providers and were generally engaged to assist in patient recruitment. Only 13 of the 44 projects (30 percent) reported the establishment of new research collaborations with community-based organizations.

7. Program Effects on Federal and Non-federal Funding for MBIH Research

An unstated objective of the MBIH Program was to stimulate other NIH ICs to fund additional mind-body research projects**. Exhibit 80** shows the NIH ICs that funded portions of the MBIH research centers, research projects, and NIH research spin-off projects from the centers. As shown, the number of ICs that funded the MBIH research center spin-off grants increased over the number originally involved in funding the MBIH research centers and projects, partially supporting the claim that the MBIH program has in fact helped to expand funding for mind-body research at NIH. **Exhibit 80** also shows the total research funds contributed by each of the participating ICs.

Exhibit 80. NIH Institutes, Centers, and Offices Participating in the MBIH Research Centers, Research Projects, and Center Spin-off Grants

NIH Institute, Center or Office	MBIH Research Centers	MBIH Research Center Spin-off Grants	MBIH Research Projects
NIAAA	$0	$279,780	
NIA	$0	$45,646,208	$22,830,810
NIAMS	$0	$5,144,889	
NCCAM	$10	$9,335,045	$13,774,658
NCI	$69,415	$7,412,267	$15,886,286
NIDA	$0	$12,463,421	
NIDCR	$43,224		$2,758,825
NIDDK	$146,292	$8,340,175	
NIEHS		$393,947	$2,419,185
NIGMS	$0	$1,868,750	
NICHD	$202,597	$4,660,565	$2,516,764
NHLBI	$2	$41,085,559	$16,897,995
NCMHD		$6,944,209	
NIMH	$3	$28,734,110	$2,810,132
NINR	$0	$3,448,949	
NINDS	$65,935	$4,303,202	
OBSSR	$94,185,882	$3,292,418	
NCRR		$1,316,336	
FIC		$111,260	
TOTAL	$94,713,360	$184,781,090	$79,894,665

As **Exhibit 80** shows, a total of 15 ICs including OBSSR partnered in establishing the MBIH research centers although only nine of the ICs provided research funding. A total of 18 ICs funded the MBIH research center spin-off research grants, including two ICs (NCMHD and NCRR) that had not been involved with the program's research centers or projects. Data on NIH research spin-off grant funding ICs and funding levels associated with the MBIH research projects were not collected, so it is not known whether any of the remaining nine ICs funded any of those. These data suggest that a greater number of ICs were funding mind-body research spin-off grants generated by the investigators associated with these projects. This finding suggests that the ICs were becoming more receptive to considering and funding mind-body research proposals over the ten years of the MBIH Program. This point is further corroborated by the Research Center PI's responses in the interviews in which they reported perceiving a greater receptivity to mind-body research ideas and projects at NIH, despite the greater degree of competition for grants in recent years.

Data are very limited on changes in receptivity or funding levels for mind-body research outside NIH. Many MBIH research center and project investigators stated that they did not typically seek grants from other federal sources, although a few investigators reported pursuing opportunities for funding at the Department of Veterans Affairs and at the Agency for Healthcare Research and Quality. In terms of sources outside the federal government, center and project investigators had some success in securing grant or contract funding. Among the sources mentioned were foundations and private philanthropic organizations, state health departments, city school programs, and pharmaceutical and biomedical research companies. If intramural support from host universities is excluded as a source of non-government funding for mind-body research, eleven of the 15 research centers (73 percent) obtained

mind-body research funding from at least one of these sources, while 12 of the 44 research projects (27 percent) obtained non-federal spin-off funding. In seven of these 12 cases, the non-federal funds were in addition to new federal funding, suggesting that these may have been contributions from the host university. The research centers appear to have been more successful than the projects in obtaining non-federal funding, but since many of the research projects were still ongoing at the time of data collection, this could change by the time these projects are completed.

8. Lessons Learned from the Mind-Body Interactions and Health Program Outcome Evaluation

This section concludes the report on the MBIH Program Outcome Evaluation by highlighting what has been innovative about this study, considering its strengths and limitations, summarizing the main findings from the evaluation, and identifying lessons learned for future NIH research center programs and future applications of the Payback Framework.

8.1 Innovative Features of the MBIH Program Outcome Evaluation

The MBIH Program Outcome Evaluation provided an intensive examination of the MBIH Program over its ten years of active funding. The evaluation included several innovative elements not included in previous NIH research program evaluations. As the first application of the Payback Framework in an evaluation of a biomedical research program in the US, the MBIH Program Outcome Evaluation represented a trial of a research program evaluation model that has been used widely in Europe, Canada, Australia, and Hong Kong. This application was important because it was conducted by a team external to the Health Economics Research Group which originated the framework, and therefore contributes to the successful diffusion of this conceptual model.

In addition to its conceptual framework, the MBIH Program Outcome Evaluation incorporated several innovative methodological features. First, as part of the examination of the MBIH research centers, data were collected on several aspects of the pilot studies and research subprojects conducted by the center investigators. In addition to characterizing the type of research conducted, information was also collected on whether these studies were completed by December 2010, and whether the studies led to research publications, oral scientific presentations, and NIH research spin-off grant funding. Based on the Madrillon evaluation team's earlier analysis of 61 NIH prior research center evaluations, the MBIH Program Outcome Evaluation is the first to report on the "success rates" associated with these studies. The evaluation team believes this methodological approach can be expanded in the future to incorporate information on research spin-off funding from other federal agencies and from non-federal funding sources, an idea discussed further below.

Second, the Outcome Evaluation employed a new approach for bibliometric analysis based upon work by Porter and Rafols (2009). In characterizing the content areas addressed by research publications, many authors have used the Web of Science's Subject Categories to classify articles in terms of the scientific journals in which they appear. This provides a general assessment of the types of topical fields which the articles address. However, this can be cumbersome to examine analytically because there are so many SCs (e.g., 237 SCs). The evaluation adapted an approach by Porter and Rafols in which they created broader 'macro-disciplines' based on a principal components factor analysis of SCs. This reduced the numerous subject categories to a more manageable number of 18 macro-disciplines comprising clusters of related subject categories. In the application of these macro-disciplines, the evaluation team found that the mind-body research literature could be characterized by six of these macro-disciplines, making it much easier to identify trends in MBIH publications over time. This analysis supported a general conclusion that mind-body research in general (and MBIH research in particular) was becoming more acceptable to the mainstream medical journals.

8.2 Summary of Main Findings from the MBIH Program Outcome Evaluation

The Mind-Body Interactions and Health Program Outcome Evaluation addressed six evaluation questions and several associated sub-questions. The main findings for the first five evaluation questions are summarized and discussed in the following sub-sections.

8.2.1 Has the MBIH Program achieved its programmatic goals and objectives?

A summary of evaluation findings related to the six evaluation sub-questions associated with this first evaluation question is presented in **Exhibit 81.**

Exhibit 81. Summary of Evaluation Findings for MBIH Program Evaluation Question 1

Evaluation Sub-Question		Evaluation Findings
1.1	Relative mix of research	• Research centers and projects addressed all three original thematic areas from the RFPs. • Research centers and projects included basic and clinical research. • Research centers and projects explored topics new to mind-body research, including health disparities, population research, and effects of environmental factors
1.2	Interdisciplinary collaboration and innovation	• Research centers promoted interdisciplinary collaboration. On an index of interdisciplinarity based on Key Personnel and their degree disciplines, the average index score for 15 centers was .67, with 12 of 13 centers for which data were available exceeding .50. • Research projects also exhibited a high level of interdisciplinarity, with an average index score of .58. • Seven themes emerged from the reviewers' appraisals of each center's grant application, including the use of interdisciplinary conceptual frameworks to guide research, fielding of interdisciplinary research teams, the development of new types of research activities, linking basic science and clinical research approaches to investigate a common question, focusing on new or under-studied research problems, creating new research measures, and developing new research products.
1.3	Development and evaluation of health interventions (research translation)	• At the research centers, about 18.5 percent of subprojects and pilot studies involved evaluation of mind-body interventions, and 80 percent of the centers developed and evaluated at least one health intervention. • Of the 44 research projects, 19 (43 percent) of the projects involved an evaluation of a mind-body intervention. The most frequent types of interventions involved mindfulness-based stress reduction, cognitive-behavioral stress reduction, tai-chi, and yoga.
1.4	Capacity development for mind-body research	• Research centers and projects were highly successful in promoting career development and training opportunities for research staff (see Evaluation Question 3). • All of the research centers developed specific research core services to support their activities. While certain types of core services (including Administrative services and Statistics and Data Management) were common across the 15 centers, other types of core services were more related to the developmental stage of the center. Established centers (P50 grantees) typically created core instrumentation or biological/neurological services. Newer centers (R21 grantees) also established Administration and Planning, and Statistics and Data Management core services; in addition they often established a mechanism for creating a common instrument battery and training and mentoring services. R24 grantees created specialized assessment core services.
1.5	Research core services	
1.6	Sustainability of centers	• By the time their MBIH center funding concluded, four research centers had evolved into new centers with a shift in research focus and five centers had been wholly or partially absorbed by another research center at their host institution. Thus 60 percent of the centers continued on in some form after MBIH funding concluded. The remaining six centers ceased to operate as formal research centers, and their investigators found other sources of research support.

The results from the MBIH Program Outcome Evaluation indicate that the program did achieve its two main program goals (expansion of scientific knowledge about mind-body relationships and the mechanisms by which they influence health and health outcomes, and translation of this knowledge into health interventions). The evaluation also provided clear evidence that two of the three programmatic

research objectives were accomplished (facilitating interdisciplinary collaboration and innovation in research ideas, and building a capacity for mind-body research through cultivation and development of research personnel and funding of research core services). The latter objective highlights a problem that is endemic to research center programs in general: it is very difficult to sustain the operation of research core services without the specific infrastructure funding that is provided through research center programs. This was a point noted by several of the research center PIs during interviews with them, and is also illustrated by the closure of the six research centers that ended after their MBIH funding concluded. The availability of core services is often described as a major advantage of research centers, and is a critical resource in generating new research projects and pilot research activities.

The third programmatic objective called for promotion of regular interactions among interdisciplinary research teams across the US. In other research center programs this is often accomplished by convening the investigators for an annual research meeting, at which the various investigators can exchange information on their current projects and identify other investigators with whom they might collaborate on areas of common interest. Two such meetings were held for the MBIH research center investigators. Several PIs expressed regret that more meetings were not held, as they had found them to be useful venues for exploring common research interests. Center investigators did report that they maintained informal communications with each other through participation in various scientific and professional meetings, and they reported a general awareness of other centers' research activities. The Research Center PI interviews and the analyses of research publications indicated that some research collaborations occurred among the MBIH research centers (i.e., five co-authored publications), but overall there was not a high level of interaction that resulted in tangible collaborations.

8.2.2 Has the research conducted through the MBIH Program increased scientific knowledge and understanding about mind-body relationships and their influences on health processes and outcomes?

A summary of evaluation findings related to the two evaluation sub-questions associated with this question is shown in **Exhibit 82**.

Exhibit 82. Summary of Evaluation Findings for MBIH Program Evaluation Question 2

Evaluation Sub-Question		Evaluation Findings
2.1	Research advances and directions	Scientific accomplishments of the MBIH research centers could be characterized in terms of five themes: • Stress mechanisms and stress reduction interventions; • Development of new conceptual approaches and perspectives; • Creation or application of new tools and instruments; • Important findings; and • Education and training in mind-body medicine.
2.2	Use of research tools, methods, models and measures	31 of 44 MBIH research projects (70 percent) reported developing a new research tool, method, instrument or measure; in 17 of these 31 projects (55 percent), there was some use of this newly developed tool by investigators at external academic institutions. Factors associated with the use of these new tools at external academic institutions included funding during the first round of MBIH research projects, one or more research publications from project, and investigator affiliation with a research center. 12 of 15 MBIH research centers (80 percent) reported developing a new research tool, method, instrument or measure; at 7 of these 12 centers (58 percent) there was some use of this newly developed tool by investigators at external academic institutions.

The MBIH research centers clearly contributed to scientific knowledge and understanding about mind-body relationships and the mechanisms by which they affect health and well-being. Responses by the research center PIs to a question eliciting the most important scientific accomplishments achieved by their centers could be classified under five distinct themes. These themes included: (1) the effects of stress on health and illness and interventions for alleviating stress; (2) the application of new conceptual approaches and perspectives such as life course developmental frameworks, and cognitive models of illness and health; (3) the development of new research tools and instruments; (4) important scientific findings (such as the effects of childhood poverty on the biology of the frontal cortex, and the use of biofeedback as a treatment modality for certain forms of fecal incontinence); (5) and the development of health professional educational curricula in mind-body medicine.

The MBIH research centers and research projects also demonstrated a high rate of development of new research tools, methods, models, and measures. Eighty percent of the centers and 70 percent of the projects reported developing new research tools; moreover, there was clear evidence that these new tools were being used by other investigators at external academic institutions. PIs at 58 percent of the research centers and 55 percent of the research projects reported that these new tools and measures were used by investigators outside their host institutions. For the MBIH research projects external utilization of these new tools was higher for projects that were conducted within a research center setting than for those not situated in a research center, and for those projects funded under the first round of project funding. The latter finding reflects the fact that many projects funded under the second or third round of funding were not yet completed at the time of data collection in May 2011.

8.2.3 How productive have the MBIH research centers and projects been in terms of the Payback Framework research benefit categories?

An important element of the MBIH Program Outcome Evaluation was the application of the Payback Framework as a conceptual model for exploring program outputs and outcomes. The Payback Framework was selected for application in this evaluation because it includes a set of research benefits that extend beyond the usual measures of research productivity that have been used in most previous evaluations of NIH research center programs. The MBIH Program Outcome Evaluation is the first application of the Payback Framework in a US biomedical research program.

A summary of the major evaluation findings related to the six evaluation sub-questions associated with this third evaluation question is presented in **Exhibit 83**. These six sub-questions include the five Payback Framework benefit categories.

Exhibit 83. Summary of Evaluation Findings for MBIH Program Evaluation Question 3

Evaluation Sub-Question		Evaluation Findings
3.1	Knowledge productivity	• MBIH research centers as a group produced a total of 429 unduplicated research publications (including 5 publications co-authored by investigators at two research centers). • MBIH research centers conducted a total of 287 scientific studies (subprojects and pilot studies). Of these, 82 percent resulted in at least one oral presentation at a scientific or professional meeting, and 73 percent produced at least one peer-reviewed publication. • MBIH research projects produced a total of 140 publications through December 31, 2009, of which 129 were research publications. • Eighteen of the 44 research projects (41 percent) produced at least one publication; three projects collectively generated 74 publications. • Nine projects (20 percent) produced at least one oral presentation.

Evaluation Sub-Question		Evaluation Findings
3.2	Research targeting	• MBIH research center investigators obtained a total of 100 new NIH-funded spin-off grants based on MBIH scientific studies; NIH spin-off funding totaled $184,781,090, or about $1.95 for every NIH dollar spent funding the MBIH research centers. • Eleven of the 15 centers obtained research funds from non-federal sources excluding their host universities. • 19 projects (43 percent) had obtained new NIH-funded spin-off grants, and 12 projects generated non-federal research spin-off funding.
	Capacity development	• Between 50 to 67 percent of the MBIH research centers reported mentoring post-doctoral fellows and junior faculty, recruiting new faculty to pursue mind-body research activities, supporting the promotions of faculty members, and enabling doctoral students to complete dissertations and obtain advanced degrees. • About 47 percent of the research centers promoted international research collaborations, often through Visiting Scientist programs. • Two-thirds of the centers created new research infrastructure as a result of MBIH activities. • Between 32 to 89 percent of the research projects reported new faculty recruitment, faculty promotions, and advanced degrees. • Most new research collaborations were with other investigators at the host institution (73 percent), or other academic institutions (64 percent); only 5 percent reported new international collaborations.
3.3	Influence on policy	• Between 40 and 87 percent of the MBIH research centers reported an impact on administrative or clinical policy in terms of policy formulation (60 percent), medical and healthcare professional education and training (87 percent), and contribution to clinical guidelines (40 percent). • Research centers influenced administrative and clinical policy at both the national and the international levels for each of these three indicators. • Between 25 and 41 percent of the MBIH research projects reported an effect on administrative or clinical policy in terms of policy formulation, medical and healthcare professional educational curricula or training, and new product development. Much of these effects were at the national or local levels.
3.4	Influence on health and healthcare service delivery	• Between 53 to 60 percent of the research centers reported some influence on adoption of center research findings and interventions by clinical practitioners or the public, improved health outcomes, or healthcare service delivery. • An unexpected finding was that several local school systems have become interested in using mind-body interventions with their students through their collaborations with MBIH research centers. • 23 of the 44 research projects (52 percent) reported some effect on clinical practice or provider behavior, 21 projects (48 percent) reported some effect on health outcomes or quality of life, and 5 projects (11 percent) reported some effect on healthcare service delivery.
3.5	Broader economic and social impacts	• Four of the 15 research centers (27 percent) reported anticipated broader economic and social impacts from their MBIH research activities. • Four of the 44 projects (9 percent) reported anticipated broader economic or social effects from their scientific findings.
3.6	Effect of research center affiliation on research project publications	• Research project investigators' affiliation status with a research center did not affect their likelihood of generating one or more publications from their research.

These findings underscore several points. First, the MBIH research centers and projects achieved outputs and outcomes across the five Payback Framework research benefit categories. This is especially noteworthy given that many of the research projects were still in progress. While it has often been noted that it can take many years for the full range of benefits from a research project (or program) to become apparent, the MBIH research centers and projects nonetheless have achieved numerous benefits within a comparatively short period of time. This has practical importance for the future application of the Payback Framework for NIH research program evaluations because such evaluations are frequently conducted at the end of program funding, rather than at some future point five or ten years after the funding ended. It is possible to examine the types of outcomes posited by the framework even though the full range of these benefits may still lie ahead in the future.

A second point is that the organizational or social level at which the Payback Framework benefits appear differed for the MBIH research centers and projects. The research centers were more likely to demonstrate effects on policy, health, health outcomes and service delivery, and even broader economic and social impacts at a national or international level, while the effects from the research projects more commonly appeared at the local community level (with some effects nationally as well). Thus the scope of research benefits appeared broader for the centers than the projects. This was apparent not only in terms of research outcomes, but also in terms of research collaborations.

A third point concerns the overall interpretation of these findings. While these are impressive, they beg some type of comparison so that it would be possible to determine not only whether the program performed but how well. As discussed in Section 2, the MBIH Program Outcome Evaluation design did not incorporate a comparison condition, since identifying an appropriate comparison condition for a program developed to "kick-start" a research field would be very difficult. The evaluation team did attempt to provide a broader context for our MBIH results by comparing them with several other evaluations conducted using the Payback Framework. That comparison (see **Exhibit 68**) showed that the MBIH research project results across the five research benefit categories were at least comparable to (and in some cases, greater than) those reported from research projects described in four earlier evaluations using the Payback Framework. When comparing the results achieved by the MBIH research centers with these earlier payback studies, the MBIH research centers exhibited stronger performance on most of the indicators and benefit categories than these prior studies.

The final evaluation sub-question associated with this evaluation question concerned the effect of investigator affiliation (or non-affiliation) with a research center on research productivity. The original intention had been to compare three groups of research investigators from the 44 MBIH research projects: those affiliated with an MBIH research center, those affiliated with another type of research center, and those not affiliated with any research center. Since the MBIH Research Project PI interviews revealed that only three of the PIs were actively affiliated with an MBIH research center at the time they were conducting the project, the evaluation therefore could only compare affiliation with a research center versus no affiliation. A total of 25 MBIH research projects were conducted by PIs affiliated with a research center (57 percent). As reported in Section 5.2.1, research projects led by unaffiliated investigators yielded a greater likelihood of research publications than projects led by center-affiliated investigators (47 versus 32 percent).

8.2.4 How has the field of mind-body research grown over time and what contributions have the MBIH investigators made to it?

A summary of the findings for the three evaluation sub-questions associated with this evaluation question is presented in **Exhibit 84**.

Exhibit 84. Summary of Evaluation Findings for MBIH Program Evaluation Question 4

Evaluation Sub-Question		Evaluation Findings
4.1	Changes in MBIH research from 1999-2009	• There has been a steady growth over the past ten years in published articles on mind-body interactions and health research. • Articles by MBIH investigators are increasingly being published in mainstream medical journals over the 2000-2009 period, reflecting a greater scientific acceptance of MBIH research. • MBIH investigators published more frequently in the macro-disciplines of gastroenterology and hepatology, oncology, and peripheral vascular disease than the field as a whole.
4.2	Interdisciplinary collaboration	• 7 of 15 MBIH research centers (47 percent) involved partnerships with other US academic universities, with the number of partnering academic institutions ranging from 1-8. • 3 centers also partnered with institutions from Canada and Europe. • Research teams for 24 of the 44 research projects (55 percent) involved investigators from other US academic institutions, with the number of partnering institutions ranging from 2-7. None of these partnerships included academic institutions outside the US. • The average index of interdisciplinarity for the 15 MBIH research centers was 0.67 (SD=.12) and for the 44 MBIH research projects it was 0.58 (SD=.25). The index of interdisciplinarity was similar for projects that were based in single versus multiple academic institutions.
4.3	Involvement with community-based organizations	• 7 of 15 MBIH research centers (47 percent) identified community organizations as partners in their original grant applications; the total number of community organizations was 17, all but two of which were providers of clinical or supportive services. • 8 of 44 MBIH research projects (18 percent) involved clinicians in planning the study.

The field of mind-body interactions and health research continued to expand throughout the 2000-2009 period we examined. In order to trace the growth and directions of mind-body publications (and the contributions the MBIH Program investigators made to this literature), we conducted a bibliometric analysis based on the Web of Science subject categories assigned to journals in which the articles appeared. Our analyses supported the conclusion that mind-body research is appearing more regularly in mainstream medical journals, an indication of the growing acceptance of this field within the scientific community, a point further corroborated by several of the Research Center PI interviews.

An important methodological innovation applied in the MBIH Program Outcome Evaluation was to adapt an approach developed by Porter and Rafols (2009) that reduces the large number of subject categories to smaller clusters of macro-disciplines through the use of principal components factor analysis. The evaluation team examined the 18 macro-discipline categories they created and made some minor subject category re-assignments for conceptual clarity. Using these modified macro-disciplines, the evaluation team compared mind-body research reviews identified through Scopus with reviews authored by the MBIH investigators during the years 2000-2009. This comparison showed that the mind-body field as a whole published most often under the macro-discipline of Integrative and Complementary Medicine, while MBIH research investigators published more frequently in three specific macro-disciplines: Gastroenterology and Hepatology; Oncology; and Peripheral Vascular Disease. This finding is consistent with the research focus of the MBIH Program on mechanisms of mind-body interactions for specific diseases.

Interdisciplinary collaboration was discussed earlier as part of the first evaluation question. In addition, the MBIH research centers and projects frequently involved academic collaborations among multiple universities. A total of 47 percent of the research centers and 55 percent of the research projects involved two or more academic institutions working together on mind-body scientific activities. Three of

the MBIH research centers included universities located in Canada or Europe, and several centers were active in conducting research studies in Latin America, Japan, Hong Kong, and several European nations.

Community involvement in MBIH research center and project scientific activities was somewhat limited. When community-based organizations were involved in these activities, the nature of the involvement was most often focused on research subject recruitment and providing a setting for specific interventions. Community-based organizations were rarely involved in developing the research agenda for the centers, or in planning research projects. However, it should also be noted that several of the MBIH research investigators were clinical providers as well as researchers, and they may have felt that this dual role provided sufficient representation of clinical perspectives in setting a research agenda.

Involvement of policy makers in setting centers' research agendas or in developing MBIH research projects was very minimal among the centers, and not evident among the research projects. Several MBIH research centers operated in organizational settings that included other research centers that were highly focused on policy research. This could have provided an ideal mechanism for linking scientific activities to policy questions, but in only a few centers was there evidence that such exchanges occurred.

8.2.5 Has the MBIH Program increased financial support for mind-body research among federal and non-federal funding sources?

A summary of the findings associated with the three evaluation sub-questions associated with this evaluation question is presented in **Exhibit 85**.

Exhibit 85. Summary of Evaluation Findings for MBIH Program Evaluation Question 5

Evaluation Sub-Question		Evaluation Findings
5.1	Support for MBIH research at NIH	• MBIH research centers obtained 100 new NIH research spin-off grants with total funding in the amount of $184,781,090. • The number of NIH ICs funding MBIH research center spin-off grants grew over the course of the program's ten year funding cycle, suggesting that other NIH ICs were more receptive to mind-body interactions and health research.
5.2	Support for MBIH research at other federal agencies	• MBIH research centers and projects reported obtaining funding for mind-body research projects from other federal agencies including the Agency for Healthcare Research and Quality and the Department of Veterans Affairs.
5.3	Support for MBIH research at non-federal agencies	• Excluding intramural support from host universities, 11 of the 15 research centers (73 percent) reported obtaining funding for mind-body research from non-federal sources including foundations and private philanthropic organizations, state health departments, pharmaceutical and biomedical research companies and city school systems. • 12 of the 44 MBIH research projects (27 percent) reported obtaining non-federal funding, a proportion which is likely to increase as current projects are completed.

These results support the conclusion that MBIH Program grantees were successful in obtaining funding for new spin-off research projects from NIH, other federal agencies, and non-federal agencies and organizations. This conclusion attests to the growing acceptance of mind-body research within the scientific community and among funding agencies noted previously.

8.3 Strengths and Limitations of the MBIH Program Outcome Evaluation

8.3.1 Strengths of the MBIH Program Outcome Evaluation

There are several strengths of the MBIH Program Outcome Evaluation. First, the evaluation was based on all of the MBIH research centers and projects, rather than a sample of projects as has been the case for many previous Payback Framework evaluation studies. Second, the data collection process drew upon multiple types of data (document review, self-report, bibliometric analysis) and emphasized triangulation across these data sources as an analytic strategy.

8.3.2 Limitations of the MBIH Program Outcome Evaluation

It is also important to be cognizant of several limitations in the outcome evaluation. From a design perspective, the absence of a comparison group or condition means that it is difficult to determine what might have occurred had the program not been funded (the counterfactual problem). The timing of the evaluation at the conclusion of the active funding for the program means that some of the MBIH research projects had not been completed at the time of data collection, and might have exhibited additional effects on some of the research benefit categories. Moreover, some of these effects may require several additional years to appear beyond the conclusion of the projects. Thus, the true effects from the scientific work of these centers and projects may be under-stated. This problem of latency is a major challenge in any evaluation of a research program.

A third important limitation of the outcome evaluation is its reliance on self-report data for evidence of effects on the wider research benefits (clinical and administrative policy, health outcomes and healthcare service delivery, and broader economic and social benefits) that comprised major evaluation outcomes. MBIH PIs were asked to state whether their center or research project work had had any effects in terms of the various indicators used for each of these three benefit categories. An attempt was made to elicit more information about the nature of the effect, the organizational level at which it occurred, and any specific evidence that could be use to verify it. Attribution was a particular challenge for this evaluation. On the one hand, it was necessary to distinguish between occurrences of actual versus anticipated effects. This was especially apparent in examining claims about broader economic and social impacts. It was also necessary to assess whether the study contributed to or actually produced the claimed effect. In some cases, it was possible to track down specific evidence (e.g., citation of a research article in the supporting material for a clinical guideline); in other cases the effect on a benefit category might be more indirect (e.g., the PI was appointed to serve on a commission or task force addressing a specific problem as a result of the MBIH study). In the latter example, it could be difficult to determine whether the appointment resulted specifically from the MBIH study, or whether the MBIH study contributed to a larger body of work by that investigator for which he or she was now being recognized. A satisfactory solution to this conundrum could not be found, and in the end, the evaluation team relied upon available evidence and the veracity of the respondents.

8.4 Lessons Learned for Future NIH Research Center Programs

The findings from this evaluation suggest several lessons or recommendations for future evaluations of NIH research center programs. These are briefly discussed below and highlighted in **Exhibit 86.**

Exhibit 86. Lessons Learned for Future NIH Research Center Programs

- The Payback Framework provides a useful conceptual model for evaluating research center programs.
- Annual investigator meetings are an important element for NIH research center programs.
- Research center sustainability deserves greater programmatic attention than it typically receives.
- Annual Progress Reports should be modified to capture meaningful information on potential research benefits.

8.4.1 The Payback Framework provides a useful conceptual model for evaluating research center programs.

Based upon experience in applying the Payback Framework in this outcome evaluation of the MBIH Program, the Payback Framework represents a useful conceptual model that could be applied to other NIH research programs. One of the major findings from the Madrillon team's earlier review of 61 NIH research center program evaluations was that many of these only considered measures of research productivity and did not include outcomes. A major strength of the Payback Framework is that while it includes program outputs such as research productivity, targeting and capacity development, it also incorporates a wider range of potential research benefits such as effects on clinical or administrative policy, health outcomes and health care service delivery, and broader economic and social benefits. The Payback Framework not only identifies these wider benefits, but also provides a conceptual model describing how these arise over time. Other major strengths of the framework include its adaptability (it can be applied to basic, clinical, or health services research) and the accumulating set of findings arising from prior applications.

8.4.2 Annual investigator meetings are an important element for NIH research center programs.

Many NIH research center programs hold annual grantee meetings at which research investigators from each funded center convene to present updates on their current scientific activities. In addition to serving as a useful venue for face-to-face meetings between PIs and NIH program officers, these meetings offer an important opportunity for informal discussions between investigators who are investigating similar research topics. These discussions can lead to future research collaborations and to the dissemination of innovative ideas and practices among grantees. They also provide an opportunity for interested NIH program officers from various ICs to learn about new developments within a field, and could therefore help promote new funding opportunities. The MBIH Program conducted two such meetings over its ten years of active funding. There was a relatively low level of formal collaboration across the MBIH research centers (for example, there were only five research publications co-authored by investigators from two centers). Several research center PIs specifically commented on the lack of these meetings in the Research Center PI interviews. Future NIH research programs should be strongly encouraged to hold such meetings on an annual basis, and use the opportunity to focus discussions and presentations on scientific issues and themes that could move new fields forward.

8.4.3 Research center sustainability deserves greater programmatic attention than it typically receives.

Are research centers necessary or desirable to support the growth of an emerging scientific field? That question cannot be answered directly from the results of the MBIH Program evaluation, however, the evaluation did show that the MBIH research centers have made substantial contributions to the MBIH program overall. In particular, research centers can play a vital role in the development of new fields by bringing together investigators from a variety of disciplines, leveraging financial and other support from various sources, and by training younger investigators who may then continue to pursue active research careers within the field. If research centers can play an important role in fostering the growth and establishment of an emerging field, then it seems advisable to consider how best to promote their sustainability. At the same time, it is equally important to emphasize that funding for centers within a specific program cannot be open-ended and that a major goal of funding research centers should be for them to achieve an independent existence beyond the conclusion of the program.

The MBIH Program funded 15 research centers. By the conclusion of their active funding, nine centers had either evolved into new research centers or been substantially absorbed by another existing research center. The remaining six centers closed, and the remaining research investigators sought to support themselves with other research grant funding. Whether a 60 percent sustainability level is greater

than what should be expected from a research program cannot be determined from the results of a single program, but it does suggest that some attention should be focused on what does represent an expected center 'survival rate' and what factors contribute to it.

One of the major hurdles research centers face in sustaining their activities is maintaining funding support for core research services, including statistics and data management, training, and specialized assessment cores. These services were described as critically important in several PI interviews because they provide resources that investigators can use to develop pilot studies and new grant applications. In the absence of continued infrastructure funding, however, these core services quickly disappear. In some cases, institutional departments or other centers can pick up the funding needed to partially or fully maintain these support services, which occurred for five MBIH research centers. For the six MBIH research centers that closed, this did not happen. Funding for infrastructure is difficult to obtain outside of specialized grant programs such as those offered by NIH. As one PI commented, private foundations and organizations are interested in solving a particular research problem, not in supporting infrastructure.

One factor that appears to contribute to center survival is the creation and maintenance of a predictable funding stream that provides infrastructure support. A predictable funding stream can facilitate longer range planning which new centers especially need to develop, maintain and support a core group of committed research investigators. For nascent research centers, one way to do this might be through a deliberate funding strategy in which investigators are encouraged to form a research team through support from a three-year R21 funding mechanism, then given an opportunity to compete on a restricted basis for five-year R24 infrastructure support that would enable successful teams to develop the types of research core services that could sustain a maturing research center. This was in fact done within the MBIH Program, although it is not clear that the 2007 restricted competition R24 funding opportunity was implemented with this strategy in mind. Providing eight years of funding with an explicit emphasis on planning for independent continuation of the center from its inception might be sufficient to enable focused research teams to evolve into a research center that eventually could rely upon support from a wider range of funding sources.

8.4.4 Annual Progress Reports should be modified to capture meaningful information on potential research benefits.

It can be argued that planning for a program evaluation should begin with the development of the initial Funding Opportunity Announcement (Request for Applications or Request for Proposals). That initial document provides PIs and their research investigators with the goals and objectives of the program and the various requirements they must address in order to obtain funding. That document should also communicate clearly to PIs that their centers will be evaluated and the types of output and outcome domains that will be addressed in that evaluation. This would enable the Annual Progress Report to provide information that could directly inform the evaluation and would increase consistency of reported information across grantees and reduce the costs of future program evaluations.

One example would be better reporting on the nature and amounts of spin-off research grants. For this project, a Research Center Data Table was developed, prepopulated, and completed by each of the 15 research center PIs. This table listed each of the various pilot studies and research subprojects conducted by investigators at each center, and obtained information on whether the study had been completed, whether it led to any research publications or oral presentations, and whether it resulted in any NIH spin-off research funding. The table did not include information on whether the study led to any non-NIH funding, although this could easily be included in the future. The value of this information is that it provided the evaluation team with the opportunity to examine how successful these pilot studies and subprojects were, and what proportion of them actually resulted in new NIH funding. This information could easily be collected in a table format as part of an Annual Progress Report, and could be further supplemented by the amount of internal funding provided to each pilot study or subproject, and whether it

resulted in non-NIH funding (either other federal agencies or non-federal agencies or organizations). This information would permit a true return-on-investment calculation for research centers that could further support the value they provide to a funding agency. By modifying the Annual Progress Report to include this additional information, the information could be readily collected and analyzed with greater accuracy and reduced effort for the investigators.

Similar information could be collected on the effects of center activities on wider research benefits, including effects on policy, health outcomes and service delivery, and wider economic and social benefits. By capturing the information on a yearly basis as part of the Annual Progress Reports, the eventual costs of evaluation could be reduced.

8.5 Lessons learned for future applications of the Payback Framework

This initial application of the Payback Framework in an evaluation of a biomedical research program at NIH provided a useful learning experience for future applications of this conceptual model. The most important lesson learned was that the Payback Framework offers a useful conceptual tool for planning and conducting an evaluation of a biomedical research program. As a conceptual framework, the Payback Framework drew attention to a range of outcomes less often considered in other NIH program evaluations and ordered these in a logical manner.

Some of the lessons learned from this evaluation arose from the nature of the MBIH Program and its inclusion of both research centers and research projects under the same organizational umbrella. Many earlier applications of the framework have focused on one type of unit or the other. Examining both types of projects using the same outcomes framework enabled a comparison of methodological approaches and results.

In considering future studies using the Payback Framework, the greatest challenge encountered concerned the use of the case study scoring methodology. Early studies using the Payback Framework noted difficulties in developing a valid and reliable scoring process, and in discussions with HERG research staff revealed that the scoring methodology has changed and evolved over time. Several problems were experienced in working with the scoring process. The first problem involved developing scales on which to score each of the 15 research centers. Some scales could be organized in an ordinal fashion, in which higher scores reflected more of a given element than lower scores. For example, in considering center effects on career development, a center that assisted 15 doctoral students to complete their dissertations and obtain advanced degrees would receive a higher score than one that assisted only 5 students. However, determining the point at which to set a threshold between two scores seemed subjective. This problem of subjectivity increased when the evaluation team devised scales to score the more qualitative effects on policy or other wider research benefits. The scales for these domains tended to include consideration of the organizational level at which the claimed effect occurred; for example, changes involving a claimed effect at an international level would receive a higher score than those at a community level. However, scale is only one possible dimension of impact; others might include the breadth of the change (e.g., does the it apply to only a narrow group of people, or to a wider range of individuals). It probably is not possible to devise a single set of scales reflecting the different types of wider research benefits that would be relevant for all applications, so a certain degree of subjectivity and customization is probably inevitable.

A second problem encountered with the scoring process concerned interpretation of the resulting profiles. The evaluation team was able to construct scales, use them to score the 15 MBIH research centers on several outcome domains, and depict these various scores on radar-graphs. However, interpreting the resulting profiles proved difficult. MBIH research centers showed considerable variability across their profiles, with some centers scoring exceptionally high on one domain but low on several others, and other centers attaining mid-level scores on most domains. A profile of scores across multiple

domains can provide useful information for individual centers, but developing approaches for comparing these profiles appears to be an area for which future work is needed.

By contrast, the 44 MBIH research projects required a different analytic approach. For these projects, the scoring process was not used, and the evaluation relied upon more traditional approaches in which projects were compared on individual domains. This allowed a description of results in terms of the percentage of research projects that achieved an effect within a given domain, and also allowed a comparison of MBIH Program evaluation results with those from several earlier payback studies. (This same approach was also applied with the research centers.) Determining whether a research project could be credited with an effect within a given benefit category still involved a degree of subjectivity, but it was easier to determine a 'hit' or a 'miss' than to score the projects. The recommendation for future applications would be to use this latter approach in preference to the case study scoring methodology for the time being.

8.6 Conclusion

The MBIH Program was a ten-year program designed to promote an emerging field of research that was perceived to be under-developed at the time the program was initiated. During the ten years from 2000 through 2009, a trans-NIH partnership provided nearly $175 million in research funding to support 15 research centers and 44 investigator-initiated research projects. The goals of the program included the expansion of scientific knowledge about mind-body relationships and how they affect health and illness, and the translation of this knowledge into health interventions. The program was evaluated using the Payback Framework, a conceptual model that identifies five categories of research benefits (knowledge productivity; research targeting and capacity development; influence on policy; influence on health outcomes and healthcare service delivery; and broader economic and social impacts). The evaluation showed that the MBIH program met its original programmatic goals and most of its objectives, and that the 15 research centers and 44 research projects produced clear and positive effects across all five of the Payback Framework research benefit categories.

The MBIH Program Outcome Evaluation also demonstrated that the Payback Framework could be successfully applied in an outcome evaluation of an NIH biomedical research program and that the framework represents a promising conceptual model for other evaluations of research programs in the US.

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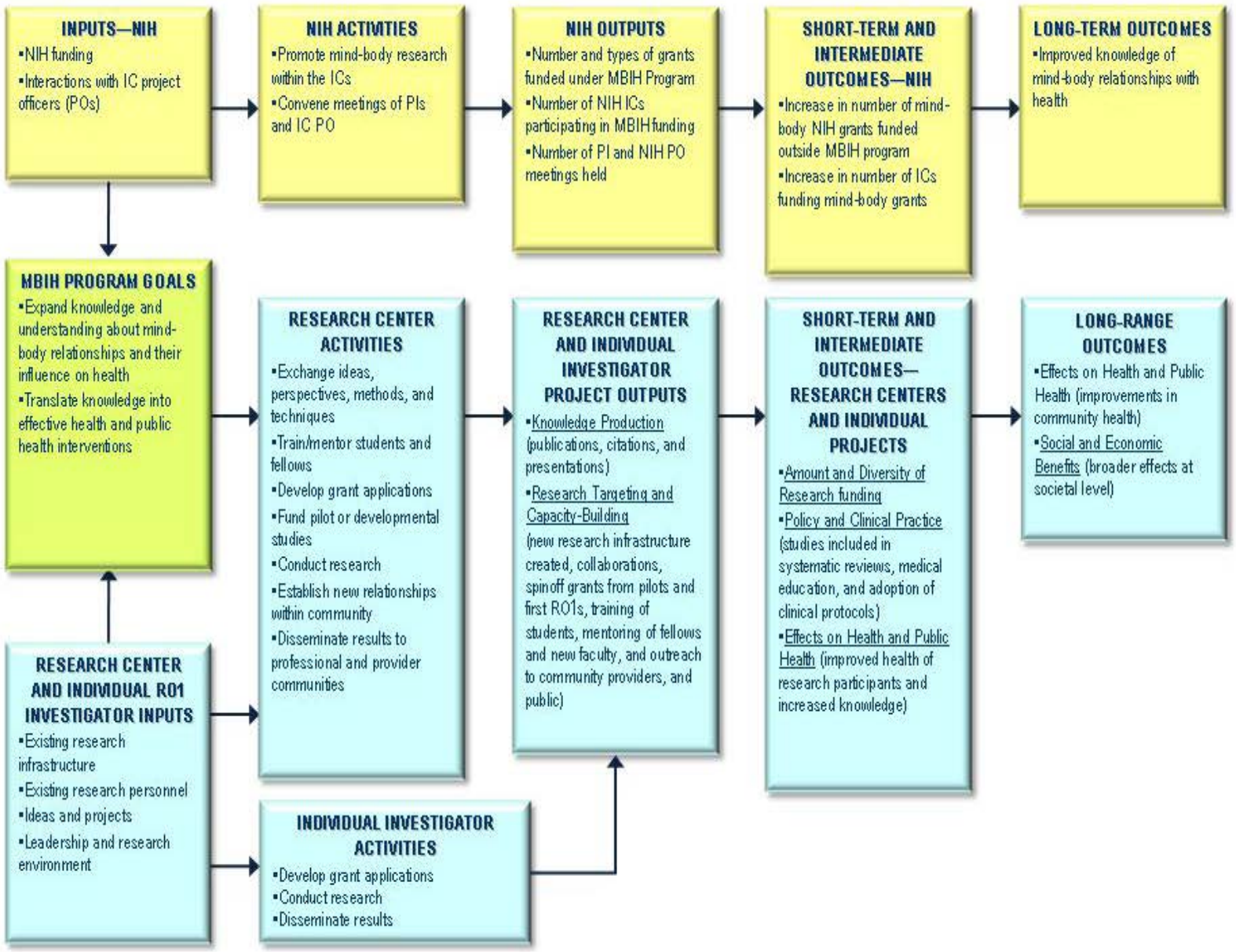
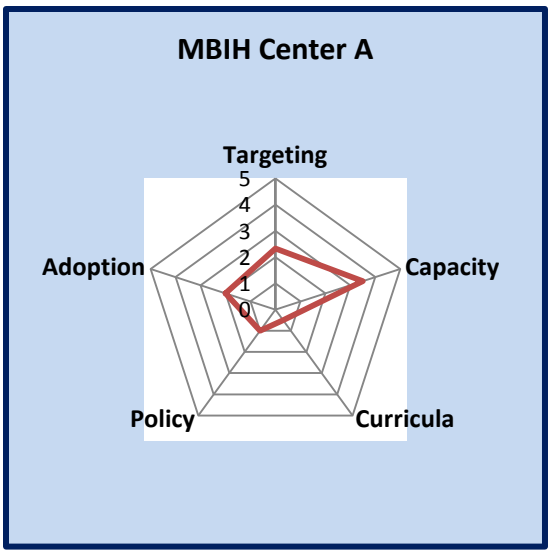
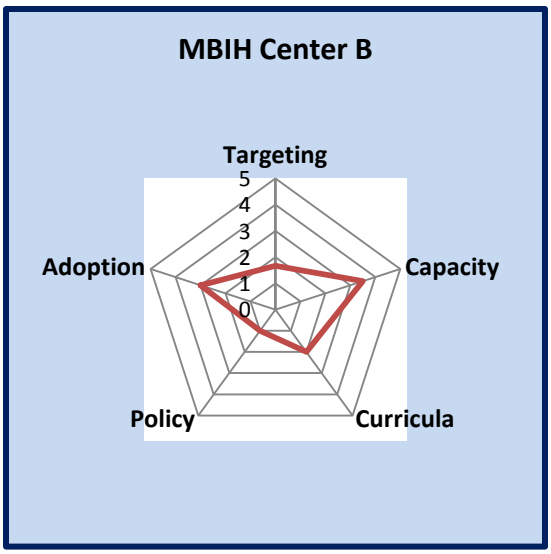
Appendix 1
Conceptual Model for Evaluation


INPUTS—NIH
•NIH funding
•Interactions with IC project officers (POs)
NIH ACTIVITIES
•Promote mind-body research within the ICs
•Convene meetings of PIs and IC PO
NIH OUTPUTS
•Number and types of grants funded under MBIH Program
•Number of NIH ICs participating in MBIH funding
•Number of PI and NIH PO meetings held
SHORT-TERM AND INTERMEDIATE OUTCOMES—NIH
•Increase in number of mind-body NIH grants funded outside MBIH program
•Increase in number of ICs funding mind-body grants
LONG-TERM OUTCOMES
•Improved knowledge of mind-body relationships with health
MBIH PROGRAM GOALS
•Expand knowledge and understanding about mind-body relationships and their influence on health
•Translate knowledge into effective health and public health interventions
RESEARCH CENTER ACTIVITIES
•Exchange ideas, perspectives, methods, and techniques
•Train/mentor students and fellows
•Develop grant applications
•Fund pilot or developmental studies
•Conduct research
•Establish new relationships within community
•Disseminate results to professional and provider communities
RESEARCH CENTER AND INDIVIDUAL INVESTIGATOR PROJECT OUTPUTS
•Knowledge Production (publications, citations, and presentations)
•Research Targeting and Capacity-Building (new research infrastructure created, collaborations, spinoff grants from pilots and first RO1s, training of students, mentoring of fellows and new faculty, and outreach to community providers, and public)
SHORT-TERM AND INTERMEDIATE OUTCOMES—RESEARCH CENTERS AND INDIVIDUAL PROJECTS
•Amount and Diversity of Research funding
•Policy and Clinical Practice (studies included in systematic reviews, medical education, and adoption of clinical protocols)
•Effects on Health and Public Health (improved health of research participants and increased knowledge)
LONG-RANGE OUTCOMES
•Effects on Health and Public Health (improvements in community health)
•Social and Economic Benefits (broader effects at societal level)
RESEARCH CENTER AND INDIVIDUAL RO1 INVESTIGATOR INPUTS
•Existing research infrastructure
•Existing research personnel
•Ideas and projects
•Leadership and research environment
INDIVIDUAL INVESTIGATOR ACTIVITIES
•Develop grant applications
•Conduct research
•Disseminate results

Appendix 2
MBIH Research Center Radar Graphs


MBIH Center A
Targeting
Capacity
Curricula
Policy
Adoption
5
4
3
2
1
0


MBIH Center B
Targeting
Capacity
Curricula
Policy
Adoption
5
4
3
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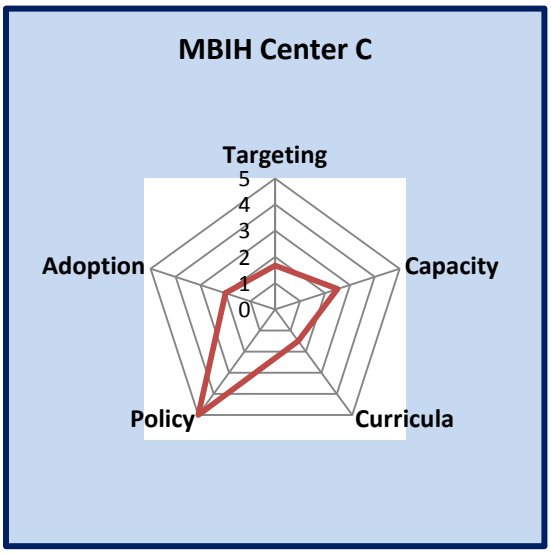
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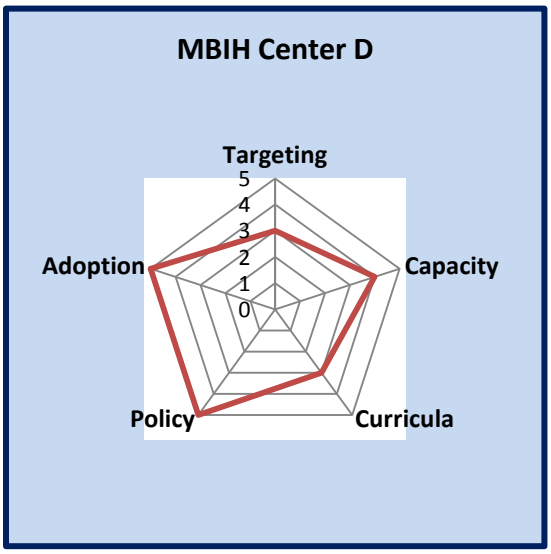
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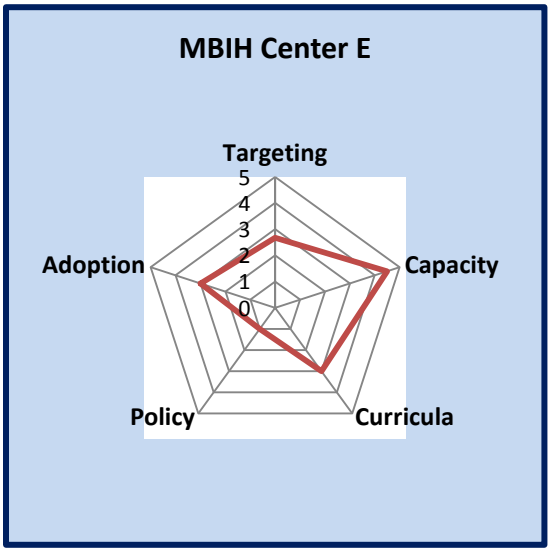
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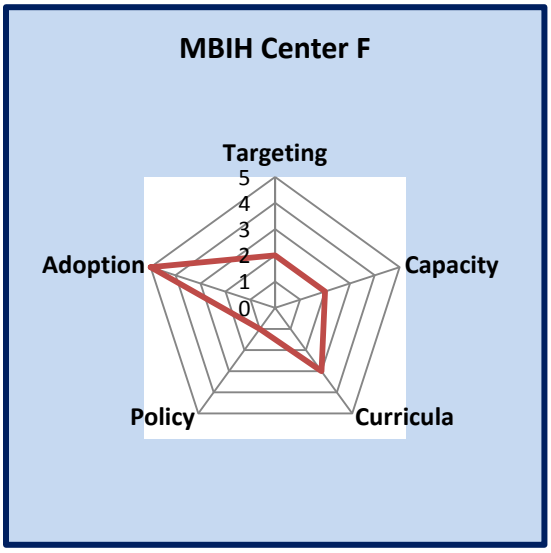
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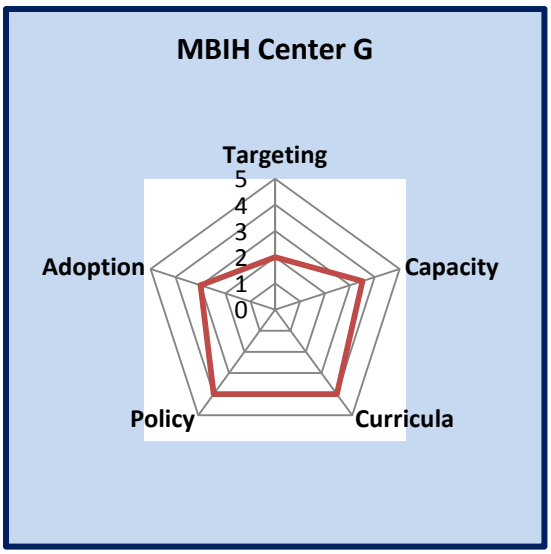
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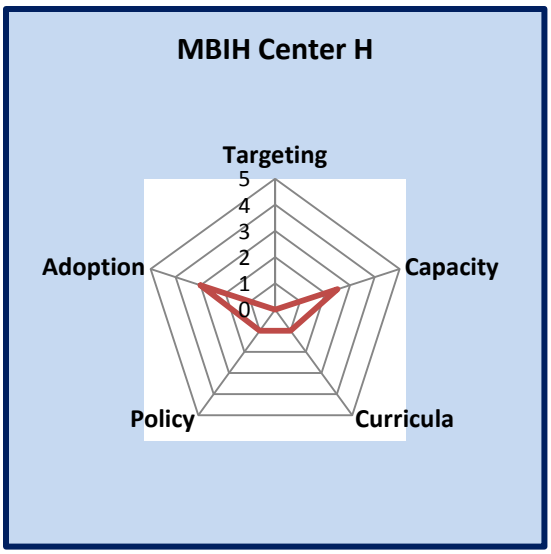
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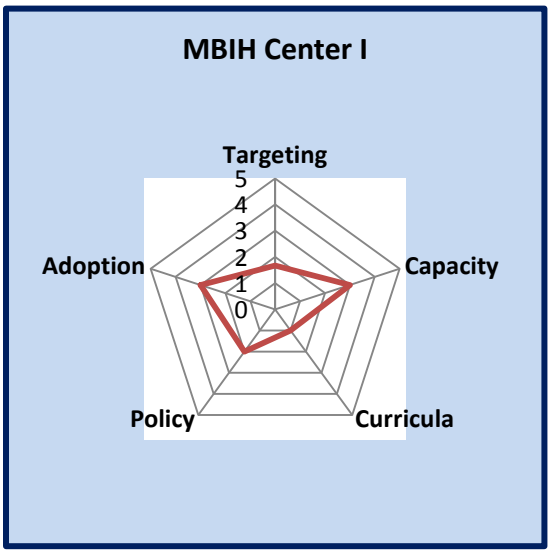
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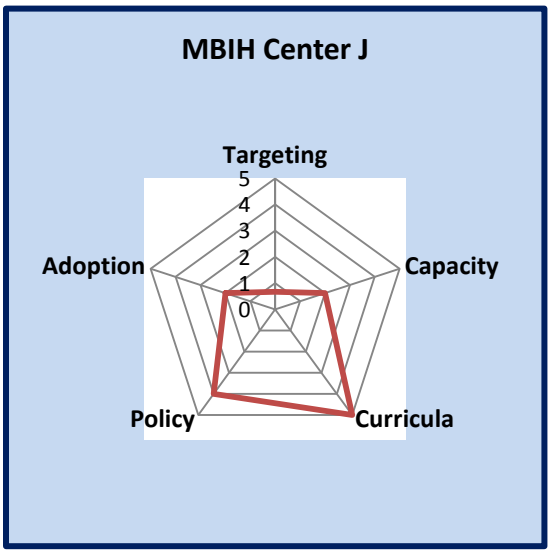
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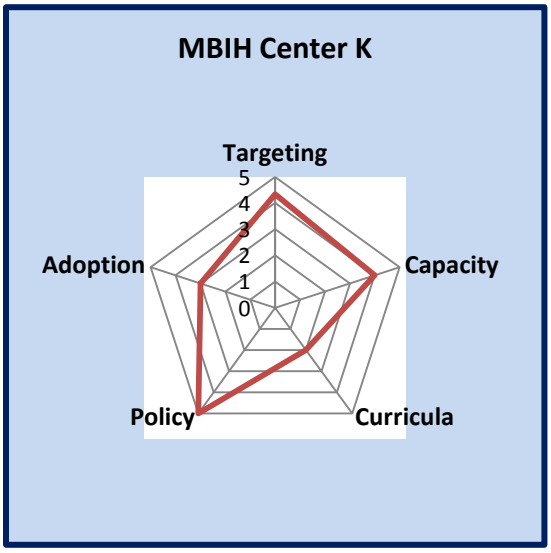
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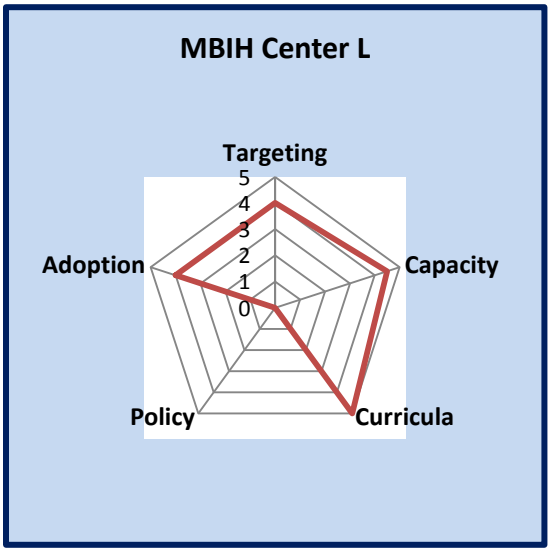
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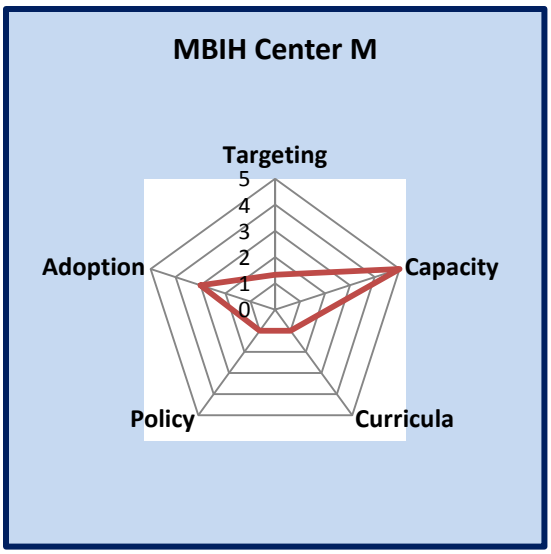
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Policy
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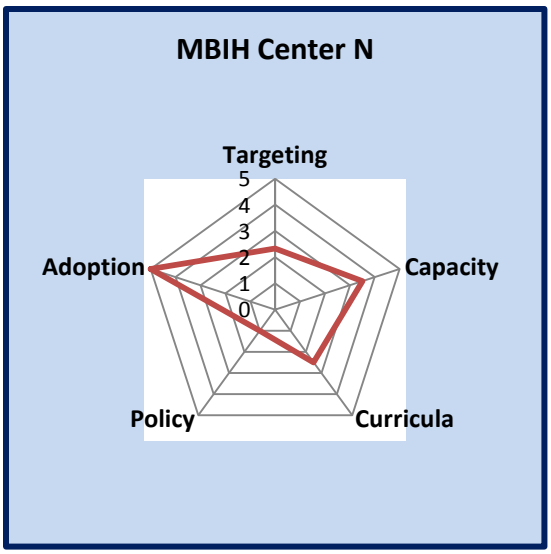
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Capacity
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Policy
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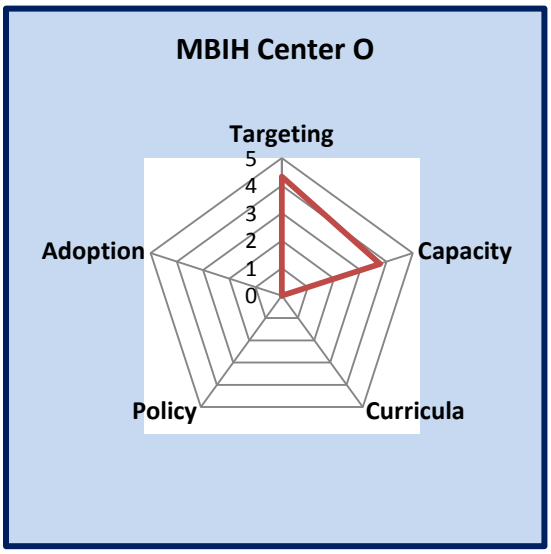
MBIH Center O
Targeting
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Capacity
Curricula
Policy
Adoption