

## Introduction

# Extramural and Intramural Research Programs

### Extramural Research Program

More than \$8 of every \$10 appropriated to NIH is awarded by the ICs through grants and contracts to the extramural community. The extramural community is composed of scientists at universities, medical centers, hospitals, and research institutions throughout the United States and abroad. The extramural research community comprises scientists and research personnel affiliated with over 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. With NIH support, these investigators and their institutions conduct the vast majority of research that leads to improvements in the prevention, detection, diagnosis, and treatment of disease and disability; contributes to training the next generation of researchers; and enhances the skills and abilities of established investigators. The NIH OD Office of Extramural Research (OER) provides leadership, oversight, tools, and guidance to administer the NIH grants management operations carried out through the ICs. OER is where [grants policy](#), program coordination, compliance, and electronic Research Administration (eRA) converge. The Deputy Director for Extramural Research executes program coordination through counterparts in each of the grant-awarding ICs.

### NIH Peer Review Process

All grant applications and contract proposals for research funding undergo evaluation through [peer review](#), in which external expert panels determine which applications or proposals are the most scientifically and technically meritorious and should be considered for funding. NIH policy requires that peer review be carried out in a manner that ensures objectivity, fairness, and maximum competition. The NIH dual (two-level) peer review system is mandated by the Public Health Service Act and Federal regulations (42 CFR 52).

CSR is the portal for NIH grant applications and their review for scientific merit. The NIH grant peer review process begins with assignment. Applications relevant to the NIH mission receive two types of assignment. One assignment is to a CSR Scientific Review Group (SRG) or, if the application is in response to a solicitation, to an IC special emphasis panel, for evaluation of scientific and technical merit. The second assignment is to an IC that has a mission encompassing the aims and objectives of the application. NIH uses established referral criteria (called Referral Guidelines) to determine the appropriate SRG to carry out review and the IC most suitable to potentially fund the project.

At the first level of review, peer reviewers evaluate and judge the overall scientific and technical merit of the research proposed in the application. SRGs conducting the first level of review are composed primarily of non-Federal researchers who are actively involved in the area of the proposed research and qualified to review the applications by virtue of their research experience and training. These peer reviewers are consultants to NIH and they provide advice about the potential of the research to advance scientific knowledge and discovery, using standardized criteria for determining the scientific and technical merit of an application, specifically:

1. **Significance:** Does the study address an important problem?
2. **Approach:** Are the concepts and methods well thought out and appropriate to the aim?
3. **Innovation:** Does the project develop or use novel concepts?

4. **Investigators:** Are the investigators appropriately trained and well suited to carry out the work?
5. **Environment:** Will the setting for the research (facilities, resources, institutional support) contribute to probability of success?

All of these criteria are necessary factors in determining the overall scientific and technical merit of an application and the final evaluation score or “priority score” of an application. Additional review criteria may be added for applications in response to solicitations (e.g., a Request for Applications, or RFA).

The second level of peer review is performed by the National Advisory Councils or Boards (Advisory Councils) of each IC, which are composed of scientific and nonscientific 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-scored applications assigned to an IC go to the appropriate Council<sup>1</sup>, 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. However, like SRGs, Advisory Councils recommend, but do not make, funding decisions.

An ongoing trans-NIH effort to examine the two-level NIH peer review system with the goal of optimizing its efficiency and effectiveness is discussed in *Enhancing Peer Review*, under the section below on *Improving Research Management*.

## Funding Decisions

Only applications that are scientifically meritorious, based on SRG review, and favorably recommended by the National Advisory Council may be considered for funding. The priority score given to an application during the peer review process is important, but not the sole factor determining an IC's funding decision. Other considerations are programmatic relevance, IC priorities, contribution to balance in light of the existing IC research portfolio, and amount of the award.

Many ICs establish a “payline”—a percentile-based<sup>2</sup> funding cutoff point determined at the beginning of the fiscal year (FY) by balancing the projected number of applications coming to an IC with the amount of funds determined by NIH and the IC to be devoted to such projects. Because the significance of the proposed research is a critical factor in determining the priority score, 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.

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<sup>1</sup> Councils do not receive unscored applications (these are applications deemed “not recommended for further consideration [NRFC]”) at the first level of peer review. Also, until enactment of the NIH Reform Act of 2006, Councils were not obligated to review applications for less than \$50,000. Moreover, of applications sent to Council, many IC Councils evaluate only those scoring over a prescribed threshold of success at the first level of peer review.

<sup>2</sup> Percentile represents the relative position or rank of each priority score (from 1 to 100).

## Post-Award Administration

NIH policies extend into the post-award phase of research as well, so that NIH can monitor research progress and ensure responsible conduct of research. Scientific monitoring includes reviewing yearly progress reports, financial reports submitted by grantees, the publications generated by the research, and any invention reports. NIH also monitors compliance with Federal rules on protection of animals used in research and on human subjects (see *Ensuring Responsible Research Conduct* below). In addition, oversight of clinical research may involve data safety monitoring.

Oversight of initiatives involves another level review. NIH staff track what is funded under each initiative and may hold follow-up advisory group meetings, workshops, and/or formal program evaluations. This type of information becomes yet another source of input for the IC as it evaluates priorities and considers midcourse adjustments to initiatives and strategic plans.

## Intramural Research Program

Approximately 10 percent of NIH funds support research 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; Phoenix, Arizona; and the Rocky Mountain Laboratories, Montana. The NIH Intramural Research Program, or IRP, conducts basic, translational, and clinical research. Most ICs have an intramural program; the exceptions are NIGMS, CSR, FIC, NCCR, and NCMHD<sup>3</sup>. Organizationally, the individual laboratories and clinics answer to their respective IC, and generally are responsible for conducting original research consonant with the goals of their IC. Approximately 1,150 principal investigators lead intramural research projects. The NIH Office of Intramural Research (OIR) is responsible for trans-NIH oversight and coordination of intramural research, human subjects' 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 and its oversight responsibilities are carried out in conjunction with the IC Scientific Directors. A summary of policies governing intramural research can be found in the [Intramural Research Sourcebook](#).

As with the extramural program, intramural research proposals are generated by scientists. In the intramural research program, however, program directions and priorities are not generally shaped through grant awards<sup>4</sup>, 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. In addition, there is a central tenure committee that reviews all candidates for tenure at the NIH. Through a competitive process, only approximately 60 percent of the individuals who enter the tenure track at the NIH, after a national search, eventually become permanent tenured staff.

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<sup>3</sup> Although NCMHD does not have an intramural program per se, some NCMHD funds are applied to intramural activities in partnership with other ICs.

<sup>4</sup> In July 2007, NIH issued NOT-RM-07-011 notifying members of the NIH IRP that Roadmap requests for allocations from the IRP will be considered on a competitive basis along with Roadmap applications from members of the extramural scientific community. CSR will be responsible for initial peer review involving competition among members of the IRP and the extramural scientific community.

Although tenure guarantees a base salary, research resources are competitive. Tenured and tenure-track scientists undergo formal, annual, internal reviews. Resource allocation and promotions are determined from these reviews. In addition, at least every 4 years, an external expert Board of Scientific Counselors (BSC) 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). The IC Director or Scientific Director reports the results of BSC reviews to the IC National Advisory Council.

Each IC intramural research program is led by a Scientific Director. Scientific Directors are evaluated for performance by an external committee every 5 years. The reviewing committee reports to the IC National Advisory Council through the IC Director and to the NIH Deputy Director for Intramural Research.

Moreover, 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.