Appendices

Appendix A:
Pub. L. No. 109-482
(Relevant Provisions)

Public Law 109-482: The National Institutes of Health Reform Act of 2006 (Relevant Provisions)

An Act

To amend title IV of the Public Health Service Act to revise and extend the authorities of the National Institutes of Health, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institutes of Health Reform Act of 2006".

TITLE I—NIH REFORM

SEC. 102. AUTHORITY OF DIRECTOR OF NIH.

(b) ***Additional Authorities***.—Section 402(b) of the Public Health Service Act, as amended by subsection (a) of this section, is amended by striking paragraphs (2) and (3) and inserting the following:

"(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

"(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

“(ii) include information on such research in reports under section 403;

SEC. 104. REPORTS

(a) Report of Director of NIH.—The Public Health Service Act (42 U.S.C. 201 et seq.), as amended by section 103(a) of this Act, is amended—

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(3) by striking section 403 <<NOTE: 42 USC 283.>> and inserting the following sections:

“SEC. 403. <NOTE: 42 USC 283.> BIENNIAL REPORTS OF DIRECTOR OF NIH.

“ (a) In General.—The Director of NIH shall submit to the Congress on a biennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after the date of the enactment of the National Institutes of Health Reform Act of 2006. Each such report shall include the following information:

“ (1) An assessment of the state of biomedical and behavioral research.

“ (2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

“ (3) Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 402(b)(7) through the Division of Program Coordination, Planning, and Strategic Initiatives.

“ (4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

“ (A) The catalog shall, for each such activity—

“ (i) identify the agency or agencies involved;

“ (ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

“ (iii) identify whether the activity was carried out through a center of excellence.

(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables and other variables that contribute to research on minority health and health disparities.

(C) Research activities listed in the catalog shall include, where applicable, the following:

(i) Epidemiological studies and longitudinal studies.

(ii) Disease registries, information clearinghouses, and other data systems.

(iii) Public education and information campaigns.

(iv) Training activities, including—

(I) National Research Service Awards and Clinical Transformation Science Awards;

(II) graduate medical education programs, including information on the number and type of graduate degrees awarded during the period in which the programs received funding under this title;

(III) investigator-initiated awards for postdoctoral training;

(IV) a breakdown by demographic variables and other appropriate categories; and

(V) an evaluation and comparison of outcomes and effectiveness of various training programs.

(v) Clinical trials, including a breakdown of participation by study populations and demographic variables and such other information as may be necessary to demonstrate compliance with section 492B (regarding inclusion of women and minorities in clinical research).

(vi) Translational research activities with other agencies of the Public Health Service.

(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories, where applicable:

(A) Cancer.

(B) Neurosciences.

(C) Life stages, human development, and rehabilitation.

(D) Organ systems.

(E) Autoimmune diseases.

(F) Genomics.

(G) Molecular biology and basic science.

(H) Technology development.

(I) Chronic diseases, including pain and palliative care.

(J) Infectious diseases and bioterrorism.

(K) Minority health and health disparities.

(L) Such additional categories as the Director determines to be appropriate.

(6) A review of each entity receiving funding under this title in its capacity as a center of excellence (in this paragraph referred to as a `center of excellence'), including the following:

(A) An evaluation of the performance and research outcomes of each center of excellence.

(B) Recommendations for promoting coordination of information among the centers of excellence.

(C) Recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(D) If no additional centers of excellence have been funded under this title since the previous report under this section, an explanation of the reasons for not funding any additional centers.

(b) Requirement Regarding Disease-Specific Research Activities.— In a report under subsection (a), the Director of NIH, when reporting on research activities relating to a specific disease, disorder, or other adverse health condition, shall—

“ (1) present information in a standardized format;

“ (2) identify the actual dollar amounts obligated for such activities; and

“ (3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

SEC. 106. <NOTE: 42 USC 284 note.> ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD.

(a) In General.—In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by—

(b) Report.—As part of the biennial report under section 403 of the Public Health Service Act, the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

Appendices

Appendix B:
Priorities and Plans of the Institutes and Centers and the Program Offices in the Office of the Director

This appendix provides brief descriptions of the missions of the NIH Institutes and Centers (ICs) and the program offices in the Office of the Director. Links to strategic plans (or strategic planning Web sites) are embedded in the names of the ICs and offices. The ICs are presented in the order in which they appear on the appropriation table in the Congressional Justification. The mission statements and strategic plans presented here classify and justify NIH priorities.

NIH Institutes and Centers

National Cancer Institute **(NCI).** NCI leads a national effort to reduce the burden of cancer. The National Cancer Act of 1971 broadened the scope and responsibilities of NCI and created the National Cancer Program, which conducts and supports basic and clinical biomedical research; training; health information dissemination; and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer and HIV/AIDS; rehabilitation from cancer; and the continuing care of cancer patients and their families. NCI aims for a future in which we can prevent cancer before it starts, identify cancers that do develop at the earliest stage, eliminate cancers through innovative treatment interventions, and biologically control those cancers that we cannot eliminate so they become manageable, chronic diseases.

National Heart, Lung, and Blood Institute ***(NHLBI).*** NHLBI provides leadership for a national research program in diseases of the heart, blood vessels, lung, and blood; sleep disorders; and blood resources management. The Institute plans, conducts, fosters, and supports an integrated and coordinated program of basic research, clinical investigations and trials, observational studies, and demonstration and education projects. In addition, NHLBI plans and directs research in the development and evaluation of interventions and devices related to the prevention of diseases and disorders within its purview and the treatment and rehabilitation of patients who suffer from them. Also, the NHLBI oversees management of the NIH Women's Health Initiative.

National Institute of Dental and Craniofacial Research ***(NIDCR).*** NIDCR's mission is to improve oral, dental, and craniofacial health through research, research training, and the dissemination of health information. The Institute accomplishes its mission through basic and clinical research; training and career development programs that ensure an adequate number of talented, well-prepared, and diverse investigators; coordination across all sectors of the research community; and the timely transfer of knowledge gained from research and its implications for health to the public, health professionals, researchers, and policymakers.

***National Institute of Diabetes and Digestive and Kidney Diseases* (NIDDK).** NIDDK conducts and supports basic and applied research and provides leadership for national programs in diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases. Several of these diseases are among the leading causes of disability and death and all can seriously affect the quality of life of those who have them.

***National Institute of Neurological Disorders and Stroke* (NINDS).** NINDS aims to reduce the burden of neurological diseases and disorders. To accomplish this goal, the Institute conducts and supports basic, translational, and clinical research on the normal and diseased nervous system, fosters the training of investigators in the neurosciences, and seeks to better understand, diagnose, treat, and prevent neurological disorders. The NINDS research portfolio encompasses hundreds of neurological disorders, from diseases such as stroke that affect millions of people and are among the leading causes of death and disability, to rare disorders that individually affect a few people but collectively have an enormous impact on patients and families.

***National Institute of Allergy and Infectious Diseases* (NIAID).** NIAID's mission is to conduct and support research to understand, treat, and prevent infectious and immune-related diseases. Infectious diseases include well-known killers such as HIV/AIDS, tuberculosis, and malaria; emerging or reemerging threats such as influenza and extensively drug-resistant tuberculosis (XDR-TB); and “deliberately emerging” threats from potential agents of bioterrorism. Immune-related disorders include autoimmune diseases such as rheumatoid arthritis as well as asthma, allergies, and problems associated with transplantation.

***National Institute of General Medical Sciences* (NIGMS).** NIGMS supports basic biomedical research that increases the understanding of life processes and lays the foundation for advances in disease diagnosis, treatment, and prevention. The Institute's programs encompass the areas of cell biology, biophysics, genetics, developmental biology, pharmacology, physiology, biological chemistry, bioinformatics, computational biology, and minority biomedical research and training.

***National Institute of Child Health and Human Development* (NICHD).** NICHD conducts and supports research on all stages of human development, from preconception to adulthood, to better understand the health of children, adults, families, and communities. This includes research on fertility, pregnancy, growth, developmental disabilities, and medical rehabilitation.

***National Eye Institute* (NEI).** NEI conducts and supports research that helps prevent and treat eye diseases and other disorders of vision. This research leads to sight-saving treatments, reduces visual impairment and blindness, and improves the quality of life for people of all ages. NEI-supported research has advanced our knowledge of how the eye functions in health and disease.

***National Institute of Environmental Health Sciences* (NIEHS).** The mission of NIEHS is to reduce the burden of human illness and disability by understanding how the environment influences the development and progression of human disease.

***National Institute on Aging* (NIA).** NIA leads a broad scientific effort to understand the nature of aging and to extend the healthy, active years of life. The Institute provides leadership in aging research, training, health information dissemination, and other programs relevant to aging and older people and serves as the primary Federal agency on Alzheimer's disease research.

***National Institute of Arthritis and Musculoskeletal and Skin Diseases* (NIAMS).** NIAMS supports research to address the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; the training of basic and clinical scientists to carry out this research; and the dissemination of information on research progress in these diseases.

***National Institute on Deafness and Other Communication Disorders* (NIDCD).** NIDCD conducts and supports biomedical research and research training on normal mechanisms as well as diseases and disorders of hearing, balance, smell, taste, voice, speech, and language. In addition, NIDCD conducts and supports research and research training related to disease prevention and health promotion; addresses special biomedical and behavioral problems associated with persons who have communication impairments or disorders; and supports efforts to create devices that substitute for lost and impaired sensory and communication function.

***National Institute of Mental Health* (NIMH).** NIMH's mission is to reduce the burden of mental illness and behavioral disorders through research on the mind, brain, and behavior. Mental disorders are brain disorders and that means that achieving progress requires a deeper understanding of the brain and behavior. To fulfill its mission, NIMH conducts and supports research and training on advancing the integrative science of brain and behavior; developing more reliable, valid diagnostic tests and biomarkers; defining the genetic and environmental risk architecture for mental disorders; developing interventions to prevent occurrence and/or reduce relapse of mental disorders; developing more effective, safer, and equitable treatment; conducting clinical trials that will provide treatment options to deliver more effective personalized care across diverse populations and settings; and creating improved pathways for rapid dissemination of science to mental health care and service efforts.

***National Institute on Drug Abuse* (NIDA).** NIDA's mission is to lead the Nation in bringing the power of science to bear on drug abuse and addiction. This charge has two critical components. The first is the strategic support and conduct of research across a broad range of disciplines. The second is ensuring the rapid and effective dissemination and use of the results of that research to significantly improve prevention and treatment, and to inform policy as it relates to drug abuse and addiction.

***National Institute on Alcohol Abuse and Alcoholism* (NIAAA).** NIAAA supports and conducts research focused on improving the treatment and prevention of alcoholism and alcohol-related problems to reduce the enormous health, social, and economic consequences of this disease. NIAAA conducts and supports research in a wide range of scientific areas including genetics, neuroscience, epidemiology, health risks and benefits of alcohol consumption, prevention, and treatment; coordinates and collaborates with international, national, State, and local institutions, organizations, agencies, and programs engaged in alcohol-related work; and communicates research findings to health care providers, researchers, policymakers, and the public.

***National Institute of Nursing Research* (NINR).** NINR promotes and improves the health of individuals, families, communities, and populations through nursing research and research training. NINR's research foci encompass health promotion and disease prevention, quality of life, health disparities, and end-of-life care. NINR seeks to extend nursing science by integrating the biological and behavioral sciences, applying new technologies to research questions, improving research methods, and developing the nurse scientists of the future.

***National Human Genome Research Institute* (NHGRI).** NHGRI's mission has expanded since the initiation of the International Human Genome Project to encompass a broad range of studies aimed at understanding the structure and function of the human genome and its role in health and disease. A critical part of the NHGRI mission continues to be the study of the ethical, legal, and social implications of genome research. NHGRI also supports the training of investigators and the dissemination of genome-related information to the public and health professionals.

***National Institute of Biomedical Imaging and Bioengineering* (NIBIB).** NIBIB's mission is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance research and medical care.

***National Center for Research Resources* (NCRR).** NCRR provides laboratory scientists and clinical researchers with the environments and tools needed to make biomedical discoveries, translate these findings to animal-based studies, and then apply them to patient-oriented research. NCRR connects researchers with one another and with patients and communities across the Nation. These connections bring together innovative research teams and the power of shared resources, multiplying the opportunities to improve human health. Together, NCRR's four integrated and complementary divisions—biomedical technology, clinical and translational research, comparative medicine, and research infrastructure—accelerate and enhance research along the entire continuum of biomedical science.

***National Center for Complementary and Alternative Medicine* (NCCAM).** NCCAM is dedicated to exploring complementary and alternative healing practices in the context of rigorous science; training complementary and alternative medicine researchers; and disseminating authoritative information to the public and professionals. To fulfill its mission, NCCAM supports a broad-based portfolio of research, research training, and educational grants and contracts, as well as various outreach mechanisms to disseminate information.

***National Center on Minority Health and Health Disparities* (NCMHD).**[1] NCMHD promotes minority health and leads, coordinates, supports, and assesses NIH efforts to reduce and ultimately eliminate health disparities. In this effort, NCMHD supports and partners with other ICs to support basic, clinical, social, and behavioral research, promote research infrastructure and training, foster emerging programs, disseminate health information, and reach out to minority and other communities that suffer from disparities in health.

***John E. Fogarty International Center* (FIC).** FIC strengthens human and institutional capacity to confront complex global health challenges through innovative and collaborative research and training programs. It builds the knowledge and skills of developing country foreign scientists, identifies crucial gaps in global health research, and supports and advances the NIH mission through international partnerships.

***National Library of Medicine* (NLM).** NLM is the world's largest research library of the health sciences, serving scientists, health professionals, and the public by collecting, organizing, and providing access to biomedical information. NLM also carries out programs designed to strengthen existing and develop new medical library services in the United States. It conducts research in health communications, supports medical informatics, and provides information services and sophisticated tools in the areas of molecular biology and toxicology/environmental health. NLM creates Web-based services for the general public containing information from NIH and other reliable sources. (Also see “The Library” in the section on “Providing the Platform for Discovery,” in Chapter 1.)

NIH Clinical Center. The Clinical Center is the NIH facility that provides the patient care, medical services, and environment necessary for NIH scientists to conduct clinical research. Clinical and laboratory research is conducted shoulder-to-shoulder at the Clinical Center and this tandem approach drives all aspects of its operations. (Also see “The Clinical Center” in the section on “Providing the Platform for Discovery” in Chapter 1)

***Center for Information Technology* (CIT).** CIT incorporates the power of modern computers into NIH's biomedical and behavioral research programs and administrative procedures by focusing on three primary activities: conducting computational biosciences research, developing computer systems, and providing computer facilities. (Also see “Information Technology” in the section on “Providing the Platform for Discovery” in Chapter 1.)

***Center for Scientific Review* (CSR).** CSR carries out peer review of the majority of research and research training applications submitted to NIH; serves as the central receipt point for all such Public Health Service applications; makes referrals to scientific review groups for scientific and technical merit review of applications and to funding components for potential award; and develops and implements innovative, flexible ways to conduct referral and review for all aspects of science. (Also see “NIH Peer Review Process” under the section on “The Extramural Research Program” in Chapter 1.)

Office of the Director

Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI). DPCPSI is a new structure within the NIH OD, mandated by the NIH Reform Act of 2006. DPCPSI incorporates functions of the Office of Portfolio Analysis and Strategic Initiatives (which has primary responsibility for trans-NIH research initiatives based on NIH-wide portfolio assessment, strategic planning, evaluation, and assessment) and most responsibilities of the four OD Program Offices (which are responsible for stimulating and coordinating specific areas of research across NIH). See “Strategic Planning and Roadmap 1.5,” in Chapter 1, for further information on DPCPSI, the Office of Portfolio Analysis and Strategic Initiatives, and the activities they support. See Appendix C for the Common Fund Strategic Planning Report, FY 2008.

The four OD Program Offices are in the areas of disease prevention; behavioral and social sciences research; women's health; and AIDS research.

Office of Disease Prevention (ODP). ODP fosters, coordinates, and assesses research in prevention research that seeks to improve public health in the Nation and throughout the world. ODP collaborates with other Federal agencies, academic institutions, the private sector, nongovernmental organizations, and international organizations in the formulation of research initiatives and policies that promote public health, and advises the NIH Director on these topics. There are three offices within ODP: Office of Rare Diseases (ORD), Office of Dietary Supplements (ODS), and Office of Medical Applications of Research (OMAR):

- ORD stimulates and coordinates research on rare diseases to respond to the needs of approximately 25 million patients who have one of the 7,000 known rare diseases. (Also see the section on the *Rare Diseases Clinical Research Network* in Chapter 4, which addresses NIH Centers of Excellence.)
- ODS promotes and supports, through collaboration with the ICs, basic and clinical research to increase understanding of the impact of dietary supplements (e.g., plant extracts, enzymes, vitamins, minerals, amino acids, hormonal extracts) on disease prevention and health maintenance.
- OMAR is the focal point for evidence-based assessments of medical practice and state-of-the-science conferences—key mechanisms for translating and disseminating the results of biomedical research to improve the delivery of health services to the public.

Office of Behavioral and Social Sciences Research (OBSSR). OBSSR coordinates and stimulates behavioral and social sciences research throughout the NIH and integrates it more fully into the NIH research enterprise. The Office provides leadership on matters relating to research on the roles of human behavior and the social environment in the development of health, prevention of disease, and therapeutic intervention, as well as in training, continuing education, and dissemination of research findings to the broader scientific community and the general public.

***Office of Research on Women's Health* (ORWH).** ORWH serves as a focal point for women's health research at NIH. ORWH promotes, stimulates, and supports efforts to improve the health of women through biomedical and behavioral research. The Office works in partnership with the NIH ICs to ensure that women's health research is part of the scientific framework at NIH and throughout the broader scientific community.

***Office of AIDS Research* (OAR).** OAR is responsible for the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. This includes responsibility for developing an annual comprehensive plan and budget for all NIH AIDS research and supporting trans-NIH Coordinating Committees to assist in these efforts.

[1] The NIH Health Disparities Strategic Plan for 2004-2008 has been approved by the National Advisory Council on Minority Health and Health Disparities, but is awaiting formal clearance.

Appendices

Appendix C:
Common Fund Strategic Planning Report, FY 2008

National Institutes of Health, Department of Health and Human Services, March 2008

Common Fund Strategic Planning Report, 2008

Scientific staff of the National Institutes of Health (NIH) are implementing new initiatives that have been approved for support through the Common Fund starting in FY 2008. The staff have consulted with experts inside and outside NIH to identify and refine initiatives that will most efficiently and directly meet the scientific need and criteria established for use of the Common Fund. This updated report describes the strategic process that guides the use of the Common Fund, new initiatives that have been chosen for implementation, additional concepts that remain in development, and plans for ongoing identification and development of Common Fund initiatives.

I. Background and Budget of the Roadmap/Common Fund

In FY 2003, Dr. Elias Zerhouni established the NIH Roadmap as a defined, centralized pool of funds to provide virtual "incubator space" or venture capital to support innovative research initiatives that address grand challenges in basic, clinical, and translational research. With funding beginning in FY 2004, the NIH Roadmap became the foundation for the Common Fund. In January 2007, President Bush signed into law the National Institutes of Health Reform Act of 2006, Pub. L. No. 109-482, which reauthorized the NIH, affirming its vital role in advancing biomedical research, and codified the Common Fund.

In FY 2004-FY 2006, the Common Fund was composed of contributions from each of the NIH Institutes and Centers as well as the NIH Office of the Director (OD). In FY 2007 and FY 2008 appropriations action, the Congress directly appropriated resources for the Common Fund to the OD. The following table shows Roadmap/Common Fund dollars and their percentage of NIH Labor/HHS budget authority by fiscal year:

Dollars in Millions	FY 2004 Actual B.A.	FY 2005 Actual B.A.	FY 2006 Actual B.A.	FY 2007 Joint Resolution	FY 2008 Appropriation

Institute or Center Roadmap/Common Fund Contribution	$93.5	$175.7	$247.3	$0.0	$0.0
OD Roadmap/Common Fund Contribution	$38.4	$64.0	$85.3	$483.0	$495.6
Roadmap/Common Fund	**$131.9**	**$239.7**	**$332.6**	**$483.0**	**$495.6**
Roadmap/Common Fund Percent of NIH Labor/HHS Budget Authority [1]	0.5%	0.8%	1.2%	1.7%	1.7%

The OD appropriation for FY 2008 included $495.6 million for the Common Fund. The NIH is using those funds to support:

- a) The cohort of NIH Roadmap/Common Fund research initiatives that began between FY 2004 and FY 2007. The estimated funding for these initiatives (summarized in Section III) in FY 2008 is $464 million.
- b) The Human Microbiome Project and the Epigenomics program, which have been added to the Common Fund in FY 2008 to support the development of novel research tools, technologies, and resources for research on microbes associated with the human body and epigenetic changes linked to human disease. The Common Fund is providing $32 million to launch these programs in FY 2008 (described in Sections III and IV).

II. Strategic Planning for the Roadmap/Common Fund

Planning and implementation of the Roadmap/Common Fund are highly dynamic processes that are intended to afford NIH the flexibility to quickly respond to new ideas, challenges, gaps, and advances in biomedical research. Nonetheless, decisions on the use of the Common Fund are based on strategic principles that defined the challenges and goals during the creation of the Roadmap and that guide the identification of new initiatives that receive support through this program.

A. Challenges Faced by NIH and the Biomedical Research Enterprise

The evolution of biomedical research in recent decades has led to an explosion of knowledge and technology that has revolutionized our understanding of basic biological systems and transformed the practice of medicine. Many of these advances, such as the Human Genome Project (HGP) and the state-of-the-art research technologies that were developed to complete that project, have created the means to compile vast amounts of biologically-relevant data and the corresponding need for new tools to effectively mine that data for new knowledge. In contrast, some research fields, such as fundamental research to characterize the microbes that live in and affect the human body, have lagged behind because they fall into "gaps" in traditional NIH programmatic approaches and funding mechanisms. The NIH recognized an opportunity to address these challenges by devising a new approach that would meet the research and training needs of biomedical research in the 21st century and accelerate the transformation of scientific knowledge into real benefits for public health.

B. Goals of the Roadmap/Common Fund

To respond to new opportunities and fill important research gaps, the NIH developed the Roadmap program (funded through the Common Fund) in consultation with leading experts from academia, industry, government, and the public. The NIH Roadmap/Common Fund supports wide-ranging and ambitious initiatives related to emerging opportunities and challenges. These activities focus on fundamental barriers to basic, clinical, and translational research that often require new multidisciplinary approaches, collaborations, synergies between basic science, clinical research, and informatics, as well as new training approaches for scientists. The Common Fund facilitates transformative research or technology development with cross-cutting relevance to many research disciplines, diseases or conditions, and biological questions.

Three broad categories of research have been identified that encompass the goals of the Roadmap/Common Fund: New Pathways to Discovery; Research Teams of the Future; and Reengineering the Clinical Research Enterprise. Initiatives funded through the first and second cohorts fit into one of these major themes, which will continue to be primary focus areas for the foreseeable future. Specific elements within each theme area will evolve as programs transition out of the Common Fund and new ideas are developed. (Section III lists the current programs that address the goals of the three overarching themes.)

C. Identification of Ideas and Criteria for Use of the Common Fund

NIH is committed to a broad, representative process for proposing, reviewing, and selecting concepts for new initiatives to be developed and implemented through the Common Fund. Ideas can be submitted by members of the extramural or intramural scientific community, health professionals, patient advocates, or the general public. After a public comment period, current initiatives were chosen for inclusion in the Common Fund by Institute and Center (IC) Directors and the NIH Director in consultation with the Advisory Council to the Director. For FY 2009 and future years, the newly-formed Council of Councils, which includes representation from each of the individual IC advisory councils, will participate in the prioritization of Common Fund projects, among other activities.

Specific criteria have been established to guide the ongoing development of Common Fund initiatives. Projects chosen for support must meet all five criteria:

- The proposed initiative must be truly transforming. It must have high potential to dramatically affect how biomedical and/or behavioral research is conducted over the next decade.
- The outcomes from the proposed initiative must synergistically promote and advance the individual missions of NIH ICs to benefit health.
- The proposed initiative must require participation from NIH as a whole and/or address an area(s) of science that does not clearly fall within the mission of any one IC or OD program office.
- The proposed initiative must be something that no other entity is likely or able to do.
- There must be a public health benefit to having the results of the research in the public domain.

D. Transition of Common Fund Initiatives

As a virtual incubator space for trans-NIH research initiatives, the Common Fund supports initiatives for a limited amount of time (5-10 years). This defined period of funding is intended to be catalytic—that is, the Roadmap initiatives are designed to establish new resources, tools, and technologies that will then be available for the broad scientific community to incorporate into research efforts funded through more typical mechanisms. Likewise, fundamental knowledge gaps that are filled through Roadmap projects will stimulate research proposals in many fields that can be submitted for review and funding by appropriate Institutes or Centers. The Roadmap is also intended to catalyze the development of critical research services that benefit the mission of all the Institutes and Centers and that, once developed, can be supported through the Institutes and Centers. Thus, the rigorous selection processes allow innovative initiatives to enter the incubator space for short-term support to prove their value to the research community.

At the end of the defined funding term, each initiative will have one of several possible outcomes. Programs that were designed from the outset to achieve their goals within the timeframe of support by the Common Fund will end. Other programs may end due to unmet objectives. Innovation often requires risk, and a fundamental goal of Roadmap programs is to foster innovative approaches to complex problems. Therefore the NIH encourages risk taking in the Roadmap and expects that some Roadmap programs may not be successful. Finally, many initiatives are expected to transition to other sources of support once the Roadmap “incubation” period has ended. If the programs have proven utility to the research missions of the Institutes and Centers, the Institutes and Centers either individually or via joint funding mechanisms will provide continued support. Alternatively, programs may continue to be funded via private foundations or research institutions. From the beginning of the funding period, each initiative has a transition plan that describes the anticipated path after Common Fund goals are achieved. Advanced planning for the strategic transition or termination of all initiatives selected for Common Fund support ensures that the program remains nimble and capable of responding to high-priority opportunities in a timely manner.

The majority of the first cohort of initiatives funded through the NIH Roadmap/Common Fund continues to receive support in FY 2008 through the Common Fund. In general, these research initiatives are expected to transition out of the Common Fund by 2013. In the meantime, each of these initiatives and all new initiatives are subject to objective reviews to ensure high quality research and to monitor progress. Continuation of support by the Common Fund is based in part on the outcome of these evaluations.

III. Implementation of the NIH Roadmap/Common Fund Strategic Plan, FY 2004-2008

FY 2008 funding continues support for the first cohort of NIH Roadmap/Common Fund initiatives. To take advantage of new opportunities, the NIH maintains a degree of flexibility in the allocation of funds. Emerging opportunities that have been identified and prioritized by the NIH for support by the Common Fund include the NIH Director's New Innovator Awards, which were first awarded in FY 2007, and the Human Microbiome Project and the Epigenomics program, which began implementation in FY 2008.

A. New Pathways to Discovery: Facilitates the development of research tools and/or methodologies that are of use to wide swaths of the scientific community; fills fundamental knowledge gaps to result in new scientific paradigms. Seven components comprise this theme, including two new initiatives for FY 2008.

1. *Molecular Libraries and Molecular Imaging*
   Establishes a national network of Centers and various supporting technologies for the discovery and development of small molecule probes to interrogate biological pathways.
2. *Building Blocks, Pathways, and Networks*
   Focuses on new technologies that are necessary to accelerate the process of scientific discovery and the understanding of biological pathways.
3. *3) Bioinformatics and Computational Biology*
   Develops informatics and computational tools tailored to handle the large amount of s cientific data generated using cutting-edge discovery technologies.
4. *Nanomedicine*
   Establishes a network of Nanomedicine Centers at academic institutions, to study how molecular structures are constructed and how they function.
5. *Structural Biology*
   Establishes Centers for Innovation in Membrane Protein Production that aim to formulate new methods and techniques for producing ample quantities of cellular membrane proteins that are of a quality suitable for structural and functional studies.
6. *Human Microbiome Project (new for FY 2008, see section IV)*
   Develops tools and generates resources to facilitate characterization of the human microbiome and analysis of its role in human health and disease.
7. *Epigenomics (new for FY 2008, see section IV)*
   Develops comprehensive reference maps of the human epigenome and new technologies for epigenomic analysis to define the relationship between the epigenome and human health and disease.

B. Research Teams of the Future: Supports investigators in new ways, encouraging team approaches to complex problems and highly innovative research.

1. *Interdisciplinary Research*
   Overcomes barriers to interdisciplinary research by building teams, training scientists in multiple disciplines, and changing academic research culture.
2. *Director's Pioneer Award*
   Supports visionary scientists to carry out extensive, high-risk, highly innovative research. These investigators perform research that is broad in its scope and may contribute to a transformation of new, fundamental principles within that research niche.

3. *Public-Private Partnerships*
   Provides a point of leadership and coordination for the harmonization, streamlining, and optimization of the NIH partnership activities.

4. *NIH Director's New Innovator Awards (new in FY 2007)*
   Stimulates highly innovative research and supports promising new investigators who propose exceptionally creative approaches that have the potential to produce an unusually high impact on the research enterprise.

C. Reengineering the Clinical Research Enterprise: Changes clinical research infrastructure to improve the ability to systematically leverage medical resources. This includes proposals and policy decisions that affect the culture and manner in which research is conducted.

1. *Clinical Translational Science Awards (CTSAs)*
   Transforms how clinical and translational research is conducted, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients.

2. *Patient-Reported Outcomes Measurement Information System (PROMIS)*
   PROMIS is a revolutionary effort to enhance the precision of measures of patient-reported symptoms and function.

3. *Translational Research Core Services*
   Makes available, on a competitive basis, certain critical resources needed for the development of therapeutic agents and to bridge the gap between discovery and clinical testing so that more efficient translation of promising discoveries may take place.

4. *Clinical Research Policy Analysis and Coordination*
   Serves as a focal point for the ongoing coordination, streamlining, and optimization of policies and requirements concerning the conduct and oversight of clinical research.

5. *The National Electronics Clinical Trials and Research Network (NECTAR)*
   Addresses the growing role of informatics in the medical field, particularly in conducting clinical trials. This initiative supports pilot studies that will provide the basis for a unified informatics system. This program has merged with the CTSAs for FY 2008 and beyond.

6. *The National Clinical Research Associates (NCRA)*
   Establishes and trains cadres of community-based health practitioners to conduct clinical research in collaboration with academic researchers. This program has merged with the CTSAs for FY 2008 and beyond.

IV. Ongoing Development of Common Fund Initiatives

To plan for the use of new funds expected to become available in FY 2008, the NIH undertook an intensive, wide-ranging, and transparent planning process that solicited input from NIH staff and scientists, extramural researchers, and the broader stakeholder community on gaps in knowledge or tools that impede certain types of research from moving forward. After reviewing and prioritizing more than 300 ideas for new initiatives, the NIH selected two major programs for implementation beginning in FY 2008 with resources from the Common Fund. Each of these multicomponent programs represents the integration of several original ideas submitted for review. Other concepts remain under consideration for future implementation. The process of solicitation, review, and prioritization of concept proposals that could advance the mission of the NIH as a whole and that meet the criteria for Common Fund support will continue in FY 2008 and will be repeated each year to allow emerging opportunities to be identified.

A. New Common Fund Initiatives for Implementation in FY 2008

The two initiatives being launched in FY 2008—the Human Microbiome Project and the Epigenomics program—are associated with the general theme of "New Pathways to Discovery." These programs each respond to the Common Fund goals of advancing basic knowledge and developing new tools or resources that will be broadly applicable to many research fields. In FY 2008, the NIH is spending a combined $32 million from the Common Fund on the first year of funding for these initiatives.

- **Human Microbiome Project:** The human body contains ten times as many microbial cells—bacteria and other micro-organisms—as it does human cells. These microbes, which are found in locations throughout the body, are thought to have a profound influence on many biological processes, including development, immunity, and nutrition. However, technical difficulties in isolating and studying many of these organisms have limited our ability to fully understand the effects of the microbiome on human health and disease. The Human Microbiome Project will generate resources and support the development of new technologies and computational approaches to facilitate the characterization of the highly complex human microbiome. This project will improve our knowledge of how changes in the microbiome correlate with changes in human health.

- **Epigenomics:** The human epigenome is the collection of all stable, "epigenetic," modifications of the human genome structure that do not change the DNA sequence. Some human diseases are known to be associated with epigenetic changes, but little is known about the factors that cause these changes. Moreover, new tools are needed to more efficiently detect epigenetic changes and correlate them with specific diseases or health conditions. The Epigenomics program will support efforts to map all common epigenetic changes in the human genome and to develop new technologies and data analysis tools for detecting and studying epigenetic modifications. Public databases will be made available to the broad research community to facilitate progress in epigenomics research.

B. Concepts in Development for Future Implementation

Two additional programs are being refined for possible future implementation. Each of these initiatives, if chosen for funding, also represents the synthesis of multiple ideas submitted through the proposal review and prioritization process. The process of soliciting, reviewing, and developing new concepts that meet the criteria for Common Fund support will continue in FY 2008 and future years to ensure that the Roadmap/Common Fund rapidly identifies and responds to emerging scientific opportunities.

- The **Protein Capture Tools/Proteome Tools** project will develop and disseminate high quality probes that can be synthesized reproducibly for the detection and analysis of proteins. Such tools would enable researchers to characterize protein function in health and disease and would reveal new targets for disease prevention and therapy. This initiative, if implemented, would address the general theme of “New Pathways to Discovery.”

- The **Phenotyping Services and Tools** project will develop resources for the systematic characterization of human phenotypes—the total physical appearance and constitution of an individual—to facilitate the study of complex diseases. If funded, this initiative would be part of the “Reengineering the Clinical Research Enterprise” theme area.

[1] Adjusted for Type I Diabetes, Global Fund for AIDS, Superfund, Secretary's transfer authority for NLM.

Appendix D: Research Training and Graduate Medical Education Data

National Research Service Award (NRSA) and National Library of Medicine (NLM) Research Training Programs

Ph.D.s Awarded to NIH Trainees and Fellows

Field of Study*	FY 2005	FY 2006
Life Sciences	**2,053**	**1,651**
Biological/Biomedical Sciences	*1,850*	*1,466*
Biochemistry	195	166
Biomedical Sciences	71	56
Biophysics	60	51
Biotechnology	5	4
Bacteriology	3	1
Plant Genetics	10	6
Plant Pathology/Phytopathology	1	1
Plant Physiology	1	3

Botany/Plant Biology	1	2
Anatomy	3	1
Biometrics & Biostatistics	34	18
Cell/Cellular Biology and Histology	109	105
Ecology	5	2
Developmental Biology/Embryology	70	48
Endocrinology	8	2
Entomology	2	3
Immunology	150	120
Molecular Biology	226	195
Microbiology	148	107
Neuroscience	292	259
Nutritional Sciences	22	9
Parasitology	2	10
Toxicology	33	23
Genetics, Human & Animal	124	82
Pathology, Human & Animal	30	24
Pharmacology, Human & Animal	117	80
Physiology, Human & Animal	55	42

Zoology, Other	2	6
Biology/Biological Sciences, General	27	21
Biology/Biomedical Sciences, Other	44	19
Health Sciences	*197*	*180*
Speech-Language Pathology & Audiology	20	11
Environmental Health	2	6
Environmental Toxicology	7	8
Health Systems/Service Administration	2	1
Public Health	24	34
Epidemiology	58	39
Kinesiology/Exercise Sciences	9	7
Nursing Science	46	56
Pharmacy	7	1
Rehabilitation/Therapeutic Services	2	2
Veterinary Medicine	1	1
Health Sciences, General	3	6
Health Sciences, Other	16	8
Agricultural Sciences/Natural Resources	*6*	*5*
Agricultural Economics	1	0

Poultry Science	1	1
Animal Science, Other	3	1
Plant Pathology/Phytopathology	1	1
Plant Sciences, Other	0	1
Environmental Science	0	1
Social Sciences	**396**	**259**
Psychology	*321*	*201*
Clinical	137	57
Cognitive & Psycholinguistics	25	27
Counseling	7	3
Developmental & Child	45	25
Human Development & Family Studies	11	4
Family Psychology	0	1
Experimental	18	9
Educational	2	1
Industrial & Organizational	1	2
Personality	4	2
Physiological/Psychobiology	28	18
Psychometrics & Quantitative	4	2

School	1	0
Social	23	25
Psychology, General	7	13
Psychology, Other	8	12
Social Sciences	75	58
Anthropology	13	4
Criminology	1	1
Demography/Population Studies	5	3
Economics	16	16
Econometrics	1	0
Geography	0	1
Political Science & Government	0	1
Public Policy Analysis	8	3
Sociology	26	25
Social Sciences, Other	5	4
Physical Sciences	150	129
Chemistry	108	88
Analytical	10	13
Inorganic	9	5

Organic	37	22
Medicinal/Pharmaceutical	15	18
Physical	7	10
Polymer	3	2
Theoretical	0	3
Chemistry, General	14	9
Chemistry, Other	13	6
Computer Sciences	*10*	*11*
Computer Science	8	5
Information Science & Systems	0	3
Computer & Information Sciences, Other	2	3
Geological & Earth Sciences	*3*	*1*\
Geology	1	0
Geochemistry	1	1
Geophysics & Seismology	1	0
Mathematics	*10*	*10*
Applied Mathematics	4	2
Geometry/Geometric Analysis	0	1
Statistics	5	4

Mathematics/Statistics, General	0	2
Mathematics/Statistics, Other	1	1
Ocean/Marine Sciences	*1*	*0*
Marine Sciences	1	0
Physics	18	19
Elementary Particle	0	1
Biophysics	9	11
Optics/Phototonics	1	1
Polymer Physics	0	1
Applied Physics	0	3
Plasma/Fusion	1	0
Condensed Matter/Low Temperature	1	0
Physics, General	2	0
Physics, Other	4	2
Engineering	**94**	**97**
Education	**8**	**9**
Humanities	**7**	**6**
Other Fields	**19**	**19**
TOTAL	2,727	2,170

*** Note:** Detailed field data are provided only for broad (i.e., **bolded**) fields with ≥100 Ph.D. recipients.

Sources: NIH Trainee and Fellow File, IMPAC II, and the Doctorate Records File.

Demographic Characteristics* of NRSA Participants

Demographic Characteristic	FY 2005	FY 2006
Sex		
Female	50.8%	52.1%
Male	47.4%	46.0%
Unreported	1.8%	1.9%
Race/Ethnicity		
White	69.3%	66.2%
Asian	15.3%	14.4%
Hispanic	6.1%	6.4%
African American	10.2%	9.1%
Native American	1.1%	1.1%
Native Hawaiian/Pacific Islander	.06%	0.6%
Unreported	4.3%	8.1%

Source: IMPAC II

* Reporting personal information such as sex, race, and ethnicity is voluntary

Graduate Medical Education:
NIH-sponsored, ACGME-Accredited, Residency and Subspecialty Training Programs

Successfully Completed Residency and Subspecialty Training By Academic Year

NIH Clinical Center Program Specialty	Successfully Completed	
	2005/2006	**2006/2007**
Allergy and Immunology	4	3
Dermatology	0	2
Medical Genetics	3	2
Critical Care Medicine	5	3
Endocrinology, Diabetes, and Metabolism	5	6
Hematology	3	3
Infectious Disease	3	3
Oncology	10	12
Rheumatology	2	10
Pathology-Anatomic and Clinical	1	3
Blood Banking/Transfusion Medicine	1	3
Cytopathology	1	1
Hematology (Pathology)	1	1
NICHD/Georgetown University Hospital	2	2

Program / Pediatric Endocrinology*		
Psychiatry	1	1
TOTAL	42	46

*Cosponsored by NICHD and Georgetown University Hospital

Source: AAMC GME Track Database

Appendices

Appendix E:

Monitoring Adherence to the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research

Comprehensive Report: Tracking of Human Subjects Research As Reported in Fiscal Year 2005 and Fiscal Year 2006

Following is an excerpt of the report—all of the report except for the appendices. The full report can be found at: http://orwh.od.nih.gov/inclusion/2007 Annual Comprehensive Report - Web Version Rev 8-22-07.pdf

NIH Tracking/Inclusion Committee

Vivian W. Pinn, M.D., Co-Chair Office of Research on Women's Health
Carl Roth, Ph.D., LL.M., Co-Chair National Heart, Lung, and Blood Institute
Angela C. Bates, M.B.A. Office of Research on Women's Health
Carlos E. Caban, Ph.D. Office of Extramural Research
Kim Jarema Liaison, NIH Clinical Center

Spring 2007

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APPENDICES

Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research

The establishment and implementation of policies for the inclusion of women and minorities in clinical research funded by the National Institutes of Health (NIH) has its origins in the women's health movement. Following the issuance of the report of the Public Health Service Task Force on Women's Health in 1985, the NIH established a policy in 1986 for the inclusion of women in clinical research. This policy, which ***urged*** the inclusion of women, was first published in the NIH Guide to Grants and Contracts in 1987. Later that year, minority and other scientists at the NIH recognized the need to address the inclusion of minority populations. Therefore, in a later 1987 version of the NIH guide, a policy ***encouraging*** the inclusion of minorities in clinical studies was first published.

In order to ensure that the policies for inclusion were firmly implemented by NIH, the Congress made what had previously been policy into Public Law, through a section in the NIH Revitalization Act of 1993 (PL 103-43)[1], entitled *Women and Minorities as Subjects in Clinical Research*. In 1994, the NIH revised its inclusion policy to meet this mandate that women and minorities must be included in all of its clinical research studies. The Revitalization Act essentially reinforced the existing NIH policies, but with four major differences:

- that NIH ensure that women and minorities and their subpopulations be included in all clinical research;

- that women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to allow for valid analyses of differences in intervention effect;

- that cost is not allowed as an acceptable reason for excluding these groups; and,

- that NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies

Revised inclusion guidelines developed in response to this law were published in the Federal Register2 in March 1994, and they became effective in September 1994. The result was that NIH could not and would not fund any grant, cooperative agreement or contract or support any intramural project to be conducted or funded in Fiscal Year 1995 and thereafter which did not comply with this policy.

Strategies to ensure uniform implementation of the revised guidelines across the NIH were developed through the establishment and deliberations of an NIH Tracking and Inclusion Committee made up of representatives of the directors of each of the ICs. This trans-NIH committee, convened by the Office of Research on Women's Health (ORWH) and co-chaired with a senior IC official, meets on a regular basis, focusing on consistent and widespread adherence to the NIH guidelines by all the ICs. Working in collaboration with the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and other components of the NIH, the ORWH coordinates the activity of developing and establishing data collection and reporting methodologies to ensure uniform standards and definitions in the reporting of data on women and minority participants in NIH-funded clinical research.

To ensure NIH-wide adherence to the revised inclusion guidelines, in 1994 NIH conducted extensive training on the revised inclusion guidelines. In June 1994, the ORWH convened a meeting of Institutional Review Board (IRB) chairs to discuss their role in implementing the revised policy. Training was especially important in light of 1990 GAO findings that an earlier policy was inconsistently applied and had not been well communicated or understood within the NIH or in the research community. A variety of outreach activities were initiated to explain the revised policy to the scientific research community and to clear up common misunderstandings about the new requirements.

Continuing Implementation and Monitoring Activities

Following a Congressional request for an assessment of NIH's progress in implementing the1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled Women's Health - NIH Has Increased Its Efforts to Include Women in Research.3 It concluded that in the past decade, NIH has made significant progress in implementing a strengthened policy on including women in clinical research.

The GAO report also included two specific recommendations to the Director of NIH to ensure the following:

- that the requirement be implemented that Phase III clinical trials be designed and carried out to allow for the valid analysis of differences between women and men and communicate this requirement to applicants as well as requiring peer review groups to determine whether each proposed Phase III clinical trial is required to have such a study design, and that summary statements document the decision of the initial reviewers; and

- that the NIH staff who transmit data to the inclusion tracking data system receive ongoing training on the requirements and purpose of the system.

Immediately following the release of this report, an *NIH Subcommittee Reviewing Inclusion Issues* was formed, consisting of representatives from several ICs, ORWH, OER, and OIR, to reexamine NIH's system for tracking data on the inclusion of women and minorities in clinical research, recommend any necessary changes to improve its accuracy and performance, and reiterate the NIH policy. Several actions resulted to clarify the requirement for NIH-defined Phase III clinical trials to include women and minority groups, if scientifically appropriate, and for analysis of sex/gender and/or racial/ethnic differences to be planned and conducted by investigators engaged in NIH-funded research. Significant actions in 2001 included:

- **Updating the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research** and posting it on the ORWH home page http://orwh.od.nih.gov/inclusion.html and NIH web page, Inclusion of Women and Minorities Policy Implementation at: http://grants.nih.gov/grants/funding/women_min/women_min.htm.

- **Developing a new term and condition of award** statement for awards made after October 1, 2000 that have NIH-defined Phase III clinical trials.

- **Incorporating language in the NIH solicitations for grant applications and contract proposals to clarify the submission requirement for NIH-defined Phase III clinical trials**, a description of plans for sex/gender and/or race/ethnicity analysis including subgroups, if applicable, and reporting accrual annually and results of analyses, as appropriate.

- **Guidelines and instructions for reviewers and Scientific Review Administrators (SRAs) were developed** to emphasize and clarify the need to review research proposals that are classified as NIH-defined Phase III clinical trials for both inclusion requirements and issues related to analyses by sex/gender and/or race/ethnicity. Instructions were developed for the proper documentation to include in summary statements to address adherence to these policies.

Training to ensure compliance with this policy was provided to NIH program and review officials, grants and contracts management staff, and current and prospective research investigators. Several initiatives were implemented for review, grants management and program staff since 2000, including specific topics addressing revisions to the NIH Inclusion policy, a grants policy update and Scientific Review Administrator (SRA) orientation on specific issues related to review meetings and proceedings.

The PHS 398 Grant Application was significantly revised to provide additional instructions about the Women and Minorities Inclusion Policy and the revised form became mandatory as of May 10, 2005. These PHS 398 instructions about the Women and Minorities Inclusion Policy have also been included in the new federal application form SF-424 (R&R) for NIH grants using the federal Grants.gov system (see http://era.nih.gov/ElectronicReceipt/). The application instructions included two significant changes in definitions. First, the NIH required use of a revised definition of clinical research that was reported in the 1997 Report of the NIH Director's Panel on Clinical research and adopted by NIH. Secondly, the Office of Management and Budget (OMB) Directive 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting", revised the definitions for the racial and ethnic categories to be used when reporting population data (see: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html). In addition, NIH policy reemphasized that that NIH-defined Phase III clinical trials must be designed and conducted in a manner to allow for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other subjects.

Many of the training sessions are available electronically for all NIH staff, and the Office of Extramural Research (OER) has made available existing training materials on the Population tracking system website on the NIH Intranet. A training subcommittee of the full NIH Tracking and Inclusion committee has been established to develop new training documents and methods of training for NIH staff and the extramural research community. Further information regarding training initiatives since the 2000 GAO report is discussed in the background section of the Appendices (See Appendix A)

Communication and Outreach Efforts to the Scientific Community

NIH staff provides outreach to the scientific community to help increase understanding of the revised inclusion policy and OMB requirements. These training and outreach efforts are designed to improve understanding of the sex/gender and minority inclusion policy and assist investigators and NIH staff to appropriately address these issues throughout the research grant and contract process. Investigators are instructed to address women and minority inclusion issues in the development of their applications and proposals for clinical research.

Reference documents such as the Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical

Research (http://orwh.od.nih.gov/inclusion/outreach.pdf) and the Frequently Asked Questions (FAQs) for the Inclusion , Recruitment and Retention of Women and Minority Subjects in Clinical Research (http://orwh.od.nih.gov/inclusion/outreachFAQ.pdf) have been published and distributed for investigators and NIH staff. These publications discuss the elements of recruitment and retention, the NIH inclusion policy, 1997 OMB requirements for reporting race and ethnicity data, as well as information for application submission, peer review, and funding. Both are posted on the ORWH website http://orwh.od.nih.gov as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm. The revised Outreach Notebook and FAQs continue to be available to the research community to further explore the inclusion policy and its intent. Additionally, a slide show available electronically and in hard copy, "Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know!" was developed for NIH staff to assist them in working with the extramural community.

Monitoring Compliance: Extramural and Intramural Population Data Analysis

When assessing inclusion data, enrollment figures should not be directly compared to the national census figures. The goal of the NIH policy is not to satisfy any quotas for proportional representation, but rather to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will be generalizable to the entire population of the United States. The numbers of women or minority subgroups included in a particular study depends upon the scientific question addressed in the study and the prevalence among women and minority subpopulations of the disease, disorder, or condition under investigation.

Scientific Review Groups are instructed to focus on scientific considerations when assessing the planned enrollment for a particular study. The Scientific Review Group (SRG) determines if the implementation plan for an application is unacceptable if it: 1) fails to provide sufficient information about target enrollment; 2) does not adequately justify limited or lack of inclusion of women or minorities; or 3) does not realistically address recruitment and retention. For NIH-defined Phase III clinical trials, the Scientific Review Group (SRG) also evaluates the description of plans to conduct analyses, as appropriate, to address differences in the intervention effect by sex/gender and/or racial/ethnic groups. Applications with unacceptable inclusion plans cannot be funded until NIH staff is assured that revised inclusion plans from the investigators meet the inclusion policy requirements. Research awards covered by this policy require the grantee to report annually on enrollment of women and men, and on the race and ethnicity of research participants so that accrual can be monitored.

NIH has monitored aggregate demographic data for study populations through the evolving NIH computerized tracking system since fiscal year 1994, and tracking the inclusion of women and minorities in clinical studies is well established in all ICs. Members of the NIH Tracking and Inclusion Committee continuously work on ways to refine and improve data collection methods and the quality of the data entered by each IC into this system. In May 2002, the NIH successfully deployed a new population tracking system for monitoring the inclusion of women and minorities in clinical research. This system provides easier data entry and project monitoring of investigator data reporting for NIH staff. An eRA Population Tracking User Group consisting of representatives from several ICs provides continuous feedback related to system use.

The aggregate data enable the NIH to measure inclusion in order to formulate more specific questions about gaps in enrollment and to design studies to respond to those questions. Data compiled in future years allows for longitudinal examination of trends and continued monitoring of compliance, although this will be more difficult for minority trends because of a change in how these data are collected (see next section).

A review of intramural inclusion data indicates that the intramural research program continues to be compliant with the reporting requirements adhered to by the extramural community and outlined in the NIH Implementation Guidelines on the Inclusion of Women and Minority Subjects in Research Studies. The Clinical Center Medical Executive Committee (MEC) has taken a leading role in assuring that investigators conducting clinical research protocols in the Clinical Center are trained and competent in the conduct of clinical research. The MEC designed and endorsed the Standards for Clinical Research within the NIH Intramural Research Program which set forth guidelines for the infrastructure, training, education, and monitoring required for safe and effective conduct of clinical research.

Format Changes for Reporting Race and Ethnicity Data

Beginning in FY2002, NIH changed how data are reported based on the 1997 Office of Management and Budget (OMB) Directive 15 minimum standards for maintaining, collecting and reporting data on race and ethnicity. Implementation of the 1997 OMB standards involved a number of changes including collecting and reporting information on race and ethnicity separately, whereas the 1977 OMB standards used a combined race and ethnicity format. NIH aggregate population data tables describe data using both the 1997 and 1977 OMB standards for reporting data on race and ethnicity. Since 2002, the number of studies reporting data using the 1997 format (NEW FORM) has steadily increased, while the number of studies using the 1977 format (OLD FORM) has steadily decreased as the studies funded prior to FY2002 are completed.

The 1997 OMB reporting format (NEW FORM) and standards does not allow direct comparison of ethnic and racial data with similar data collected under the 1977 OMB reporting format (OLD FORM) and standards because the categories and methods for collecting the data are fundamentally different. Changes in the standardization of definitions and business rules across the NIH for improving the data entered in the population tracking system are reflected in data reported beginning in FY2002. While implementation of these changes will improve the consistency and comparability for future reporting, comparisons with prior FY 2002 data are difficult.

As demonstrated below, the primary differences are: (1) the Hispanic population is considered an ethnic category and reported separately from racial data; (2) there is a separate racial category for Asian population data and Hawaiian and Pacific Islander population data; and 3) respondents are given the option of selecting more than one race. (See Appendix H)

Race and ethnicity data from the OLD and NEW Forms are combined differently as described below for purposes of reporting on the minority population enrolled in NIH clinical research:

- the OLD FORM uses the 1977 OMB combined Race and Ethnicity Format, which has mutually exclusive categories, and allows Hispanics to be reported as either "Hispanic, Not White" or "White".
- the NEW FORM uses the 1997 OMB Race and Ethnicity Categories, with separate reporting for Ethnicity (Hispanic or Latino; Not Hispanic or Latino) and Race (Part A); in this format, an individual is classified both by Ethnic Category and by Race Category. Part B of the NEW FORM therefore provides a distribution of only "Hispanics or Latinos" by the five main Race categories. Since minority categories are defined to include both "Hispanic or Latino ethnicity" and non-white racial categories when providing summary totals of minorities, it is necessary to add White Hispanics" and "Unknown/Other Hispanics" based on their ethnicity to the non-white racial categories.
- Hispanics are defined by country of origin, and may be identified as belonging to any one, or more than one, race category.

OLD FORM (1977) versus NEW FORM (1997)						
Race/Ethnicity Category	Minority Total	Minority Total				
	Old Form	New Form				
OLD FORM: Combined 1977 OMB Race/Ethnicity Categories						
American Indian/Alaska Native	X					

Asian/Pacific Islander	X					
Black or African American	X					
Hispanic, Not White	X					
White						
Unknown/Other						

NEW FORM: Separate 1997 OMB Race/Ethnicity Categories						
Part A: Total Enrollment Report Ethnic Category **Hispanic or Latino**** Not Hispanic or Latino Unknown (ethnicity not reported) Ethnic Category Total of All Subjects*						
Racial Categories						
American Indian/Alaska Native		X				

Asian		X
Black or African American		X
Hawaiian/Pacific Islander		X
White		
More Than One Race		X
Unknown/Other		
Racial Categories: Total of all Subjects*		
Part B: Hispanic Enrollment by RACE		
American Indian/Alaska Native		
Asian		
Black or African American		
Hawaiian/Pacific Islander		
White (Hispanic)		X
More Than One Race		

Unknown/Other (Hispanic)		X
Racial Categories: Total of Hispanics or Latinos**		

* The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects"
** The "Hispanic or Latino"(Part A) must be equal to "Racial Categories: Total of Hispanics or Latinos"(Part B).

DEFINITIONS:

Clinical Research as defined by the 1997 Report of the NIH Director's Panel on Clinical Research,

http://www.nih.gov/news/crp/97report/execsum.htm

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies;

2. Epidemiologic and behavioral studies; and

3. Outcomes research and health services research

NIH-Defined Phase III Clinical Study

For the purpose of these guidelines, an NIH-defined "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Valid Analysis

The term “valid analysis” means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- allocation of study participants of both sexes/genders (males and females) and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- unbiased evaluation of the outcome(s) of study participants, and
- use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Significant Difference

For purposes of this policy, a “significant difference” is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used “statistically significant difference,” which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

Domestic Organization

A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.

Foreign Institution

An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PI.

Conclusion and Current Status

NIH staff continues to monitor, document, and work with grantees and contractors to ensure compliance with the inclusion policy. Program Officials provide technical assistance to investigators as they develop their applications and proposals throughout the application process. Review Officials introduce and discuss with reviewers the Guidelines/Instructions for reviewing the Inclusion of Women and Minorities in Clinical Research as well as the instructions and requirements for designing Phase III Clinical Trials in order that valid analyses can be conducted for sex/gender and ethnic/racial differences. At the time of award and submission of progress reports, program officials monitor and verify that inclusion policy requirements are met. When new and competing continuation applications that are selected for payment are deficient in meeting policy requirements, grants management staff and program officials are required to withhold funding until the principal investigator has satisfactorily addressed the policy requirements.

References

1. Public Law 103-43. National Institutes of Health Revitalization Act of 1993. 42 USC 289 (a)(1).

2. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508-14513 (1994).

3. Women's Health: NIH Has Increased Its Efforts to Include Women in Research (GAO/HEHS-00- 96, May, 2000).

4. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, NIH Guide for Grants and Contracts, Amended 2001.

For Additional Information on the implementation of the inclusion policy, please visit:

NIH Office of Extramural Research Inclusion of Women and Minorities Policy Implementation Website:
http://grants.nih.gov/grants/funding/women_min/women_min.htm

Revitalization Act of 1993, 42 USC 289 (a)(1): http://grants.nih.gov/grants/guide/notice-files/not94-100.html

NIH Policy on Reporting Racial and Ethnicity Data: Subjects in Clinical Research, NIH Guide for Grants and Contracts Web page: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html

Office of Research on Women's Health Website: http://orwh.od.nih.gov/inclusion.html

Aggregate Enrollment Data Tables For Extramural and Intramural Research Protocols

Fiscal Year 2006 Summary Reports

Twelve-year Trend Summary Reports

Summary Report of NIH Inclusion Data

NIH AGGREGATE POPULATION DATA REPORTED IN FY2005 AND FY2006

The following section is provided in order to guide consideration of the data especially in trend of human subjects participation in NIH-funded extramural and intramural clinical research. Because new studies are added each year and other studies are ending, it is not appropriate to compare data over time or to compare data with census population data. Looking at the trend data represents the best interpretation of the aggregate data. Data on inclusion is tabulated from human subject populations in NIH-defined Phase III clinical trials and other human subject research studies. NIH clinical research studies are determined in accordance with the NIH definition of clinical research to include, for example, non-intervention clinical research, clinical trials, epidemiologic studies, behavioral studies, and database studies.

Analysis of aggregate NIH data on inclusion for FY2005 and FY2006 document that substantial numbers of women and men, especially non-minority men, and minorities have been included as research subjects in NIH-defined Phase III clinical trials and other human subject research studies during these fiscal years. Because the data included in the tables are aggregate data from across NIH, it does provide documentation of the tracking and inclusion across the NIH, and some degree of analysis of the data. But caution should be utilized in not over-interpreting the figures that are provided. The NIH Tracking and Inclusion committee has provided for the reader's interest, conclusions that can be reasonably drawn from the data.

Previous inclusion reports and aggregate enrollment figures for women, men and minority groups for FY1994 to the present can be found on the ORWH website at http://orwh.od.nih.gov/inclusion.html. For this report, the FY2005 and FY2006 data tables have been reformatted and some tables may vary slightly or differ from prior reported summary data in an effort to better clarify reporting.

NIH CLINICAL RESEARCH: Fiscal Years 2005 and 2006

In FY2005, there were 14,798 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,233 protocols reported human subject participation. Of these, 96.4% were domestic protocols and 3.6% were foreign protocols. Approximately 15.7 million participants were enrolled in extramural and intramural research protocols of which 80.6% were domestic participants and 19.4% were foreign participants. Of the 15.7 million participants, 60.4% were women, 37.8% were men and 1.8% did not provide sex identification. Further, 39.7% of the total participants, and 27.4% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (Table 6)

Correspondingly, in FY2006 there were 15,320 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,758 protocols reported human subject participation as noted in this report's trend summary tables. Of these, 95.7% were domestic protocols and 4.3% were foreign protocols. Approximately 14.8 million participants were enrolled in extramural and intramural research protocols of which 77.0% were domestic participants and 23.0% were foreign participants. Of the 14.8 million participants, 63.9% were women, 34.9% were men and 1.3% did not provide sex identification. Further, 43.1% of the total participants, and 28.9% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (Table 1)

While the number of participants in all extramural and intramural clinical research decreased (15.7M in FY2005 and 14.8M in FY2006), there was no significant change in the ratio of women and men (60.4%F and 37.8%M in FY2005; and 63.9%F and 34.9%M in FY2006). One large study involving approximately 1.6M participants that ended in FY2005 and therefore was not included in the FY2005 figures, accounted for the net decreased number of participants reported.

NIH Defined Phase III Clinical Research: FY2005 and FY2006

In FY2005, there were 665 extramural and intramural Phase III clinical research protocols, of which 547 protocols reported human subject participation. Of these, 94.5% were domestic protocols and 5.5% were foreign protocols. Approximately 493,000 participants were enrolled in extramural and intramural Phase III research protocols of which 88.8% were domestic participants and 11.2% were foreign participants. Of the 493,000participants, 59% were women, 40% were men and 1% did not provide sex identification. Further, 31.3% of the total participants, and 25.1% of the Domestic-only participants, in Phase III clinical research were reported as minorities following the 1997 OMB categories for race and ethnicity. (Table 7)

According to the trend summaries in this report , of the 210 extramural and intramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.5 % and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 6.9%, Asian/Pacific Islanders were 5.6% and Whites (not Hispanic) 73.2% of the participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (Table 7)

Furthermore, in FY2005, there were 337 extramural and intramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 28.5% and lowest for Hawaiian/Pacific Islanders 0.3%. Asians represented 5.2%, American Indian/Alaska Natives 1.2% and Whites 57.3% of participants. Participants identifying as More Than One Race were 1.7% of the total number of participants. In addition, 5.8% did not identify a race category. Of the 337 extramural and intramural Phase III research protocols designating an ethnicity in FY2005, 88.6 % of total participants identified as "Not Hispanic", 5.9% of the total participants identified as "Hispanic or Latino" and 5.5% of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (Table 7)

Correspondingly, in FY2006 there were 760 extramural and intramural Phase III clinical research protocols, of which 624 protocols reported human subject participation as noted in this report’s trend summary tables. Of these, 90.4% were domestic protocols and 9.6% were foreign protocols. Approximately 499,430 participants were enrolled in extramural and intramural Phase III research protocols of which 80.2% were domestic participants and 19.8% were foreign participants. Of the 499,430 participants, 62.9% were women, 36.0% were men and 1.1% did not provide sex identification. Further, 33.5% of the total participants, and 20.7% of Domestic-only participants, in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (Table 3)

According to the trend summaries in this report, of the 215 extramural and intramural Phase III research protocols that report following the 1977 OMB standards in FY2006, minority representation was highest for Blacks (not Hispanic) at 8.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 4.1%, Asian/Pacific Islanders were 7.3% and Whites (not Hispanic) 76.5% of the participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (Table 7)

Moreover, in FY 2006, there were 409 extramural and intramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 18.8% and lowest for Hawaiian/Pacific Islanders 0.2%. Asians represented 12.0%, American Indian/Alaska Natives 1.7% and Whites 47.0% of participants. Participants identifying as More Than One Race were 1.6% of the total number of participants. In addition, 18.7% did not identify a race category. Of the 409 extramural and intramural Phase III research protocols designating an ethnicity in FY2006, 75.0 % of total participants identified as "Not Hispanic", 11.5 % of the total participants identified as "Hispanic or Latino", and 13.5% of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (Table 7)

While the number of participants in Phase III extramural and intramural clinical research slightly increased (493,000 in FY2005 and 499,430 in FY2006), there was no significant change in the ratio of women and men (59.0% F and 40.0%M in FY2005; and 62.9%F and 36.0%M in FY2006).

The following sections provide data on extramural research and intramural research separately.

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2005 and 2006

In FY2005, there were 13,003 extramural clinical research protocols, including Phase III and other clinical studies, of which 8,763 protocols reported human subject participation as noted in this report’s trend summary tables. Approximately 13.8 million participants were enrolled in extramural research protocols of which 62.1% were women, 36.1% were men and 1.9% did not provide sex identification. (See 2006 Report, Table 2 and Appendix table 3A)

Correspondingly, in FY2006, there were 13,522 extramural clinical research protocols, including Phase III and other clinical studies, of which 9,235 protocols reported human subject participation. Of these, 95.7% were domestic protocols and 4.3% were foreign protocols. Approximately 13.02 million participants were enrolled in extramural research protocols of which 76.6% of the total enrollment is domestic participants and 23.4% of the total enrollment is foreign participants. Of the 13.02 million participants, 65% were women, 33.8% were men and 1.2% did not provide sex identification. Further, 45.9% of the total participants were reported as minorities following the OMB categories for race and ethnicity. (Table 2 and Appendix Table 3A)

While the number of participants in all extramural clinical research decreased (13.8 million in FY2005 and 13.02 million in FY2006), there was no significant change in the ratio of women and men (62%F and 36%M in FY2005 and 65%F and 34%M). However, when sex-specific studies were excluded, the proportions of women and men in all extramural clinical research were proportional to the percentages of the general population. (52.4%F and 45.8 % M)

NIH Defined Phase III Extramural Clinical Research: FY2005 and FY2006

In FY2005 of the 273 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7%, Asian/Pacific Islanders were 1.9% and Whites (not Hispanic) 76% of the participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See 2006 Report)

In FY2006 there were 707 extramural Phase III clinical research protocols, of which 580 protocols reported human subject participation as noted in this report‘s trend summary tables. Approximately 467,954 participants were enrolled in extramural Phase III research protocols of which 63.5% were women, 35.4% were men and 1% did not provide sex identification. (Table 4 and Appendix Table 5A)

According to trend summaries in the 2006 report, in FY2005, there were 621 extramural Phase III clinical research protocols, of which 511 protocols reported human subject participation. Of these, 88.5% were domestic protocols and 4.9% were foreign protocols. Approximately 465,956 participants were enrolled in extramural Phase III research protocols of which 86% of total enrollment is domestic participants and 8.6% of total enrollment is foreign participants. Of the 465,956 participants, 59.5% were women, 39.5% were men and 1% did not provide sex identification. Further, 29.9% of the total participants in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (See 2006 Report, Table 4 and Appendix Table 5A)

Correspondingly, in FY2006, there were 382 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 19.7% and lowest for Hawaiian/Pacific Islanders 0.2%. Asians represented 12.67%, American Indian/Alaska Natives 1.8% and Whites 46.32% of participants. Participants identifying as More Than One Race were 15% of the total number of participants. In addition, 17.8 % did not identify a race category. Of the 382 extramural Phase III research protocols designating an ethnicity in FY 2006, 75.8 % of total participants identified as "Not Hispanic", 11.14 % of the total participants identified as "Hispanic or Latino", and 13.1 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (Appendix Table 5A)

In FY 2005, there were 319 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 30.00 % and lowest for Hawaiian/Pacific Islanders 0.28%. Asians represented 5.44%, American Indian/Alaska Natives 1.30% and Whites 55.75% of participants. Participants identifying as More Than One Race were 1.56% of the total number of participants. In addition, 5.66 % did not identify a race category. Of the 319 extramural Phase III research protocols designating an ethnicity in FY2005, 88.7 % of total participants identified as "Not Hispanic", 5.98 % of the total participants identified as "Hispanic or Latino", and 5.32 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (See 2006 Report, Appendix Table5A)

Of the 192 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 13.03 and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7.23%, Asian/Pacific Islanders were 1.81% and Whites (not Hispanic) 76.1% of the participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See 2006 Report, Appendix Table 5A)

While the number of participants in Phase III extramural clinical research protocols slightly increased, there was also some change in the ratio of women and men (59.5%F and 39.5%M in FY2005 and 63.5 %F and 35.4% M in FY2006).

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2005 and 2006

Substantial numbers of women and minorities were included in NIH intramural studies in FY 2005 and FY2006.

In FY2005, there were 1,795 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,470 protocols reported human subject participation. Of these, 13.7% of the total protocols were domestic protocols and 0.7% of the total protocols were foreign protocols. Approximately 1.94 million participants were enrolled in intramural research protocols of which 10.4% of the total enrollment is domestic participation and 1.9% of the total enrollment is foreign participation. Of the 1.94 million participants, 48.7% were women, 50.5% were men and 0.79% did not provide sex identification. (See 2006 Report, Table 2 and Appendix Table 7A)

In FY2005, approximately 1.94 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 733 intramural research protocols that report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 17.8% and lowest for American Indian/Alaska Natives at 1.8%. Blacks (not-Hispanic) represented 7.5%, Hispanics 4.7%;

and Whites (not Hispanic) 60.9% of the intramural research study population. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See 2006 Report, Appendix Table 7A)

For the 737 intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2005 the largest racial minority group was Blacks at 4.74% and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.19%. Asians represented 3.1%, American Indian/Alaska Natives 0.42% and Whites 86.2% of participants in all intramural clinical research. Approximately 1% of participants reported More Than One Race as their racial category. In addition, 4.42 % did not identify a race category. Of the 737 intramural research protocols following the current 1997 OMB standards designating an ethnicity in FY 2005, 95.58 % of total participants identified as "Not Hispanic", 2.10 % of the total participants identified as "Hispanic or Latino", and 2.32 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (See 2006 Report, Appendix 7A)

Correspondingly, in FY2006 there were 1,798 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,523 protocols reported human subject participation. Approximately 1.8 million participants were enrolled in intramural research protocols of which 55.4% were women, 43.0% were men and 1.6% did not provide sex identification. (See Table 2 and Appendix Table 7A)

In FY 2006, approximately 1.8 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 590 intramural research protocols that report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 19.9% and lowest for American Indian/Alaska Natives at 3.3%. Blacks (not-Hispanic) represented 7.2%, Hispanics 3.5%; and Whites (not Hispanic) 62.0% of the intramural research study population. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See Appendix Table 7A)

For 933 intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2006, the largest racial minority group was Asian at 8.6 % and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.07%. Blacks represented 5.0%, American Indian/Alaska Natives 0.4% and Whites 79.1% of participants in all intramural clinical research. Approximately 0.8% of participants reported More Than One Race as their racial category. In addition, 6.0 % did not identify a race category. Of the 933 intramural research protocols following the current 1997 OMB standards designating an ethnicity in FY2006, 91.3 % of total participants identified as "Not Hispanic", 4.1 % of the total participants identified as "Hispanic or Latino", and 4.6 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (See Appendix Table 7A)

There was an increase in female participants from 48.7% to 55.4% and a corresponding decrease in male participants from 50.5% to 43.0%. The number of participants in all intramural clinical research decreased slightly from 1.9M to 1.8M from FY2005 to FY2006.

NIH Defined Phase III Intramural Clinical Research: FY2005 and FY2006

In FY2005, there were 44 intramural Phase III clinical research protocols, of which 36 protocols reported human subject participation. Of these, 6% of the total protocols is domestic protocols and 0.5% of the total protocols is foreign protocols. Approximately 27,044 participants were enrolled in intramural Phase III research protocols of which 2.86% of total enrollment is domestic participation and 2.6% of total enrollment is foreign participation. Of the 27,044 participants, 50.5% were women, 49.5% were men and 0% did not provide sex identification. Further, 54.5% of the total participants in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (See 2006 Report, Table 4 and Appendix Table 9A)

Correspondingly, in FY2006 there were 53 intramural Phase III clinical research protocols, of which 44 protocols reported human subject participation. Of these, 6.3% of the total number of protocols is domestic and 0.7% of the total number of protocols is foreign. Approximately 31,476 participants were enrolled in intramural Phase III research protocols of which 2.34% of the total enrollment is domestic participants and 3.5% are foreign participants. Of the 31,476 participants, 54% were women, 46% were men and 0% did not provide sex identification. Further, 54% of total participants in Phase III clinical research protocols were reported as minorities following the OMB categories for race and ethnicity. (Table 4 and Appendix Table 9A)

There was a small increase in women (50.5% to 54.0%) and corresponding decrease in men (49.5% to 46.0%). The number of participants in Phase III intramural clinical research increased from 27,044 to 31,476.

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY 1995 – FY 2006

The following section is a new addition to the Annual Comprehensive report. Tables 5-11 provide trend data on the collection and reporting of human subject participation in NIH funded clinical research, which includes Phase III clinical studies; trend data are also provided in terms of foreign and domestic participation. Trend data vary over time because the data for each year represent the net total of data resulting from: (1) studies continuing from the prior year; (2) the addition of new studies reported; and (3) the subtraction of studies that are no longer reported.

Table 5 is a twelve year summary report showing a steady increase in the number of protocols and enrollment. The number of protocols with enrollment increased from 3,188 in FY1995 to 10,758 in FY2006 – a 3.4 fold increase. Reported enrollment increased from approximately 1.0 million (FY1995) to 14.8 million (FY2006) – a 14.5 fold increase; minority enrollment increased from approximately 0.4 million (FY2002) to 6.4 million (FY2006) – a 17.1 increase in minority representation in NIH clinical research. Over the last five years, the total number of protocols reported with enrollment data has leveled off at about 10,000 protocols per year.

With the deployment of a new population tracking system in 2002 and the requirement to report data using a new format, NIH was able to report domestic and foreign data in a better way. Thus, trend data are now available for domestic and foreign protocols and participation beginning in FY2002. Domestic enrollment increased from 10.2 million (FY2002) to 11.4 million (FY2006) – a 1.1 fold increase. Foreign enrollment increased from 0.9 million (FY2002) to 3.4 million (FY2006) – a 3.6 fold increase. Overall, the total enrollment has increased with domestic participation averaging between 75.9-91.5% and foreign participation averaging between 8.5-24.1%. In FY2006, domestic and foreign enrollment was 77.0% and 23.0% respectively.

Table 6 is a summary report of all extramural and intramural clinical research by sex/gender and minority representation following the old and new data formats for domestic and foreign studies. The report demonstrates that female participation in all extramural and intramural research generally averaged between 51.7% and 63.9%, male participation in all extramural and intramural research averaged between 34.9% and 45.0%. Overall minority participation in all extramural and intramural clinical research averaged between 31% and 43%. Table 6E provides a comparison of domestic and foreign participation between FY2002 and FY2006. The vast majority of protocols are domestic (~94%-96%) of the total clinical research protocols. While the number of foreign protocols has increased, they incorporate only about 4%-6% of the total clinical research protocols with enrollment. Table 6F shows domestic and foreign enrollment for the five-year period. Domestic minority enrollment varied between 24.1% and 28.9% of total domestic participation, while foreign minority enrollment varied between 82.2% and 90.9% of total foreign participation.

Table 7 is a summary report of NIH-funded Phase III extramural and intramural clinical research by sex/gender and minority representation following the old and new data reporting formats for domestic and foreign studies. The report demonstrates that female participation in NIH funded Phase III extramural and intramural clinical research generally averaged between 54.1% and 74.8% and male participation in NIHfunded Phase III extramural and intramural clinical research averaged between 24.3% and 44.6%. Overall minority participation in NIH-funded Phase III extramural and intramural clinical research increased from 26.9% to 33.5%. Table 7E provides a comparison of domestic and foreign participation between FY2002 and FY2006. The vast majority of protocols are domestic (75.5% and 95.8%) of the total clinical research protocols. While the number of foreign protocols has decreased, they incorporate only about 4.2%-9.6% of the total clinical research protocols with enrollment in the last three years. Table 7F shows domestic and foreign enrollment for the five-year period. Domestic minority enrollment varied between 20.7% and 25.4% of total domestic participation, while foreign minority enrollment in NIH-funded Phase III clinical research varied between 48.4% and 85.2% of total foreign participation. Comparing both domestic and foreign Phase III enrollment over the five year period shows that the small percentage of foreign protocols(9.6%) in FY2006 account for a significant proportion (19.8%) of the total enrollment.

Tables 8-11 provide summary reports of domestic and foreign participation for NIH funded clinical research and NIH-funded Phase III clinical research. For extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation averaged between 61.8 and 67.3% while male participation averaged between 31.2 and 36.9%. (Table 8) For NIH-funded Phase III extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation averaged between 54.8 and 64.6% while male participation averaged between 34.4 and 44.8%. (Table 9) For all extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 39.2% to 58.5% while male participation varied from 40.1% to 60.4%. (Table 10) For NIH-funded Phase III extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 47.4% to 56.7% while male participation varied from 42.0% to 52.5%. (Table 11)

Table 1. Summary of NIH Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

1A. Protocols Reported	Total All Clinical Studies*	Domestic	%	Foreign	%
Protocols with Enrollment	10,758	10,294	95.7%	464	4.3%
%	70.2%	70.3%		69.3%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,562	4,356	95.5%	206	4.5%
	29.8%	29.7%		30.7%	

Total Number of Protocols	**15,320**	**14,650**	95.6%	**670**	4.4%
%	100.0%	100.0%		100.0%	

1B. Enrollment Reported	Total All Clinical Studies*	Domestic	%	Foreign	%
Females Enrolled	9,473,273	7,684,453	81.1%	1,788,820	18.9%
%	63.9%	67.3%		52.5%	
Males Enrolled	5,172,205	3,566,577	69.0%	1,605,628	31.0%
%	34.9%	31.2%		47.2%	
Sex of Subjects is Unknown	185,452	174,671	94.2%	10,781	5.8%
%	1.3%	1.5%		0.3%	
Total Subjects Enrolled	**14,830,930**	**11,425,701**	77.0%	**3,405,229**	23.0%
%	100.0%	100.0%		100.0%	

1C. Minority Enrollment Reported	Total All Clinical Studies*	Domestic	%	Foreign	%
Minority Total**	**6,388,316**	**3,301,135**	51.7%	**3,087,181**	48.3%
% Minority Enrollment	**43.1%**	**28.9%**		90.7%	

* Clinical research studies include non-intervention clinical research, clinical trials, epidemiologic studies, behavioral studies, database studies, etc., based on the NIH definition of clinical research. “Total All Clinical Studies” includes NIH Defined Phase III Clinical Trials.

** See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Comments

Table 1. Summary of NIH Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

Table 1A: Total Number of Protocols

1. The total number of protocols reported in the NIH database in FY2006 was 15,320; of these, 10,758 (70.2%) reported subject enrollment.
2. Subsequent Tables reporting “Enrollment Reported” are based on the 10,758 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting “Enrollment reported.”

Total Domestic Protocols

4. Domestic protocols made up the vast majority of protocols (14,650; 95.6%); of these, 10,294 (70.3%) reported domestic subject enrollment.
5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Table 1B: Total Enrollment Reported

1. The total “Enrollment Reported” in the NIH database in FY2006 was 14,830,930 subjects in 10,758 protocols with enrollment.
2. Females made up 63.9% (9.5M) of the total subjects enrolled, while Males made up 31.2%(5.2M), with 1.3% unknown.

Total Domestic Enrollment Reported

3. The total Domestic Enrollment reported was 11,425,701 (77%).
4. Females made up 67.3%(7.7M) of the domestic subjects enrolled, while Males made up 31.2%(3.56M), with1.5%(.17M) unknown.

Table 1C Comments: Minority Enrollment Reported

1. Minorities made up 43.1% (6.4M) of the total subjects enrolled.
2. Minorities made up 28.9%(3.3M) of the Domestic Enrollment.
3. The Total Minority Enrollment was made up of 51.7% Domestic and 48.3% Foreign enrollment The small percentage of foreign protocols (4.0%) account for a significant proportion (48.3%) of the total minority enrollment.

Table 2: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2006: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

			Domestic				Foreign			
2A. Protocols Reported		Total All Clinical Studies	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Number of Protocols reporting females only		1,338	1,162	86.8%	124	9.3%	46	3.4%	6	0.4%

%		8.7%	9.0%		7.3%		8.1%		6.1%	
Number of Protocols reporting males only		581	468	80.6%	93	16.0%	17	2.9%	3	0.5%
%		3.8%	3.6%		5.5%		3.0%		3.0%	
Number of Protocols with Both Female and Male Enrollment (excluding sexspecific protocols)		8,839	7,221	81.7%	1,226	13.9%	321	3.6%	71	0.8%
%		57.7%	55.8%		72.2%		56.2%		71.7%	
Total Number of Protocols with Enrollment		**10,758**	**8,851**	82.3%	**1,443**	13.4%	**384**	3.6%	**80**	0.7%
%		70.2%	68%		84.9%		67.3%		80.8%	
Number of Protocols with zero enrollment. Enrollment data has not yet been submitted.		4,562	4,100	89.9%	256	5.6%	187	4.1%	19	0.4%
%		29.8%	31.7%		15.1%		32.7%		19.2%	
Total Number of Protocols		**15,320**	**12,951**	84.5%	**1,699**	11.1%	**571**	3.7%	**99**	0.6%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
2B. Enrollment Reported		Total All Clinical Studies*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
In Protocols reporting females only		4,120,055	3,678,382	89.3%	202,024	4.9%	115,369	2.8%	124,280	3.0%
%		27.8%	36.9%		13.9%		3.8%		35.0%	
In Protocols reporting males only		336,717	274,774	81.6%	3,294	1.0%	32,552	9.7%	26,097	7.8%
%		2.3%	2.8%		0.2%		1.1%		7.3%	
In Protocols excluding female-only and male-only enrollment protocols		10,374,158	6,018,281	58.0%	1,248,946	12.0%	2,902,088	28.0%	204,843	2.0%
%		69.9%	60.4%		85.9%		95.2%		57.7%	
Enrollment Totals for all studies		**14,830,930**	**9,971,437**	67.2%	**1,454,264**	9.8%	**3,050,009**	20.6%	**355,220**	2.4%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
2C. Minority Enrollment Reported**		Total All Clinical Studies*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Minority Totals for all studies		**6,388,316**	**3,102,731**	48.6%	**198,404**	3.1%	**2,878,826**	45.1%	**208,355**	3.3%
% Minority enrollment		43.1%	31.1%		13.6%		94.4%		58.7%	

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

Comments

Table 2: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2006: Number of Sex- Specific Protocols, and Domestic versus Foreign Protocols

Table 2A Total Number of Protocols with Enrollment

1. Female Only Protocols: There were 1,338 protocols reporting females only, representing 12.4 %(1338/10,758) of protocols with enrollment.

90% were Extramural projects(1,162+46); 10% were NIH intramural projects(124+6).

96% were Domestic protocols(1162+124);4% were Foreign protocols(40+6).

2. Male Only Protocols: There were 581 protocols reporting males only, representing 5%(558/10,758) of protocols with enrollment.

83 % were Extramural projects(468+17); 17% were NIH intramural projects(93+3)

97% were Domestic protocols(468+93); 3 % were Foreign protocols(17+3).

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 8,839 protocols reporting both female and male participants representing 82%(8,839/10,758) of the total number of protocols.

85% were Extramural projects(7,221+321); 15% were NIH intramural projects(1,226+71)

Table 2B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 4.1 M females, representing 28% of total enrollment.

92.1% were in Extramural projects; 7.9% were in NIH intramural projects.

94.2% were in Domestic protocols; 5.8% were in Foreign protocols.

2. In Male Only Protocols: There were approximately 336,717 males, representing 2.3% of total enrollment.

91.3% were in Extramural projects; 18.8% were in NIH intramural projects.

82.6% were Domestic in protocols 17.4 % were Foreign protocols.

3. In Protocols Reporting Both Females and Males (excluding sex-specific studies): There were approximately 10,374,158 subjects, representing 70% of total enrollment.

86% were in Extramural projects;14% were in NIH intramural projects. 70% were in Domestic protocols; 30% were in Foreign protocols. 96% were Domestic protocols(7,221+1,226);4% were Foreign protocols(321+71).

Table 2C Minority Enrollment Reported

1. Total Minority Enrollment: 43.1% of Total Enrollment (14.8M).

Total Minority Enrollment, Domestic only: 28.9% (3,301,135/11,425,701)
Total Domestic Minority Enrollment: 51.7% (3,301,135/6,388,316)
Total Foreign Minority Enrollment: 48.3% (3,087,181/6,388,316)
Total Extramural projects Minority enrollment: 40.33% (5,981,557/14,830,930)
Total Intramural Projects Minority enrollment: 2.74% (406,759/14,830,930)

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

3A. Protocols Reported	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%

Protocols with Enrollment	624	564	90.4%	60	9.6%
%	82.1%	82.0%		83.3%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	136	124	91.2%	12	8.8%
	17.9%	18.0%		16.7%	
Total Number of Protocols	760	688	90.5%	72	9.5%
%	100.0%	100.0%		100.0%	

3B. Enrollment Reported	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Females Enrolled	314,066	258,467	82.3%	55,599	17.7%
%	62.9%	64.6%		56.1%	
Males Enrolled	179,975	137,621	76.5%	42,354	23.5%
%	36.0%	34.4%		42.7%	

Sex of Subjects is Unknown	5,389	4,209	78.1%	1,180	0.0%
%	1.1%	1.1%		1.2%	
Total Subjects Enrolled	**499,430**	**400,297**	80.2%	**99,133**	19.8%
%	100.0%	100.0%		100.0%	

3C. Minority Enrollment Reported **	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Minority Total for all Phase III studies	**167,446**	**83,034**	49.6%	**84,412**	50.4%
	33.5%	20.7%		85.2%	

* An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Comments

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols.

Table 3A Total Number of Protocols

1. The total number of NIH defined Phase III Clinical protocols reported in the NIH database in FY2006 was 760; of these, 624(82.1%) reported subject enrollment.
2. Subsequent Tables reporting “Enrollment Reported” are based on the 624 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting “Enrollment reported.”

Total Domestic Protocols

4. Domestic protocols made up the vast majority of protocols (688; 90.5%); of these 564(82%) reported domestic subject enrollment.
5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Table 3B: Total Enrollment Reported

1. The total “Enrollment Reported” in NIH Defined Phase III Protocols in the NIH database in FY2006 was 499,430 subjects in 624 protocols.
2. Females made up 62.9% (314,068) of the total subjects enrolled, while Males made up 36.0%(179,975), with 1.1%(5,389) unknown.
3. Minorities made up 33.5% (167,446) of the total subjects enrolled.

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 400,297(80.2%).
5. Females made up 64.6%(258,467) of the domestic subjects enrolled, while Males made up 34.4%(137,621), with 1.1%(4,209) unknown.

Table 3C Comments: Minority Enrollment Reported

1. Minorities made up 33.5% of total subjects enrolled.
2. Minorities made up 20.7%(83,034) of the Domestic Enrollment (400,297).
3. The Total Minority Enrollment was made up of 49.6% Domestic and 50.4% Foreign enrollment.

Table 4: Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2006: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

			Domestic				Foreign			
4A. Protocols Reported		Total All Clinical Studies*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Number of Protocols reporting females only		118	101	85.6%	2	1.7%	14	11.9%	1	0.8%
%		15.5%	15.8%		4.2%		20.9%		20.0%	
Number of Protocols reporting males only		47	39	83.0%	4	8.5%	4	8.5%	0	0.0%
%		6.2%	6.1%		8.3%		6.0%		0.0%	
Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)		459	384	83.7%	34	7.4%	38	8.3%	3	0.7%
%		60.4%	60.0%		70.8%		56.7%		60.0%	
Total Number of Protocols with Enrollment		**624**	**524**	84.0%	**40**	6.4%	**56**	9.0%	**4**	0.6%
%		82.1%	82%		83.3%		83.6%		80.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.		136	116	85.3%	8	5.9%	11	8.1%	1	0.0%

%		17.9%	18.1%		16.7%		16.4%		20.0%	
Total Number of Phase III Protocols		760	640	84.2%	**48**	6.3%	**67**	8.8%	**5**	0.7%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
4B. Enrollment Reported		Total of Phase III Clinical Trials*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Protocols reporting female only		167,624	148,185	88.4%	4	0.0%	17,195	10.3%	2240	1.3%
%		33.6%	38.4%		0.0%		21.0%		13.0%	
Protocols reporting male only		27,723	23,312	84.1%	177	0.6%	4,234	15.3%	0	0.0%
%		5.6%	6.0%		1.2%		5.2%		0.0%	

Protocols excluding female-only and men-only enrollment protocols		304,083	214,619	70.6%	14,000	4.6%	60,409	19.9%	15,055	5.0%
%		60.9%	55.6%		98.7%		73.8%		87.0%	
Total Subjects Enrolled		**499,430**	**386,116**	77.3%	**14,181**	2.84%	**81,838**	16.39%	**17,295**	3.5%
%		100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
4C. Minority Enrollment Reported**		Total of Phase III Clinical Trials*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Minority Total for all Phase III studies		**167,624**	**80,622**	48.1%	**2,412**	1.4%	**69,820**	41.7%	**14,592**	8.7%

%		33.5%	20.9%		17.0%		85.3%		84.4%	

* An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

Comments

Table 4. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2006 : Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

Table 4A Total Number of Protocols with Enrollment

1. Female Only: There were 118 protocols reporting females only, representing 19 % (118/624) of protocols with enrollment, and 15.5% of the Total Number of Protocols.
97% were Extramural projects (115);3% were NIH intramural projects (3).
87% were Domestic protocols (103); 13% were Foreign protocols (15).
2. Male Only: There were 47 protocols reporting males only, representing 8% (47/624) of protocols with enrollment, and 6.2% o the Total Number of Protocols.
91% were Extramural projects (43); 9% were NIH intramural projects (4).
91% were Domestic protocols (43);9% were Foreign protocols (4).
3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 459 protocols reporting both males and females representing 60.4 % of the total number of protocols.
92.0% were Extramural projects (422); 8.0% were NIH intramural projects (37).
91% were Domestic protocols (418); 9.0% were Foreign protocols (41).

Table 4B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 167,624 females, representing 33.6% of total enrollment.
98.7% (165,380) were in Extramural projects; 1.3% (2,244) were in NIH intramural projects.
88.4% (148,189) were in Domestic protocols; 11.67% (19,435) were in Foreign protocols.
2. In Male Only Protocols: There were approximately 27,723 males, representing 5.6% of total enrollment.
99.4% (27,546) were in Extramural projects; 0.6% (177) were in NIH intramural projects.
84.7% (23,489) were in Domestic protocols; 15.3% (4,234) were in Foreign protocols.
3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were approximately 304,083 subjects, representing 60.9% of total enrollment.
90.45% (275,028) were in Extramural projects; 9.55% (29,055) were in NIH intramural projects.
75.2% (228,619) were in Domestic protocols; 24.8% (75,464) were in Foreign protocols.

Table 4C Minority Enrollment Reported

1. Total Minority Enrollment was 33.5% (167,446) of Total Enrollment (499,430).
Total Minority enrollment, Extramural protocols (150,442), was 30.12% of Total Enrollment (499,430) and 89.9% of Total Minority Enrollment (167,446).
Total Minority enrollment, Intramural Projects (17,004), was 3.4% of Total Enrollment (499,430) and 10.15% of Total Minority Enrollment (167,446).
2. Total Minority Enrollment, Domestic only (83,034), was 20.7% of total Domestic Enrollment (400,297) and 49.6% of Total Minority Enrollment (167,446).
3. Total Minority Enrollment, Foreign (84,412), was 85.15% of Total Foreign Enrollment (99,133) and 50.4% of Total Minority Enrollment (167,446).

5A. Twelve Year Increases in Protocols and Enrollment Data				
FY Reported	1995		2006	Relative Increase,

				2006 / 1995
Total Protocols with Enrollment	3,188		10,758	3.4
Total Enrollment	1,021,493		14,830,930	14.5
Total Minorities	374,433		6,388,316	17.1
% of Minority	36.7%		43.1%	1.2
FY Reported	2002		2006	Relative Increase 2006 / 2002
Total DOMESTIC Enrollment data	10,192,401		11,425,701	1.1
Total FOREIGN Enrollment	946,083		3,405,229	3.6

Table 5A Comments:

1. There was a 3.4 fold increase in protocols with enrollment reported from 1995 to 2006, from 3,188 protocols to 10,758 protocols.
2. There was a 14.5 fold increase in enrollment reported from 1995 to 2006, from approximately 1M to 15 M.
3. There was a 17.1 fold increase in minority enrollment from 1995 to 2006, from approximately 0.4 M to 6.4 M.
4. Domestic and Foreign data were reported for FY 2002-2006, and showed 1.1 fold increase in domestic enrollment (from 10.2M to 11.4M) and a 3.6 fold increase in foreign enrollment (from 0.95M to 3.4M).
5. See Table 6 for 12 year enrollment totals 1995-2006.

*NOTE: Trend data varies over time because the data for each year represent the net toal of data resulting from (1) studies continuing from the prior year; (2) the addition of new studies reported and (3) the subtraction of studies that are no longer reported.

5B. Twelve Year Summary of Total Number of Protocols Reported: FY 1995-2006

FY Reported	FY Funded	Number of Protocols with Enrollment data (Old +New Forms):	Number of DOMESTIC Protocols with Enrollment data	Number of FOREIGN Protocols with Enrollment data	Percent Domestic Protocols	Protocol Form*
1995	1994	3,188				OLD
1996	1995	6,036				
1997	1996	5,692				
1998	1997	7,602				
1999	1998	8,285				
2000	1999	9,390				
2001	2000	10,212				
2002	2001	8,945	8,463	482	94.6%	Old + New
2003	2002	10,216	9,578	638	93.8%	
2004	2003	10,125	9,760	365	96.4%	
2005	2004	10,233	9,862	371	96.4%	

2006	2005	10,758	10,294	464	95.7%	

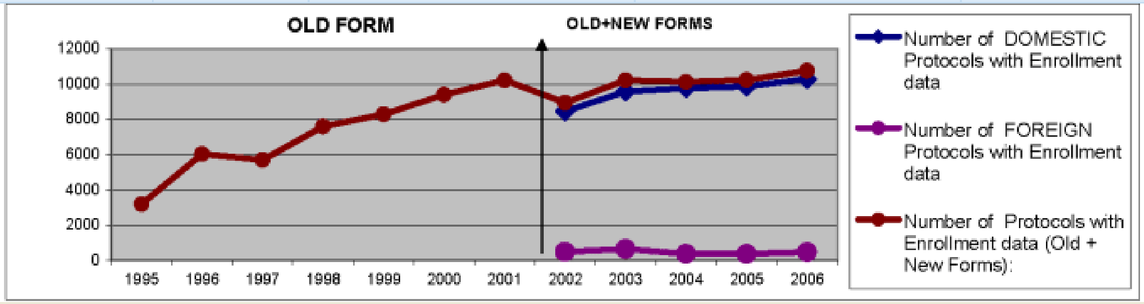


Table 5B Comments:

1. Table 5B and 5B Graph provide the number of OLD and NEW protocols year by year (1995-2006) and the distribution between domestic and foreign protocols for years 2002-2006.
2. The total number of protocols reported with enrollment have leveled off at about 15,000 over the last 4 years.
3. The vast majority of protocols were for domestic studies for 2002-2006, ranging from 93.8% to 96.4% of protocols.

* Data have been reported using a combined race/ethnicity format (OLD FORM) since 1995. New protocols began reporting separate race and ethnicity data in FY2002 (NEW FORM). During 2002-2006, data have been reported using both Old and New Forms.

*See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

5C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2006						
FY Reported	FY Funded	Total Enrollment data (Old +NewForms):	Total DOMESTIC Enrollment data	PercentDOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGNEnrollment
2002	2001	11,138,484	10,192,401	91.5%	946,083	8.5%

2003	2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%
2004	2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%
2005	2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%
2006	2005	14,830,930	11,425,701	77.0%	3,405,229	23.0%

Percent Comparison of Domestic and Foreign Enrollment

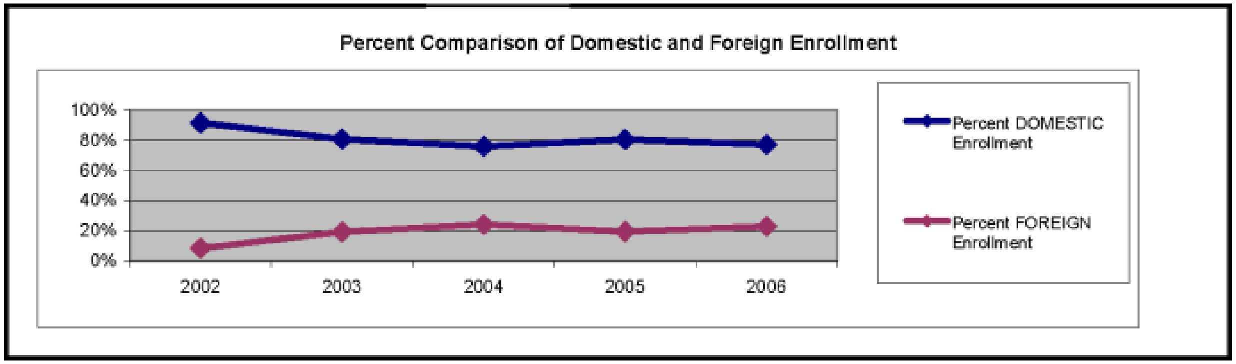


Table 5C Comments:

1. Overall total enrollment has increased, as well as total domestic and foreign enrollment during the last five years. The percentage of domestic enrollment has decreased to approximately 79% as the foreign enrollment has increased to approximately 21%.

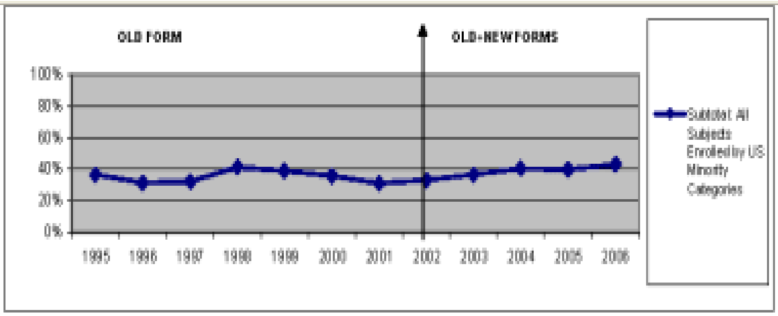
6A. TWELVE YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER AND MINORITY CATEGORIES IN ALL

PROTOCOLS (Old + New Forms)								
FY Reported	**FY Funded**	**Form**	**Females**	**Males**	**Unknown**	**Total All Subjects (Old + New Forms)**	**Subtotal: All Subjects Enrolled by US Minority Categories**	**Number of Protocols with Enrollment data (Old + New Forms):**
1995	**1994**	Old	528,421	459,921	33,151	1,021,493	374,433	3,188
	%		51.7%	45.0%	3.2%	100.0%	36.7%	
1996	**1995**	Old	4,130,385	2,583,865	91,054	6,805,304	2,125,958	6,036
	%		60.7%	38.0%	1.3%	100.0%	31.2%	
1997	**1996**	Old	3,320,610	1,930,783	65,540	5,316,933	1,709,223	5,692
	%		62.5%	36.3%	1.2%	100.0%	32.2%	
1998	**1997**	Old	4,246,130	2,716,880	115,566	7,078,576	2,923,662	7,602
	%		60.0%	38.4%	1.6%	100.0%	41.3%	
1999	**1998**	Old	5,102,306	2,712,068	169,863	7,984,237	3,108,228	8,285
	%		63.9%	34.0%	2.1%	100.0%	38.9%	
2000	**1999**	Old	5,585,042	3,919,065	64,990	9,569,097	3,406,297	9,390

	%		58.4%	41.0%	0.7%	100.0%	35.6%	
2001	**2000**	Old	6,808,822	4,740,887	44,547	11,594,256	3,619,119	10,212
	%		58.7%	40.9%	0.4%	100.0%	31.1%	
2002	**2001**	Old + New	7,155,549	3,904,560	78,375	11,138,484	3,666,880	8,945
	%		64.2%	35.1%	0.7%	100%	32.9%	
2003	**2002**	Old + New	8,514,481	6,121,496	136,277	14,772,254	5,387,692	10,216
	%		57.6%	41.4%	0.9%	100.0%	36.5%	
2004	**2003**	Old + New	10,889,097	7,741,892	292,931	18,923,920	7,611,611	10,125
	%		57.5%	40.9%	1.5%	100.0%	40.2%	
2005	**2004**	Old + New	9,503,922	5,941,907	276,923	15,722,752	6,245,436	10,233
			60.4%	37.8%	1.8%	100.0%	39.7%	
2006	**2005**	Old + New	9,473,273	5,172,205	185,452	14,830,930	6,388,316	10,758
			63.9%	34.9%	1.25%	100.0%	43.1%	

Total Minority Enrollment by Year Reported

Sex/Gender Enrollment by Year Reported



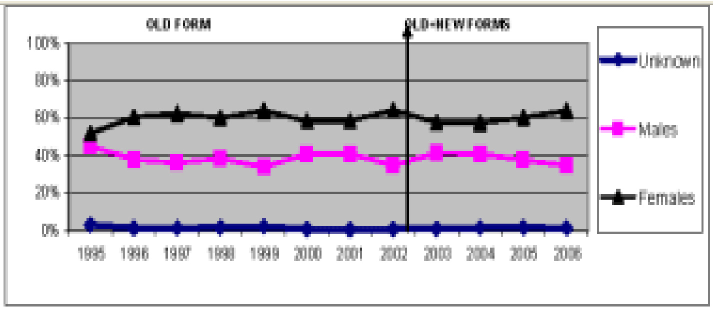


Table 6A Comments:

1. Table 6A summarizes enrollment by sex/gender and minority race/ethnicity categories for the twelve year reporting period (1995-2006). The data are compiled from Tables 6B, 6C and 6D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 6B) and the NEW Enrollment Form (Tables 6C and 6D).

2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

NOTE: Trend data varies over time because the data for each year represent the net total of data resulting from:(1) studies continuing from the prior year; (2) the addition of new studies reported; (3) and the subtraction of studies that are no longer reported.

Notes Tables B-D

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 6B, 6C and 6D are combined to provide the summary data in Table 6A.

6B. OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format										
FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/Other	Total	Subtotal Using US Minority Categories shaded): OLD FORM	Number Protocols with Enrollment data (Old Form):
1995	1994	11,221	38,952	234,976	89,284	540,313	106,747	1,021,493	374,433	3,188
	%	1.1%	3.8%	23.0%	8.7%	52.9%	10.5%	100.0%	36.7%	
1996	1995	146,319	617,211	823,102	539,326	4,114,249	565,097	6,805,304	2,125,958	6,036
	%	2.2%	9.1%	12.1%	7.9%	60.5%	8.3%	100.0%	31.2%	
1997	1996	36,638	321,479	864,102	487,004	3,199,778	407,932	5,316,933	1,709,223	5,692
	%	0.7%	6.0%	16.3%	9.2%	60.2%	7.7%	100.0%	32.1%	
1998	1997	71,436	1,429,022	1,081,210	526,560	4,470,966	405,043	7,984,237	3,108,228	8,285
	%	1.2%	17.5%	15.5%	7.1%	52.5%	6.2%	100.0%	41.3%	
1999	1998	71,436	1,429,022	1,081,210	526,560	4,470,966	405,043	7,984,237	3,108,228	8,285

	%	0.9%	17.9%	13.5%	6.6%	56.0%	5.1%	100.0%	38.9%	
2000	1999	82,728	1,525,392	1,209,769	588,408	5,588,942	573,858	9,569,097	3,406,297	9,390
	%	0.9%	15.9%	12.6%	6.1%	58.4%	6.0%	100.0%	35.6%	
2001	2000	105,067	1,495,279	1,199,625	819,148	7,314,449	660,688	11,594,256	3,619,119	10,212
	%	0.9%	12.9%	10.3%	7.1%	63.1%	5.7%	100.0%	31.2%	
2002	2001	45,843	1,222,296	702,234	398,657	4,044,052	321,349	6,734,431	2,369,030	6,187
	%	0.7%	18.1%	10.4%	5.9%	60.1%	4.8%	100.0%	35.2%	
2003	2002	36,579	730,542	472,426	288,523	3,238,284	278,901	5,045,255	1,528,070	4,903
	%	0.7%	14.5%	9.4%	5.7%	64.2%	5.5%	100.0%	30.3%	
2004	2003	29,387	307,052	342,188	214,322	2,348,529	172,130	3,413,608	892,949	2,782
	%	0.9%	9.0%	10.0%	6.3%	68.8%	5.0%	100.0%	26.2%	
2005	2004	22,375	254,598	229,615	134,972	1,267,089	102,405	2,011,054	641,560	1,786
	%	1.1%	12.7%	11.4%	6.7%	63.0%	5.1%	100.0%	31.9%	

2006	2005	19,648	131,786	148,948	78,596	883,041	63,231	1,325,250	378,978	1,391
	%	1.5%	9.9%	11.2%	5.9%	66.6%	4.8%	100.0%	28.6%	

ORIENTATION TO TABLES 6C and 6D.

1. The New Form consists of Parts A and B (Tables 6C and 6D) for reporting years 2002-2006. This Form is provided as part of the annual progress report.
2. Table 6C displays the New Form Part A for reporting separate race and ethnicity data.
3. Table 6D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the “Hispanic or Latino” column in Part A.

6C. New Form Part A: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats													
Total of All Subjects by Race										Total of All Subjects by Ethnicity			
FY Reported	**FY Funded**	**American Indian/ Alaska Native**	**Asian**	**Black or African American**	**Hawaiian /Pacific Islander**	**White**	**More Than One Race**	**Unknown /Other**	**Total***	**Not Hispanic**	**Hispanic or Latino****	**Unknown /Not Reported**	**Total***
2002	**2001**	77,734	354,049	547,776	21,636	2,651,541	30,955	720,362	4,404,053	3,071,952	292,429	1,039,672	4,404,053
	%	1.8%	8.0%	12.4%	0.5%	60.2%	0.7%	16.4%	100.0%	69.8%	6.6%	23.6%	100.0%
2003	**2002**	63,544	2,138,00	960,090	37,569	5,415,71	99,462	1,012,62	9,726,999	8,162,259	611,641	953,099	9,726,999

			2			0		2					
	%	0.7%	22.0%	9.9%	0.4%	55.7%	1.0%	10.4%	100.0%	83.9%	6.3%	9.8%	100.0%
2004	**2003**	98,047	4,345,396	1,379,857	54,452	8,065,069	186,241	1,381,250	15,510,312	13,168,842	756,339	1,585,131	15,510,312
	%	0.6%	28.0%	8.9%	0.4%	52.0%	1.2%	8.9%	100.0%	84.9%	4.9%	10.2%	100.0%
2005	**2004**	292,215	3,046,370	1,358,262	53,286	7,672,890	182,953	1,105,722	13,711,698	11,804,164	773,939	1,133,595	13,711,698
	%	2.1%	22.2%	9.9%	0.4%	56.0%	1.3%	8.1%	100.0%	86.1%	5.6%	8.3%	100.0%
2006	**2005**	141,567	3,463,202	1,251,339	38,460	7,089,017	321,554	1,200,541	13,505,680	11,308,244	1,054,313	1,143,123	13,505,680
	%	1.0%	25.6%	9.3%	0.3%	52.5%	2.4%	8.9%	100.0%	83.7%	7.8%	8.5%	100.0%

6D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos EnrollSeudbt ottoa UDsatgeU (SCumulative)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total Hispanic or Latino**	Minority Categories (shaded): NEW FORM Parts A+B	Number of Protocols with Enrollment data (New Form):
2002	**2001**	4,867	1,305	13,066	101	159,252	7390	106,448	292,429	1,297,850	2,758

	%	1.7%	0.4%	4.5%	0.0%	54.5%	2.5%	36.4%	100.0%	29.5%	
2003	**2002**	5,400	1,953	14,566	679	350,439	28,088	210,516	611,641	3,859,622	5,313
	%	0.9%	0.3%	2.4%	0.1%	57.3%	4.6%	34.4%	100.0%	39.7%	
2004	**2003**	6,408	5,040	25,276	2,037	361,112	62,909	293,557	756,339	6,718,662	7,343
	%	0.8%	0.7%	3.3%	0.3%	47.7%	8.3%	38.8%	100.0%	43.3%	
2005	**2004**	22,739	7,816	19,446	1,981	388,874	51,166	281,916	773,938	5,603,876	8,447
	%	2.9%	1.0%	2.5%	0.3%	50.2%	6.6%	36.4%	100.0%	40.9%	
2006	**2005**	45,074	6,641	21,712	2,193	417,495	185,477	375,721	1,054,313	6,009,338	9,367
	%	4.3%	0.6%	2.1%	0.2%	39.6%	17.6%	35.6%	100.0%	44.5%	

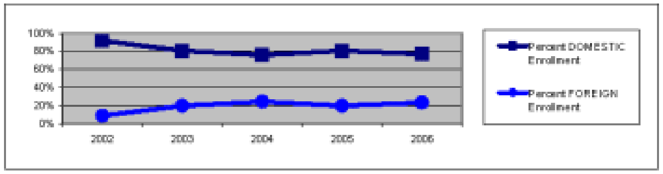
* These totals must agree.

**These totals must agree.

6E. Comparison of Domestic and Foreign Enrollment & Protocols with Total Enrollment for the period FY2002-2006											
ENROLLMENT							**PROTOCOLS**				
FY Reported	**FY Funded**	**Total Enrollment**	**Total DOMESTIC**	**Percent DOMESTIC**	**Total FOREIGN**	**Percent FOREIGN**	**Number of Protocols**	**Number of**	**Percent Domestic**	**Number of**	**Percent Foreign**

		data (Old + New Forms):	Enrollment	Enrollment	Enrollment	Enrollment	with Enrollment data (Old + New Forms):	DOMESTIC Protocols	Protocols	FOREIGN Protocols	Protocols
2002	**2001**	11,138,484	10,192,401	91.5%	946,083	8.5%	8,945	8,463	94.6%	482	5.4%
2003	**2002**	14,772,254	11,911,357	80.6%	2,860,897	19.4%	10,216	9,578	93.8%	638	6.2%
2004	**2003**	18,923,920	14,359,793	75.9%	4,564,127	24.1%	10,125	9,760	96.4%	365	3.6%
2005	**2004**	15,722,752	12,669,858	80.6%	3,052,894	19.4%	10,233	9,862	96.4%	371	3.6%
2006	**2005**	14,830,930	311,425,701	77.0%	3,405,229	23.0%	10,758	10,294	95.7%	464	4.3%

Percentage of Domestic and Foreign Enrollment



Number of Domestic and Foreign protocols

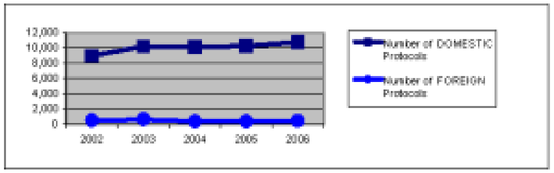


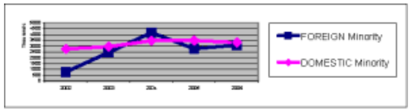
Table 6 E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2006.
2. The Domestic enrollment decreased to approximately 80%, while the Foreign enrollment increased to approximately 20%.
3. The vast majority of protocols are domestic protocols (approximately 94-96%), while foreign protocols make up approximately 4-6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

6F. Comparison of Domestic and Foreign Minority Participation for FY 2002-2006

FY Reported	FY Funded	FOREIGN Minority	Foreign Totalt	DOMESTIC Minorityt	Domestic Totalt
2002	2001	11,138,484	10,192,401	91.5%	946,083
2003	2002	14,772,254	11,911,357	80.6%	2,860,897
2004	2003	18,923,920	14,359,793	75.9%	4,564,127
2005	2004	15,722,752	12,669,858	80.6%	3,052,894

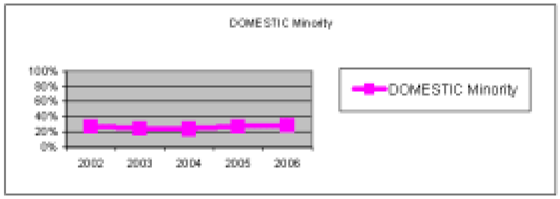
Number of Minority Participants for FY2002-2005



2006	2005	14,830,930	311,425,701	77.0%	3,405,229

NOTE MINORITY % WILL NOT ADD TO 100%

Percentage Comparison of Domestic Minority Enrollment to Total Domestic Enrollment for FY 2002-2006



Percentage Comparison of Foreign Minority Enrollment to TotalForeign Enrollment for FY 2002-2006

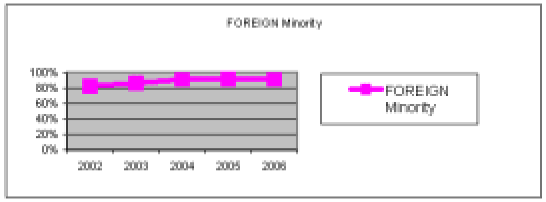


Table 6 F Comments:

1. Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment. research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary
2. The Total Minority Enrollment reported in FY2006 was 52% Domestic and 48 % Foreign (see Table 1). The small percentage of foreign protocols account for a significant proportion (48%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

Table 7: Twelve Year Minority rend Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2006: Enrollment by Race and Ethnicity.

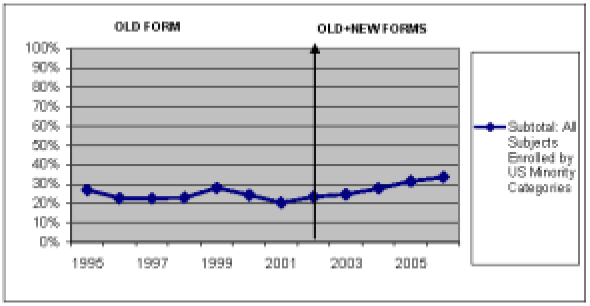
7A. Phase III TWELVE YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER IN ALL PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms):
1995	1994	171,181	108,324	19,818	299,323	80,562	560
	%	57.2%	36.2%	6.6%	100.0%	26.9%	
1996	1995	264,755	203,698	21,210	489,663	110,669	608
	%	54.1%	41.6%	4.3%	100.0%	22.6%	
1997	1996	264,755	203,698	21,210	489,663	110,000	608
	%	54.1%	41.6%	4.3%	100.0%	22.5%	
1998	1997	228,417	74,389	2,705	305,511	69,599	320
	%	74.8%	24.3%	0.9%	100.0%	22.8%	
1999	1998	339,533	163,950	1,446	504,929	141,449	578
	%	67.2%	32.5%	0.3%	100.0%	28.0%	
2000	1999	313,952	180,705	1,086	495,743	120,339	589

	%	63.3%	36.5%	0.2%	100.0%	24.3%	
2001	2000	412,379	168,085	1,273	581,737	117,873	645
	%	70.9%	28.9%	0.2%	100.0%	20.3%	
2002	2001	278,876	195,090	781	474,747	111,269	754
	%	58.7%	41.1%	0.2%	100.0%	23.4%	
2003	2002	294,950	239,403	1,914	536,267	132,302	852
	%	55.0%	44.6%	0.4%	100.0%	24.7%	
2004	2003	301,353	242,913	1,101	545,367	150,456	573
	%	55.3%	44.5%	0.2%	100.0%	27.6%	
2005	2004	290,977	197,300	4,723	493,000	154,191	547
		59.0%	40.0%	1.0%	100.0%	31.3%	
2006	2005	314,066	179,975	5,389	499,430	167,446	624
		62.9%	36.0%	1.1%	100.0%	33.5%	

Total Phase III Enrollment by Year Reported

Sex/Gender Phase III Enrollment by Year Reported



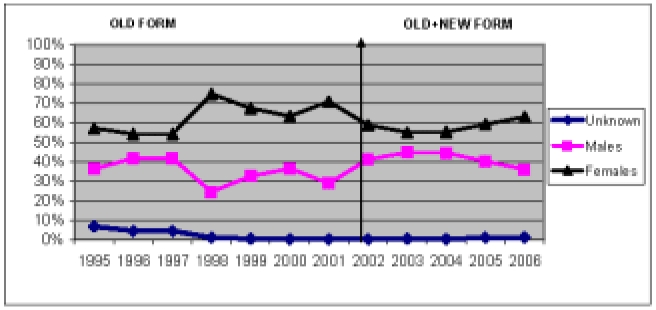


Table 7A Comments:

1. Table7A summarizes enrollment by sex/gender and minority race/ethnicity categories for the twelve year reporting period (1995-2006). The data are compiled from Tables 7B, 7C and 7D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 7B) and the NEW Enrollment Form (Tables 7C and 7D).

2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

NOTE: Trend data varies over time because the data for each year represent the net total of data resulting from:(1) studies continuing from the prior year; (2) the addition of new studies reported; (3) and the subtraction of studies that are no longer reported.

Notes Tables 7B-D

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 7B, 7C and 7D are combined to provide the summary data in Table 7A.

7B. Phase III OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format										
FY Reported	**FY Funded**	**American Indian/ Alaska Native**	**Asian/ Pacific Islander**	**Black or African American**	**Hispanic, Not White**	**White**	**Unknown /Other**	**Total**	**Subtotal Using US Minority Categories (shaded): OLD FORM**	**Number of Foreign Protocols with Enrollment data (Old Form):**
1995	**1994**	5,358	2,740	52,433	20,031	172,773	45,988	299,323	**409**	560
	%	1.8%	0.9%	17.5%	6.7%	57.7%	15.4%	100.0%	26.9%	
1996	**1995**	4,235	40,126	46,838	19,470	321,445	57,549	489,663	110,669	608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%	100.0%	22.6%	
1997	**1996**	4,235	40,126	46,838	19,470	321,445	57,549	489,663	110,669	608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%	100.0%	22.6%	
1998	**1997**	5,030	5,324	42,805	16,440	229,534	6,378	305,511	69,599	215
	%	1.6%	1.7%	14.0%	5.4%	75.1%	2.1%	100.0%	22.8%	
1999	**1998**	3,685	20,276	76,921	40,567	336,703	26,777	504,929	141,449	578
	%	0.7%	4.0%	15.2%	8.0%	66.7%	5.3%	100.0%	28.0%	

2000	**1999**	3,726	24,017	62,512	30,084	335,824	39,580	495,743	120,339	589
	%	0.8%	4.8%	12.6%	6.1%	67.7%	8.0%	100.0%	24.3%	
2001	**2000**	4,079	11,132	70,110	32,552	422,802	41,062	581,737	117,873	645
	%	0.7%	1.9%	12.1%	5.6%	72.7%	7.1%	100.0%	20.3%	
2002	**2001**	1,645	20,560	51,991	29,636	315,543	12,228	431,603	103,832	660
	%	0.38%	4.8%	12.0%	6.9%	73.1%	2.8%	100.00%	24.1%	
2003	**2002**	1,689	20,038	49,255	29,066	337,654	16,615	454,317	100,048	656
	%	0.4%	4.4%	10.8%	6.4%	74.3%	3.7%	100.0%	22.0%	
2004	**2003**	1,505	18,807	45,285	32,974	265,764	14,050	378,385	98,571	296
	%	0.4%	5.0%	12.0%	8.7%	70.2%	3.7%	100.0%	26.1%	
2005	**2004**	1,319	17,740	39,402	21,829	231,492	4,507	316,289	80,290	210
	%	0.4%	5.6%	12.5%	6.9%	73.2%	1.4%	100.0%	25.4%	
2006	**2005**	1,012	16,800	20,355	9,524	175,724	6,348	229,763	47,691	215
	%	0.4%	7.3%	8.9%	4.1%	76.5%	2.8%	100.0%	20.8%	

ORIENTATION TO TABLES 7C and 7D.

1. The New Form consists of Parts A and B (Tables 7C and 7D) for reporting years 2002-2006. This Form is provided as part of the annual progress report.
2. Table 7C displays the New Form Part A for reporting separate race and ethnicity data.
3. Table 7D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the "Hispanic or Latino" column in Part A.

7C. Phase III New Form: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity													
		Total of All Subjects by Race								**Total of All Subjects by Ethnicity**			
FY Reported	**FY Funded**	**American Indian/ Alaska Native**	**Asian**	**Black or African American**	**Hawaiian/ Pacific Islander**	**White**	**More Than One Race**	**Unknown /Other**	**Total**	**Not Hispanic**	**Hispanic or Latino**	**Unknown/ Not Reported**	**Total**
2002	**2001**	159	799	4,647	52	34,654	560	2,273	43,144	36,224	1,629	5,291	43,144
	%	0.37%	1.85%	10.77%	0.12%	80.32%	1.30%	5.27%	100.00%	83.96%	3.78%	12.26%	100.00%
2003	**2002**	484	2,609	21,641	220	47,869	989	8,138	81,950	64,295	7,831	9,824	81,950
	%	0.6%	3.2%	26.4%	0.3%	58.4%	1.2%	9.9%	100.0%	78.5%	9.6%	12.0%	100.0%
2004	**2003**	1,396	4,385	43,721	611	106,793	4,419	5,657	166,982	145,742	13,435	7,805	166,982
	%	0.8%	2.6%	26.2%	0.4%	64.0%	2.6%	3.4%	100.0%	87.3%	8.0%	4.7%	100.0%

2005	**2004**	2,164	9,192	50,338	462	101,238	3,063	10,254	176,711	156,650	10,397	9,664	176,711
	%	1.2%	5.2%	28.5%	0.3%	57.3%	1.7%	5.8%	100.0%	88.6%	5.9%	5.5%	100.0%
2006	**2005**	4,630	32,360	50,780	535	126,670	4,246	50,446	269,667	202,358	31,034	36,275	269,667
	%	1.7%	12.0%	18.8%	0.2%	47.0%	1.6%	18.7%	100.0%	75.0%	11.5%	13.5%	100.0%

7D. Phase III Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	FSubtotal Using US Minority Categories (shaded): NEW	Number of Protocols with Enrollment data(New Form):
2002	**2001**	49	22	31	4	660	304	560	1,630	**7,437**	**94**
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	17.2%	
2003	**2002**	37	70	186	23	2,115	203	5,197	7,831	**32,254**	**196**
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	39.4%	
2004	**2003**	269	59	193	26	7,264	3,052	2,572	13,435	**54,405**	**277**
	%	2.0%	0.4%	1.4%	0.2%	54.1%	22.7%	19.1%	100.0%	32.6%	
2005	**2004**	759	42	446	45	3,667	423	5,015	10,397	**73,901**	**337**

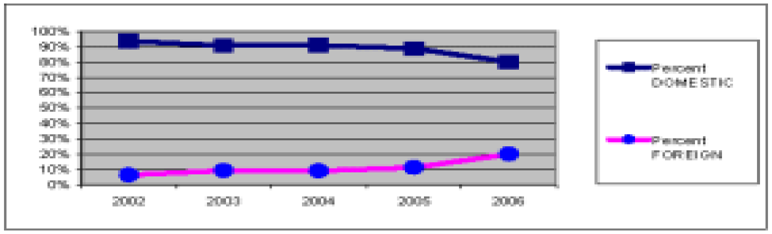
	%	7.3%	0.4%	4.3%	0.4%	35.3%	4.1%	48.2%	100.0%	41.8%	
2006	**2005**	2,307	50	720	40	6,872	713	20,332	31,034	**119,755**	**409**
	%	7.4%	0.2%	2.3%	0.1%	22.1%	2.3%	65.5%	100.0%	44.4%	

*** These totals must agree**

**** These totals must agree**

7E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2006											
ENROLLMENT							**PROTOCOLS**				
FY Reported	**FY Funded**	**Total Enrollment data (Old + New Forms):**	**Total DOMESTIC**	**Percent DOMESTIC**	**Total FOREIGN**	**Percent FOREIGN**	**Number of Protocols with Enrollment data (Old + New Forms)**	**Number of DOMESTIC Protocols**	**Percent Domestic Protocols**	**Number of FOREIGN Protocols**	**Percent Foreign Protocols**
2002	**2001**	474,747	444,436	93.6%	30,311	6.4%	754	582	77.2%	172	22.8%
2003	**2002**	536,267	486,857	90.8%	49,410	9.2%	852	643	75.5%	209	24.5%
2004	**2003**	545,367	496,241	91.0%	49,126	9.0%	573	549	95.8%	24	4.2%
2005	**2004**	493,000	437,902	88.8%	55,098	11.2%	547	517	94.5%	30	5.5%
2006	**2005**	499,430	400,297	80.2%	99,133	19.8%	624	564	90.4%	60	9.6%

Percentage of Phase III Domestic and Foreign Enrollment



Number of Phase III Domestic and Foreign protocols

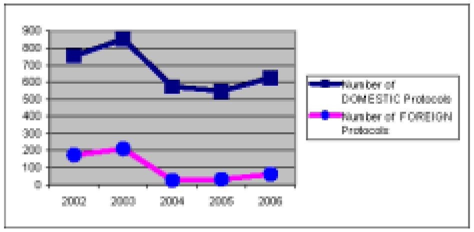


Table 7 E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2006.
2. The Domestic enrollment decreased to approximately 80%, while the Foreign enrollment increased to approximately 20%.
3. The vast majority of protocols in FY2004-2006 are domestic protocols (approximately 90.4-95.8%), while foreign protocols make up approximately 4.2-9.6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

7F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2006

FY Reported	FY Funded	FOREIGN Phase III Minority	FOREIGN Phase III Total	DOMESTIC Phase III Minority	DOMESTIC Phase III Total
2002	2001	18,308	30,311	92,961	444,436

		60.4%	100.0%	20.9%	100.0%
2003	2002	23,927	49,410	109,376	486,857
		48.4%	100.0%	22.5%	100.0%
2004	2003	37,126	49,126	125,813	496,241
		75.6%	100.0%	25.4%	100.0%
2005	2004	44,281	55,098	109,910	437,902
		80.4%	100.0%	25.1%	100.0%
2006	2005	84,412	99,133	83,034	400,297
		85.2%	100.0%	20.7%	100.0%

Number of Minority Participants in Phase III Clinical Studies for FY2002-2006

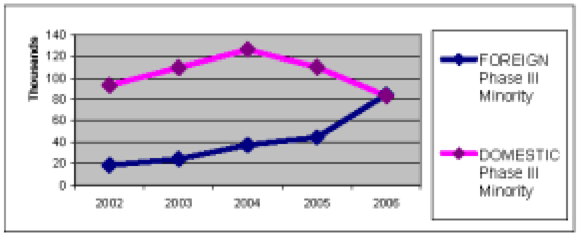


Table 7 F Comments:

1. Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment.
2. Foreign Minority Enrollment has varied from 82.2% to 90.9% of Total Foreign Enrollment, reflecting that most of the foreign research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary minority data used in this report.
3. The Total Minority Enrollment reported in FY2006 was 52% Domestic and 48 % Foreign (see Table 1). The small percentage of foreign protocols account for a significant proportion (48%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

8A. Five Year Summary Totals: Domestic Subjects in Domestic Protocols(Old + New Forms)

FY Reported	**FY Funded**	**Females**	**Males**	**Unknown**	**Total Domestic Subjects (Old + New Forms)**	**Subtotal: Domestic Subjects Enrolled by US Minority Categories**	**Number of Domestic Protocols with Enrollment data (Old +**
2002	**2001**	6,583,087	3,506,787	59,995	10,149,869	2,754,820	8,425
	%	64.9%	34.6%	0.6%	100.0%	27.1%	
2003	**2002**	7,392,404	4,393,496	125,457	11,911,357	2,935,363	9,578
	%	62.1%	36.9%	1.1%	100.0%	24.6%	
2004	**2003**	8,881,299	5,199,765	278,729	14,359,793	3,464,356	9,760

	%	61.8%	36.2%	1.9%	100.0%	24.1%	
2005	**2004**	7,887,209	4,515,242	267,407	12,669,858	3,468,864	9,862
		62.3%	35.6%	2.1%	100.0%	27.4%	
2006	**2005**	7,684,453	3,566,577	174,671	11,425,701	3,301,135	10,294
		67.3%	31.2%	1.5%	100.0%	28.9%	

Table 8A Comments:

1. There were approximately an average of 63% females, 35% males and 2% of unknown sex enrolled in domestic protocols from 2002-2006.
2. There were approximately an average of 27% domestic minority subjects enrolled in domestic protocols from 2002-2006.
3. Total domestic enrollment ranged from 10.1M to 11.5M during these 5 years.
4. The number of domestic protocols increased from 8,425 to 10,294 in 2006.

NOTE on FY2002 Reported Data:
One domestic study had an enrollment of 540,833 subjects (Old Form).
One domestic study had an enrollment of 1,571,305 subjects (Old Form).

NOTE on FY2003 Reported Data:
One domestic study had an enrollment of 800,000 subjects (New Form).
One domestic study had an enrollment of 1,389,920 subjects (New form).
One domestic study had an enrollment of 1,799,820 subjects (New form).

NOTE on FY2004 Reported Data:
One domestic study had an enrollment of 540,833 subjects (New Form).

One domestic study had an enrollment of 800,000 subjects (New Form).
One domestic study had an enrollment of 1,138,302 subjects (New form).
One domestic study had an enrollment of 1,419,475 subjects (New form).
One domestic study had an enrollment of 1,799,820 subjects (New form).

NOTE on FY2005 Reported Data:
One domestic study had an enrollment of 540,833 subjects (New Form).
One domestic study had an enrollment of 800,000 subjects (New Form).
One domestic study had an enrollment of 1,595,620 subjects (New form).
One domestic study had an enrollment of 1,799,820 subjects (New form).

NOTE on FY2006 Reported Data:
One domestic study had an enrollment of 875,010 subjects (New Form).
One domestic study had an enrollment of 1,964,668 subjects (New Form).
One domestic study had an enrollment of 540,833 subjects (New form).

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 8B, 8C and 8D are combined to provide the summary data in Table A.

8B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other		Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority ategories (shaded):		Number of Domestic rotocols with Enrollment data (Old Form):

										OLD FORM		
2002	2001	45,639	752,203	673,726	378,300	3,880,431	316,053		6,046,352	1,849,868		5,783
	%	0.8%	12.4%	11.1%	6.3%	64.2%	5.2%		100.0%	30.6%		
2003	2002	36,238	249,420	455,329	264,336	3,100,815	266,339		4,372,477	1,005,323		4,478
	%	0.8%	5.7%	10.4%	6.0%	70.9%	6.1%		100.0%	23.0%		
2004	2003	28,953	196,647	322,078	194,762	2,273,619	157,464		3,173,523	742,440		2,702
	%	0.9%	6.2%	10.1%	6.1%	71.6%	5.0%		100.0%	23.4%		
2005	2004	22,375	89,119	210,465	126,351	1,245,337	93,239		1,786,886	448,310		1,736
	%	1.3%	5.0%	11.8%	7.1%	69.7%	5.2%		100.0%	25.1%		
2006	2005	19,628	51,701	148,224	74,312	866,683	61,480		1,222,028	293,865		1,361
	%	1.6%	4.2%	12.1%	6.1%	70.9%	5.0%		100.0%	24.0%		

8C. NEW FORM PART A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Total of All Subjects by Race										Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total All Subject by Ethnic Catego
2002	2001	74,593	174,215	473,699	7,623	2,626,547	30,200	716,640	4,103,517	2,785,590	285,921	1,032,006	4,103,5
	%	1.8%	4.2%	11.5%	0.2%	64.0%	0.7%	17.5%	100.0%	67.9%	7.0%	25.1%	100.0%
2003	2002	61,526	295,061	897,518	23,068	5,161,965	94,138	1,005,604	7,538,880	6,003,326	602,018	933,536	7,538,8
	%	0.8%	3.9%	11.9%	0.3%	68.5%	1.2%	13.3%	100.0%	79.6%	8.0%	12.4%	100.0%
2004	2003	97,854	485,137	1,280,129	42,945	7,772,927	172,185	1,335,093	11,186,270	8,893,158	720,551	1,572,561	11,186,
	%	0.9%	4.3%	11.4%	0.4%	69.5%	1.5%	11.9%	100.0%	79.5%	6.4%	14.1%	100.0%
2005	2004	291,044	655,959	1,232,957	42,993	7,485,193	164,096	1,010,730	10,882,972	9,120,293	721,138	1,041,541	10,882,
	%	2.7%	6.0%	11.3%	0.4%	68.8%	1.5%	9.3%	100.0%	83.8%	6.6%	9.6%	100.0%
2006	2005	111,048	946,613	1,032,199	35,142	6,844,960	178,275	1,055,436	10,203,673	8,384,360	796,556	1,022,757	10,203,
	%	1.1%	9.3%	10.1%	0.3%	67.1%	1.7%	10.3%	100.0%	82.2%	7.8%	10.0%	100.0%

8D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	**FY Funded**	American Indian/ Alaska Native	**Asian**	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	**More Than One Race**	**Unknown or Not Reported**	****Total of Hispanics or Latinos by Racial Categories**	Domestic Subtotal Using US Minority Categories (shaded):NEW FORM Parts A+B	Number of Domestic Protocols with Enrollment data (New Form):
2002	**2001**	1,163	436	12,005	98	69,313	5,626	75,309	163,950	904,952	**2,642**
	%	0.7%	0.3%	7.3%	0.1%	42.3%	3.4%	45.9%	100.0%	22.1%	
2003	**2002**	3,756	1,950	13,345	678	349,844	23,560	208,885	602,018	1,930,040	**5,100**
	%	0.6%	0.3%	2.2%	0.1%	58.1%	3.9%	34.7%	100.0%	25.6%	
2004	**2003**	6,293	5,026	12,498	2,037	356,575	51,031	287,091	720,551	**2,721,916**	**7,058**
	%	0.9%	0.7%	1.7%	0.3%	49.5%	7.1%	39.8%	100.0%	24.3%	
2005	**2004**	22,057	7,810	19,282	1,981	362,707	36,503	270,798	721,138	**3,020,554**	**8,126**
	%	3.1%	1.1%	2.7%	0.3%	50.3%	5.1%	37.6%	100.0%	27.8%	
2006	**2005**	15,498	6,540	19,870	1,505	374,830	49,150	329,163	796,556	**3,007,270**	**8,933**
	%	1.9%	0.8%	2.5%	0.2%	47.1%	6.2%	41.3%	100.0%	29.5%	

*** These Totals must agree**

****These totals must agree**

9A . Phase III Five Year Summary Totals: Domestic Subjects In Domestic Protocols(Old + New Forms)

FY Reported	**FY Funded**	Females	Males	**Unknown**	**Total DomesticSubjects (Old + New Forms)**	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**264,517**	**179,179**	**740**	**444,436**	**92,961**	**582**
	%	59.5%	40.3%	0.2%	100.0%	20.9%	
2003	**2002**	**266,913**	**218,166**	**1,778**	**486,857**	**109,376**	**643**
	%	54.8%	44.8%	0.4%	100.0%	22.5%	
2004	**2003**	**277,333**	**217,890**	**1,018**	**496,241**	**125,813**	**549**
	%	55.9%	43.9%	0.2%	100.0%	25.4%	
2005	**2004**	**261,589**	**174,137**	**2,176**	**437,902**	**109,910**	**517**
		59.7%	39.8%	0.5%	100.0%	25.1%	
2006	**2005**	**258,467**	**137,621**	**4,209**	**400,297**	**83,034**	**564**

		64.6%	34.4%	1.1%	100.0%	20.7%	

Table 9A Comments:

1. There were approximately an average of 57% females, 42% males and 0.3% of unknown sex enrolled in domestic protocols from 2002-2005.
2. There were approximately an average of 23.5% domestic minority subjects enrolled in domestic Phase III protocols from 2002-2006.
3. Total domestic Phase III enrollment ranged from 400,297to 496,241 during these 5 years.
4. The number of domestic Phase III protocols ranged from 517 to 564 in 2006.

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 9B, 9C and 9D are combined to provide the summary data in Table A.

9B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	**FY Funded**	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	**Total Domestic Enrollment (Old Form)**	Domestic Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Domestic Protocols with Enrollment data (Old Form):
2002	**2001**	1,586	8,291	49,184	27,912	305,964	10,670	403,607	86,973	494

	%	0.4%	2.1%	12.2%	6.9%	75.8%	2.6%	100.0%	21.5%	
2003	**2002**	1,612	7,610	48,975	25,567	322,600	8,538	414,902	83,764	468
	%	0.4%	1.8%	11.8%	6.2%	77.8%	2.1%	100.0%	20.2%	
2004	**2003**	1,504	6,739	45,233	31,967	262,671	6,447	354,561	85,443	286
	%	0.4%	1.9%	12.8%	9.0%	74.1%	1.8%	100.0%	24.1%	
2005	**2004**	1,319	5,488	39,401	20,646	229,235	4,493	300,582	66,854	205
	%	0.4%	1.8%	13.1%	6.9%	76.3%	1.5%	100.0%	22.2%	
2006	**2005**	996	4,505	20,325	9,512	171,191	5,673	212,202	35,338	207
	%	0.5%	2.1%	9.6%	4.5%	80.7%	2.7%	100.0%	16.7%	

9C. NEW FORM Part A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)													
Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race													
		Total of All Subjects by Race								**Total of All Subjects by Ethnicity**			
FY Reported	**FY Funded**	American Indian/	**Asian**	Black or African	Native Hawaiian	White	**More Than**	**Unknown or Not**	***Total of All**	**Not Hispanic**	**Hispanic or	**Unknown/ Not**	*Total of All

		Alaska Native		American	or Pacific Islander		**One Race**	**Reported**	**Subjects by Racial Categories (New Form)**		Latino	**Reported**	Subjects by Ethnic Category
2002	**2001**	159	798	3,199	52	34,541	560	1,520	40,829	34,662	1,629	4,538	40,829
	%	0.4%	2.0%	7.8%	0.1%	84.6%	1.4%	3.7%	100.0%	84.9%	4.0%	11.1%	100.0%
2003	**2002**	477	2,586	14,031	220	46,774	989	6,878	71,955	55,575	7,828	8,552	71,955
	%	0.7%	3.6%	19.5%	0.3%	65.0%	1.4%	9.6%	100.0%	77.2%	10.9%	11.9%	100.0%
2004	**2003**	1,396	4,373	22,307	611	106,260	1,849	4,884	141,680	123,770	10,863	7,047	141,680
	%	1.0%	3.1%	15.7%	0.4%	75.0%	1.3%	3.4%	100.0%	87.4%	7.7%	5.0%	100.0%
2005	**2004**	1,775	4,920	24,390	462	93,662	3,063	9,048	137,320	118,528	9,773	9,019	137,320
	%	1.3%	3.6%	17.8%	0.3%	68.2%	2.2%	6.6%	100.0%	86.3%	7.1%	6.6%	100.0%
2006	**2005**	2,724	5,312	23,267	530	118,577	4,077	33,608	188,095	141,688	13,550	32,857	188,095
	%	1.4%	2.8%	12.4%	0.3%	63.0%	2.2%	17.9%	100.0%	75.3%	7.2%	17.5%	100.0%

9D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	**FY Funded**	American Indian/ Alaska Native	**Asian**	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	**More Than One Race**	**Unknown or Not Reported**	****Total of Hispanics or Latinos by Racial Categories**	**Domestic Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B**	**Number of Domestic Protocols with Enrollment data (New Form):**
2002	**2001**	49	21	31	4	660	304	560	1,629	5,988	88
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	14.7%	
2003	**2002**	37	70	186	23	2,113	203	5,196	7,828	**25,612**	**175**
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	35.6%	
2004	**2003**	269	59	193	26	7,262	482	2,572	10,863	**40,370**	**263**
	%	2.5%	0.5%	1.8%	0.2%	66.9%	4.4%	23.7%	100.0%	28.5%	
2005	**2004**	371	42	446	45	3,663	423	4,783	9,773	**43,056**	**312**
	%	3.8%	0.4%	4.6%	0.5%	37.5%	4.3%	48.9%	100.0%	31.4%	
2006	**2005**	458	47	507	40	5,544	712	6,242	13,550	**47,696**	**357**
	%	3.4%	0.3%	3.7%	0.3%	40.9%	5.3%	46.1%	100.0%	25.4%	

*** These totals must agree**

**** These totals must agree**

10A . FIVE YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)							
FY Reported	**FY Funded**	Females	Males	**Unknown**	**Total Domestic Subjects (Old + New Forms)**	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	**2001**	**553,056**	**379,294**	**13,833**	**946,083**	**777,461**	**482**
	%	58.5%	40.1%	1.5%	100.0%	82.2%	
2003	**2002**	**1,122,077**	**1,728,000**	**10,820**	**2,860,897**	**2,452,329**	**638**
	%	39.2%	60.4%	0.4%	100.0%	85.7%	
2004	**2003**	**2,007,798**	**2,542,127**	**14,202**	**4,564,127**	**4,147,255**	**365**
	%	44.0%	55.7%	0.3%	100.0%	90.9%	
2005	**2004**	**1,616,713**	**1,426,665**	**9,516**	**3,052,894**	**2,776,565**	**371**
	%	53.0%	46.7%	0.3%	100.0%	90.9%	
2006	**2005**	**1,788,820**	**1,605,628**	**10,781**	**3,405,229**	**3,087,181**	**464**
	%	52.5%	47.2%	0.3%	100.0%	90.7%	

Table 10A Comments:

1. The percent females varied from 39.2% to 58.5% in foreign protocols from 2002-2005; the percent males varied from 40.1% to 60.4%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in foreign protocols increased from 82.2% to 90.9% from 2002 to 2005.
3. Total foreign enrollment ranged from 777,461 to 4.15M during these 5 years.
4. The number of foreign protocols ranged from 638 in 2003 to 317 in 2005.

NOTE on FY2002 Reported Data:
One study in Vietnam had an enrollment of 302,381 subjects (Old Form).

NOTE on FY2003 Reported Data:
One study in Vietnam had an enrollment of 302,381 subjects (Old Form).
One study in China had an enrollment of 1,910,000 subjects (New form).

NOTE on FY2004 Reported Data:
One study in India had an enrollment of 2,000,000 subjects (New Form).
One study in China had an enrollment of 1,910,000 subjects (New form).

NOTE on FY2005 Reported Data:
One study in India had an enrollment of 2,200,000 subjects (New Form).

NOTE on FY2006 Reported Data:
One study in India had an enrollment of 2,200,000 subjects (New Form).

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 10B, 10C and 10D are combined to provide the summary data in Table A.

10B.OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	Total Foreign Enrollment (Old Form)	Foreign Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Domestic Protocols with Enrollment data (Old Form):
2002	2001	69	468,958	21,407	19,075	143,768	3,565	656,842	509,509	380
	%	0.0%	71.4%	3.3%	2.9%	21.9%	0.5%	100.0%	77.6%	
2003	2002	341	481,122	17,097	24,187	137,469	12,562	672,778	522.747	425
	%	0.1%	71.5%	2.5%	3.6%	20.4%	1.9%	100.0%	77.7%	
2004	2003	434	110,405	20,110	19,560	74,910	14,666	240,085	150,509	80
	%	0.2%	46.0%	8.4%	8.1%	31.2%	6.1%	100.0%	62.7%	
2005	2004	0	165,479	19,150	8,621	21,752	9,166	224,168	193,250	50
	%	0.0%	73.8%	8.5%	3.8%	9.7%	4.1%	100.0%	86.2%	
2006	2005	20	80,085	724	4,284	16,358	1,751	103,222	85,113	30

	%	0.0%	77.6%	0.7%	4.2%	15.8%	1.7%	100.0%	82.5%	

10C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	3,271	180,022	68,071	14,013	19,970	741	3,153	289,241	278,618	6,064	4,559	289,241
	%	1.1%	62.2%	23.5%	4.8%	6.9%	0.3%	1.1%	100.0%	96.3%	2.1%	1.6%	100.0%
2003	2002	2,018	1,842,941	62,572	14,501	253,745	5,324	7,018	2,188,119	2,158,933	9,623	19,563	2,188,119
	%	0.1%	84.2%	2.9%	0.7%	11.6%	0.2%	0.3%	100.0%	98.7%	0.4%	0.9%	100.0%
2004	2003	193	3,860,259	99,728	11,507	292,142	14,056	46,157	4,324,042	4,275,684	35,788	12,570	4,324,042
	%	0.0%	89.3%	2.3%	0.3%	6.8%	0.3%	1.1%	100.0%	98.9%	0.8%	0.3%	100.0%

2005	2004	1,171	2,390,404	125,305	10,293	187,697	18,857	94,999	2,828,726	2,683,871	52,801	92,054	2,828,72
	%	0.0%	84.5%	4.4%	0.4%	6.6%	0.7%	3.4%	100.0%	94.9%	1.9%	3.3%	100.0%
2006	2005	30,519	2,516,589	219,140	3,318	244,057	143,279	145,105	3,302,007	2,923,885	257,756	120,366	3,302,00
	%	0.9%	76.2%	6.6%	0.1%	7.4%	4.3%	4.4%	100.0%	88.5%	7.8%	3.6%	100.0%

10D. NEW FORM Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Foreign Protocols with Enrollment data (New Form):
2002	2001	1,461	0	4	0	1,659	683	175	3,982	267,952	102
	%	36.7%	0.0%	0.1%	0.0%	41.7%	17.2%	4.4%	100.0%	92.6%	
2003	2002	1,644	3	1,222	0	632	4,528	1,594	9,623	1,929,582	213
	%	17.1%	0.0%	12.7%	0.0%	6.6%	47.1%	16.6%	100.0%	88.2%	
2004	2003	115	14	12,778	0	4,537	11,878	6,466	35,788	3,996,746	285
	%	0.3%	0.0%	35.7%	0.0%	12.7%	33.2%	18.1%	100.0%	92.4%	

2005	2004	682	6	164	0	26,161	14,664	11,124	52,801	2,583,315	321
	%	1.3%	0.0%	0.3%	0.0%	49.5%	27.8%	21.1%	100.0%	91.3%	
2006	2005	29,576	101	1,842	688	42,665	136,326	46,558	257,756	3,002,068	434
	%	11.5%	0.0%	0.7%	0.3%	16.6%	52.9%	18.1%	100.0%	90.9%	

*** These totals must agree**

**** These totals must agree**

11A. Part A. Phase III FIVE YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):
2002	2001	14,359	15,911	41	30,311	18,308	172
	%	47.4%	52.5%	0.1%	100.0%	60.4%	
2003	2002	28,037	21,237	136	49,410	23,927	209
	%	56.7%	43.0%	0.3%	100.0%	48.4%	
2004	2003	24,020	25,023	83	49,126	37,126	24

	%	48.9%	50.9%	0.2%	100.0%	75.6%	
2005	2004	29,388	23,163	2,547	55,098	44,281	30
	%	53.3%	42.0%	4.6%	100.0%	80.4%	
2006	2005	55,599	42,354	1,180	99,133	84,412	60
	%	56.1%	42.7%	1.2%	100.0%	85.2%	

Table 11A Comments:

1. The percent females varied from 47.4% to 56.7% in Phase III foreign protocols from 2002-2006; the percent males varied from 42.0% to 52.5%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in Phase III foreign protocols increased from 60.4% to 85.2% from 2002 to 2006.
3. Total Phase III foreign enrollment increased from 30,311 to 99,133 during these 5 years.
4. The number of Phase III foreign protocols dropped from 209 in 2003 to 60 in 2006.

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 11B, 11C and 11D are combined to provide the summary data in Table A.

11B.OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	Total Foreign Enrollment (Old Form)	Foreign Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Foreign Protocols with Enrollment data (Old Form):
2002	2001	59	12,269	2,807	1,724	9,579	1,558	27,996	16,859	166
	%	0.2%	43.8%	10.0%	6.2%	34.2%	5.6%	100.0%	60.2%	
2003	2002	77	12,428	280	3,499	15,054	8,077	39,415	16,284	188
	%	0.2%	31.5%	0.7%	8.9%	38.2%	20.5%	100.0%	41.3%	
2004	2003	1	12,068	52	1,007	3,093	7,603	23,824	13,128	10
	%	0.0%	50.7%	0.2%	4.2%	13.0%	31.9%	100.0%	55.1%	
2005	2004	0	12,252	1	1,183	2,257	14	15,707	13,436	5
	%	0.0%	78.0%	0.0%	7.5%	14.4%	0.1%	100.0%	85.5%	
2006	2005	16	12,295	30	12	4,533	675	17,561	12,353	8
	%	0.1%	70.0%	0.2%	0.1%	25.8%	3.8%	100.0%	70.3%	

11C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race

and Ethnicity Formats)													
Part A: Total Enrollment Report: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race													
		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	0	1	1,448	0	113	0	753	2,315	1,562	0	753	2,315
	%	0.0%	0.0%	62.5%	0.0%	4.9%	0.0%	32.5%	100.0%	67.5%	0.0%	32.5%	100.0%
2003	2002	7	23	7,610	0	1,095	0	1,260	9,995	8,720	3	1,272	9,995
	%	0.1%	0.2%	76.1%	0.0%	11.0%	0.0%	12.6%	100.0%	87.2%	0.0%	12.7%	100.0%
2004	2003	0	12	21,414	0	553	2,570	753	25,302	21,972	2,572	758	25,302
	%	0.0%	0.0%	84.6%	0.0%	2.2%	10.2%	3.0%	100.0%	86.8%	10.2%	3.0%	100.0%
2005	2004	389	4,272	25,948	0	7,576	0	1,206	39,391	38,122	624	645	39,391
	%	1.0%	10.8%	65.9%	0.0%	19.2%	0.0%	3.1%	100.0%	96.8%	1.6%	1.6%	100.0%
2006	2005	1,906	27,048	27,513	5	8,093	169	26,838	91,572	60,670	17,484	3,418	81,572

	%	2.1%	29.5%	30.0%	0.0%	8.8%	0.2%	29.3%	100.0%	74.4%	21.4%	4.2%	100.0%

11D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded):NEW FORM Parts A+B	Number of oreign Protocols with Enrollment data (New Form):
2002	2001	0	0	0	0	0	0	0	0	1,449	6
	%	0.0%	0.0%	0.0%	0.0%	0.00%	0.0%	0.0%	0.0%	62.6%	
2003	2002	0	0	0	0	2	0	1	3	7,643	21
	%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	33.3%	100.0%	76.5%	
2004	2003	0	0	0	0	2	2,570	0	2,572	23,998	14
	%	0.0%	0.0%	0.0%	0.0%	0.1%	99.9%	0.0%	100.0%	94.8%	
2005	2004	388	0	0	0	4	0	232	624	30,845	25
	%	62.2%	0.0%	0.0%	0.0%	0.6%	0.00%	37.2%	100.00%	78.3%	

2006	2005	1,849	3	213	0	1,328	1	14,090	17,484	72,059	52
	%	10.6%	0.0%	1.2%	0.0%	7.6%	0.00%	80.6%	100.0%	78.7%	

*** These totals must agree**

**** These totals must agree**

Appendices

Appendix F:
Report of the Advisory Committee on Research on Women's Health

Office of Research on Women's Health and NIH Support for Research on Women's Health Issues
Fiscal Years 2005 & 2006

Following are excerpts of the report—the Introduction and Overview. The full report will be available at http://orwh.od.nih.gov/.

Introduction

When the National Institutes of Health announced that it was establishing an Office of Research on Women's Health (ORWH) in September 1990, there were great expectations of what might result, but it is unlikely that, at that time, anyone expected the magnitude of programs and accomplishments related to women's health research and careers that would flourish across the NIH in the years that would follow.

The ORWH became the first office within the Department of Health and Human Services to have the specific purpose of addressing women's health issues, yet its initial intent was to abate the criticisms that NIH did not have a consistent or enforced policy that required the inclusion of women in the research that it funded, especially when that research was on conditions that were not female specific. Over the years that have followed, the NIH institutes and centers (ICs), often with ORWH's collaborative support, have funded research that addresses specific gaps in knowledge about women. But they also have independently given increasing attention to ensuring research that allows comparisons of differences, or similarities, between men and women in responses to interventions being examined through clinical research. And, these concepts are beginning to penetrate the thinking at the basic laboratory research level, although without a specific NIH policy requirement. While the ORWH has specific goals to enhance women's health research, develop programs to promote biomedical career advancement for women, and for both men and women to conduct women's health research or studies that provide sex/gender aspects of health by comparing men and women in their responses to the interventions studied, the ORWH has continued its initial mission by leading trans-NIH efforts for consistent monitoring of the inclusion of women and minorities in clinical research.

This report is a comprehensive summary of all of the activities and programs of the ORWH, as well as an Executive Summary followed by more detailed information of highlights of women's health research within the NIH ICs and OD Program Offices.

Many continue to attempt to evaluate progress on women's health research by referring to budgetary expenditures on women's health when compared to men's health. This is not the most reliable way to assess progress, primarily because basic laboratory studies are at the foundation of progress about women's health, and often such basic studies have the potential to increase knowledge about both men and women, or serve as the foundation for ensuing clinical research. Further, with the current concepts of women's health extending beyond that of the reproductive system, and with the NIH policy of inclusion requiring that both men and women be included in clinical research on conditions that affect them – therefore, referring to research that is not female specific, both sexes are included in the studies. The result is that NIH research dollars must be summarized as that related to women's health research, that related to men's health research, and that related to, or including, both men and women. Consequently, the figures reported as specific for women's health research must be considered to be less than the total spent to explore women's health, with consideration of the additional amount listed under 'both'. A section included in this report, based upon figures provided by the ICs, provides specific amounts for FY 2005 and FY 2006 included in this report.

Approximately $ 3.5 billion was spent each year on sex/gender-specific research related to women's health. In addition, over $ 22.5 billion was spent on research that benefits both women and men as either basic or laboratory research or clinical studies that included both women and men. Another way of reporting this data is that almost 13% of the NIH research budget was expended on research specific to women, almost 6%0 was expended on research specific to men, while the overwhelming majority (over 81%) of research funds were spent on research that either included both women and men, or was laboratory investigation that was important for exploring the health of both women and men.

In accordance with the NIH Revitalization Act of 1993[1], the Office of Research on Women's Health (ORWH) collaborated with NIH staff and members of the Coordinating Committee on Research on Women's Health (CCRWH)[2] to provide these programmatic summaries of NIH research and other efforts related to women's health in FY 2005 and 2006. The ORWH also describes its role in catalyzing interdisciplinary career development and research centers on women's health and sex/gender research. In addition, the Office develops programs to strengthen and foster women's participation and advancement in biomedical careers and to promote careers for both men and women to conduct women 's health or sex/gender based research. A complete listing of research, career development, and other projects supported by the ORWH during FY 2005 and 2006 is included in the appendices. The specific trans-NIH activities that monitor and track the inclusion of women and minorities in clinical research are also described. Highlights of women's health and sex/gender research supported by the NIH institutes, centers, and offices are also included in this report. The NIH Institutes and Centers (ICs) with grant-making authority have reported progress in basic, clinical, and/or translational research that is benefiting girls and women, as well as serving to identify if and when sex/gender differences exist. The Offices within the Office of the NIH Director have also contributed to this research and this report.

A major ORWH research area relates to interdisciplinary programs. One of these programs is the

Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCOR). Eleven SCOR Centers have demonstrated exciting new developments from interdisciplinary research approaches to advancing studies on how sex and gender factors affect women's health. Each SCOR promotes interdisciplinary collaborations and the development of research bridging basic and clinical sciences on sex and gender factors underlying a priority health issue. Research areas addressed by the centers include mental health, reproductive health, pain disorders, substance abuse, and urinary tract health. The SCOR program complements other federally supported programs addressing women's health issues. Another major interdisciplinary program is the Building Interdisciplinary Research Careers in Women's Health (BIRCWH). The BIRCWH program grants provide an opportunity for institutions to be involved in women's health and sex/gender oriented research and to build a national supply of investigators by providing research training in conjunction with strong scientific and career mentoring that will enhance the career development of the women and men who are selected as scholars. This program has made impressive progress, with the 35 BIRCWH centers producing 287 scholars, most of whom have gone on to academic positions and received NIH grant awards. Other career development programs supported by the ORWH include the Women's Reproductive Health Research Career Development Centers (WRHR) of the National Institute of Child Health and Human Development, and numerous other NIH RFAs and PAs.

The NIH ICs and Offices present a brief accounting of their scientific advances in the Executive Summary section of this report. More detailed discussions of these advances are included in the section on Reports of the Institutes, Centers, and Offices.

This report is prepared for, and reviewed by, the Advisory Committee on Research on Women's Health, that has the responsibility for preparing a report on the activities related to women's health at the NIH.

You are invited to read this in-depth report to become acquainted with the tremendous advancements that have taken place during this two-year period and the promise for even greater advancements in the future, representing the broad diversity and success of the ORWH, and the trans- NIH activities to advance the health of women and men, and career opportunities in biomedical sciences.

Vivian W. Pinn, M.D.
Associate Director for Research on Women's Health
Director, Office of Research on Women's Health

Executive Summary

Overview

The scope and expansion of women's health research across the NIH has been remarkable over the past two years. This report is evidence of the progress that has been achieved. In this Overview, we describe the missions of the NIH Institutes and Centers (ICs), with a special focus on how they address women's health issues. The Highlights of Institute and Center Activities section that follows provides a synopsis of their research agenda and accomplishments in women's health that have been achieved in FY 2005 and 2006. Readers are encouraged to review the detailed reports of the individual NIH ICs that follow. These present important advances in understanding diseases and conditions that disproportionately affect women.

The Fogarty International Center (FIC) supports a range of research and research training programs, many of which include activities on women's health. Research training programs working in low- and mid-income nations on topics, such as population and health, maternal and child health, AIDS, and stigma and global health, represent FIC's efforts that include significant attention to women's health issues. The ORWH supports many of these efforts, along with other NIH Institutes. In addition, the FIC and the ORWH have teamed up to explore issues facing women in science in developing countries and to consider gender and global health issues. These initiatives have informed the programmatic directions of the FIC and other NIH ICs.

Cancer continues to take a devastating toll on American women. However, important progress is being achieved in the fight against cancer overall as well as specific cancers differentially affecting women. These include cancer of the breast, cervix, ovaries, endometrium, colon and rectum, and lung as well as malignancies associated with acquired immunodeficiency syndrome (AIDS). In 2007, an estimated 678,060 women will be diagnosed with cancer, and approximately 270,100 women will die of the disease. Despite these grim statistics, the U.S. is making important progress against cancer. Incidence rates for cancer of all sites, sexes, and populations combined were stable from 1992 through 2003 after increases that started in 1975. Incidence rates for cancer overall for women were stable from 1975 through 1979 but then increased from 1979 through 2003. However, there was a 6 percent relative decline in breast cancer incidence among women between 2002 and 2003, including a 14 percent decrease in 50- to 60-year-olds who had been diagnosed with estrogen receptor (ER) positive breast cancer. The decrease in this age group may be due to the recent decline in use of hormone therapy (HT) by postmenopausal women. Mortality rates for all cancers have declined, but the annual decline in men is twice as large as that for women. While mortality has decreased for 10 of the top 15 cancers in women, lung cancer deaths in women continue to increase, although at a slower rate in more recent years. Survival rates for cancer patients show improvement overall, although the amount of improvement is slightly less for women than men. The National Cancer Institute (NCI) supports an extensive research program through their intramural and extramural programs, with a number of programs and activities focusing on women's cancers, including the NCI Office of Women's Health, located within the NCI Office of Science Planning and Assessment; the Breast and Gynecologic Cancer Research Group in the Division of Cancer Prevention; the Breast Cancer Surveillance Consortium (BCSC) and the International Breast Screening Network in the Division of Cancer Control and Population Sciences; the Gynecologic Oncology Group (GOG) and the Clinical Trials Cooperative Group in the Division of Cancer Treatment and Diagnosis; the intramural Breast and Gynecologic Malignancies Faculty and the trans-NCI Human Papillomavirus (HPV) Working Group. By working with partners from public, private, and academic settings and focusing investment in strategic areas with high potential, we hope to accelerate the pace of discovery and facilitate the translation of research knowledge into clinical applications.

The mission of the National Center for Complementary and Alternative Medicine (NCCAM) is to explore complementary and alternative healing practices in the context of rigorous science, train CAM researchers, and disseminate authoritative information to the public and professionals. Complementary and alternative medicine (CAM) encompasses those health care and medical practices that are not currently an integral part of conventional medicine. The list of CAM practices and therapies changes as interventions proven to be safe and effective become accepted as mainstream health care practices. The NCCAM groups CAM practices within the following areas: (1) whole medical systems (i.e., traditional Chinese medicine, naturopathic medicine, Ayurveda); (2) mind-body medicine (i.e., meditation, yoga); (3) biologically based practices (i.e., herbal therapies, special diets); (4) manipulative and body-based practices (i.e., chiropractic, massage); and (5) energy medicine (i.e., Reiki, Qi gong). The NCCAM conducts and supports basic and applied (clinical) research and research training within these areas. CAM therapies are used to treat a broad range of health conditions by both men and women, including back and neck problems, allergies, fatigue, arthritis, headaches, diabetes, and CVD. CAM therapies for women treat a variety of conditions, such as menopausal symptoms, breast cancer, osteoporosis, pain associated with osteoarthritis and fibromyalgia, and reproductive issues. Thus, NCCAM's research portfolio includes investigations focused on a variety of diseases, using a myriad of CAM therapeutic interventions.

The National Center for Research Resources (NCRR) provides laboratory scientists and clinical researchers with the environments and tools they need to understand, detect, treat, and prevent a wide range of diseases. This support enables discoveries that begin at a molecular and cellular level to move to animal-based studies and on to patient-oriented clinical research, resulting in cures and treatments for both common and rare diseases. The NCRR develops and supports a wide range of biomedical resources. Through its support of multidisciplinary research, the NCRR is uniquely positioned to provide funds directly for research or to act in partnership with other NIH components to address emerging clinical and basic research needs, including those addressing women's health issues.

The National Center on Minority Health and Health Disparities (NCMHD) promotes minority health and leads, coordinates, and assesses the NIH effort to reduce and eliminate health disparities. To achieve its mission, the NCMHD employs a multifaceted strategy to conduct and support research in basic, clinical, social, and behavioral sciences; disseminate information, promote research infrastructure and training; foster emerging programs; and extend its reach to minority and other health disparity communities. Congress mandated the development of three principal programs within the NCMHD aimed at addressing health disparities: the Loan Repayment Program, the Centers of Excellence Program, and the Research Endowment Program. Additionally, the NCMHD supports the Research Infrastructure in Minority Institutions Program (RIMI) and the Minority Health and Health Disparities International Research Training Program (MHIRT). These combined efforts position the NCMHD to lead and coordinate the NIH health disparities activities for the benefit all affected populations, including women of diverse populations.

The mission of the National Eye Institute (NEI) is to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of blind persons. The major causes of blindness (i.e., glaucoma, macular degeneration, diabetic retinopathy, uveitis, and cataract) affect both women and men. However, because women live longer on average than men, more women than men are affected by these age-related eye diseases in the U.S. Several eye conditions affect women significantly more frequently than men. These conditions are optic neuritis, a demyelinating disease of the optic nerve that may be a precursor of multiple sclerosis; dry eye, a common condition that is associated with decreased tear secretion and in most cases mild discomfort, but in more severe cases may result in corneal scarring and blindness; corneal endothelial dystrophy, a slowly progressive disease that occurs when endothelial cells deteriorate as a result of cell loss from age or trauma; keratoconus, a visually disabling thinning disorder of the central cornea that results in irregular astigmatism, progressive corneal distortion, and corneal scarring; and age-related macular degeneration, a deterioration of the region of the retina that is responsible for high-resolution vision.

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for research, training, and education programs to promote the prevention and treatment of heart, lung, and blood diseases. The NHLBI stimulates basic discoveries about the causes of disease, speeds the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public. The NHLBI creates and supports a collaborative research infrastructure in partnership with private and public organizations. The Institute also collaborates with patients, families, health care professionals, scientists, professional societies, patient-advocacy groups, community organizations, and the media to maximize the use of research results and resources to address the public health needs of the nation. The NHLBI places high priority on improving the cardiovascular health of women through its research programs, which have generated new knowledge about the influences of lifestyle, menopause, chest pain, hypertension, diabetes, and drug treatment (including hormone therapy) in women and also have led to improved diagnostic tests and treatment guidelines for women. The NHLBI has had responsibility for the NIH Women's Heath Initiative since 1998 and provides support for the Women's Ischemia Syndrome Evaluation as well as other important studies.

The National Human Genome Research Institute (NHGRI) led the NIH's contribution to the International Human Genome Project (HGP). The finished sequence of the human genome was completed in April 2003, and has already begun to change the way we address research on women's health. In October 2005, a different international consortium of scientists from six countries, led by the NHGRI, announced the production of a different map of the human genome, one that may prove even more powerful because of its medical applications. The result is the "HapMap. " Like the earlier sequence, all of the data from the HapMap has been placed in the public domain. The HPG spelled out the letters of the DNA code that all human beings share. The HapMap provides detailed information about the variation in the genome. The HapMap investigates those spelling differences in the human instruction book that predispose some people to different types of cancer as well as other diseases. In December 2006, the NHGRI awarded a contract to continue the HapMap Project to make it an even more powerful tool to reveal the way in which genetic variation is organized into chromosomal neighborhoods. As this information unfolds, the NHGRI will continue to investigate diseases specific to women. In 1994, NHGRI investigators were among the first to report that women carrying the gene mutations called Breast Cancer 1 (BRCA1) or Breast Cancer 2 (BRCA2) have a higher risk of developing both breast and ovarian cancer than women without such mutations. The NHGRI continues to investigate the role of these genes in breast and ovarian cancer, and this research has led to better screening and treatment of those with a family history of breast cancer. In hopes of expanding the usefulness of this research, the NHGRI also supports research that explores the effect of educating women of different ages and ethnic group about benefits of genetic screening in evaluating their risk of inherited diseases.

The National Institute of Allergy and Infectious Diseases (NIAID) funds basic and applied research to prevent, diagnose, and treat infectious and immune-mediated illnesses that affect the health of women and girls. The NIAID involves women in many of its clinical studies on the treatment and prevention of autoimmune diseases, human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), and sexually transmitted infections (STIs). The NIAID also collaborates with other organizations on research initiatives aimed at improving women's health.

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports basic, clinical, and epidemiologic research, research training, and information programs on many of the more debilitating diseases affecting Americans. The NIAMS supports research on a number of diseases that disproportionately affect women including osteoarthritis, osteoporosis, rheumatoid arthritis, temporomandibular joint and muscle disorders (TMJD), fibromyalgia, scleroderma, and systemic lupus erythematosus (lupus). Scleroderma and lupus are diseases in which health disparities have been clearly identified. The NIAMS is committed to uncovering the bases of these gender, racial, and ethnic disparities and to devising effective strategies to treat or prevent them.

The National Institute of Biomedical Imaging and Bioengineering (NIBIB), which was established by law in December 2000, is the newest research institute within the NIH. This Institute serves as the hub within the NIH for the coordination of biomedical imaging and bioengineering efforts. The NIBIB: (1) fosters, conducts, supports, and administers research and research training programs in biomedical imaging and bioengineering by means of grants, contracts, and cooperative agreements; (2) provides coordination, integration, and review of progress and planning of biomedical imaging and bioengineering research; (3) formulates research goals and long-range plans with the guidance of the National Advisory Council for Biomedical Imaging and Bioengineering; and (4) sponsors scientific meetings and symposia, collaborates with industry and academia, and fosters international cooperation regarding biomedical imaging and bioengineering. The NIBIB recognizes the significant potential of improved imaging technologies in early disease detection. During FY 2005 and 2006, the NIBIB funded grants that were focused on women's health research or technologies aimed at improving devices for female populations. These projects range from advanced imaging methodologies to new drug delivery systems designed specifically for women's diseases, such as breast cancer, and disorders and conditions that predominate in women, such as osteoporosis. Researchers supported by the NIBIB plan to develop high resolution x-ray grids in mammography to detect breast cancer at its earliest stage, thereby greatly increasing patient survival rates. In addition, NIBIB-funded investigators are working on novel drug delivery treatments that will promote bone resorption for women suffering from osteoporosis. During the past two years, the NIBIB supported research on women's health in the following disease areas: aging, autoimmune disease, breast cancer, cervical cancer, reproduction, diabetes-related research, obesity, epilepsy, HIV/AIDS, heart disease, osteoporosis, and TMJD.

The National Institute of Child Health and Human Development (NICHD) sponsors research that spans human growth and development, starting from before conception and continuing through infancy, childhood, and adolescence. This research covers all critical stages of development that provide the foundation for adult health. The Institute's research aims to overcome many of the complex challenges that face women in addition to those faced by their children and families. The NICHD's portfolio includes research on infertility, preterm birth, complications of childbirth, HIV infection in women, parenting, and many other scientific areas that are critical to improving the quality of life for women.

The mission of the National Institute of Dental and Craniofacial Research (NIDCR) is to promote the general health of the American people by improving craniofacial, oral, and dental health through research. As a central part of this mission, the NIDCR funds scientific research to prevent diseases and improve the quality of life for the millions of Americans who suffer from chronic and infectious diseases affecting the mouth and face. NIDCR-supported research spans areas as diverse as understanding the oral infections that lead to dental decay, periodontal diseases, and recurrent herpes lesions; oral manifestations of osteoporosis and other bone diseases; salivary gland dysfunction and disease; craniofacial birth defects and developmental disorders; and connective tissue diseases and disorders. The NIDCR has a long tradition of support and leadership in the field of pain research, including conditions where gender-based differences have been reported, such temporomandibular joint and muscle disorders (TMJD). The NIDCR's commitment to the fundamental study of the body's hard tissues, such as teeth, cartilage, and bone, has led to advances in biomaterials research and to the emerging field of tissue engineering and biomimetics, fields that use the body's own cellular and molecular processes to repair and regenerate tissues and organs. Among the NIDCR's efforts in this area are studies that are characterizing the TMJ disk at tissue and cellular levels, thus providing vital information that will one day allow for biological approaches to reconstruct or regenerate the temporomandibular joint. Recognizing the importance of gene-to-gene, gene-environment, and behavioral interactions, the Institute has long emphasized the importance of genetic, behavioral, social science, and epidemiological research. The research advances that affect women in particular are to be found within many of the Institute's broad research categories.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports basic and clinical research on diabetes, endocrinology, and metabolic diseases; digestive diseases and nutrition; and kidney, urologic, and hematologic diseases. Within NIDDK's research mission, diseases and health risks that disproportionately, predominantly, or solely affect women include gestational diabetes; obesity (especially in racial and ethnic minority populations); coronary artery disease; cardiovascular and end-stage renal disease associated with diabetes; eating disorders; irritable bowel syndrome (IBS) and other functional gastrointestinal disorders; osteoporosis; thyroid diseases (including

Graves disease, goiter, and hypothyroidism); hyperparathyroidism; gallstones; primary biliary cirrhosis; painful bladder syndrome/interstitial cystitis (PBS/IC); urinary tract infections (UTIs); urinary NIDDK mission also may have an important impact on diseases that are primarily within the mission of other ICs, such as hormonal factors in breast cancer and the relationship of obesity to cardiovascular disease (CVD). The NIDDK supports research that directly addresses important women's health issues, both through basic research directed to understanding underlying disease processes and through clinical research that translates this understanding into therapies and preventive interventions.

Because environmental agents are likely to play a role in a numbers of diseases that differentially affect females, the National Institute of Environmental Health Sciences (NIEHS) supports research on diseases such as breast cancer, osteoporosis, ovarian dysfunction, uterine fibroids,and autoimmune diseases. The Institute's approach is to define the underlying susceptibilities to these diseases, to investigate the role of estrogenic and other endocrine-active compounds in their etiology, to identify important environmental triggers for their development and important nutritional factors that can reduce risk, and to determine the importance of the timing of exposure on disease risk. As results of these studies become available, women can better determine how to alter lifestyle factors leading to these diseases, and environmental health regulators can better define standards that protect women from environmental triggers of these diseases. The Institute has several groups that focus on women's health, including the Laboratory of Reproductive and Developmental Toxicology, the Hormones and Cancer Group, the Chromatin and Gene Expression Group, and the Comparative Pathology Group. These research groups and others are conducting basic research on issues such as toxicology and reproductive and developmental health, hormone regulation of tumor development and growth in target organs, including the uterus and mammary gland, genetic regulation of cancer susceptibility, as well as epidemiologic research on women 's health issues, such as fertility, early pregnancy, and uterine fibroids. By understanding the basic mechanisms of disease, new therapeutic interventions can be developed to prevent and treat these diseases.

The mission of the National Institute of General Medical Sciences (NIGMS) is to support research and research training for the basic biomedical sciences. For example, the NIGMS supports research on cell structure and function, from the outer plasma membrane to the activation of genes in the nucleus. This knowledge is necessary to understand the disease process. Most studies supported by the NIGMS do not target any particular disease or condition but rather encompass basic research in cellular and molecular biology, chemistry, biochemistry, molecular biophysics, and genetics. Often basic research supported by the Institute will result in findings pertinent to women's health.

The National Institute of Mental Health (NIMH) supports research on a range of mental disorders, including those that affect women exclusively, such as perinatal depression, or are more prevalent in women, such as eating disorders. Through programs, such as the Women's Mental Health Team, the NIMH has fostered interdisciplinary collaboration and research to improve diagnosis, treatment, services, and the prevention of mental disorders in women. Data on the epidemiology of mental disorders and associated disability highlight differences in both the prevalence and clinical course of mental disorders between men and women. Starting in childhood, girls have higher rates of anxiety disorders and eating disorders than boys, while boys are more likely to suffer from autism and attention deficit disorder. After puberty, women have higher rates than men of depression, eating disorders, and anxiety disorders, including posttraumatic stress disorder. The course and severity of mental disorders also differ between men and women. For example, men have an earlier average age of onset of schizophrenia, while women are more likely to suffer from the rapid cycling form of bipolar disorder. Within the female populations, some women are at increased risk of depression during certain times of reproductive change, such as the perinatal period. Through its research programs and related programmatic activities, the NIMH seeks to improve scientific understanding of the effects of sex and gender differences in mental health and mental illness.

The National Institute of Neurological Disorders and Stroke (NINDS) mission is to reduce the burden of neurological disease, a burden borne by every age group, every segment of society, and people all over the world. Most nervous system disorders affect men and women equally, but certain disorders are more prevalent in or are of special interest to women. Examples of such diseases include multiple sclerosis (MS), pain, stroke, epilepsy, and Rett syndrome. MS is a chronic autoimmune disease of the central nervous system that causes inflammation and the loss of myelin, a protective covering around nerve fibers. MS is one of the most common neurological disorders leading to disability in young adults. Hormonal factors may influence some forms of MS, making them more common in women. Strokes are caused by a rapid disruption in the blood supply to part of the brain as a result of blood vessel blockage (ischemic stroke) or blood vessel rupture (hemorrhagic stroke). A stroke can result in sudden numbness or weakness, confusion, trouble with vision, speech, or coordination, or a sudden severe headache. Stroke is the third leading cause of death in the U.S. and a major cause of disability in both women and men. In general, women have a lower risk of stroke than men, but because of their longer life expectancy, they account for 60 percent of stroke fatalities. Epilepsy is characterized by chronic, recurring seizures caused by abnormal electrical activity in the brain. Although anti-epileptic drugs (AEDs), brain stimulation, or surgery can help many patients control the disorder, for others, the seizures are resistant to therapy or the treatments cause unacceptable side effects. Women with epilepsy can face special problems, such as increased seizure frequency during phases of the menstrual cycle (called catemenial epilepsy). Female patients taking selected AEDs must consider changing medications if they wish to become pregnant since certain AEDs can cause higher-than-normal rates of birth defects. Rett syndrome is a childhood neurological impairment seen almost exclusively in females, causing severe cognitive impairment, autistic behavior, stereotypic movements, and frequently seizures. The NINDS supports basic, translational, and clinical research on these and other neurological disorders.

The mission of the National Institute of Nursing Research (NINR) is to support clinical and basic research that establishes a scientific basis for the care of individuals across the life span. NINR-supported research encompasses the health of individuals, their families, and their caregivers. It also focuses on the special needs of at-risk and underserved populations, with an emphasis on health disparities. The Institute's research focus transcends many disciplines to promote health and improve patient and caregiver quality of life across a broad rangeof diseases and conditions. The NINR unites the disciplines of biological and behavioral sciences to elucidate the complex interactions between the physiological factors of health and disease and the behavior, decisions, and perceptions of the individual. In 2006, the

NINR released its new five-year strategic plan, titled *Changing Practice, Changing Lives*. Developed in close consultation with representatives of the extramural community, this new plan details the NINR's scientific priorities. The Institute will focus its research on health promotion and disease prevention; improving quality of life through self-management, symptom management, and caregiving; eliminating health disparities; and leading critical research on the end of life. The plan also highlights four cross-cutting strategies for advancing nursing science, including advancing the integration of biological and behavioral sciences, promoting the design and use of new patient care technologies, improving nursing science methods, and developing the next generation of investigators. The NINR's mission and research goals are inherently suited to addressing the current challenges in women's health research.

The National Institute on Aging (NIA) conducts and supports a diverse portfolio of research on older women's health, including studies of Alzheimer's disease and other dementias, menopause and hormone therapy, osteoporosis, physical disability, and other diseases and conditions. NIA-supported investigators continue to explore the reasons behind gender differences in disability, morbidity, and mortality at older ages. In addition, the NIA supports an extensive program of research pertaining to health disparities among special populations. The NIA has several on going research initiatives dealing specifically with women's health, including the Study of Women's Health Across the Nation (SWAN),the Women's Health Initiative Study of Cognitive Aging (WHISCA), and Women's Health and Aging Study (WHAS). These studies and others are providing valuable information about the menopausal transition in women of diverse racial and ethnic backgrounds; the effects of hormone therapy on memory and cognitive functions; disability among older women; and other health issues of importance to older women, who are more likely than men to live alone and in poverty and to be institutionalized at an earlier age.

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) supports research on the behavioral and medical causes and consequences of alcohol use, abuse, and alcoholism, and on new ways to prevent and treat these significant public health problems. It is estimated that there are 18 million alcohol-abusing or alcohol-dependent individuals in the U.S., of which more than four million are women. Women drink less alcohol and have fewer alcohol-related problems and dependence symptoms than men, but among the heaviest drinkers, women equal or surpass men in the problems that occur because of their drinking. In contrast to young people who begin drinking at age 21, equal numbers of young men and women who begin drinking at age 13 are four times more likely to develop alcohol dependence sometime during their lifetime. The NIAAA continues to expand its research portfolio on the impact of alcohol and alcohol misuse on women's health. Research related to women' s health is found in each programmatic division of the institute. Because of the multidimensional and multidisciplinary nature of alcohol use disorders and their prevalence worldwide, collaborative research endeavors on a national and international scale are required for progress toward the goals of reducing alcohol abuse disorders and alcoholism among women. Significant scientific advances in understanding the causes, consequences, prevention, and treatment of alcohol use, abuse, and dependence among women have occurred in the past two fiscal years.

The National Institute on Deafness and Other Communication Disorders (NIDCD) conducts and supports research and research training on normal mechanisms as well as diseases and disorders of hearing, balance, smell, taste, voice, speech, and language. The Institute also conducts and supports research and research training that is related to disease prevention and health promotion. The research portfolio addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders. The Institute also supports efforts to create devices that substitute for lost and impaired sensory and communication functions. A number of diseases, disorders, or conditions within the mission of the NIDCD affect women disproportionately.

The National Institute on Drug Abuse (NIDA) addresses critical questions concerning drug abuse and addiction by monitoring emerging trends, identifying and studying underlying physiological and social factors, and determining how best to use this knowledge to develop, test, and implement prevention and treatment programs. An important focus in NIDA's portfolio is research to investigate issues specific to women and to sex/gender differences in drug abuse and addiction. There is a complex relationship between drug use and biological vulnerability that may vary by sex or gender. Growing evidence suggests that drug abuse may begin and progress differently for men and women. These patterns of progression are characterized by different risk and protective factors and motivations and carry different consequences. In recognition of the important role that sex/gender plays in drug abuse, sex/gender research findings are being taken into account in the design, testing, and implementation of interventions to prevent and treat drug abuse and to provide services for both males and females. NIDA has established a Women and Gender Research Group to promote research on issues specific to women and substance abuse. This group has representation from all of NIDA's divisions and offices, covering topics from genetics and basic biology to risk factors, prevention, consequences, and treatment of substance abuse. The major goal of this effort is to infuse the study of sex/gender differences and female-specific issues in all areas of drug abuse research and to disseminate research findings.

In addition to the involvement of the NIH ICs mentioned before, several of the Offices within the Office of the Director of NIH participate in activities related to women's health and sex/gender issues. The Office of Dietary Supplements (ODS) supports research to expand the evaluation of the role of dietary supplements in disease prevention and risk reduction associated with diseases of interest to women, including breast cancer. In addition, ODS supports research to further scientific understanding of the biochemical and cellular effects of dietary supplements on biological systems and their physiological impact across the life cycle. The Office of Behavioral and Social Sciences Research (OBSSR) opened on July 1, 1995. Congress established OBSSR in recognition of the key role that behavioral and social factors play in illness and health. The OBSSR mission is to stimulate behavioral and social sciences research throughout the NIH and to integrate these areas of research more fully into other NIH health research enterprises, thereby improving the understanding, treatment, and prevention of diseases. Many of these diseases are related to women's health, such as type two diabetes, coronary heart disease, obesity, addictive behaviors, and disorders of mood and affect. The Office of Rare Diseases (ORD) seeks to stimulate and coordinate research on rare diseases and to support research to respond to the needs of patients who have one of the approximately 7,000 rare diseases recognized today. Several of these rare diseases differentially affect women, including lymphangioleiomyomatosis, Rett syndrome, congenital adrenal hyperplasia, and preeclampsia. The ORD collaborates with the NIH ICs and Offices to stimulate research on rare diseases, to foster collaborations with other national and international entities, and to support a range of outreach activities related to rare diseases. The Office of AIDS Research (OAR) was established in 1988. Perhaps no other disease so thoroughly transcends every area of clinical medicine and basic scientific investigation, crossing the boundaries of nearly every NIH IC. The NIH supports a comprehensive program of basic, clinical, and behavioral research on HIV infection, its associated co-infections, opportunistic infections, malignancies, and other complications. This diverse basic, clinical, and behavioral research portfolio demands an unprecedented level of scientific coordination and management of research funds. The OAR coordinates the scientific, budgetary, and policy elements of NIH AIDS research. Through its unique, trans-NIH planning, budgeting, and portfolio assessment processes, the OAR ensures that research dollars are invested in the highest priority areas of scientific opportunity. As such, the OAR represents the roadmap for NIH AIDS research, allowing NIH to pursue a united research front against the pandemic. The trans-NIH strategic plan for AIDS research establishes an agenda in the following areas of emphasis: vaccines; therapeutics; etiology and pathogenesis; natural history and epidemiology; behavioral and social science; training, infrastructure, and capacity building; and information dissemination. Research relevant to the needs of women is addressed in all of these areas.

[1] Public Law 103-43, 107, stat, 22 (codified at 42 USC [sec.486 (A)]. See pages 17-20 for a list of the CCRWH members.

[2] See pages 17-20 for a list of the CCRWH members.