

Biennial Report of the Director, National Institutes of Health, Fiscal Years 2006 & 2007

Preface

When Congress passed and the President subsequently signed into law the National Institutes of Health (NIH) Reform Act of 2006, it was only the third NIH omnibus reauthorization in NIH's history and it signaled renewed confidence in the NIH mission, its employees, and its leadership. NIH hopes that the information in this report—the first submitted under the new requirement established by Section 104 of the NIH Reform Act (Pub. L. No. 109-482)—justifies that confidence.

By amending Section 403 of the Public Health Service Act—to require the Director of NIH to submit, on a biennial basis, a report to Congress—Congress revived, but reinvented, a prior NIH reporting mandate. Instead of an Institute- and Center-based report, like those NIH traditionally generated, Congress required the new biennial report to provide an integrated portrait of NIH research activities.

The report represents the work of many NIH staff members, who collaborated in trans-NIH teams, to capture the remarkable array of important NIH research activities presented herein. As this is the first report submitted under the new requirement—Attachment A provides the language in Pub. L. No. 109-482 relevant to the NIH Director's Biennial Report—NIH welcomes feedback from Congress not only on the activities conveyed in this report, but also on the nature of the report and those aspects that improve NIH transparency and accountability as well as those that could be handled better in the next biennial report.

Chapter Organization

Chapter 1 opens with a statement from the Director, NIH, providing an assessment of the state of biomedical and behavioral research. It then provides a description of NIH policies and procedures focusing on the operations of the extramural and intramural research programs, mechanisms for strategic planning (including recommendations for the next set of Roadmap initiatives), and various cross-cutting activities not covered in the chapters that follow.

Chapter 2 addresses NIH research activities from the perspective of diseases, disorders, and adverse health conditions. The topics covered include:

- Cancer
- Neuroscience and Disorders of the Nervous System
- Infectious Diseases and Biodefense
- Autoimmune Diseases
- Chronic Diseases and Organ Systems
- Life Stages, Human Development, and Rehabilitation
- Minority Health and Health Disparities.

These topics, all categories specified in NIH Reform Act of 2006 (see Appendix A), are grouped together in one chapter to address the intent of the statute, in terms of presenting information on diseases, disorders, and adverse health conditions in a standardized format. Each topic is addressed in a separate section. The material in each section is organized as follows:

A brief introduction describes and defines the disease or condition and indicates the scope of NIH research activity,

A brief introduction describes and defines the disease or condition and indicates the scope of NIH research activity, provides data on disease burden and related health statistics, and, when available, presents aggregate data on NIH funding for research on the disease or condition.

This introduction is followed by a summary of NIH activity that reflects the breadth and depth of the research and related efforts of Institutes and Centers (ICs) and Office of the Director (OD) program offices whose missions encompass these diseases and conditions.

The summary is followed by notable examples of research activities, such as key programs, initiatives, studies, and accomplishments. The notable examples provide snapshots and highlights of research and related activities and, in so doing, illustrate the depth and breadth of NIH efforts.

Following the notable examples is a list of strategic plans relevant to the disease/condition. These plans are listed by IC and OD program office, with plans most closely aligned to the topic listed first. Whenever possible, links are provided to Web sites where additional information is available. Many ICs and OD program offices have research plans and agenda that, while not specific enough to a topic to be listed in Chapter 2, nonetheless are worth noting because the plans crosscut and underpin NIH activities specific to diseases, disorders, and adverse health conditions. Such plans include those of the [National Institute of General Medical Sciences](#), [National Institute of Environmental Health Sciences](#), [National Human Genome Research Institute](#), [National Institute of Biomedical Imaging and Bioengineering](#), [National Center for Research Resources](#), [National Library of Medicine](#), [NIH Clinical Center](#), [Office of Behavioral and Social Sciences Research](#), and [Office of Research on Women's Health](#).

Chapter 2 concludes with a table on NIH funding. The funding information is based on the standard table of NIH [Estimates of Funding by Various Diseases, Conditions, Research Areas](#), which presents information NIH routinely collects on agency-wide funding in areas of special interest.

Chapter 3 addresses NIH research activities from the perspective of key research approaches and resources. The topics covered include:

Fields and Approaches

- Epidemiological and Longitudinal Studies
- Genomics
- Molecular Biology and Basic Sciences
- Clinical and Translational Research

Tools and Training

- Disease Registries, Databases, and Biomedical Information Systems
- Technology Development
- Research Training and Career Development

Health Information and Communication

- Health Communication and Information Campaigns and Clearinghouses

These topics are all categories specified in the NIH Reform Act (see Appendix A).

NIH research spans many disciplines and every stage of inquiry. Those addressed in this report are of particular interest, based on their citation in the statute. *Epidemiological and longitudinal studies* examine the causes,

courses, and outcomes of health and disease at the population level. *Genomic research* studies an organism's entire genome (the complete assembly of its genes) focusing on the genome as an interrelated network. *Molecular biology and the basic sciences* are providing insights into human health and disease at the most fundamental levels, providing information essential to understanding basic human biology and behavior in their normal and diseased states. Through investments in *clinical and translation research*, NIH is moving basic discoveries into effective treatments and disease preventives as well as uncovering knowledge gaps that require more basic inquiry.

Similarly, research enabling research activities such as *information systems, technology development, and training* provide efficient collection, storage, and access to critical biomedical and behavioral information; generate the tools, tests, devices, and methods that foster new fields of science and medicine; and prepare and hone the minds that propel discovery. All of these areas of endeavor extend the capacity of the national biomedical and behavioral research enterprise in critical ways.

Ensuring the uptake of the research results by clinical practitioners and the public is another important facet of NIH's mission. Targeted *health communication plans and information campaigns* that provide science-based information are essential to improving people's health and saving lives.

The material on each of these topics is organized as follows: A brief introduction describes and defines the approach or resource and indicates the scope of NIH research activity. This introduction is followed by a summary of NIH activity that reflects the breadth and depth of the research and related efforts of ICs and OD program offices whose missions encompass the topic area. The summary is followed by notable examples of research activities, such as significant programs, initiatives, studies, and accomplishments. The notable examples provide snapshots and highlights of research and related activities and, in so doing, illustrate the depth and breadth of NIH efforts. Whenever possible, links are provided to Web sites where additional information can be found. The topic sections in Chapters 2 and 3 each provide an overview and highlights; they are representative rather than comprehensive.

In future editions of the Biennial Report, NIH will have the benefit of using the NIH Research, Conditions, and Disease Categorization (RCDC) system, an NIH-wide automated research categorization system currently in development. RCDC is intended to improve the consistency, transparency, and efficiency of NIH reporting on the areas of research captured in the table of NIH [Estimates of Funding by Various Diseases, Conditions, Research Areas](#). This tool also will enable NIH to catalog research activities for the various areas. Some expansion of RCDC capacity beyond the areas for which NIH currently captures trans-NIH funding information is needed but will be possible.

Chapter 4 addresses certain NIH Centers of Excellence. Overall, NIH Centers of Excellence are diverse in focus, scope, and origin. The NIH Centers of Excellence described in this report are a subset—those established by statutory mandate. The chapter provides overviews, outcomes (in the form of programmatic and research accomplishments), recommendations, evaluation plans, and future directions for the six congressionally mandated NIH Centers of Excellence programs, described in order of their establishment:

- Alzheimer's Diseases Centers (1984)
- Claude D. Pepper Older Americans Independence Centers of Excellence (1989)
- Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers (2001)
- National Center on Minority Health and Health Disparities Centers of Excellence (2001)
- Rare Diseases Clinical Research Network (2002)

- New Autism Centers of Excellence (2006) (which merged the previously existing Collaborative Programs of Excellence in Autism and Studies to Advance Autism Research and Treatment)

The Appendices present reference documents and supporting data. *Appendix A* provides a copy of the sections of the NIH Reform Act of 2006 (Pub. L. No. 109-482) that require this biennial report. *Appendix B* lists and briefly describes the missions of the NIH ICs and the program offices in the Office of the NIH Director. It also supplies links to IC and office strategic plans. *Appendix C* supplies a copy of the *Common Fund Strategic Planning Report, FY 2008*. *Appendix D* consists of data on the primary NIH research training program, the National Research Service Award program, National Library of Medicine training programs, and graduate medical education. *Appendix E* excerpts sections of *Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research*, in order to identify clinical research study populations by demographic variables. *Appendix F* excerpts sections of the *Report of the Advisory Committee on Research on Women's Health*, in order to include, by reference, that biennial report, within this one, as required by Section 486(d)(5) and Section 403 of the Public Health Service Act, 42 U.S.C. 283, which predate the reporting requirement established by the NIH Reform Act of 2006.