

Preface

This is the second NIH Biennial Report submitted under the requirement established by Section 104 of the NIH Reform Act (Pub. L. No. 109-482). Appendix A provides the language in the Reform Act that is relevant to this report, along with the language of two subsequent laws that supplement the provisions of the Reform Act—the Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85) and the Newborn Screening Saves Lives Act of 2007 (Pub. L. No. 110-204).

NIH hopes that the information in this report serves as a useful reference for understanding NIH activities and operations and welcomes feedback on the report. Did you find the information you were looking for in the report? Was the information useful? What didn't you find that you were looking for? How can the report be enhanced to improve NIH transparency and accountability?

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 structure, policies, and procedures focusing on the operations of the extramural and intramural research programs, mechanisms for strategic planning (including the activities and processes of the Division of Program Coordination, Planning and Strategic Initiatives, and its management of the Common Fund), and various cross-cutting activities not covered in the chapters that follow, such as NIH implementation of the American Recovery and Reinvestment Act of 2009, programs that provide the platform for discovery, endeavors to improve research management (such as the effort to enhance peer review), activities to capitalize on discovery, and ways NIH is ensuring responsible conduct of research.

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 the 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, 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. Now that the NIH [Research, Condition, and Disease Categories \(RCDC\)](#) system is in place, for categories on which NIH collects agency-wide funding data, in the electronic version of the report, we provide a live link to detailed project listings. NIH expects to expand the capacity of RCDC in future years, and this will increase the number of

Biennial Report categories for which NIH has aggregate agency-wide funding data and project listings.

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 the diseases and conditions addressed in the section.

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, provide further details on many of the activities addressed in the summary as well as details about other activities.

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 websites where additional information is available.

Many ICs and OD program offices have research plans and agendas that, although 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 [Center for Scientific Review](#), [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 AIDS Research](#), [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 for Various Research, Condition, and Disease Categories \(RCDC\)](#), 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 translational research, NIH is moving basic discoveries into effective treatment and prevention strategies as well as uncovering knowledge gaps that require more basic inquiry.

Similarly, research-enabling activities, such as design, implementation, and maintenance of information systems, the development of new technology, and the training and career development of scientists, 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. The activities in each of these areas extend the capacity of the national biomedical and behavioral research enterprise in critical ways.

Ensuring the uptake of 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. In the electronic version of the document, whenever possible, **links** are provided to websites 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.

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. This chapter provides overviews, progress reports for the FY 2008 and 2009 biennial period (covering programmatic and research activities and outcomes), recommendations, evaluation plans, and future directions for the six congressionally mandated NIH Centers of Excellence programs, which are described in the order of their establishment:

- Alzheimer's Disease 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 (2003)
- 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

Tables listing the centers funded under each mandated Centers of Excellence program appear at the end of the narrative on each program.

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, as well as the relevant text from two subsequent laws that supplement the provisions of the Reform Act—the Food and Drug Administration Amendments Act of 2007 (Pub. L. No. 110-85) and the Newborn Screening

Saves Lives Act of 2007 (Pub. L. No. 110-204). Appendix B lists and briefly describes the missions of the NIH ICs and the OD program offices. It also supplies links to IC and OD program office strategic plans. Appendix C supplies a copy of the *Common Fund Strategic Planning Report, FY 2009*. Appendix D provides excerpts 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, as is required by the Reform Act. Appendix E consists of data on the primary NIH research training program, the National Research Service Award program, the National Library of Medicine training programs, and NIH graduate medical education activities. Appendix F provides excerpts 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.