

About NIH

Extramural and Intramural Research Programs

As noted above, NIH *supports* research and research training through extramural activities and *conducts* research and research training through intramural activities. The sections below provide overviews of the extramural and intramural programs.

Extramural Program

More than \$8 of every \$10 appropriated to NIH is awarded by the ICs to the extramural biomedical and behavioral research community through grants and contracts. The extramural research community is composed of scientists, clinicians, and other research personnel affiliated with more than 3,100 organizations, including universities, medical schools, hospitals, and other research facilities located in all 50 states, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and points abroad. In FY 2009, NIH funded more than 37,000 principal investigators on research grants, with many thousands more personnel supported by the projects. With NIH support, these investigators, with their research teams, conduct the vast majority of research that leads to improvements in the prevention, detection, diagnosis, and treatment of disease and disability.

OER is led by the Deputy Director for Extramural Research (DDER), who provides leadership and coordinates policy, guidance, and oversight for IC grant and programmatic management operations and is a conduit for extramural policy issues with the biomedical research community beyond NIH. OER is where [grants policy](#), program coordination, compliance, and services converge to support and sustain the NIH extramural research program.

A primary service OER provides for the NIH grants program is the electronic Research Administration (eRA) system. eRA supports the grant administration functions for grantees and Federal staff from the submittal of applications to close out of awards. eRA also provides services to other operating divisions of the Department of Health and Human Services (HHS) and other Federal agencies. eRA has more than 215 registered users (of which more than 150,000 are principal investigators) at 16,500 research institutions worldwide.

Grants Overview

NIH announces the availability of funds for grant programs by issuing [funding opportunity announcements \(FOAs\)](#)⁷ in the [NIH Guide for Grants and Contracts](#) and on www.Grants.gov. The majority of NIH grant funding is investigator-initiated, submitted through omnibus [parent announcements](#) that span the breadth of the NIH mission. NIH uses [program announcements \(PAs\)](#) and [requests for applications \(RFAs\)](#), and other types of FOAs, to express interest in particular areas of research. Because many FOAs are trans-NIH opportunities, considerable collaboration can be involved in their preparation. During 2008 and 2009, NIH refined and further developed an internal electronic document/content management system in support of the *NIH Guide* publication process that facilitates communications, collaborations, and the exchange of documents and information among ICs and within the NIH OD, thereby providing a more

efficient and cost-effective means of developing and publishing NIH FOAs.

The main [types of grant funding](#) provided by NIH are Research Grants (R series), Career Development Awards (K series), Research Training and Fellowships (T and F series), and Program Projects/Centers Grants (P series). Activity codes that incorporate the funding series differentiate the wide variety of research and research-related awards made by NIH. The most commonly used activity code is the R01, which designates a grant for a discrete, specified research project, generally awarded for 3 to 5 years. Receipt of an R01 traditionally is the mark of a scientist achieving scientific independence, and a faculty member's track record with R01 awards normally is a significant factor in university promotion and tenure decisions. Examples of other activity codes are:

- R41/R42 and the R43/R44 for the Small Business Technology Transfer program and the Small Business Innovative Research program, respectively;
- R24 for research projects that will enhance the capability of biomedical research resources;
- R25 for research education projects;
- F32 for postdoctoral individual fellowships under the National Research Service Award;
- T32 for enabling institutions to make National Research Service Awards for both pre- and postdoctoral training;
- K08, a career development award for providing support and "protected time" to individuals with a clinical doctoral degree for an intensive, supervised research career development experience;
- P01 for research program projects that are broadly based, multidisciplinary, often long-term research, which have a specific major objective or a basic theme;
- P30 for shared resources and facilities at research centers; and
- P40 for animal model and biological materials resources.

ICs vary in the extent to which they use various activity codes.

⁷An FOA is a publicly available document by which a Federal agency makes known its intentions to award grants or cooperative agreements. Funding opportunity announcements may be known as program announcements, requests for applications, solicitations, or parent announcements.

NIH Peer Review Process

All grant applications and contract proposals for research and development funding undergo evaluation through [peer review](#), in which external expert panels determine which applications or proposals are the most scientifically and technically meritorious—the first tier of peer review—and are most programmatically relevant and therefore should be considered for funding—the second tier of peer review. The NIH peer review process is designed to evaluate the scientific, technical, and programmatic merit of each application for potential research funding with processes that are fair, equitable, timely, and free of bias. The NIH dual (two-tier) peer review system is mandated by statute (section 492 of the PHS Act) and by Federal regulations governing “Scientific Peer Review of Research Grant Applications and Research and Development Contract Proposals” (42 CFR Part 52h).

CSR is the portal for receipt and referral of NIH grant applications and for most applications is the locus for the first level of review. Applications relevant to the NIH mission receive two assignments. One assignment is to an IC that has a mission encompassing the aims and objectives of the application and thus potential interest in funding the application. The other assignment is to the group or panel that will conduct the first level of review, i.e., evaluation of scientific and technical merit. The assignment may be to either a Scientific Review Group (SRG) or a Special Emphasis Panel (SEP). If the application is in response to an RFA, the SRG or SEP most often will be convened by the IC(s) responsible for the initiative. NIH uses established referral criteria to determine the appropriate SRG to carry out review and

the IC(s) most suitable to potentially fund the project.

As noted above, the first level of review is conducted by SRGs or SEPs that evaluate and give expert advice on the overall scientific and technical merit of the research proposed in the application, as well as the protection of human subjects, vertebrate animal welfare, and the budget and period of support requested. SRGs and SEPs conducting the first level of review are composed primarily of non-Federal experts qualified by training or experience in particular scientific or technical fields, or as authorities knowledgeable in the various disciplines and fields related to the applications under review. No more than one-fourth of the members of any SRG or SEP may be Federal employees.

The second level of peer review is performed by the National Advisory Councils (or Boards) of each IC, which are composed of scientific and public members chosen for their expertise, interest, or activity in matters related to a specific area of health and disease. The vast majority of SRG- or SEP-reviewed applications assigned to an IC go to the respective Council,⁸ which then recommends those applications that should be considered for funding. Identifying applications that further specific program priorities is a particularly important function of this second level of peer review. Advisory Councils recommend projects for funding, but do not make funding decisions.

An ongoing trans-NIH effort to optimize the efficiency and effectiveness of the NIH Peer Review system is discussed in *Enhancing Peer Review*, under the section below on *Improving Research Management*.

⁸ An application may be designated “Not Recommended for Further Consideration (NRFC)” at the first level of peer review, if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or Select Agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

Funding Decisions

Applications that are scientifically meritorious, based on SRG or SEP review, and favorably recommended by an IC’s National Advisory Council, are considered for funding. The score given to an application during the initial peer review process is important, but not the sole factor determining an IC’s funding decision. Other considerations are portfolio balance, requirements specified in congressional appropriations, programmatic relevance, IC priorities, and availability of funds. (Also see the section later in this chapter on *Enhancing Peer Review* for information on recent changes in the scoring of applications during initial review.)

Many ICs establish a “payline”—a percentile-based⁹ funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications assigned to an IC with the amount of funds expected by NIH and the IC to be available for such projects. Applications that score within the payline are most likely to be funded. However, Advisory Councils consider, evaluate, and make recommendations on specific applications that score both within and beyond the payline.

In addition to setting paylines, many ICs establish procedures for funding applications that scored beyond the payline. Terms used for this category of awards vary by IC, but include “select pay,” “exception pools,” “high program-priority,” and “special emphasis.” What is consistent is the use of these funds, with strong justification, to support highly innovative or high program-priority applications that score beyond the payline.

Prior to award, NIH ensures that the planned research meets all requirements for safe and responsible

conduct. This includes making sure that the research has undergone all necessary reviews and has obtained required approvals from boards and committees charged with protection of human subjects; inclusion of minorities, women, and children; humane animal care and use; biosafety; and other matters as appropriate. NIH also ensures that the institution where the research takes place has necessary and appropriate policies in place for avoidance of financial conflicts of interest in research. (Also see the section on *Ensuring Responsible Research* later in this chapter).

⁹ Percentile represents the relative position or rank (from 1 to 100) of each overall impact/priority score.

Post-Award Administration

NIH policies extend into the post-award phase of research as well, so that NIH can monitor research progress and provide oversight to ensure responsible conduct of research. Scientific monitoring includes reviewing yearly progress and financial reports submitted by grantees, the publications generated by the research, and any invention reports. NIH also monitors compliance with Federal laws and policies pertaining to protection of human subjects, the care and use of vertebrate animals used in research, data sharing, the NIH Public Access Policy, and other matters. In addition, oversight of clinical research may involve data and safety monitoring and tracking of inclusion of women and minorities in research. (Also see the sections on *Capitalizing on Discovery* and on *Ensuring Responsible Research* later in this chapter).

Intramural Research Program

Approximately 10 percent of NIH funds support research and training activities carried out by NIH scientists in NIH laboratories on its campuses in the Bethesda (including the NIH Clinical Center), Rockville, Frederick, and Baltimore, Maryland, areas; Research Triangle Park, North Carolina; Detroit, Michigan; Phoenix, Arizona; and the Rocky Mountain Laboratories, Montana. Approximately 1,150 principal investigators lead intramural research projects that involve more than 6,000 trainees ranging from high school students to postdoctoral and clinical fellows. OIR is responsible for trans-NIH oversight and coordination of intramural research, human subject protections, animal welfare, training, policy development, laboratory safety, and technology transfer conducted within NIH laboratories and clinics. OIR is led by the NIH Deputy Director for Intramural Research (DDIR), and each IC intramural research program is led by an IC Scientific Director; OIR oversight is carried out in conjunction with the IC Scientific Directors. A summary of policies governing intramural research can be found in the [Intramural Research Sourcebook](#).

Research Programs and Priorities

The NIH intramural research programs conduct basic, translational, and clinical research. Organizationally, the individual laboratories and clinics report to their respective IC and are responsible for conducting original research consistent with the goals of the parent IC. Most ICs have an intramural program, the exceptions being NIGMS, CSR, FIC, and NCRR. As with the extramural program, intramural research proposals are generated by scientists. In the intramural research program, however, program directions and research priorities are not shaped primarily through grant awards,¹⁰ but rather through professional hiring and promotion decisions, external reviews, and the allocation of resources to laboratories and branches.

Each intramural research program has a promotion and tenure committee that evaluates all recommendations for professional appointment or promotion, and tenured and tenure-track scientists undergo formal, annual, internal reviews. Resource allocations and promotions are determined from these reviews. In addition, at least every 4 years, an external expert Board of Scientific Counselors reviews the work of each tenured/tenure-track scientist and makes recommendations regarding continuation or modification of projects and adjustment of resources (budget, space, personnel). Moreover, IC Scientific Directors are evaluated by an external committee every 5 years, and each IC intramural research program is reviewed, in its entirety, by a “blue ribbon” panel approximately every 10 years. These panels assess and make recommendations concerning the impact of the research program, program balance, and other significant matters that play a role in the success of the program.

Two offices manage research training for OIR. The Office of Intramural Training and Education (OITE) is charged with helping trainees in the intramural research program, including graduate students in partnership with universities in the United States and abroad, develop scientific and professional skills to become leaders in the biomedical research community. The Office of Clinical Research Training and Medical Education (OCRTME) deals with all aspects of clinical training. Many training programs were developed or updated during 2008 and 2009 (also see the section on *Research Training and Career Development* in Chapter 3).

¹⁰ The exception is that intramural investigators are eligible to compete for most NIH Roadmap initiatives to allow qualified intramural researchers to contribute to the goals of Roadmap programs.

NIH Clinical Center

The Clinical Center is the Nation’s largest hospital devoted entirely to clinical research. Research at the Clinical Center is conducted with access to cutting-edge technologies in an environment of compassionate care. This world-class national resource promotes translational research—that is, the transformation of scientific observations and laboratory discoveries into applications for diagnosing, treating, and preventing disease that benefit patient health and medical care. Composed of two facilities—the Mark O. Hatfield Clinical Research Center (2005) and the original Warren Grant Magnuson Clinical Center (1953)—the Center houses 234 inpatient beds, 82 day hospital stations, an ambulatory care research facility, 12 operating rooms, critical care facilities, advanced radiology and imaging capabilities, and research laboratories. The unique design of the facility locates patient care units in close proximity to laboratories conducting related research. This design facilitates interaction and collaboration among intramural clinicians and researchers. More than 1,400 studies are in progress at the Clinical Center, bringing 21,000 patients per year from all 50 states and throughout the world. The Center has more than 90,000 outpatient visits a year and 6,000 inpatient admissions. Approximately 1,200 credentialed physicians, dentists, and Ph.D. researchers, 660 nurses, and 630 allied health care professionals, such as pharmacists, dietitians, and medical technologists, work at the Center. As a research facility, generally only a patient with the precise kind or stage of illness under investigation and meeting other inclusion criteria of a protocol is enrolled as a subject in a study. However, in May 2008, NIH launched the [Undiagnosed Diseases Program](#), a clinical research program in collaboration with NHGRI and the NIH Office of Rare Diseases designed to provide answers to patients with mysterious conditions that have long eluded diagnosis by their health care providers. Within its first 6 months, more than 1,000 potential subjects sought to participate in the new program—a tangible reminder that the NIH Clinical Center truly is a “house of hope.”