The National Institutes of Health

A RESOURCE GUIDE April 2005



The Ad Hoc Group for Medical Research Funding

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THE AD HOC GROUP FOR MEDICAL RESEARCH FUNDING Since its inception in 1982, the Ad Hoc Group for Medical Research Funding has pursued one goal: to improve the health of the American people by advocating for an enhanced federal investment in biomedical and behavioral research by increasing the appropriations for the National Institutes of Health. Each year, the Ad Hoc Group holds extensive meetings with the leadership of the NIH and its constituent institutes and centers. The Ad Hoc Group uses the information collected in these meetings to develop a proposed NIH budget that reflects the scientific opportunities currently available as well as the health needs that face the United States.

The underlying principle of the Ad Hoc Group continues to be that the whole of the nation's medical research effort is greater than the sum of its individual parts. As a result, the Ad Hoc Group proposal represents a bottomline recommendation for the NIH rather than an articulation of individual requests for specific institutes, programs or diseases.

Year-round, the Ad Hoc Group for Medical Research Funding brings together the community of organizations concerned with medical research and NIH funding. The Ad Hoc Group holds "Policy Briefings" on Capitol Hill that give major Washington policy makers and opinion leaders an opportunity to discuss medical research and their own legislative proposals. The group also provides a forum for NIH Institute and Center Directors to address NIH advocates about promising research sponsored or conducted by the NIH.

The membership of the Ad Hoc Group represents the broad scope of the research community as well as the patients who are the ultimate recipients of the benefits of medical research.

THE NATIONAL INSTITUTES OF HEALTH

AN OVERVIEW

The National Institutes of Health (NIH) is the world's premier medical research institution, supporting more than 212,000 scientists at over 2,800 research universities, medical schools, teaching hospitals, independent research institutions and industrial organizations throughout the United States. It is comprised of 27 distinct institutes and centers, nearly all of which are located in Bethesda, Maryland.

The NIH is located in the Department of Health and Human Services and is part of the Public Health Service. Since its origin in 1798, the Public Health Service, comprised of eight health and research agencies, has represented this nation's federal investment in basic biomedical and behavioral research, health services research, primary prevention and early intervention strategies, health care services for vulnerable populations and education of a primary health care and public health care workforce.

Congress created each of the NIH institutes and centers with an explicit mission directed to the advancement of an aspect of biomedical and behavioral sciences. An institute or center's focal point may be a given disease, like the National Cancer Institute or the National Institute of Diabetes and Digestive and Kidney Diseases; a particular organ, such as the National Heart, Lung and Blood Institute or the National Eye Institute; or a stage of development, like the National Institute on Aging or the National Institute of Child Health and Human Development. Other institutes and centers have broad, cross-cutting missions, such as developing tools and resources to foster research like the National Library of Medicine and the National Center for Research Resources.

The NIH mission is to uncover new knowledge that will lead to better health for everyone. NIH works toward that mission by:

- Supporting the research of non-federal scientists in universities, medical schools,
- hospitals and research institutions throughout the country and abroad;
- · Conducting research in its own labs;
- Helping in the training of research investigators; and
- Fostering communication of medical information.

In support of this mission, the NIH devoted approximately 85 percent of its budget in FY 2005 to the extramural research program, 9.5 percent to the intramural research program, and 3.7 percent for research, management and support costs.

The Extramural Research Program includes grants and contracts supporting research and training by scientists across the country. In the extramural program, the NIH emphasizes funding investigator-initiated applications originating with individual scientists. Scientists compete for NIH funding through the peer review process in which a panel of scientific experts, who are active and productive researchers in the biomedical sciences, evaluate the scientific merit of a research application, examine how the proposal merits overall and determine the application's priority in advancing the overall mission of the NIH.

The NIH also maintains an in-house, or intramural, research program conducted by more than 6,000 government-scientists in institute laboratories on the NIH campus and the NIH Clinical Center, a research hospital serving more than 7,000 inpatients and over 72,000 outpatients per year while administering over 1,100 active clinical trial protocols. NIH also supports intramural research at the Gerontology Research Center in Baltimore; the Rocky Mountain Laboratories in Hamilton, Montana; the Frederick Cancer Research Center in Frederick, Maryland; the Phoenix Epidemiology and Clinical Research Branch in Arizona; and Research Triangle Park, North Carolina.

HOW THE NIH FUNDS SCIENTIFIC EXCELLENCE

Medical research activities at NIH are funded through a variety of mechanisms of support including grants, cooperative agreements, and contracts. Research is either intramural or extramural. Intramural research is defined as research conducted within NIH facilities by NIH scientists. Extramural research is defined as research performed at institutions outside of NIH, including academic institutions, medical schools, independent research organizations, state and local governments, and private industry.

The major funding instruments used by NIH to fund extramural research are financial assistance award grants, cooperative agreement grants, and acquisition awards or contracts. Grants are the most common funding mechanism, and are generally initiated by the investigator. They are used to support scientific research or training. NIH also supports cooperative agreements — assistance awards that involve a substantial programmatic NIH role in the project. Research and development contracts are awarded for specific scientific inquiry directed toward particular areas of research needed by NIH, and include significant NIH staff involvement.

Within each of the mechanisms of support, NIH strives to manage its public funds prudently. The NIH requires that appropriate steps be taken to ensure high quality results, to establish safeguards to prevent conflicts of interest, to ensure the integrity of the scientific research community and the integrity of research results, to uphold the highest protections for human participants in research, and to require that minorities, women and children be included in study populations, as appropriate. All grants are identified as either competing (for NIH support) or non-competing continuations (receiving support previously committed). A competing application may be new (Type 1), a competing continuation or renewal (Type 2) or a competing supplement (Type 3).

A new application is the original application requesting NIH support for a specific project. If the application competes successfully, a Type 1 award for a specific amount will generally be made for 12 months. A research grant provides a commitment of support for an average of four years of funding. Thus, after the competing year, the grantee receives noncompeting continuations each year for the specified length of the grant. Over three-quarters of funding allocated to research project grants (RPGs) supports noncompeting (Type 5) continuations. Administrative supplements (Type 3), which account for a small proportion of RPG support, provide additional funds to ongoing grants, administrative adjustments, or a few months of orderly phase-out for large RPGs. Following the initial period of committed support, an investigator may submit a competing continuation application (Type 2) requesting an additional three to five years of funding.

The majority of applications for grant support originate with individual investigators who develop proposals for research or research training within an area of interest to NIH. Principal investigators of research project grants are most often Ph.D.s or M.D.s with an outstanding background in biomedical research at a university, medical school, or other not-for-profit research institution. In addition, NIH publicizes two types of announcements to stimulate submissions in areas of high priority or special concern:

- **Program Announcements (PAs)**, describe new, continuing or expanded program interests of an Institute of Center (IC), or announce the availability of a new mechanism of support and an approximate level of support.
- **Requests for Applications (RFAs)**, are solicited applications that invite grant applications in a welldefined scientific area to accomplish a scientific program purpose for the IC at a specified funding level.

HOW THE NIH FUNDS SCIENTIFIC EXCELLENCE

Peer Review of Research Grant Applications

When an investigator in the extramural scientific community seeks grant funds for support of a specific research project, a detailed application must be prepared that will be subject to peer review. Most grant applications submitted to the NIH are reviewed through a two-tier system.

The first level of review is performed by a scientific review group, often called a study section, review committee, or Integrated Review Group (IRG). These groups are composed of primarily non-government scientists expert in the subject areas of the applications under review. The main purpose of this initial review is to evaluate the scientific and technical merit of applications. This initial review at the NIH is performed either by the Center for Scientific Review (CSR) or by Institutes' or Centers' study sections. Over a dozen referral officers review the contents of some 10,000 applications each grant cycle and, using written guidelines, assign applications to appropriate review groups and Institutes or Centers. Applications received in response to special announcements or to meet specific program needs are likely to be peer reviewed by the Institutes or Centers.

A CSR study section is composed generally of 18 to 20 individuals from among the active and productive researchers in the biomedical community, to serve for multi-year terms. The goal is to have the group's combined knowledge span the diversity of subject matter assigned to the study section for review. To ensure this expertise, the study section's membership is frequently supplemented by temporary members and written outside opinions. In some instances, Special Emphasis Panels (SEPs) are formed on an ad-hoc basis to review applications requiring special expertise, or due to special circumstances. In addition to assessing scientific and technical merit, initial reviewers assign numerical scores to those applications recommended for consideration for funding. They also review, and when necessary comment on, the appropriateness of proposed procedures for the protection of human subjects and the treatment of animals.

To be considered for funding, a grant application must be favorably recommended in initial review and must also pass the second level of review — concurrence of the National Advisory Council of the Institute or Center to which it has been assigned. Councils review the recommendations from the study sections and may make recommendations about funding priorities. Councils have major roles in providing advice and guidance on the research and programmatic activities of the Institute or Center.

Council recommendations are based not only on considerations of scientific and technical merit, as judged in the initial review, but also on the relevance of the proposed study to an Institute's programs and priorities. Councils include senior scientists with broad experience, as well as members of the public with general knowledge of, and interest in, the mission of the Institute or Center.

Additional guidance is provided by the NIH Director's Council of Public Representatives (COPR), which advises the Director on issues affecting the broad development of NIH programs, outreach activities and research goals. Established in 1998, the COPR is comprised of 21 members representing patients, family members of patients, health care professionals, scientists, health and science communicators, and educators, each of whom serve terms of up to three years. The role of the COPR is to bring important matters of public interest to NIH leadership; help increase public participation in the many NIH activities and initiatives that affect the public; and increase public understanding of the NIH and its programs.

NIH ROADMAP

The NIH Roadmap for Medical Research is a set of trans-NIH research initiatives designed to accelerate the pace of discovery and improve the translation of research findings into medical and health interventions for public benefit. The Roadmap is purposefully focused on efforts that no single or small group of Institutes or Centers could or should conduct on its own, but that NIH as a whole must address to ensure both efficient and effective discovery. Based on input from stakeholders representing academia, industry, government and the public, NIH developed a vision for a more efficient and productive system of medical research, a framework of priorities that the NIH must address in order to optimize its entire research portfolio, and a set of initiatives for implementing the vision and priorities. The initiatives selected for funding met these criteria: they will dramatically change the content or the process of medical research in the next decade; the outcomes from the initiative will be used by, and synergize the work of, many Institutes; the initiatives are compelling to NIH stakeholders; and the initiatives position the NIH to do something that no other entity can or will do. The NIH began implementing the Roadmap in FY 2004, with specific plans extending to FY 2009.

The Roadmap has three major themes:

New Pathways to Discovery: As witnessed with the sequencing of the human genome, addressing some of the most complex gaps in biomedical science provides scientists with new tools, new ideas, and even new disciplines with which to solve public health problems. Initiatives under the NIH Roadmap's *New Pathways to Discovery* theme seek to identify and study complex networks of cellular machinery at the levels of proteins, metabolites (lipids, carbohydrates, amino acids), and molecules, as well as at the even smaller level of atoms.

Research Teams of the Future: The scale and complexity of today's biomedical research problems require today's researchers to intellectually extend themselves beyond their own areas of research to create new collaborative science teams and new scientific disciplines. *Research Teams of the Future* encourages new ways of combining skills and disciplines in the physical, biological, and social sciences; the training of investigators; and the development of novel support mechanisms to facilitate these endeavors.

Re-engineering the Clinical Research Enterprise: To capitalize on the revolutionary discoveries emerging from basic science, there is a pressing need to strengthen and accelerate the clinical research process and to more efficiently transmit research findings to practitioners on the front lines. NIH Roadmap initiatives will incorporate modern information technology; promote improved integration of clinical research networks; stimulate the development of more effective means to assess pain, fatigue, and other subjective clinical outcomes; facilitate the coordination of clinical research policies; improve clinical research workforce training; and support key elements of the translational research infrastructure.

More information on the NIH Roadmap is available at: http://nihroadmap.nih.gov/.

Research Project Grants (RPGs) (54.0% of Total Budget in FY 2005)

Funding investigator-initiated grants continues to be one of the NIH's highest priorities. The use of research project grants (RPGs) as a mechanism of support covers the entire medical research continuum, from basic scientific research at the molecular and cellular levels to studies of human beings in both healthy and diseased states. Most grant applications originate with individual investigators who develop proposals for research in their area of interest. Research project grants are awarded to institutions on behalf of a principal investigator to support medical research activities in the areas that represent both the specific interests and competence of the principal investigators and also the NIH Institutes' identified program needs.

The NIH uses several RPG mechanisms to support the best research applications from the most talented researchers. The most common include:

- **Research Project Grant (RO1)** support for health-related research and development based on the mission of the NIH. R01s can be investigator initiated or can be in response to a program announcement or request for application. The NIH awards R01 grants to organizations of all types (universities, colleges, small businesses, for-profit, foreign and domestic, faith-based, etc.) and the R01 mechanism allows an investigator to define the scientific focus or objective of the research based on a particular area of interest and competence. Although the Principal Investigator writes the grant application and is responsible for conducting the research, the applicant is the research organization.
- **Program Project Grant (P01)** support multi-project grants which fund a variety of broad-based multi-disciplinary projects conducted by numerous investigators working on various aspects of a specific major research initiative or theme.

Along with the R01 and P01 grants, there are other RPG awards used for specific circumstances. Some of these are:

- Method to Extend Research in Time (MERIT) Awards (R37) awarded to long-term researchers of superior competence and productivity.
- Academic Research Enhancement Awards (AREA) (R15) support small scale research at primarily baccalaureate degree granting institutions.
- Small Grants (R03) research support specifically limited in time and amount for initiating studies that are generally for short-term or pilot projects.
- Research Project Cooperative Agreements (U01) support projects with a senior principal investigator in an area representing their specific interests and competencies. There is substantial NIH staff involvement in the project.
- Small Business Innovative Research (SBIR) (R43, R44) and Small Business Technology Transfer (STTR) (R41, R42) Awards support small businesses conducting research and development projects that may lead to commercial products or services. A congressionally mandated set-aside of 2.5% for SBIRs and 0.15% for STTRs determines the minimum funding level. NIH also supports SBIR and STTR contracts.
- James A. Shannon Award (R55) support up to \$100,000 for up to a 24-month period for innovative research proposals that fall close to the cutoff for funding.

Research Centers (9.4% of Total NIH Budget in FY 2005)

Research Center Grants are awarded to extramural research institutions to provide support for long-term multi-disciplinary programs of medical research. They also support the development of research resources, aim to integrate basic research with applied research and transfer activities, and promote research in the areas of clinical applications with an emphasis on intervention including prototype development and refinement of products, techniques, processes, methods and practices. A description of centers follows:

- **Specialized Comprehensive Centers** support a full range of research and development from very basic to clinical. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or medical problem area.
- General Clinical Research Centers support clinical research in a specialized environment where each center is a discrete unit of research beds separated from the general care ward with specialized equipment and expert personnel necessary to provide a controlled environment and assist in the rapid transfer of basic research results to patient care.
- **Biotechnology Research Centers** support regional and national access to the sophisticated research instrumentation and technology needed to solve medical and clinical research problems that are beyond the purview of conventional means. Investigators on NIH grants share these expensive resources, which results in considerable savings to the government.
- **Comparative Medicine Centers** support the development of mammalian and non-mammalian models for research, or to make animal or biological materials resources available to all qualified investigators.
- **Research Centers in Minority Institutions (RCMI)** support the development and enhancement of the research infrastructure of predominantly minority institutions that grant doctoral degrees in the health professions or in a health-related science, to enable them to become more competitive in seeking NIH and PHS research project grant support.

Other Research (5.7% of Total NIH Budget in FY 2005)

- **Research Career Programs (K Awards)** designed to provide increased career opportunities in medical research to scientists of superior potential. The program provides support for young investigators who desire advanced development and scientists who need experience to qualify for senior positions. Included within this category are the following awards: Research Career Development Awards; Clinical Investigator Awards, including K23, K24 and K30 awards for clinical researchers; Academic Investigator Awards; Career Transition Awards; Special Emphasis Research Career Awards; and Physician/Scientist Development Awards.
- **Cancer Education Program** grants awarded to schools of medicine, dentistry, public health, and nursing (with Ph.D. programs) and to teaching hospitals affiliated with medical schools. The grantee institutions develop and adopt curricula in cancer prevention, epidemiology, and nutrition. Students participate for 6-10 weeks per year in ongoing cancer research.
- **Cooperative Clinical Research** grants awarded to multiple institutions where investigators are asked to follow common research protocols, because there are insufficient numbers of subjects available at a single institution to conduct a major clinical trial. NIH staff is substantially involved in the management of these awards.
- Biomedical Research Support (BRS) grants awarded to NIH-supported institutions to fund instrumentation needs, to support pilot studies, and to improve research resources.

- Minority Biomedical Research Support (MBRS) designed to increase the number and quality of ethnic minority biomedical research scientists by strengthening the capability of eligible institutions to conduct quality research in the health sciences and to support undergraduate students in biomedical research at minority institutions.
- Other Research Related Grants various small grants, including scientific review and evaluation, small instrumentation and conference grants.

Research Training (2.7% of Total NIH Budget in FY 2005)

The National Research Service Awards (NRSA) program serves to replenish the nation's corps of biomedical and behavioral research investigators. Through institutional awards and individual fellowships, NIH supports both basic and applied research training in the biomedical and behavioral sciences. Institutional awards provide the foundation for the manpower development effort by supporting the national capacity for excellent, up-to-date training in a variety of settings. They enable NIH to aid institutions in maintaining vigorous and effective research training programs and, in particular, to support research training programs in areas of national need. Decisions on the number of research trainees to be supported by NIH are based upon assessment of program needs and opportunities by the NIH Institutes and the NIH Director, recommendations of the National Academy of Sciences (NAS) and other groups, and the availability of funds.

- Ruth L. Kirschstein National Research Service Awards (NRSAs) support trainees and fellows at a predoctoral and postdoctoral level through grants to individuals and institutions such as medical schools and universities.
- A trainee or fellow receives a stipend for full-time concentrated study and may elect, under supervision, an individual research focus.
- Funds are awarded for predoctoral and postdoctoral stipends and for tuition where warranted, with a modest allocation to defray training-related expenses not covered by tuition.
- NRSAs also include funds for travel, fees, indirect costs, and other expenses.
- Stipend levels constitute the largest dollar portion of NRSAs.

Research and Development Contracts (9.2% of Total NIH Budget in FY 2005)

The NIH awards research and development (R&D) contracts to non-profit and commercial organizations for scientific inquiry directed toward particular areas of research and development. Their purpose is to utilize advances in knowledge and technology to search for solutions to specific questions. Contract performance is closely monitored by NIH to help ensure accomplishment of project goals for the benefit of, or use by, the awarding Institute or Center.

There are fundamental distinctions between acquisition and assistance arrangements. A contract is a legal instrument that is used to reflect a relationship between the federal government and the recipient whenever the principal purpose of the transaction is to acquire goods or services for the direct benefit or use of the government. In competitive situations, the government states the work to be undertaken or the problem to be solved

in a Request for Proposals (RFP), or a sealed Invitation for Bids (IFB). Respondents compete for a common requirement open to all offerers/bidders. Proposals are evaluated using technical and business evaluation criteria and generally involve negotiations. Bids are awarded to the bidder who is responsible and offers the lowest overall price.

Intramural Research (9.7% of Total NIH Budget in FY 2005)

Through the intramural program, the NIH conducts basic and clinical research at its on-campus research facilities in Bethesda, Maryland as well as several off-campus locations. One of the unique aspects of the intramural program is the close proximity of the NIH Clinical Center, which provides an opportunity for bridging the gap between basic and clinical science by carrying basic laboratory research to the bedside. NIH intramural scientists serve as a resource to academia and industry, providing expertise, materials and collaborative opportunities.

Research Management and Support (RMS) (3.8% of Total NIH Budget in FY 2005)

The Research Management and Support (RMS) activity provides support for leadership, program guidance, planning and evaluation for the overall management of NIH programs. Major categories include:

- Program support for salaries and expenses for Institute or Center Directors, their administrative staffs (financial management, personnel management, etc.), and scientific program managers. In addition to administering, managing, and reviewing research grants, research training and research and development contract portfolios, staff is responsible for developing research initiatives in areas of scientific promise. These areas have great potential for the development of disease intervention and health promotion strategies.
- RMS supports Department of Health and Human Services activities such as Program Evaluation, the Program Support Center and special projects. These costs are shared by all Public Health Service agencies.
- RMS also provides support for a number of non-administrative programs that supplement and are integral to both the intramural and extramural research studies supported by NIH, including public health education, information dissemination activities, epidemiological studies, international collaborative efforts and science education efforts.

Portions of this section have been reprinted with permission from the NIH Office of Budget "Key Facts and History of Funding FY 1990 — FY 1999."

NIH FUNDING

Throughout its history, the funding of NIH has been a bipartisan issue, supported strongly by both parties, regardless of which party controlled the Congress.

Authorization: In the House of Representatives, NIH is within the jurisdiction of the House Energy and Commerce Committee and its Subcommittee on Health. In the Senate, the NIH falls within the purview of the Senate Health, Education, Labor and Pensions Committee. Although some NIH programs need periodic reauthorization, the Public Health Service Act provides a general, standing authorization for most of the NIH's programs.

Appropriations: Funding for the NIH is contained in the annual Labor, Health and Human Services, Education and Related Agencies appropriations bill, developed by the House and Senate Labor, Health and Human Services, Education and Related Agencies Appropriations Subcommittees.

Budget: Funding for the NIH is contained in Function 550 (Health) in the yearly Congressional budget resolutions.

Appropriations History

(\$ in thousar	ıds)
FY 2001	\$20,458,130 (+14.8%)
FY 2002	\$23,296,382 (+13.9%)
FY 2003	\$27,066,782 (+16.2%)
FY 2004	\$27,887,512 (+3.0%)
FY 2005	\$28,495,157 (+2.1%)

Extramural Research Project Grants Supported

(Includes SBIR/STTR)

FY 2001	34,122
FY 2002	36,206
FY 2003	38,170
FY 2004	39,241
FY 2005	39,141

Success Rate —

Research Project Grants

FY 2001	32%
FY 2002	31%
FY 2003	30%
FY 2004	25%
FY 2005	22%

Research Training

(# of FTTPs supported)	
FY 2001	16,486
FY 2002	16,884
FY 2003	17,306
FY 2004	17,670
FY 2005	17,839

Research Centers Supported

FY 2001	1,067
FY 2002	1,137
FY 2003	1,266
FY 2004	1,337
FY 2005	1,376

Source: NIH Congressional Justification FYs 2003 — 2006. Figures for FY 2005 are estimates.

HOW TO LEARN MORE ABOUT THE NIH

There are a variety of resources available to answer questions about the National Institutes of Health. This Resource Guide lists the postal addresses, Web site location, phone and fax numbers of the directors and legislative contacts of each of the NIH's component institutes, centers and offices. These individuals would be pleased to provide information about the programs and scientific missions of their organizations. Information about the NIH as a whole is available from the following individuals.

National Institutes of Health

Elias Zerhouni, M.D., director (301) 496-2433 (phone) (301) 402-2700 (fax) Web site: www.nih.gov

Extramural Research Norka Ruiz Bravo, Ph.D., deputy director (301) 496-1096 (phone) (301) 402-3469 (fax) Web site: http://grants.nih.gov/grants/oer.htm

Intramural Research Michael Gottesman, M.D., deputy director (301) 496-1921 (phone) (301) 402-4273 (fax)

Office of Budget Richard Turman, associate director (301) 496-4477 (phone) (301) 496-4332 (fax) Web site: http://officeofbudget.od.nih.gov/ *Office of Legislative Policy and Analysis* Mark Smolonsky, associate director (301) 496-3471 (phone) (301) 496-0840 (fax) Web site: www.olpa.od.nih.gov

Office of Communications and Public Liaison John Burklow, director (301) 496-5787 (phone) (301) 496-0017 (fax)

Office of Science Policy Lana Skirboll, Ph.D., director (301) 496-2122 (phone) (301) 402-1759 (fax)

Ad Hoc Group for Medical Research Funding

The Ad Hoc Group for Medical Research Funding, representing over 300 organizations interested in the NIH, has a host of resources available to congressional offices and the public. For example, the Ad Hoc Group can identify constituents and community-based organizations that can provide information on how the NIH impacts your state and congressional district. For more information, contact:

David B. Moore Executive Director Ad Hoc Group for Medical Research Funding 2450 N Street, NW Washington, DC 20037 (202) 828-0525 (phone) (202) 862-6218 (fax) Email: dbmoore@aamc.org or adhoc@aamc.org Web site: www.aamc.org/adhocgp/

Ad Hoc Group for Medical Research Funding

