NIH Extramural Fundamentals

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Association of American Universities
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NIH Budget in FY 2006: $28.6 Billion

- 83% Spending Outside NIH: $23.8 B
- 17% Spending at NIH: $4.8 B

<table>
<thead>
<tr>
<th>Amount</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>$2.8B 6,000 intramural scientists &amp; research personnel</td>
</tr>
<tr>
<td>3.8%</td>
<td>$1.1B Administrative costs (RM&amp;S)</td>
</tr>
<tr>
<td>3.2%</td>
<td>$1.0B NLM, OD, etc.</td>
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83% of the total NIH budget supports over 212,000 extramural scientists and research personnel at 2,800 institutions nationwide.
NIH Funding Across the U.S.
Fiscal Year 2006:

- 46,406 research grants awarded ($19.8 billion)
- 38,317 research project grants ($15.3 billion)
- 73% of NIH extramural awards go to institutions of higher education
- More than 75,000 grant applications received (all mechanisms)
## NIH Funding Stats
### Research Project Grants

**Fiscal Year 2006:**

<table>
<thead>
<tr>
<th>Type</th>
<th>Reviewed</th>
<th>Awarded</th>
<th>Success Rate</th>
<th>$$$</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Applications</td>
<td>38,220</td>
<td>6,390</td>
<td>16.7%</td>
<td>2.17 B</td>
</tr>
<tr>
<td>Continuation Applications</td>
<td>7,320</td>
<td>2,694</td>
<td>36.8%</td>
<td>1.17 B</td>
</tr>
<tr>
<td>Competing Supplements</td>
<td>148</td>
<td>44</td>
<td>29.7%</td>
<td>0.01 B</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>45,688</strong></td>
<td><strong>9,129</strong></td>
<td><strong>20.0%</strong></td>
<td><strong>3.36 B</strong></td>
</tr>
</tbody>
</table>
### What’s the Difference Between a Grant and a Contract?

<table>
<thead>
<tr>
<th><strong>GRANT</strong></th>
<th><strong>CONTRACT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistance</td>
<td>Acquisition</td>
</tr>
<tr>
<td>Government is Partner/Patron</td>
<td>Government is purchaser</td>
</tr>
<tr>
<td>Purpose: to support and stimulate research</td>
<td>Purpose: to acquire goods or services</td>
</tr>
<tr>
<td>Benefit a public purpose</td>
<td>The direct benefit and use of the government</td>
</tr>
<tr>
<td>Investigator initiated</td>
<td>Government initiated</td>
</tr>
</tbody>
</table>
Award Mechanisms: Research Project Grants

• Traditional – $R01$
• Exploratory/Development Grants – $R03/R21/R15$
• Program Project – $P01$
• Research Center Grants – $P50/P60$
• Small Business – $R41, R42, R43, R44$
Research Training and Career Awards

• Training Grants – $T$
  – Institutional $T32$
    (Predoctoral and Postdoctoral)

• Fellowships – $F$
  – Individual
    • Predoctoral – $F31$
    • Postdoctoral – $F32$

• Career Development Awards – $K$
  – Mentored Clinical Scientist Research Career Development Award $K08$
  – Mentored Patient-Oriented Research Career Development Award $K23$
NIH Consists of
27 Institutes and Centers

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NIH Application Process Overview

- CSR assigns to SRG, IC
- Review by CSR SRG
- Fundable
  - IC Negotiates Award
  - Grant Ends, Renewal Application Prepared
- Not Fundable
  - PI Evaluates Feedback
  - Revised Application Prepared

RFAs & others
- CSR sends to IC
- Review by IC
- Summary Statement to PI
- Second Level Council Review
- PI can request SRG and IC
- Application to NIH (R&R/CSR)
- PI Notified, Given Feedback

Research application
Who Makes Actual Funding Decisions?

The Institute Director!

Factors Considered:
- Scientific Merit
- Contribution to Institute Mission
- Program Balance
- Availability of Funds
The Research Partnership

NIH

- Review Administrator
- Program Administrator
- Grants Management Administrator

Applicant Institution

- Principal Investigator
- Authorized Institutional Official
- Sponsored Research Administrator
The Grantee Institution

- Actual recipient of award
- Legally responsible for proper conduct and execution of grant
- Protection of human subjects
- Animal welfare
- Provides fiscal management
- Provides oversight on allocation decisions
- Assures compliance with Federal, NIH, and organization-wide requirements
Responsibilities of the Principal Investigator(s) (PIs) 

*Designated by the grantee institution*

- Responsible for the scientific and technical aspects of project
- Assures scientific compliance by maintaining contact with the Program Director
- Ensures Federal support is acknowledged in publications
- Can have Multiple Principal Investigators
  - Leadership Plan
Multiple PIs - Features

• Permit more than one Principal Investigator on grants, cooperative agreements and contracts
  – Named PIs responsible and accountable for the proper conduct of the project and requirements and reports
  – All Principal Investigators identified on notices of grant award and in NIH reports
• Encourage collaboration and interdisciplinary research
• Recognize the contributions of PIs and other Key Personnel on the project
NIH Reauthorization...

- Jan 15 - President signed the NIH Reform Act of 2006, following unanimous support by Congress.
- Affirms the importance of NIH and its vital role in advancing biomedical research to improve the health of the Nation.
- Provisions for new trans-NIH, trans-agency high-risk/high-reward demonstration programs.
  - Establishes Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) w/in NIH/OD
Key Provisions in the Bill

- Common Fund
- Council of Councils to advise on research proposals that would be funded by the Common Fund
- Establishes Scientific Management Review Board (SMRB) to conduct periodic organizational reviews of NIH, and to make recommendations on the use of NIH organizational authorities
  - Requires public process for reorganizing NIH programs
- Many reporting requirements subsumed in new biennial report
The Time is Now!

Get More Information

- Transition from the Public Health Service 398 (PHS398) to the new federal government-wide Standard Form 424 Research and Related (SF424 (R&R)) dataset.
- Simultaneously transition to electronic submission through the federal government-wide Grants.gov “Find and Apply” Web site.

http://era.nih.gov/ElectricReceipt

New investigators

• National Academy of Sciences reports: concerns and recommendations
  – Transition from postdoc to faculty member
  – Status/”plight” of the postdoc

• NIH Working Group on New Investigators
  – New Definitions
  – Numeric targets – based on previous new investigator award rates
  – Pilot shortened review cycle for new investigators
  – New Programs
    • Pathways to Independence Award K99/R00
    • NIH Director’s New Innovator Award Program (DP2) – May 22
    • NIH Director’s Bridge Award (R56) for continuing projects (ICs nominate from existing applications – Can’t apply for an NDBA)
Resources for New Investigators

Statement of Commitment to New Investigators

New investigators are the innovators of the future—they bring fresh ideas and technologies to existing biomedical research problems, and they pioneer new areas of investigation. Entry of new investigators into the ranks of independent, NIH-funded researchers is essential to the health of this country's biomedical research enterprise. NIH's interest in the training and research funding of new investigators is undeniably deep and longstanding. Over the years, special programs to assist new investigators in obtaining independent research funds have been created—for example, the New Investigator Research Award (NIRA or R22), in 1987, and the First Independent Research Support and Transition (FIRST or R22) Award, superseded the NIRA in 1996. Both of these special programs were discontinued because neither was able to significantly and positively affect the overall ability of new investigators to obtain independent research support (see Report of the Working Group on New Investigators) in spite of these and other efforts; the average age at which an investigator receives funding has increased by five to six years (to 42 for PhD degree holders and 44 for MD and MD/PhD degree holders). In addition, although the overall number of R01 successes, the proportion of R01 grants going to new investigators has remained at approximately 10% of the total R01's awarded throughout the past decade.

Currently, NIH encourages new investigators to self-identify by checking a box on the face page of their R01 applications so that they may be instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be expected of an experienced investigator. In addition, many NIH institutes and centers give new investigators special consideration in their selection for funding, and in some cases, even for the initial period that is the NIH average duration for a grant.

We at NIH remain committed to identifying and attracting new independent biomedical researchers. Although the number of new investigators may not double by 1999, we can work with this. However, we cannot do it alone. Institutions—our partners in this venture—must continue to look for ways to reduce the barriers to entry and to compete successfully for extramural funding. I would welcome your ideas in this regard.

Nora Ruiz Brown, PhD, Deputy Director for Extramural Research, NIH

History of Commitment to New Investigators

• New Investigator Research Awards—June 1987
• First Independent Research Support and Transition—February 1, 1988
• New Investigator Research Awards—December 19, 1997

New Investigator

The purpose of review and funding, applicants are considered new investigators if they have not previously served as the principal investigator (PI) on any Public Health Service-supported research project other than a small grant (R03). An Academic Research Enhancement Award (AURE), exploratory/developmental grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research career (K01, K02, and K12). Current or past recipients of Independent Scientist and other non-mentored career awards (K02, K04) are not considered new investigators. (see http://grants.nih.gov/grants/guide/notices-files/97-001.html)

Help with the Application Process

NIAID—National Institute of Allergy and Infectious Diseases

• Who Can Qualify for an NIH Grant
• Overview of the Grant Application Process
• About Grants Tutorial

NIH-funded investigators are requested to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs from NIH.

NIH Guide, February 3, 2005

Effective May 2, 2005
Why Public Access?

**ARCHIVE** Keep a central archive of NIH-funded research publications—for now and in the future, preserving vital medical research results and information for years to come.

**ADVANCE SCIENCE** Create an information resource that will make it easier for scientists to mine medical research publications, and for NIH to better manage its entire research investment.

**ACCESS** Provide electronic access to NIH-funded research publications for patients, families, health professionals, teachers, and students.
OUTREACH!

The National Institutes of Health Office of Extramural Research (OER) welcomes you to your first update on NIH extramural issues via the NIH Extramural Nexus. The OER is the hub for grants policy and operations, grants administration, and the coordination of NIH's extramural programs and activities. Through the Nexus, the OER will provide the extramural community with updates on NIH policies and activities as well as an opportunity to gain a better understanding of the operation of extramural programs. We intend the Nexus to be a two-way communications portal— we will be listening to you and plan to modify the content of the Nexus accordingly.

The Nexus appears at a time of considerable change at the NIH. Among other things, the President has signed the FY 2006 budget and we have developed financial operations policies; we are moving quickly to electronic submission of applications; we are considering new policies to facilitate the careers of new investigators; and, we are redesigning our grant programs to recognize the contribution of multiple members of research teams.

Click on graphic to expand (opens in new window)

Each monthly issue of the NIH Extramural Nexus will contain updates with topical information about extramural policies and initiatives as well as the various programs that comprise the OER. In the article below, identified by the Nexus Symbol, you will be...
Not the view from the NIH!
NIH Funding Across the U.S.