THE NIH MISSION

The National Institutes of Health (NIH) is the principal medical research component of the United States Government, and one of the health agencies of the Public Health Service (PHS), a component of the Department of Health and Human Services (DHHS). Included within the NIH are 27 components, mainly Institutes and Centers (IC).

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

• conducting research in its own laboratories;
• supporting the research of non-Federal scientists in universities, medical schools, hospitals, research institutions and companies throughout the country and abroad;
• helping in the training of research investigators; and
• fostering communication of medical information.

The goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold.

Approximately 84 percent of tax dollars provided to NIH is invested in the Extramural Research Program, funding grants and contracts that support research and training conducted by about 50,000 project directors/principal investigators (PD/PI) at more than 2,000 research institutions throughout the US and abroad. Approximately ten percent of the budget goes to the Intramural Research Programs -- the more than 2,000 projects conducted mainly in NIH’s own laboratories. About eight percent of the budget is for both intramural and extramural research support costs.

THE NIAID MISSION

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 60 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world. The scope of the NIAID research portfolio has expanded considerably in recent years in response to new challenges such as bioterrorism; emerging and re-emerging infectious diseases including acquired immunodeficiency syndrome (AIDS), severe acute respiratory syndrome (SARS), West Nile virus, malaria, and tuberculosis; and increase in asthma prevalence among children in this country.

The growth of NIAID programs also has been driven by unprecedented scientific opportunities in the core NIAID scientific disciplines of microbiology, immunology, and infectious diseases. Advances in these key fields have led to a better understanding of the human immune system and the mechanisms of infectious and immune-mediated diseases.
TYPES OF FUNDING OPPORTUNITY ANNOUNCEMENTS (FOA)

The NIH solicits applications for grant support through two mechanisms:

1) Applications for grant support from investigators who develop plans for research within an area of interest to NIH (investigator-initiated grant applications) are solicited through parent FOAs with standard receipt dates.

2) Institutes, such as NIAID, solicit the submission of grant applications in areas of high priority or special concern. These targeted FOAs may be either a Program Announcement (PA) or a Request for Applications (RFA). PAs describe new, continuing, or expanded program interests at NIAID or announce the availability of a new mechanism of support. PAs use standard receipt dates, while Program Announcements Reviewed in an Institute (PARs) often have special receipt dates. RFAs invite investigators to submit grant applications to accomplish a specific programmatic objective. For RFAs, a receipt date (usually one-time) is specified and funds are “set aside” to make awards.

The need for a PA or RFA is usually identified with the assistance of an advisory group or as the result of a workshop. A formal concept (including the amount of set-aside funds for RFAs) is presented to the NIAID Council for comment and approval (i.e. concept clearance). The corresponding FOA is then prepared and advertised in the NIH Guide for Grants and Contracts (http://grants.nih.gov/grants/guide). The document describes the nature of the research problem and describes the anticipated increase in scientific knowledge to be achieved; the research objectives and the types of research and experimental approaches that are being sought; any special considerations unique to the program; and the method and criteria by which applications will be evaluated.

RESEARCH FUNDING MECHANISMS

There are three main categories of support for extramural research:

Grants are a form of assistance, where the Government provides resources to investigators who develop concepts, methods, and approaches for a research project. Most grants funded by the NIH are investigator-initiated. In addition, the individual ICs may issue Funding Opportunity Announcements (FOAs) to support areas of special interest. Grants are awarded to the applicant institution of the individual PD/PI who proposes and conducts the research. More than 80% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 325,000 researchers at over 3,000 universities, medical schools, and other research institutions in every state and around the world.

Cooperative agreements are also a form of assistance, but include substantial programmatic involvement by NIH staff.

Contracts are a form of acquisition, where the Government purchases specific goods or services according to plans, protocols and requirements established by the awarding IC. Contracts are normally solicited through a Request for Proposals (RFP) or a Broad Agency Announcement (BAA), and are awarded to the specific institution (Offeror) responsible for conducting the work.

Research grants are used to support a wide variety of biomedical research and related activities. The NIH actively awards over 80 different types of grants. The types most commonly funded by NIAID include:
**Research Project (R-series)** awards support individual research projects under the direction of a single (or multiple) Project Director/Principal Investigator (PD/PI).

**Program Projects and Centers (P-series)** support organized efforts of collaborating groups of investigators who conduct integrated research projects related to the objectives of an overall program.

**Training Programs (T-series)** provide funds for research training programs, primarily at the predoctoral and postdoctoral levels.

**Fellowships (F-series)** support the training of individual awardees at the predoctoral and postdoctoral levels.

**Career Development Awards (K-series)** are offered to research and academic institutions on behalf of scientists with clear research potential. Each of these awards is part of an integrated program designed to foster the development of outstanding scientists and enable them to expand their potential for making important scientific contributions.

**Cooperative Agreements (U-series)** differ from grants in that, while grants require minimal or no involvements of NIAID staff during the performance of project activities, cooperative agreements involve a substantial programmatic (i.e. scientific/technical) role. This role may involve cooperation and/or coordination to assist awardees in carrying out the project, or review and approval of certain processes/phases in scientific management of the project. Applications for cooperative agreements are solicited with an RFA describing the program, functions, or activities that NIAID proposes to support, and the nature of the proposed staff involvement. Terms and conditions are outlined in the RFA, above and beyond those required for the usual stewardship of grants, to establish the rights, responsibilities, and authorities of the prospective awardees and NIAID.

Policies and procedures for application submission, review, and post-award administration are similar for grants and cooperative agreements.

**PEER REVIEW**

All research and development projects funded by the NIH are legislatively required (42 USC 289) to undergo peer review. Applications for grants and cooperative agreements as well as proposals for contracts are initially evaluated by Scientific Review Groups (SRGs) made up primarily of scientists actively engaged in research. SRGs that review grant and cooperative agreement applications are termed Study Sections or Special Emphasis Panels, and may be constituted by either a funding IC or by NIH’s Center for Scientific Review (CSR). SRGs that review contract proposals are termed Technical Evaluation Groups (TEGs) and are constituted only by the individual ICs. The mission of both types of SRGs is to advise NIH on the selection of the most meritorious and promising research projects for support. Currently, more than 88,000 research and training applications are reviewed annually through the NIH peer review system.

NIAID reviews applications where Institute programmatic priorities will be a significant factor in the subsequent award decision. These include: all applications responding to NIAID RFAs; some applications responding to NIAID PAs; and applications for Program Projects, Centers, Training Programs, Career Development Awards, and Conference Grants. The CSR generally reviews investigator-initiated applications for Research Projects (R-series) responding to a parent FOA, and Fellowship Awards (F-series), as well as many applications responding to PAs.
The primary peer review is conducted by a Study Section or a Special Emphasis Panel (SEP) that evaluates each application against a set of specific review criteria. Standard review criteria are established for the various types of grants that NIH awards. Additional review criteria may be specified for applications responding to a RFA. The review group assigns a numeric Overall Impact/Priority score to each of the applications. Reviewers also provide their evaluations of special issues and requested budgets in a grant application. Special issues include: protection of human subjects; inclusion of women, minorities and children in clinical research; data and safety monitoring plans (in clinical trials); vertebrate animal issues; hazardous research materials and methods (biological, chemical and other hazards); resource sharing; involvement of foreign organizations; and overlap between the proposed research and other activities for which the applicant is funded.

Applications receive a second level of review by the NIAID Advisory Council. The Council is composed of both scientific and lay representatives selected for their expertise, interest, or activity in health and disease-related activities relevant to NIAID's mission. Council's recommendations are based not only on considerations of scientific merit (as judged by the review committee), but also on the relevance of a grant application to NIAID's programs and priorities. For the vast majority of applications, Council concurs with the recommendations of the initial review group.