Fundamentals of the NIH

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Extramural Policy Coordination Officer
National Institutes of Health
Overview

• The big picture
• Finding funding opportunities
• Interacting with the NIH
• Peer review process
Understanding the Dual Nature of NIH

NIH is an institution
(Intramural Research)
~Approx. 6,000 scientists
~Approx. 16% of NIH budget

NIH supports institutions & people
(Extramural Research)
>4,000 institutions
>300,000 scientists & research personnel
~Approx. 84% of the NIH budget
27 Separate Institutes & Centers (IC) each with different:

- missions & priorities
- budgets
- ways of deciding which grants to fund
Funding Distribution

- Basic Research: 52.0%
- Applied Research (Clinical): 34.6%
- Applied Research (Other): 10.5%
- Training & Overhead: 2.6%
- R&D Facilities: 0.3%
FUNDING OPPORTUNITY ANNOUNCEMENTS (FOAs)
What's the Difference Between Grants and Contracts?

<table>
<thead>
<tr>
<th>Grant (application)</th>
<th>Contract (proposal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Assistance</td>
<td>• Acquisition</td>
</tr>
<tr>
<td>• Purpose: To support and stimulate research</td>
<td>• Purpose: To acquire goods or services</td>
</tr>
<tr>
<td>• Investigator-initiated</td>
<td>• Benefit and use of the government</td>
</tr>
<tr>
<td>• Benefits a public purpose</td>
<td>• Government-initiated</td>
</tr>
<tr>
<td>• Government is patron or partner</td>
<td>• Government is purchaser</td>
</tr>
</tbody>
</table>
How Does NIH Solicit Applications?

**Parent Announcements**
- NIH-wide funding opportunity
- Some ICs may limit their participation
- On-going programs within NIH
- Investigator-initiated
- Multiple submission dates

**Program Announcements (PA, PAR, PAS)**
- Formal statement about a new or ongoing program
- Most are investigator-initiated
- Most have multiple submission dates
- Most are reviewed using standard peer review processes

**Requests for Applications (RFA)**
- Solicits applications in a well-defined scientific area to accomplish specific program objectives
- Awarded through set-aside funds
- Usually reviewed by a special emphasis panel convened by the IC
- Most have a single submission date
<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Title</th>
<th>Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Research Project Grant</td>
<td>Provides three to five years of support to investigators who have preliminary data</td>
</tr>
<tr>
<td>R03</td>
<td>Small Research Grant</td>
<td>Provides up to two years of funding to obtain preliminary data that supports a hypothesis that will likely lead to a major project</td>
</tr>
<tr>
<td>R21</td>
<td>Exploratory / Developmental Research Grant</td>
<td>Provides up to two years of support for exploratory or developmental research</td>
</tr>
<tr>
<td>R15</td>
<td>Academic Research Enhancement Award (AREA)</td>
<td>Supports small research projects (up to three years) at academic institutions that have not been major recipients of NIH research grant funds</td>
</tr>
<tr>
<td>Mechanism</td>
<td>Title</td>
<td>Goal</td>
</tr>
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</tr>
<tr>
<td>R43/R44</td>
<td>Small Business Innovation Research (SBIR) Grant</td>
<td>Supports small business research on a project intended for commercialization.</td>
</tr>
<tr>
<td>R41/R42</td>
<td>Small Business Technology Transfer Research (STTR) Grant</td>
<td>Supports a partnership of ideas and technologies between small businesses and non-profit research institutions</td>
</tr>
<tr>
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<td>Goal</td>
</tr>
<tr>
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</tr>
<tr>
<td>R13</td>
<td>NIH Support for Conferences and Scientific Meetings</td>
<td>Support high quality conferences/scientific meetings that are relevant to the mission of the NIH</td>
</tr>
<tr>
<td>R24</td>
<td>Resource-Related Research Projects</td>
<td>The proposed resource must provide a significant benefit to currently funded high priority projects in need of further coordination and support</td>
</tr>
<tr>
<td>R25</td>
<td>Education Projects</td>
<td>Supports creative and innovative research education programs that will 1) increase the public's understanding of biomedical research, or 2) encourage K-12 students to enter areas in biomedical science</td>
</tr>
</tbody>
</table>
Features of Multi-Component Grants

- Collaboration and interaction among investigators to achieve a common goal
- Support for shared resources - core resources or facilities - that provide services or resources to multiple research projects
### Program Project and Center Grants (P-series)

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<thead>
<tr>
<th>Mechanism</th>
<th>Title</th>
<th>Procedure</th>
</tr>
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<tbody>
<tr>
<td>P01</td>
<td>Research Program Project Grant</td>
<td>Supports integrated, multiproject research programs that have a well-defined, central research focus or objective.</td>
</tr>
<tr>
<td>P30</td>
<td>Center Core Grant</td>
<td>Supports shared resources and facilities for a multidisciplinary research team or a group of investigators focusing on a common research topic.</td>
</tr>
<tr>
<td>P50</td>
<td>Specialized Center</td>
<td>Supports any aspects of R&amp;D from basic research to clinical research and may involve ancillary support activities such as patient care. May also serve as regional or national resources for special research.</td>
</tr>
</tbody>
</table>
Cooperative Agreements (U-series)

• Used when there is a demonstrated need for assistance and substantial involvement of NIH scientific/programmatic staff in the performance of an activity

• Project Director/Principal Investigator (PD/PI) retains the primary responsibility and dominant role for planning, directing, and executing the proposed project
# Common Cooperative Agreements (U-series)

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>Title</th>
<th>Comparable to…</th>
</tr>
</thead>
<tbody>
<tr>
<td>U01</td>
<td>Research Project</td>
<td>R01</td>
</tr>
<tr>
<td>U13</td>
<td>Conference Grant</td>
<td>R13</td>
</tr>
<tr>
<td>U19</td>
<td>Research Program</td>
<td>P01</td>
</tr>
<tr>
<td>U54</td>
<td>Specialized Center</td>
<td>P50</td>
</tr>
</tbody>
</table>
Fellowship Awards (F-series)

• Awarded to predoctoral or postdoctoral fellows who are working with mentors
• Training can be at domestic or foreign institutions
• Opportunities in basic and/or clinical research
• Open to any scientific area within the NIH scientific mission
• PhDs and MD/PhDs receive most of the awards
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<tr>
<td>F30</td>
<td>Individual Predoctoral NRSA for M.D./Ph.D. Fellowships (ADAMHA)</td>
<td>Individual fellowships for predoctoral training which leads to the combined M.D./Ph.D. degrees.</td>
</tr>
<tr>
<td>F31</td>
<td>Predoctoral Individual National Research Service Award</td>
<td>Provides predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).</td>
</tr>
<tr>
<td>F32</td>
<td>Postdoctoral Individual National Research Service Award</td>
<td>Provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.</td>
</tr>
</tbody>
</table>
Career Development Awards (K-series)

• More senior award than a research or clinical fellowship
• Opportunities for mentored and independent awards
• MDs: Support development to become independent investigators (K01, K08, K23) or to support mentoring of clinical researchers (K24)
• PhDs: Support the transition of postdocs to independent faculty positions (K22 and K99/R00); also support specialized training through mentored awards (K01 and K25)

• [http://grants.nih.gov/training/careerdevelopmentawards.htm](http://grants.nih.gov/training/careerdevelopmentawards.htm)
Institutional Training Grants (T-series)

• NRSA - National Research Service Award
• Training centered around a theme and includes participation of a large number of mentors (basic or clinical)
• Support pre-doctoral students and/or postdoctoral fellows
• Trainees work in a mentor’s lab
• Awards go the best training programs in the Nation
## Institutional Training Grants (T-series)

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<th>Procedure</th>
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<tbody>
<tr>
<td>T32</td>
<td>Institutional National Research Service Award</td>
<td>Enables institutions to make National Research Service Awards to individuals selected by them for predoctoral and postdoctoral research training in specified shortage areas.</td>
</tr>
<tr>
<td>T35</td>
<td>NRSA Short-Term Research Training</td>
<td>Provides individuals with research training during off-quarters or summer periods to encourage research careers and/or research in areas of national need.</td>
</tr>
</tbody>
</table>
Funding Across the Career Spectrum

F31 – Predoctoral Fellowship to Promote Diversity in Health-Related Research
F32 – Postdoctoral NRSA
K01 – Research Scientist Development Award
K02 – Independent Scientist Award
K08 – Clinical Investigator Award
K22 – Research Scholar Development Award
K23 – Mentored Patient-Oriented Research Award
K24 – Midcareer Investigator Award in Patient-Oriented Research
K99/R00 – Pathway to Independence Award
P series – Program Project and Center grants
R01 – Research Project
R03 – Small Research Award
R15 – AREA grant
R21 – Exploratory/Developmental Research Grant
R37 – MERIT Award
T32 – Institutional Research Training Grant
U series – Cooperative Agreements
INTERACTING WITH THE NIH
Successful grants require close coordination between all members of the grantee team.

- Grants are awarded to institutions - represented by AORs.
- PIs manage and perform the science.
- Research Administrators support business aspects.
A team of experts will guide your application from conception through award

- **POs** provide scientific and technical advice about your research and application
- **SROs** manage the scientific and technical review of applications
- **GMOs** manage the administrative and fiscal aspects of an award
Electronic Interaction Points

NIH Grants Web site

NIH Guide

Grants.gov

eRA Commons

Prepare to Apply

Find Opportunities

Download App Package

Prepare Application

Submit Application

Check Submission Status

Check Assembled Application

Check Review Assignment

Check Review Outcome

Submit Pre-Award Information

Prepare/Submit Post-Award Reports

Closeout Grants

NIH Guide

NIH Grants Web site

Grants.gov

eRA Commons
**Two Systems Working Together**

**Grants.gov**
- The Federal government
- Used by 26 Federal agencies
- Interaction with organization

**eRA Commons**
- electronic Research Administration
- The NIH
- Interaction with organization and PI

**IMPORTANT:**
Each system has its own registration and validations requirements
Receipt and Referral of Applications

Application submitted through grants.gov

Center for Scientific Review (CSR) Referral Office assigns the application...

to an NIH Institute (IC)

a unique identifier (application number)

to Integrated Review Group (IRG) and then a study section (SRG)
OVERVIEW OF THE PEER REVIEW PROCESS
Review System for Grants

Scientific Review Group (SRG)
- Independent outside review
- Evaluates scientific and technical merit
- Recommend length and level of funding

Output: Impact Score and Summary Statement

Advisory Council
- Assess quality of SRG process
- Offer recommendations to Institute Staff
- Evaluate program priorities and relevance
- Advise on policy

Output: Funding Recommendations

1st level

Institute Director
- Makes final decision based on Council input, programmatic priorities
- Must also pass administrative review

Output: Funding decision

3 - 7 months

2nd level

1 - 3 months
Scientific Review Groups

- **Study Sections**
  - Reviewers appointed to multi-year terms
  - Subject-matter specific
  - Most R01, R03, R21, and R15 grant applications

- **Special Emphasis Panels (SEPs)**
  - Formed on ad hoc basis
  - Conflicted applications from study section
  - Special solicitations (RFAs, PARs)
  - Certain grant mechanisms (Fellowships, SBIRs, AREA, etc.)
 NICHT Scoring System

• Numerical scores
  – 9-point scale
  – 1 (exceptional) to 9 (poor)
  – Whole numbers only (no decimals)

• Overall Impact scores
  – Voted by all eligible (w/o COI) reviewers
  – Voted by private ballot at the meeting

• Scored Review Criteria
  – Given by assigned reviewers as part of their critiques
  – Generally not discussed at the meeting
<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Evaluation of Grant Applications

- Overall Impact
- Scored Review Criteria
- Additional Review Criteria
- Additional Review Considerations
Evaluation of Grant Applications

• Overall Impact
  – “Final Score” and overall evaluation
  – Assessed in consideration of Scored Review Criteria and Additional Review Criteria

• Scored Review Criteria
• Additional Review Criteria
• Additional Review Considerations
Evaluation of Grant Applications

- Overall Impact
- Scored Review Criteria
  - Significance
  - Investigator(s)
  - Innovation
  - Approach
  - Environment
- Additional Review Criteria
- Additional Review Considerations
Evaluation of Grant Applications

• Overall Impact
• Scored Review Criteria

• Additional Review Criteria
  – Protections for Human Subjects
  – Inclusion of Women, Minorities, and Children
  – Vertebrate Animals
  – Biohazards
  – Resubmission, Renewal, and Revision Applications

• Additional Review Considerations
Evaluation of Grant Applications

- Overall Impact
- Scored Review Criteria
- Additional Review Criteria
- Additional Review Considerations
  - Applications from Foreign Organizations
  - Select Agent Research
  - Resource Sharing Plans
  - Budget and Period of Support
Evaluation of Grant Applications

- Overall Impact
- Scored Review Criteria
  - Contributes to Overall Impact Score
- Additional Review Criteria
  - Contributes to Overall Impact Score
- Additional Review Considerations
  - Recorded as Administrative Notes
Summary Statement

- Impact Score (Percentile Ranking)
- Resumé and Summary of Discussion (if discussed)
- Reviewer critiques – essentially unedited
- Administrative Notes
- Budget Recommendations
- Meeting roster
Streamlining

- Allows discussion of the most meritorious applications
- Non-competitive applications are not discussed
  - Streamlining candidates are based on preliminary impact scores.
  - Requires concurrence of the entire review panel
- Summary statement:
  - “Score” designated Not Discussed (ND)
  - No “Resume and Summary of Discussion”
  - Contains reviewer critiques and criterion scores
QUESTIONS?