Funding and Grantsmanship for Junior Investigators

Cold Spring Harbor Laboratory
“Scientific Writing Retreat”

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Course: “Funding and Grantsmanship for Research and Career Development Activities”
http://grantscourse.columbia.edu/
Topics to be Discussed

- Funding Agencies
  - Government
    - Federal: National Institutes of Health, Dept. of Defense
  - Non-Government: Voluntary Health Organizations, Professional Societies, Foundations, Industry

- Types of Awards
  - Grants, Contracts, Cooperative agreements,
    - e.g. Research grants, fellowships, career development awards

- Funding Announcements

- Grant Review Processes: National Institutes of Health

- Identifying Funding

- Approaches for Competitive Applications

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- **Identifying Funding**

- **Approaches for Competitive Applications**
U.S. Dept. of Health and Human Services

Food and Drug Administration

Centers for Medicare & Medicaid Services

Centers for Disease Control and Prevention

Substance Abuse and Mental Health Services Administration

National Institutes of Health

Health Resources and Services Administration

Agency for Healthcare Research And Quality

Agency for Toxic Substances and Disease Registry

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

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Agency for Healthcare Research and Quality (AHRQ)

- Supports research designed to improve the quality, safety, efficiency, and effectiveness of health care.
  - Comparative Effectiveness
  - Prevention and Care Management
  - Value
  - Health Information Technology
  - Patient Safety
  - Innovations/Emerging Issues

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Food and Drug Administration (FDA)

- Supports food safety, orphan drug development, and clinical training programs

Centers for Disease Control and Prevention (CDC)

- Supports programs to promote health and quality of life by preventing and controlling disease, injury, and disability
Health Resources and Services Administration (HRSA)

**Mission:**

“To improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.”

- Bureau of Health Workforce
- Bureau of Primary Health Care
- Healthcare Systems Bureau
- HIV/AIDS Bureau
- Maternal and Child Health Bureau

Substance Abuse and Mental Health Services Administration (SAMSHA)

- Supports programs providing substance abuse and mental health services.

Centers for Medicare & Medicaid Services (CMS)

- Supports programs related to the costs, access, quality, delivery, or financing of health services.
A Typical NIH I/C/D

National Advisory Council

Office of the I/C/D Director

Board of Scientific Counselors

Extramural

Scientific Programs

Grants

Contracts

Intramural

Laboratory Studies

Clinical Studies

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

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NIH FY14 Budget - $30,143M

Grants and Contracts: $24,358
Intramural: $3,396
Other: $2,389

$ in millions

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NIH EXTRAMURAL & INTRAMURAL FUNDING: FY 2014 ENACTED

Spending at NIH
$5,785,000,000
(19%)

Spending Outside NIH
$24,358,000,000
(81%)
## Summary of Trends in NIH Funding
**FY1995-FY2013**

<table>
<thead>
<tr>
<th></th>
<th>FY1995</th>
<th>FY2003</th>
<th>FY2013</th>
<th>% Change since 1995</th>
<th>% Change since 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NIH Budget (in millions)</strong></td>
<td>$11,300</td>
<td>$27,067</td>
<td>$29,151</td>
<td>158.0%</td>
<td>7.7%</td>
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<tr>
<td><strong>NIH Budget (constant 1995 $ millions)</strong></td>
<td>$11,300</td>
<td>$21,003</td>
<td>$16,309</td>
<td>44.3%</td>
<td>-22.4%</td>
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<tr>
<td><strong>R01 Equivalent Funding ($ millions)</strong></td>
<td>$4,718</td>
<td>$10,102</td>
<td>$10,175</td>
<td>115.7%</td>
<td>0.7%</td>
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<tr>
<td><strong>Total # R01 Equivalent Grants</strong></td>
<td>21,680</td>
<td>29,626</td>
<td>25,069</td>
<td>15.6%</td>
<td>-15.4%</td>
</tr>
<tr>
<td><strong>R01 Equivalent Applications</strong></td>
<td>22,542</td>
<td>24,634</td>
<td>28,044</td>
<td>24.4%</td>
<td>13.8%</td>
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<tr>
<td><strong># of R01 Equivalent Awards</strong></td>
<td>5,849</td>
<td>7,430</td>
<td>4,902</td>
<td>-16.2%</td>
<td>-34.0%</td>
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<tr>
<td><strong>R01 Equivalent Success Rates</strong></td>
<td>25.9%</td>
<td>30.2%</td>
<td>17.5%</td>
<td>-32.4%</td>
<td>-42.0%</td>
</tr>
</tbody>
</table>
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- Grant Review Processes: National Institutes of Health
- Identifying Funding
- Approaches for Competitive Applications
## NIH Extramural Program

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant</td>
<td>Patron (Assistance, encouragement)</td>
</tr>
<tr>
<td>Cooperative</td>
<td>Partner (Assistance but substantial</td>
</tr>
<tr>
<td>Agreement</td>
<td>program involvement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser (Procurement)</td>
</tr>
</tbody>
</table>
Not All Funding Opportunities Are the Same

- **Different mission statements**
  - Career development (K’s)/ Scholar awards
  - Research project (R’s)

- **Different funding**
  - Stipend/Salary
  - Pilot awards
  - Comprehensive research costs

- **Different time frames**
  - Not renewable: 5 years (K’s), 3 years (F’s), 2 years (T’s)
  - Renewable: 4years-5years (R01) each competitive period

Types of Awards

- Individual fellowships
- Training grants
  - Career transition awards
  - Career development awards
- Research grants
- Program Projects
- Loan Repayment Program
- Administrative supplements
- Cooperative agreements
- Institutional Clinical & Translational Science Award (CTSA)
- Subcontracts
- Contracts
Not All Funding Opportunities Are the Same

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Timeline of Funding for Junior Investigators

Graduate School

- Individual Fellowship Training Grant
- Mentor’s Research Grant

Post-doctoral Years

- Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot

Instructor/Assistant Professor

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Timeline of Funding for Junior Investigators

- Medical School
- Internship/Residency
- Fellowship – Research Years
- Instructor/Assistant Professor

Short term Training
Research Support
Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot

Year-long Enhancement Programs
MD/PhD Fellowship or Institutional T32

Fellowship Programs

Predoctoral Individual Fellowship (F31)

Dual-Degree Predoctoral Individual Fellowship (F30)

- Supports specific individual in research degree program (e.g., PhD, MD/PhD candidate)
- Stipend, health fees, tuition, travel

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Postdoctoral Individual Fellowship (F32)

- Supports specific individual
- Stipend, health fees, tuition, travel
- NIH: F32
- Review criteria:
  - Individual fellow
  - Mentor
  - Research project
  - Research environment
Post-doc Fellowships (F32s)
Applications, awards, and success rates

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Training Programs

Institutional Training Award (T32)

- Pre-docs/Post-docs (e.g. PhD, MD) selected by institution
- Research training in specific area
- Defined number of slots
- Stipend, health fees, tuition, travel

Short-Term Research Training (T35)

- Short term (e.g. summer) support
- e.g. Medical students in summer after 1\textsuperscript{st} year

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Training Grants and Fellowships: Pre- and Post-Doctoral Positions

[Graph showing the number of positions from 1998 to 2014 for Pre-Doctoral Training, Post-Doctoral Training, Pre-Doctoral Fellowship, and Post-Doctoral Fellowship.]
Types of Awards

- Individual fellowships
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- **Career transition awards**
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Career Transition Awards
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- Research Support
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- Year-long Enhancement Programs
  - MD/PhD Fellowship or Institutional T32

- Career Transition Awards

Pathway to Independence Award

- Career Transition Award *(K99/R00)*
- No citizenship requirement
- Applicants must:
  - Have earned a clinical or research doctorate
  - Have no more than 4 years of research experience since completing the requirements of the doctoral degree
  - Have not been the principal investigator of an NIH research grant (e.g., R01, R03, R21), career development award (e.g., K01, K07, K08, K23, K25), other peer-reviewed NIH or non-NIH research grant over $100,000 direct costs per year, or have been a project leader on a sub-project of a program project (P01) or a center (P50) grant.

1-2 years as a mentored K award for “post-docs”

- Funding level is Institute-specific
  - NHLBI: $75K for salary plus fringe benefits, $25K for research support (+ 8% I.C.)
- 75% effort

3 years as a Research award for independent investigators

- Total/year:=$249,000 (salary and research expenses)
  - D.C. + institution’s I.C. rate
- Must have an independent research position
Career Transition Awards

- **BWF: Career Awards for Medical Scientists**
  - To support physician-scientists during the last years of a mentored postdoctoral/fellowship position and the beginning years of an independent faculty position.
  - Candidates must hold an M.D., D.D.S., or D.V.M. degree.
  - 75% effort to research-related activities
  - **Funding:** $700,000 over five years
    - Postdoctoral/Fellowship Portion: Years 1 and 2
      - Annual Total: $95,000
    - Faculty Portion of the Award: Years 3-5
      - Annual Total: $170,000

Career Transition Awards

- American Heart Association (National) Fellow-to-Faculty Transition Award
  - Provides funding for the “period of career development that spans the completion of research training through the early years of the first faculty/staff position”
  - Training stage: Maximum of $65,000 per year
  - Faculty stage: Maximum of $132,000 per year
  - Award Duration: 5 years
Types of Awards

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- Contracts
Timeline of Funding for Junior Investigators

- Short term Training
- Research Support
- Fellowship – Research Years
- Instructor/Assistant Professor

- Medical School
- Internship/Residency
- Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot
- Institutional K12 Career Development Slot

- Year-long Enhancement Programs
- MD/PhD Fellowship or Institutional T32
- Career Transition Awards
- Individual Mentored K Career Development Award

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Research Career Programs (K)

- Provides predominantly salary support
- Minimum requirements for the amount of effort that must be devoted to research and career development (e.g. 75%, some exceptions to 50%)
- Up to 5 years
- Specified salary levels
  - e.g. NIDDK: $90K, NCI: $100K
- US citizen/permanent resident.
- Can reduce effort to 50% in last 2 years if PI of NIH research grant

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Mentored Clinical Scientist Development Award (K08)

- Support to develop outstanding independent clinician research scientists
- Basic and translational science

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Mentored Patient-Oriented Research Career Development Award (K23)

- **Patient-oriented research:** Research conducted with human subjects (or on material of human origin) for which an investigator directly interacts with human subjects.

- **Research areas:** (1) Mechanisms of human disease, (2) Therapeutic interventions, (3) Clinical trials, and (4) Development of new technologies.
Mentored Research Scientist Development Award (K01)

Not all NIH Institutes participate in program
Participating Institutes may use for different purposes.

- Train in a new field
- Specific research areas
- Hiatus in research career
- Increase research workforce diversity
Mentored Research Scientist Development Awards (K01)

- **Many Institutes**: Big Data Science

- **NIMH**
  - Broad spectrum of basic and translational research, including basic neuroscience, human genetics, adult and developmental translational research, services and intervention research, and AIDS-related research

- **NCI, NHLBI, NINDS**: Underrepresented faculty

- **NIAID**:
  - (a) Epidemiology
  - (b) Modeling Techniques
  - (c) Outcomes Research

Mentored Research Scientist Development Awards (K01)

- **NIDDK:**
  - Advanced postdoctoral and/or newly independent research scientists

- **NHLBI:**
  - (a) Epidemiology
  - (b) Biostatistics
  - (c) Comparative effectiveness

- **NHGRI**
  - (a) Genomics, proteomics, population genomics
  - (b) Ethical, legal and social issues (ELSI)

- **NIA:** Aging and Health Disparities Research

Mentored Research Scientist Development Awards (K01)

- **NINR**
  - (a) Symptom management
  - (b) Pulmonary, critical care, trauma
  - (c) Reproductive health
  - (d) End-of-life and palliative care

- **NICHD:**
  - (a) Medical Rehabilitation Research
  - (b) Child Abuse and Neglect
  - (c) Population Research

- **FIC:**
  - International Research Scientist Development Award (IRSDA)
Mentored Quantitative Research Career Development Award (K25)

- Investigators with quantitative scientific and engineering backgrounds outside of biology or medicine
- Focus their research on behavioral and/or biomedical research (basic or clinical)
Cancer Prevention, Control, Behavioral, and Population Sciences Career Development Award (K07)

- NCI program
- Support individuals with health professional or science doctoral degrees who are not fully established investigators
Research Career Development Awards

![Bar chart showing the number of awards by fiscal year and type]

- **K01**
- **K08**
- **K23**
- **K25**
- **K99**

Number of Awards

Fiscal Year

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Activity Code</th>
<th>NIH Institute / Center</th>
<th>Number of Applications Reviewed</th>
<th>Number of Applications Awarded</th>
<th>Success Rate$^2$</th>
<th>Total Funding$^3$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>K23</td>
<td>NCCAM</td>
<td>6</td>
<td>2</td>
<td>33%</td>
<td>$261,783</td>
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<tr>
<td>2014</td>
<td>K23</td>
<td>NCI</td>
<td>28</td>
<td>5</td>
<td>18%</td>
<td>$818,759</td>
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<tr>
<td>2014</td>
<td>K23</td>
<td>NEI</td>
<td>3</td>
<td>3</td>
<td>100%</td>
<td>$581,417</td>
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<tr>
<td>2014</td>
<td>K23</td>
<td>NHLBI</td>
<td>77</td>
<td>29</td>
<td>38%</td>
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<tr>
<td>2014</td>
<td>K23</td>
<td>NIA</td>
<td>42</td>
<td>17</td>
<td>41%</td>
<td>$2,679,257</td>
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<tr>
<td>2014</td>
<td>K23</td>
<td>NIAAA</td>
<td>9</td>
<td>5</td>
<td>56%</td>
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<td>2014</td>
<td>K23</td>
<td>NIAID</td>
<td>36</td>
<td>19</td>
<td>53%</td>
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<td>2014</td>
<td>K23</td>
<td>NIAMS</td>
<td>10</td>
<td>4</td>
<td>40%</td>
<td>$524,639</td>
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<td>2014</td>
<td>K23</td>
<td>NIBIB</td>
<td>2</td>
<td>1</td>
<td>50%</td>
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<tr>
<td>2014</td>
<td>K23</td>
<td>NICHD</td>
<td>58</td>
<td>19</td>
<td>33%</td>
<td>$2,509,294</td>
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<td>2014</td>
<td>K23</td>
<td>NIDA</td>
<td>20</td>
<td>4</td>
<td>20%</td>
<td>$688,051</td>
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<td>K23</td>
<td>NIDCD</td>
<td>14</td>
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<td>2014</td>
<td>K23</td>
<td>NIDCR</td>
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<td>K23</td>
<td>NIDDK</td>
<td>64</td>
<td>21</td>
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<td>2014</td>
<td>K23</td>
<td>NIEHS</td>
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<td>K23</td>
<td>NIGMS</td>
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<td>5</td>
<td>33%</td>
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<td>2014</td>
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<td>NIMH</td>
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<td>39</td>
<td>51%</td>
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<td>2014</td>
<td>K23</td>
<td>NINDS</td>
<td>41</td>
<td>12</td>
<td>29%</td>
<td>$2,230,479</td>
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<tr>
<td>2014</td>
<td>K23</td>
<td>NIRN</td>
<td>15</td>
<td>7</td>
<td>47%</td>
<td>$916,208</td>
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<td>2014</td>
<td>K23</td>
<td>Activity Total</td>
<td>524</td>
<td>201</td>
<td>38%</td>
<td>$32,567,685</td>
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</tbody>
</table>
AHRQ K08: Mentored Clinical Scientist Research Career Development Award Health Services Research

- Safety and Quality
- Effectiveness
- Efficiency

AHRQ K08: Patient-Centered Outcomes Research (PCOR) Mentored Clinical Investigator Award

AHRQ K01: Patient-Centered Outcomes Research (PCOR) Mentored Research Scientist Development Award (K01)
- **CDC K01:** Mentored Public Health Research Scientist Development Award
  - Basic, behavioral, and applied sciences
  - Health promotion
  - Disease prevention
  - Injury and disability prevention
  - Health protection from infectious, environmental and terrorist health threats

Mentored Clinical Scientist Development Program Award (K12)

- Support to an institution for career development experiences for clinicians leading to research independence.

- Institutions recruit and select candidates into their programs.

- Candidates must meet the same criteria as for the individual mentored clinical scientist development award.

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Mentored Clinical Scientist Development Program Award (K12)

- **Multi-Institute:** Women’s Health

- **Institute specific**
  - NCI: Clinical oncology
  - NEI: Clinical vision scientists
  - NIDDK: Pediatric diabetes research
  - NICHD:
    - Pediatric scientist/Child health
    - Rehabilitation research
    - Reproductive health

Mentored Clinical Scientist Development Program Award (K12)

- **Institute specific**
  - NIDCR: Temporomandibular joint disorders and orofacial pain
  - NHLBI
    - Clinical hematology/Transfusion medicine
    - Emergency Medicine
  - NIDA: Drug abuse and addiction
  - NINDS: Neurological sciences, Neuro Surgery

- **CTSA - Clinical and Translational Scientist Award (KL2)**
Career Development (K) Support to Research Grant (R01)

K01/K08/K23 → R01

K12 K23 → R01

K12 K23 → R01

K01/K08/K23 → R01

K12 → R01
Types of Awards

- Individual fellowships
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R01 Research Award

Independent Investigator

Funds research project
- Salaries of PI and other research personnel
- Supplies, reagents, etc
- Animal costs
- Patient care costs
- Core facilities
- Page charges for publications

Multi-Year (4yrs – 5yrs)
Renewable (e.g. original grant + 2 renewals = 15yrs)
R01 Research Grant

- Supports a discrete, specified project (Specific Aims)
- “Comprehensive” funding
  - Salaries of PI and other research personnel (e.g. post-docs), Supplies, Animal costs, Core facilities, Patient care (research-related), Travel to conferences, Subcontracts to collaborating institutions
- Modular budgets up to $250,000/year
- Multi-year (4yrs – 5yrs)
- Renewable (e.g. original grant + 2 renewals = 15 years)
- Flexibility
- Most NIH-supported investigator-initiated research is through this funding mechanism

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Small Research Grants (R03)

- Supports, e.g.:
  - Pilot or feasibility studies;
  - Collection of preliminary data
  - Secondary analysis of existing data
  - Small, self-contained research projects
  - Development of new research technology

- 2 years of funding
- Budget: Direct costs up to $50,000/yr
- Not renewable
- Some Institutes only accept applications in response to their specific funding opportunity announcements

Exploratory/ Developmental Grants (R21)

- Encourages new, exploratory and developmental research projects by providing support for the early stages of project development. Sometimes used for pilot and feasibility studies.

- 2 years of funding

- Budget: $275,000 (D.C.) over two years

- Investigator-initiated R21 studies not funded by all Institutes
Research Project Grants: Applications, Awards, and Success Rates
Success Rate: Number of awards made divided by the sum of the applications reviewed (in a specific fiscal year). Revisions submitted in the same fiscal year are “combined” and counted as one application.

- Metric represents success of a specific project in receiving funding, rather than of the success of an individual application.
**Award Rate:** Number of awards (in a specific fiscal year) divided by the absolute number of applications (resubmissions (A1’s) are not combined)

- Increases the denominator (applications) for the same number of awards (in the numerator)
- Award Rates are lower than Success Rates
- Similar to Institute Paylines which are based on all the applications considered for funding
**Funding Rate:** Number of individual investigators applying for and receiving funding (in a given specific year).

- Person-based rather than application-based metric
  - Counts individual applicants as funded whether they receive one or more than one award (in a given fiscal year). The numerator is the number of applicants receiving any funding and the denominator is the number of applicants.

- Funding rates are higher than either Award or Success Rates
Funding, Award and Success Rates* for R01 Equivalents
Fiscal Years 1990-2013

*Excludes awards made with American Recovery and Reinvestment Act (ARRA) funds, and ARRA-solicited applications.

Rate (%)

Funding Rate
Success Rate
Award Rate

A3+ revisions phased out
A2 revisions phased out

Fiscal Year

Program Projects and Centers

Program Projects (P01)

- Specific major objective or a basic theme
- Usually 3 or more Research Projects (“R01-like”) and Cores (administrative and technical)

Center Core Grants (P30)

- Shared resources and facilities for a number of investigators who focus on a common research problem
Types of Awards

- Individual fellowships
- Training grants
- Career transition awards
- Career development awards
- Research grants
- Program Projects
- Loan Repayment Program
- Administrative supplements
- Cooperative agreements
- Institutional Clinical & Translational Science Award (CTSA)
- Subcontracts
- Contracts

Administrative Supplements

- To promote **reentry** into biomedical and behavioral research careers
  - Individuals who have interrupted their research careers to care for children or parents or to attend to other family responsibilities
- To promote **diversity** in health-related research
  - Individuals from underrepresented racial and ethnic groups
  - Individuals with disabilities
  - Individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research

Administrative Supplements

- NIH-wide program
- Supplemental funding to existing research grants-most R’s, P’s and U awards (may be Institute dependent)
- Awarded administratively, i.e. not following a peer-review competitive process
- Funding for named individuals who meet specified criteria
Instrumentation

National Institutes of Health

- **Shared Instrumentation Grant Program (S10)**
  - Major User group of $\geq 3$ PI’s of active NIH research grants
  - NIH-funded projects: Minimum of 75% of the instrument time
  - Major User Group: Minimum of 35% of the total usage time
  - “Purchase or upgrade a single item of expensive, specialized, commercially available instrumentation or an integrated system”
  - $100,000 - $600,000

Instrumentation

National Institutes of Health

- **High-End Instrumentation Grant Program (S10)**
  - Major user group of \( \geq 3 \) PI’s of active NIH research grants
  - NIH-funded projects: Minimum of 75% of the instrument time
  - Single piece of equipment
  - \$750,000 - \$2,000,000

Instrumentation

National Science Foundation -
Major Research Instrumentation Program (MRI)

- “Acquisition (Track 1) or Development (Track 2) of a single research instrument for shared inter- and/or intra-organizational use”
- $100,000 - $4 million
- <$100,000 if in the areas of social, behavioral or economic sciences
- FY2015: $75M available, up to $30M to support applications $1M - $4M
- Up to 3 applications allowed per institution
  - If 3 applications are submitted, at least one must be for instrument development
- Cost-sharing required

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Instrumentation

National Science Foundation - Major Research Instrumentation Program (MRI)

- **Will not support:**
  - Research with disease-related goals
  - Education projects/courses
  - “General purpose ancillary laboratory equipment or multiple instruments that serve to outfit a laboratory or research environment”

- **Will support:**
  - “Bioengineering research, with diagnosis- or treatment-related goals that applies engineering principles to problems in biology and medicine, while also advancing engineering knowledge”
  - “Instrumentation for research in bioinformatics and biocomputing, or for bioengineering research to aid persons with disabilities”
Instrumentation

Department of Defense (DoD) - Defense University Research Instrumentation Program (DURIP)

- Army Research Office, Office of Naval Research, Air Force Office
- "augment current or develop new research capabilities to support research in the technical areas of interest to the DoD"
- Usually, $50,000 - $1,500,000
- FY 2014: $40 million, 149 awards, $50,000 - $1,102,000, averaging $267,824
- FY 2015: $46 million

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Types of Awards

- Individual fellowships
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NIH CTSA Awards: A Home for Clinical and Translational Science

Source: Zerhouni (NIH) [9/06]

Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
Types of Awards

- Individual fellowships
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- Career transition awards
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- Administrative supplements
- Cooperative agreements
- Institutional Clinical & Translational Science Award (CTSA)
- Subcontracts
- **Contracts**
Contracts

- Awards for specific inquiry directed towards particular areas of research and development
- Funding sponsor wishes to utilize advances in knowledge and technology to search for solutions to specific requirements
- Contract performance is monitored closely to ensure accomplishment of contract goals
Review Criteria

- Differs from that of grants
- Offerors respond to a ‘Request for Proposal’ (RFP) or a ‘Broad Agency Announcement’ (BAA)
- Proposals evaluated against criteria specified in RFP
- Recommendations of peer reviewers, and the results of separate NIH staff reviews, provide the basis for discussions with offerors in the competitive range
Offeror is requested to submit **Best And Final Offer (BAFO)**

Final selection of offeror is made on the basis of the BAFO, judged most advantageous to the government, according to the RFP evaluation criteria.
Special Instructions

- Investigator-initiated clinical trials
- Investigator-initiated epidemiology studies
- Direct Costs > $500,000 per year
- Exceptions to the standard Feb, June, and Oct deadlines
Topics to be Discussed

- Funding Agencies
  - Government
    - Federal: National Institutes of Health, Dept. of Defense
    - Non-Government: Voluntary Health Organizations, Professional Societies, Foundations, Industry
  - Types of Awards
    - Grants, Contracts, Cooperative agreements,
      - e.g. Research grants, fellowships, career development awards

- Funding Announcements
- Grant Review Processes: National Institutes of Health
- Identifying Funding
- Approaches for Competitive Applications

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Funding Announcements

- RFA: Targeted research
- Institute-Specific PA: Research in a stated area of scientific interest
- Parent PA: Investigator-initiated research in any area

narrow

broad

Funding Opportunity Announcement (FOA)

- **FOA Mechanism**
  - Published in the [NIH Guide for Grants and Contracts](http://grants.nih.gov/grants/guide/) (RFAs, PAs) and [Grants.gov](http://grants.gov)
  - [Grants.gov](http://grants.nih.gov/grants/guide/) notice includes application information and forms
Program Announcement (PA)

- No set-aside of funds
- Describes existence of an NIH extramural research program
- May describe new or expanded interest in a particular extramural program
- May be a reminder of a continuing interest in an extramural program
- Applications reviewed at Center for Scientific Review (CSR) not the Institute
- Published in the *NIH Guide for Grants and Contracts* and Grants.gov

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Parent Announcement

- Funding Opportunity Announcement for unsolicited investigator-initiated grant applications (e.g. R03, R21, R01)
  - Allows electronic submission of grant applications that are not in response to specific Program Announcement or RFA.
  - Published in the *NIH Guide for Grants and Contracts* and Grants.gov
  - Grants.gov notice includes application information and forms

Program Announcement (PAR)

- PAR Mechanism
  - Grant applications are reviewed at the Institute and not the Center for Scientific Review (CSR)
  - Usually some applications are funded
Program Announcement (PAR): Example

- PAR-15-343:

  National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) - Small Grant Program for K01/K08/K23 Recipients (R03)

Program Announcement (PAS)

- **PAS Mechanism**
  - Program Announcement with dedicated funding
    - “Set aside funds”
  - Funds applications that receive a score below the payline
  - Research area coincides with programmatic interests of Institute
  - Funds allocated throughout duration of the PAS

Request For Applications (RFA)

- Formal announcement describing an Institute initiative in a well-defined scientific area
- Invitation to the field to submit an application for a grant or a cooperative agreement.
- May be a one-time competition
- Set-aside of funds for a certain number of awards
- Published in the *NIH Guide for Grants and Contracts* and Grants.gov

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Request For Proposals (RFP)

- Formal announcement describing an institute initiative in a well-defined scientific area
- Invitation to the field to submit contract applications for a one-time competition
- Set-aside of funds for a certain number of awards
- Published in FedBizOpps
Broad Agency Announcement (BAA)

- Describes research areas of interest to government
- Describes government’s general research and technical objectives
- Requests contract proposals that use creative and innovative approaches
- Similar to RFPs, except:
  - The applicant, not the government, develops the ‘Statement of Work’
  - The applicant, not the government, develops the work requirements and performance specifications

Topics to be Discussed

- Funding Agencies
  - Government
    - Federal: National Institutes of Health, Dept. of Defense
    - Non-Government: Voluntary Health Organizations, Professional Societies, Foundations, Industry
  - Types of Awards
    - Grants, Contracts, Cooperative agreements,
      - e.g. Research grants, fellowships, career development awards
- Funding Announcements
- **Grant Review Processes: National Institutes of Health**
- Identifying Funding
- Approaches for Competitive Applications

# Application Due Dates

<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</th>
<th>Application Instructions</th>
<th>Cycle I Due Date</th>
<th>Cycle II Due Date</th>
<th>Cycle III Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01 new</td>
<td>Research Grants</td>
<td>SF424 (R&amp;R)</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
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<tr>
<td>U01 new</td>
<td>Research Grants - Cooperative Agreements</td>
<td>SF424 (R&amp;R)</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
</tr>
<tr>
<td>K series new</td>
<td>Research Career Development</td>
<td>SF424 (R&amp;R)</td>
<td>February 12</td>
<td>June 12</td>
<td>October 12</td>
</tr>
<tr>
<td>R03, R21, R33, R21/R33, R34, R36 new</td>
<td>Other Research Grants</td>
<td>SF424 (R&amp;R)</td>
<td>February 16</td>
<td>June 16</td>
<td>October 16</td>
</tr>
<tr>
<td>F Series Fellowships new, renewal, resubmission</td>
<td>Individual National Research Service Awards (Standard) (see NRSA Training Page)</td>
<td>SF424 (R&amp;R)</td>
<td>April 8</td>
<td>August 8</td>
<td>December 8</td>
</tr>
<tr>
<td>F31 Diversity Fellowships new, renewal, resubmission</td>
<td>Individual Predoctoral Fellowships (F31) to Promote Diversity in Health-Related Research (see NRSA Training Page)</td>
<td>SF424 (R&amp;R)</td>
<td>April 13</td>
<td>August 13</td>
<td>December 13</td>
</tr>
</tbody>
</table>

**All Activity Codes Cited Above new, renewal, resubmission, revision**

**AIDS and AIDS-Related Applications**

NOTE: See Key Dates section of funding opportunity announcement to determine if AIDS dates apply.

Based on Activity Code

<table>
<thead>
<tr>
<th>May 7</th>
<th>September 7</th>
<th>January 7</th>
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http://grants.nih.gov/grants/funding/submissionschedule.htm

# Application Due Dates

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<tbody>
<tr>
<td>R01 renewal, resubmission, revision</td>
<td>Research Grants</td>
<td>SF424 (R&amp;R)</td>
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<tr>
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http://grants.nih.gov/grants/funding/submissionschedule.htm
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<tr>
<th>Review and Award Cycles</th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
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<tbody>
<tr>
<td>Scientific Merit Review</td>
<td>June - July</td>
<td>October - November</td>
<td>February - March</td>
</tr>
<tr>
<td>Advisory Council Round</td>
<td>August or October *</td>
<td>January</td>
<td>May</td>
</tr>
<tr>
<td>Earliest Project Start Date</td>
<td>September or December *</td>
<td>April</td>
<td>July</td>
</tr>
</tbody>
</table>

http://grants.nih.gov/grants/funding/submissionschedule.htm

Shortened Review Cycle for New Investigator R01 Applications to CSR

- NOT-OD-07-083 (August 9, 2007)
  - Study sections will meet on a schedule to allow consecutive cycle resubmissions
    - Already in place for applications reviewed by “AIDS and AIDS Related Research” IRG
  - New investigators will receive their summary statements no later than March 1, July 1, or November 1
  - Resubmission applications for consideration at the next cycle must be submitted by March 20, July 20, or November 20
  - New Investigators who do not choose this option, use the standard resubmission dates (July 5, November 5, March 5)

NIH: one round of applications
Dual Review System for Grant Applications

First Level of Review

Scientific Review Group
• Provides initial scientific review of grant applications
• Makes recommendations for appropriate level of support and duration of award

Second Level of Review

Institute’s Council
• Assesses quality of SRG review of grant applications
• Makes recommendations to institute staff on funding
• Evaluates program priorities and relevance
• Advises on policy

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
<table>
<thead>
<tr>
<th>CSR</th>
<th>Institutes</th>
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<tbody>
<tr>
<td>• Research Grants (R01, R03)</td>
<td>• Multi-Project Grants (P01, P50, etc)</td>
</tr>
<tr>
<td>• Fellowships (F’s)</td>
<td>• Training Grants (T’s)</td>
</tr>
<tr>
<td>• Small Business</td>
<td>• Career Development (K’s)</td>
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<tr>
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<td>• Conference Grants (R13)</td>
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<tr>
<td></td>
<td>• Research Grants in response to RFAs</td>
</tr>
<tr>
<td></td>
<td>• Contracts</td>
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</tbody>
</table>

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Application to CSR

CSR assigns to IRG, IC

Review by CSR IRG

Summary statement to applicant

Second level Council review

Fundable

NIAID negotiates award

Grant ends, renewal

Not funded

Applicant evaluated, sent feedback

Revised application

New RFAs, other*

Applicant can request IRG and IC

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
How are Assignments Made?

To Study Sections Based on:

- Specific review guidelines of each study section

To Institutes Based on:

- Overall mission of the institute
- Specific programmatic mandates and interests of the institute

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Center for Scientific Review
- Integrated Review Groups (IRG's) -

- AIDS and Related Research
- Biobehavioral and Behavioral Processes
- Biological Chemistry and Macromolecular Biophysics
- Biology of Development and Aging
- Bioengineering Sciences and Technologies
- Brain Disorders and Clinical Neuroscience
- Cell Biology

- Cardiovascular and Respiratory Sciences
- Digestive, Kidney, and Urological Sciences
- Emerging Technologies and Training Neurosciences
- Endocrinology, Metabolism, Nutrition and Reproductive Sciences
- Genes, Genomes and Genetics
- Healthcare Delivery and Methodologies

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Oncology 2 - Translational Clinical IRG

- Basic Mechanisms of Cancer Therapeutics [BMCT]
- Cancer Biomarkers [CBSS]
- Chemo/Dietary Prevention [CDP]
- Cancer Immunopathology and Immunotherapy [CII]
- Clinical Oncology [CONC]
- Drug Discovery and Molecular Pharmacology [DMP]
- Developmental Therapeutics [DT]
- Radiation Therapeutics and Biology [RTB]
- 3 Translational Clinical Small Business Special Emphasis Panels
How to Direct a Grant Application to the Appropriate Study Section

- Review research areas of Integrated Review Group
- Review research areas of Study Section
- Review roster of Study Section members
  - Do not contact reviewers
- Review Study Section’s funded grants in RePorter
- Discuss with colleagues in similar research area
- Request via Cover Letter in Application

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Oncology 2 - Translational Clinical IRG [OTC]

The Oncology 2 - Translational Clinical Integrated Review Group (OTC IRG) will consider applications involving translational and clinical investigations that encompass cancer prevention, diagnosis and treatment. Specifically, the OTC IRG reviews research grant applications related to mechanism of action of cancer therapeutic agents in both in vitro and in vivo model systems; development and evaluation of experimental therapies of neoplastic diseases; translation of basic research to clinical practice; development or optimization of treatment modalities; radiation biology and therapy; chemoprevention; and development of biomarkers/signatures for tumor detection and diagnosis.


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Radiation Therapeutics and Biology Study Section [RTB]

The Radiation Therapeutics and Biology [RTB] Study Section reviews applications on therapeutic interactions of ionizing radiation, radionuclides, electromagnetic radiation, and heat at the molecular, cellular, organ and patient levels. This ranges from basic studies of DNA damage responses and DNA repair to preclinical applications in which dose, dose rate, type of radiation, and quality of radiation are variables. RTB focuses on both clinical work and animal model.
# Membership Roster - RTB

## Radiation Therapeutics and Biology Study Section
Center For Scientific Review  
(Terms end 6/30 of the designated year)

### CHAIRPERSON

Sgouros, George, PHD (17)  
Professor  
Department of Radiology  
School of Medicine  
Johns Hopkins University  
Baltimore, MD 21231

### MEMBERS

Ahmad, Nihal, PHD (19)  
Professor  
Department of Dermatology  
University of Wisconsin - Madison  
Madison, WI 53706

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http://internet.csr.nih.gov/Rosters/MemberRoster.aspx?s=RTB

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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<tbody>
<tr>
<td>Study Section</td>
<td>Radiation Therapeutics and Biology</td>
</tr>
</tbody>
</table>
Pink Sheet: Reviewers’ Comments
Initial Review Group or Study Section

Actions

- Discussed applications:
  - Receives Impact/Priority Scores
  - Receives Scores for individual core review criteria

- Not Discussed
  - Receives Scores for individual core review criteria

- Not Recommended for Further Consideration (NRFC)

- Other: e.g. Deferred

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NIH's Review Criteria-1

- Overall Impact Score
  - Reflects project’s potential to exert a sustained, powerful influence on the research field(s) involved
    (using five core review criteria, and additional review criteria)
  - An application does not need to be strong in all categories to be judged likely to have major scientific impact.
NIH's Review Criteria-2

Core Review Criteria

A separate score is given for each for each.

(A) “Significance:

(1) Does the project address an important problem or a critical barrier to progress?

(2) If the aims of the application are achieved, how will scientific knowledge, technical capability, and/or clinical practice be advanced?

(3) What will be the effect of the successful completion of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?”

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
(B) “Investigators:

(1) Are the investigators appropriately trained and well suited to carry out this work?

(2) Do the Early Stage Investigators/New Investigators have appropriate experience and training?

(3) Have the established investigators demonstrated an ongoing record of accomplishments that has advanced their field(s)?

(4) If collaborative/multi-PI, do the investigators have complementary and integrated expertise?

Is their leadership approach, governance and, organizational structure appropriate for the project?
NIH's Review Criteria-4

(C) "Innovation:

(1) Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

(2) Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

(3) Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
NIH's Review Criteria-5

(D) “Approach:

1. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

2. Are potential problems, alternative strategies, and benchmarks for success presented?

3. If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

4. If appropriate, what are the plans for a) the protection of human subjects from research risks, and 2) the (exclusion) inclusion of minorities/both genders/children?
NIH's Review Criteria-6

(E) "Environment:

(1) Will the scientific environment contribute to the probability of success?

(2) Are the institutional support, equipment, and other physical resources available adequate for the project proposed?

(3) Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?
NIH's Review Criteria-7

Considered in determining merit, but not given scores

**Protections for Human Subjects:** Justification for involvement of human subjects and the proposed protections from research risk…

**Inclusion of Women, Minorities and Children:** Proposed plans for inclusion (or exclusion) of minorities and members of both genders, as well as the inclusion (or exclusion) of children…

NIH's Review Criteria-8

Vertebrate Animals: Five points [specified in the grant application instructions] will be assessed

Requests for Applications (RFAs) May include additional elements, relating to the specific programmatic needs of the RFA

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NIH's Review Criteria-9

Addressed, but not given scores and not considered in overall impact score

**Budget and Period of Support:** Whether budget and requested period of support are fully justified and reasonable in relation to the proposed research

**Resource Sharing Plans:** Whether Resource Sharing Plans [1) Data Sharing Plan, 2) Sharing Model Organisms, and 3) Genome Wide Association Studies (GWAS)] are reasonable.
Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

Notice Number: NOT-OD-16-011

These updates focus on four areas deemed important for enhancing rigor and transparency:

1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications

Notice Number: NOT-OD-16-012

These updates focus on four areas deemed important for enhancing rigor and transparency:

1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.

https://grants.nih.gov/grants/peer/critiques/k.htm
NIH’s Review of Research Grants

- Guidelines for Reviewers - R01 Research Grants

- Fill-able Templates

- Review Criteria and Considerations
# NIH's Evaluation System

9-point rating scale (1=exceptional; 9=poor)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
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<td><strong>High Impact</strong></td>
<td>1</td>
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<td>3</td>
<td>Excellent</td>
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<td><strong>Moderate Impact</strong></td>
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<td>Very Good</td>
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<td>5</td>
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<td></td>
<td>6</td>
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<tr>
<td><strong>Low Impact</strong></td>
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<td>8</td>
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<td>9</td>
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<table>
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<tr>
<th>Impact</th>
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<th>Additional Guidance on Strengths/Weaknesses</th>
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<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptionally strong with essentially no weaknesses</td>
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<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>
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<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>

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact

**Moderate Weakness:** A weakness that lessens impact

**Major Weakness:** A weakness that severely limits impact
Separate Scores for the 5 Individual Criteria

- All applications receive scores (even those not discussed at study section)
- Individually reported in summary statement
- Major strengths and weaknesses that influenced the overall impact/priority score - ¼ page per criterion

<table>
<thead>
<tr>
<th>1. Significance</th>
<th>Please limit text to ¼ page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengths</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>Weaknesses</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
</tbody>
</table>

http://enhancing-peer-review.nih.gov/docs/ReviewerVideoslides030609_Modified.ppt

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Impact Score

- Preliminary Impact Scores determine which applications discussed at study section
  - Impact Score given by each member of the study section
- Overall Impact Score (for discussed applications):
  Average of reviewers’ Impact Scores (rounded to one decimal place) x10
  - 81 possible overall Impact Scores
    (10 – 90, whole numbers)

http://enhancing-peer-review.nih.gov/timelines.html
http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/7payline.aspx
Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
## Calculating Percentile

<table>
<thead>
<tr>
<th>Rank</th>
<th>Impact Score</th>
<th>Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Percentile Value Calculation

- Relative rank for each priority score on a scale from 10 to 90.
- Follows NIH convention: Inverse relationship of priority score to scientific merit - lowest percentile value represents the highest scientific merit.
- Specifies the percent of applications with scores equal to or better than (lower impact score) the application.

\[ P = \frac{100}{N} \times (k^{-\frac{1}{2}}) \]

- \( P \) = Percentile Value
- \( k \) = Numerical Rank of Impact Score
- \( N \) = Total number of applications

Calculating Percentile

80 applications*, 14 of which were not recommended for further consideration

<table>
<thead>
<tr>
<th>Rank</th>
<th>Impact Score</th>
<th>Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11</td>
<td>0.6</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td>1.9</td>
</tr>
<tr>
<td>3</td>
<td>20</td>
<td>3.1</td>
</tr>
<tr>
<td>4</td>
<td>21</td>
<td>4.4</td>
</tr>
<tr>
<td>//</td>
<td>//</td>
<td>//</td>
</tr>
<tr>
<td>80</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rank = 3
P = 100/80 x (3-½) = 3.1

* Study section’s last three review cycles

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
What’s the problem?

Study Section A

Great application

Not great application

Study Section B

Payline

Courtesy of Dr. Jon Lorsch, NIGMS

CollinsF NIH Council of Councils 1-31-14

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
What’s the problem?

Payline

Study Section A

Study Section B

Great application
Not great application

Courtesy of Dr. Jon Lorsch, NIGMS
What Determines which Awards are Made?

- Scientific Merit
- Program Considerations
- Availability of Funds

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Number of Scored Applications from First-time Investigators are Dropping

- 535 Applications
- +339 Applications

From Established Investigators
From First-time Investigators
### Challenging Times for All Researchers

<table>
<thead>
<tr>
<th></th>
<th>1999</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall success rate for NIH RO1* Proposals</td>
<td>32%</td>
<td>24%</td>
</tr>
<tr>
<td>Success rate on first submission</td>
<td>29%</td>
<td>12%</td>
</tr>
</tbody>
</table>

### Especially for Young Investigators

<table>
<thead>
<tr>
<th></th>
<th>Then 1990</th>
<th>Now 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at first Ro1* grant</td>
<td>39</td>
<td>43</td>
</tr>
<tr>
<td>% of Ro1s* that go to first-time investigators</td>
<td>29%</td>
<td>25%</td>
</tr>
</tbody>
</table>

*R01 Equivalents: RO1, R29, R37
Source: National Institutes of Health
Age Distribution of NIH RPG Investigators: 1980

Average Age New R01 Investigator: 37.2

Sources: IMPAC II Current and History Files

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Age Distribution of NIH RPG Investigators: 2006

Average Age
New R01 Investigator: 42.2

Sources: IMPAC II Current and History Files

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Preliminary Projection of Age Distribution of NIH RPG Investigators: 2020

Sources: IMPAC II Current and History Files and Preliminary Demographic Projection Model
Figure 1. Average Age of Principal Investigators with MD, MD-PhD, or PhD at the time of First R01 Equivalent Award from NIH, Fiscal Years 1980 to 2011
“Over the past three decades, we’ve seen profound shifts in the average age at which a principal investigator receives their first R01. During the period from 1980 to 2001, the average age increased nearly 0.3 years per year. Since that time, the average age at first R01 award has leveled off near 42 for PhDs. It is higher for researchers with an MD or an MD/PhD.” [Dr. Sally Rockey, NIH Deputy Director for Extramural Research (2/3/12)]
NIH R01 Principal Investigators: Age 36 and Younger / Age 66 and Older

http://nexus.od.nih.gov/all/rock-talk/

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Young, Brilliant and Underfunded

By ANDY HARRIS

We'll never know what medical breakthroughs were missed because young scientists were not provided with resources.

Comments

The New York Times

OCT. 2, 2014
A study for the National Bureau of Economic Research from 2005 examined the age at which over 2,000 Nobel Prize winners and other notable scientists in the 20th century came up with the idea that led to their breakthrough. Most were between 35 and 39. Yet the median age of first-time recipients of R01 grants, the most common and sought-after form of N.I.H. funding, is 42, while the median age of all recipients is 52. More people over 65 are funded with research grants than those under age 35.
Young scientists lead the way on fresh ideas

Analysis of millions of papers finds that junior biomedical researchers tend to work on more innovative topics than their senior colleagues do.

Young researchers are much more likely than older scientists to study exciting innovative topics, according to a text analysis of more than 20 million biomedical papers published over the past 70 years. More-senior researchers are more likely to publish in hot areas when they are supervising a younger scientist.

http://www.nature.com/news/young-scientists-lead-the-way-on-fresh-ideas-1.16934
http://www.nber.org/papers/w20920

Age and the Trying Out of New Ideas

Mikko Packalen, Jay Bhattacharya

NBER Working Paper No. 20920

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
**HOT SPOT**

Pairings of young first authors and mid-career last authors are the most likely to work on the hottest biomedical topics.

Share of publications trying out new ideas
- >23%
- 20–23%
- 17–20%
- <17%

Early Stage Investigator (ESI)

- Has **not** previously been awarded “significant NIH independent research award”
  - Includes R01’s, projects on P01
  - Does not include: R03’s, R21’s, F’s, K’s, loan repayment

- **Within 10 years of terminal research degree/completion of medical residency**
  - Extensions permitted (family care, additional clinical training)

Early Stage Investigators: e.g. NHLBI

- Separate R01 payline for Early Stage Investigators:
  - 5 percentile points above the regular R01 payline

- Applications that are $> 5$ but $\leq 10$ percentile points above the regular R01 payline
  - May undergo expedited administrative review
# Early Stage Investigators: NHLBI

<table>
<thead>
<tr>
<th>Grant Program</th>
<th>Percentile</th>
<th>Priority Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RO1</td>
<td>11.0</td>
<td></td>
<td>Research Project Grant</td>
</tr>
<tr>
<td>ESI</td>
<td>21.0*</td>
<td></td>
<td>Early Stage Investigators</td>
</tr>
<tr>
<td>R21</td>
<td>11.0</td>
<td></td>
<td>Innovative Research Grants</td>
</tr>
</tbody>
</table>

*Summary Statement issues must be satisfactorily resolved on applications >16 percentile.*

**FY15**

http://www.nhlbi.nih.gov/research/funding/general/current-operating-guidelines
Early Stage Investigators: NIDDK

For FY 2015 NIDDK is establishing a nominal “payline” for new (Type 1) and renewal or competing continuation (Type 2) R01 applications of 13th percentile. Most R01 applications which have a primary assignment to NIDDK and which request less than $500,000 direct costs per year and score at or better than the 13th percentile will receive an award. Applications which establishing a nominal payline for R01 applications submitted by ESIs at the 18th percentile. In addition, when possible and appropriate the full period of support recommended will be awarded.

FY15

http://www.niddk.nih.gov/research-funding/process/award-funding-policy/Pages/award-funding-policy.aspx

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
R01-Equivalent grants, New (Type 1)
Success rates, by career stage of investigator
Topics to be Discussed

- **Funding Agencies**
  - Government
    - Federal: National Institutes of Health, **Dept. of Defense**
    - Non-Government: Voluntary Health Organizations, Professional Societies, Foundations, Industry

- **Types of Awards**
  - Grants, Contracts, Cooperative agreements,
    - e.g. Research grants, fellowships, career development awards

- **Funding Announcements**

- **Grant Review Processes: National Institutes of Health**

- **Identifying Funding**

- **Approaches for Competitive Applications**

Federal Agencies

- Dept. of Agriculture
- Dept. of Defense
  - Congressionally Directed Medical Research Programs (CDMRP)
- Dept. of Education
- Dept. of Energy
- Dept. of Health & Human Services
  - National Institutes of Health
- Dept. of Homeland Security
- Dept. of Justice
- Environmental Protection Agency
- National Aeronautics & Space Administration
- National Science Foundation
DoD Congressionally Directed Medical Research Programs (CDMRP)

1992-2014: $8.712 Billion (appropriations)
1992-2013: 12,423 grants/contracts awarded

- Breast Cancer: $3.044B
- Prostate Cancer: $1.370B
- Peer Reviewed Medical: $844.5M

http://cdmrp.army.mil/about/fundinghistory.shtml
### Table A-1. Overview of Appropriations, Applications Received, and Awards Made for FY92–FY13

<table>
<thead>
<tr>
<th>Programs Managed by CDMRP&lt;sup&gt;x&lt;/sup&gt;</th>
<th>Fiscal Year</th>
<th>Appropriations Received (in millions)</th>
<th>Applications Received</th>
<th>Applications Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amyotrophic Lateral Sclerosis</td>
<td>2007, 2009-2013</td>
<td>$39.40</td>
<td>302</td>
<td>30</td>
</tr>
<tr>
<td>Autism</td>
<td>2007-2013</td>
<td>$47.40</td>
<td>1,081</td>
<td>114</td>
</tr>
<tr>
<td>Bone Marrow Failure</td>
<td>2008-2013</td>
<td>$20.15</td>
<td>337</td>
<td>46</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>1992-2013</td>
<td>$2,924.50</td>
<td>49,180</td>
<td>6,421</td>
</tr>
<tr>
<td>Chronic Myelogenous Leukemia</td>
<td>2002-2006</td>
<td>$22.05</td>
<td>252</td>
<td>61</td>
</tr>
</tbody>
</table>

![FY92–FY13 BCRP Research Portfolio](image_url)

*Analysis by number of awards.*

---

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- **Grant Review Processes: National Institutes of Health**

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Total support for biomedical research in the U.S. in 2012 = $130.4 billion*.

- $41.1 billion
  Federal Government

- $17.8 billion
  Other

- $2.4 billion
  Foundations & Public Grantmaking Charities

- $69.2 billion
  Industry

*Source: Research!America
In 2012, **46 organizations** made **3,206 awards** to **2,579 investigators** totaling **$866 million** (36% of non-profit sector funding).

### Private foundations
- **53%**
- **42%**
- **5%**

### Public fundraising organizations
- **32%**
- **13%**
- **55%**

- Basic Discovery Research
- Mechanisms of Disease
- Prevention, Diagnosis, Treatment and Outcomes

Award funding covers the broad spectrum of basic discovery and translational and clinical research.

- 61% Translational and Clinical Research
- 38% Basic Discovery Research
- 1% Other

Nearly half of the award dollars were for early career development and training, compared to about 5% of NIH grants.

- 51% Research
- 44% CD&T*
- 5% Other

*CD&T: Career Development and Training
Individual Fellowships

**Non-government, Non-profit agencies**

- Voluntary Health Organizations
- Professional Societies
- Private Foundations
Post-doc: Individual Fellowship

- Voluntary Health Organizations, Foundations, Professional Societies -

- American Cancer Society
- American Heart Association (Founders)
- American Kidney Fund
- American Liver Foundation
- Daland Fellowships in Clinical Investigation
- Helen Hay Whitney Foundation
Research Career Development/Scholar Programs

- AGA Research Foundation
  - Research Scholar Awards

- American Heart Association
  - Scientist Development Grant

- American Academy of Neurology
  - Clinician-Scientist Development Awards

- Damon Runyon Cancer Research Foundation
  - Clinical Investigator Award

- Doris Duke Charitable Foundation
  - Clinical Scientist Development Grant

Example: Research Interests in Digestive Diseases

Non-government, non-profit agencies

• Voluntary Health Organizations
• Professional Societies
• Private Foundations
Voluntary Health Organizations

- **American Cancer Society**
  - Mentored Training and Career Development Grants
    - Postdoctoral Fellowships
    - Mentored Research Scholar Grant
  - Research Grants for Independent Investigators
    - Research Scholar Grants
  - Professors
    - Research Professor, Clinical Research Professor
  - New Initiatives and Request for Applications

American Liver Foundation

- Postdoctoral Research Fellowship Award
- Liver Scholar Award
- Research Award

Cancer Research Institute, Inc.

- Student Training and Research in Tumor Immunology (STaRT) Grants
- Cancer Research Institute-Irvington Fellowship Program
- Clinic and Laboratory Integration Program (CLIP) Grants
- Investigator Awards
- Cancer Immunotherapy Consortium (CIC)
Crohn’s & Colitis Foundation of America
- Student Research Awards (college/graduate/medical)
- Research Fellowship Awards
- Career Development Awards
- Senior Research Awards
- Scientific Conferences and Workshops

Damon Runyon Cancer Research Foundation
- Damon Runyon Fellowship Award
- Damon Runyon Clinical Investigator Award
- Damon Runyon Physician-Scientist Training Award
- Damon Runyon-Rachleff Innovation Award

Lustgarten Foundation (pancreatic cancer)
Professional Societies

- American Association for the Study of Liver Diseases
  - Advanced/Transplant Hepatology Fellowship Program
  - Career Development Award in Liver Transplantation
  - Sheila Sherlock Clinical and Translational Research Award in Liver Diseases
  - Pinnacle Research Award in Liver Diseases
  - Clinical and Translational Research Awards
  - Liver Scholar Awards
- American College of Gastroenterology
  - Junior Faculty Development Grants
  - Clinical Research Awards
  - “Smaller Programs” Clinical Research Award

- American Society for Gastrointestinal Endoscopy
  - Endoscopic Research Career Development Award
  - Endoscopic Research Award
  - NYSGE Florence Lefcourt Research Award
American Gastroenterological Association/AGA Research Foundation

- Student Awards
  - Student Research Fellowships
  - Student Abstract Prizes

- Career Development Awards
  - Research Scholar Award
  - Elsevier Pilot Research Award
  - Career Development Technology and Innovation Award
  - Junior Investigator Research Award

- Established Investigator Awards
  - Funderburg Research Award in Gastric Cancer
  - Elsevier Pilot Research Awards
Private Foundations

- **Kenneth Rainin Foundation**
  - Inflammatory Bowel Disease (IBD)
    - Innovator Awards Program
    - Breakthrough Awards Program
    - Synergy Awards Program

- **Leona M. and Harry B. Helmsley Charitable Trust**
  - IBD and Crohn's Disease
Grantseeking from Corporations

- Identify companies that might be interested in your research
- Learn as much as possible about the company (e.g. business activities, past giving history)
- Determine the best method of approach (e.g. formal application, personal contacts)
- Articulate your research objectives so as to be in line with the company's giving rationale
Pharmaceutical/Biotech Companies

- Independent foundations

- Research agreements:
  - Companies support investigators for a specific research project
  - Agreement reviewed/negotiated by Columbia Technology Ventures (e.g. intellectual property protection)

- Clinical trials

- On going nationally competitive research awards/honorific awards

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Gifts

- Gifts are not sponsored projects.
- Although funds may be used to support research efforts, they are not for a specific research project (i.e. no listing of specific aims). Unlike sponsored projects, gift agreements do not contain an itemized budget and do have the same university financial reporting requirements.
- Gifts are solicited and managed by the university's development offices, not by the grants office.
Topics to be Discussed

- Funding Agencies
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    - Federal: National Institutes of Health, Dept. of Defense
  - Non-Government: Voluntary Health Organizations, Professional Societies, Foundations, Industry

- Types of Awards
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- Funding Announcements

- Grant Review Processes: National Institutes of Health

- Identifying Funding

- Approaches for Competitive Applications

How to Find Funding Opportunities

- Networking
- Speak to colleagues who are in a similar field
- Speak to colleagues who have been on governmental or private agency review panels
- Speak to colleagues who are on (advisory) boards of private agencies
- Acknowledgement section of publications, oral/poster presentations, press releases, etc.
General Resources

- **Grants.gov**
  - Database and application system for Federal grants

- **FedBizOpps (Federal Business Opportunities)**
  - Single point-of-entry for Federal contracts

- **InfoEd SPIN funding database**
  - [https://www.infoed.columbia.edu/](https://www.infoed.columbia.edu/)
  - e-mail alerts matching research area(s) of interest
- **National Institutes of Health**

- **Tips for Writing Grant Applications**
  - [http://grantscourse.columbia.edu/writing.htm](http://grantscourse.columbia.edu/writing.htm)
Other Sources of Information

- Sponsor publications/website/social media which describe research/programmatic interests (e.g. newsletters, strategic plans, annual reports)

- Sponsor e-mail alert modules
  - NIH
    - “List of Lists”: https://list.nih.gov/
      - Able to save queries and have “ongoing” results e-mailed as funding alerts

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
The Foundation Center

New York
32 Old Slip, 24th Floor
New York, NY 10005-3500
tel: 212-620-4230
http://foundationcenter.org/
http://foundationcenter.org/newyork/

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Library: Books, periodicals, and other print and electronic resources; Lending program, “Foundation Directory Online Professional”

Courses:
- Proposal Writing
- Proposal Budgeting
- Guide to Online Grantseeker Resources
- Grantseekers Basics

Hardcopy/Digital Grant Guides
The Foundation Directory Online

- 120,000+ foundations and corporate donors
- 3 million+ grants
- Tax statements (990’s) showing previous awards
- Access via Columbia University
  - [http://www.columbia.edu/cgi-bin/cul/resolve?clio3328966](http://www.columbia.edu/cgi-bin/cul/resolve?clio3328966)

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- Identifying Funding

- Approaches for Competitive Applications

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Prepare to Complete the Grant Application

- Speak with Program Officer
- Speak with colleagues who are/were awardees
- Review funded applications if possible
- Identify what will make the application more competitive (e.g. research arrangements)
- Strengthen “Preliminary Work/Data”
Prepare to Complete the Grant Application

- Identify and meet with Co-investigators, Collaborators, Consultants, Advisors
  - Identify roles and responsibilities
  - Administrative requirements (e.g. if other countries/institutions are involved)
- Identify necessary core facilities and other research resources
- Meet with research administrators
- Human subjects, lab animals and any other regulatory issues?

Research and Career Development Arrangements

- Multiple Principle Investigators (research awards)
  - Now permitted by NIH
- Multiple Mentors (mentored awards)
- Advisors (mentored awards)
- Co-investigators/Collaborations
- Subcontracts
- Multidisciplinary/Interdisciplinary

Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
Complete the Grant Application

- Review the application instructions
- Identify the different components
- Create a checklist
- Identify and delegate responsibilities for the different components
  - Technical/Scientific
  - Administrative – e.g. budget
  - Regulatory
  - Draft letters of collaboration/support

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Complete the Grant Application

- Confirm page limits for each component
- Create a schedule for any required meetings
- Determine:
  - Shared computer drive/folders
  - Naming of files (dates?)
  - Track changes?
  - Font, margin, format of literature citation
- Set a **firm** time-line for each responsibility
  - Writing milestones
  - Absolute deadline date for final compilation
Complete the Grant Application

- Read instructions
- Never assume that reviewers “will know what you mean”
- Refer to literature thoroughly and thoughtfully
- Explicitly state the rationale of the proposed investigation
- Discuss “challenges” and how these will be addressed (e.g., alternate approaches)
- Include well-designed tables and figures
- Present an organized, lucid write-up
- Ask colleagues to review and comment
Elements of a Good Proposal

- Feasible
- Relevant
- Unique
- Innovative
- Clear
- Brief
- Consistent
Investigator

- Competent
- Enthusiastic
- Thorough
- Professional

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Anticipate Questions and Answer them before they are asked
Common Problems with Grant Applications from New Investigators

- **Title**
  - Too long
  - Confusing
  - Cute but distracting
  - Not program related

- **Cover Page**
  - Does not follow format precisely
  - Does not include all necessary information
- **Abstract**
  - Not comprehensive
  - Omits significant elements
  - Poor grammar or spelling
  - Too long
  - Cut and paste job

- **Table of Contents**
  - Not included
  - Inaccurate pagination
  - Not informative
Institution/School Description

- Irrelevant information
- Does not lead reader to proposal objectives
- Good history: so what?
- Too long
- Objectives/Outcomes
  - Not clear
  - Too ambitious
  - Omitted
  - Procedures rather than objectives

- Innovation
  - Not new or innovative
  - Attempt to justify new equipment/materials
  - Not clearly described
Statement of Need

- Deals with wants, not needs
- No documentation
- Unrelated to objectives/outcomes desired
- Problem already solved
- Not supported by current research
Task/Activity Plan

- Insufficient detail
- Tasks not related to objectives
- Tasks not justified by needs
- Time and task charts not included
- Responsibilities not clear
- Does not address “contingency” plans (alternate approaches)
Evaluation of Project Progress

- Unrelated to objectives
- Unrelated to innovation
- Uses outmoded or inaccurate methods
Project Staffing

- No identification of responsibilities and roles
- No documentation of competence (e.g. bio sketches)
- No indication of time and effort for each individual contributing to project
- **Budget**
  - Unrelated to activities proposed
  - Little or no contribution from institution
  - Amounts not supported by proposal
  - Budget justification missing
  - Categories not those of funding agency
  - Budget cannot be sustained after project ends
Collaborative Efforts

- Names and responsibilities of all involved in proposal not identified
- No identification of institutions involved

Review of Literature

- Unrelated to needs, objectives, innovations
- Does not lead reader to proposed project
- Dated material
- Should not be a review article

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Why Are Proposals Turned Down?

Research Plan

- The problem is trivial or is unlikely to produce new or useful information.
- The proposed research is based on a hypothesis that rests on doubtful, unsound or insufficient evidence.
- The proposal is more complex than the author realizes.
The problem is **local in significance**, production, or control, or otherwise fails to fall clearly in the mainstream of the discipline.

The problem is **intellectually premature** - only a pilot study.

The problem as proposed is **overly involved** with too many elements required to be investigated simultaneously.

The description of the research leaves the proposal **nebulous**, diffuse, and without a clear aim.

Investigator

- Investigator does not have experience or training for the proposed research.
- Investigator appears to be unfamiliar with pertinent literature or methods, or both.
- Investigator's previously published work in the field does not inspire confidence.
- Investigator relies too heavily, or insufficiently, on experienced associates.
- Other responsibilities prevent investigator from devoting sufficient time to this project.
Resources & Environment

- Available equipment is unsuited to the research.
- Institutional setting unfavorable.
The proposed methodology, including tests and procedures, are *unsuited* to the objective. May be *beyond the competence* of the investigator.

The over-all design is *not carefully thought out*.

*Statistical* aspects are not given sufficient consideration.
Approach lacks imagination or originality.

Controls are either inadequately conceived or described.

Proposed material for research is unsuited or difficult to obtain.

The number of observations proposed is unsuitable.
Additional Problems

- Requirements for equipment, personnel or time are unrealistic.

- Current research grants are adequate in scope and funding to cover the proposed research.
Common Problems with Grant Applications from New Investigators

- Does not address/follow funding agency’s mission, specific instructions, budget limits, etc.
- Overly ambitious
- Not independent of previous mentor’s research
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- Unfocussed
- No or insufficient preliminary data
- Unrealistic budget
- Methodologies beyond the expertise of investigator or research team

Possible Problems Specific for Mentored Career Development Awards

**Mentor**

- Too many other responsibilities (e.g. administrative, clinical)
- Too many other mentees (e.g. students, post-docs)
- Not appropriate scientifically
- Too junior
- Limited experience as a mentor
- Limited funds to support proposed research

Possible Problems Specific for Mentored Career Development Awards

Institution

- Limited scientific/technical resources
- Limited career development opportunities
- Limited opportunities for career advancement
Bell Curve of Reviewer’s Grant Applications

Definitely do not fund

Definitely fund

Great

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Poor Statistics
Research Resources
not Adequately Described
Career Development/Research Training Plan not Comprehensive
Figure Caption Font too Small
All Components of the Application are as Strong as Possible
Good Luck!