Transitioning to Research Independence: Funding and Grantsmanship for Newly Independent Investigators

May 15, 2019

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College of Physicians and Surgeons
Columbia University

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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- 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

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DoD Congressionally Directed Medical Research Programs (CDMRP)

1992-2019: $14.7 Billion (appropriations)
- Breast Cancer: $3.6679 B
- Prostate Cancer: $1.82 B
- Peer Reviewed Medical: $2.3507 B

http://cdmrp.army.mil/about/fundinghistory.shtml
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DoD Congressionally Directed Medical Research Programs (CDMRP)

Funding announcements typically have “Topic Areas”, one of which must be addressed in the application, and “Areas of Encouragement”.

e.g., Peer Reviewed Medical Research Program (PRMRP) – FY2019
PRMRP (FY2019) – “Topic Areas”

- Acute Lung Injury
- Antimicrobial Resistance
- Arthritis
- Burn Pit Exposure
- Cardiomyopathy
- Cerebellar Ataxia
- Emerging Infectious Diseases
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- Frontotemporal Degeneration
- Guillain-Barré Syndrome
- Hemorrhage Control
- Hepatitis B
- Hereditary Angioedema
- Hydrocephalus
- Immunomonitoring of Intestinal Transplants
- Inflammatory Bowel Diseases
- Interstitial Cystitis
- Lung Injury
- Metals Toxicology
- Mitochondrial Disease
- Musculoskeletal Disorders
- Myotonic Dystrophy
- Nanomaterials for Bone Regeneration
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Eating Disorders
- Nutrition Optimization
- Pancreatitis
- Pathogen-Inactivated Blood Products
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Pressure Ulcers
- Pulmonary Fibrosis
- Resilience Training
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Spinal Muscular Atrophy
- Tinnitus
- Tissue Regeneration
- Tuberculosis
- Vascular Malformations
- Women’s Heart Disease
National Institutes of Health

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

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

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

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Not All Funding Opportunities Are the Same

- **Different mission statements**
  - Fellowships (F’s)/Training grants (T’s)
  - Career development (K’s)/Scholar awards
  - Research project (R’s)/Multi-Project (P’s)

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

- **Different time frames**
  - Not renewable: e.g. 5 years (K’s), 3 years (F’s), 2 years (T’s)
  - Renewable: 4 - 5 years (R01) each competitive period
Timeline of Funding for Junior Investigators

Graduate School
- Individual Fellowship Training Grant
- Mentor’s Research Grant

Post-doctoral Years
- Individual Post-doc Fellowship
- Institutional T32 Post-doc Training Grant slot
- Mentor’s Research Grant

Instructor/Assistant Professor
- Career Transition Awards

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Timeline of Funding for Junior Investigators

Short term Training

Medical School

Research Support

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

Fellowship – Research Years

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

Instructor/Assistant Professor

Career Transition Awards

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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.

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1-2 years as a mentored K award for “post-docs”
- Funding level is Institute-specific
  - Salary and Research Support
- 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
Research Career Development Awards

K01  K08  K23  K25  K99

Number of Awards

1.4K
1.2K
1.0K
0.8K
0.6K
0.4K
0.2K
0.0K
1997 1999 2001 2003 2005 2007 2009 2011 2013 2015 2017
Fiscal Year

NIH Data Book
Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
## NIH Research Portfolio Online Reporting Tools (RePORT)

<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</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>K99</td>
<td>NHLBI</td>
<td>77</td>
<td>34</td>
<td>44%</td>
<td>$3,373,194</td>
</tr>
<tr>
<td>2010</td>
<td>K99</td>
<td>NHLBI</td>
<td>91</td>
<td>35</td>
<td>38%</td>
<td>$3,759,077</td>
</tr>
<tr>
<td>2011</td>
<td>K99</td>
<td>NHLBI</td>
<td>106</td>
<td>22</td>
<td>21%</td>
<td>$2,353,970</td>
</tr>
<tr>
<td>2012</td>
<td>K99</td>
<td>NHLBI</td>
<td>130</td>
<td>39</td>
<td>30%</td>
<td>$4,121,559</td>
</tr>
<tr>
<td>2013</td>
<td>K99</td>
<td>NHLBI</td>
<td>112</td>
<td>25</td>
<td>22%</td>
<td>$2,680,777</td>
</tr>
<tr>
<td>2014</td>
<td>K99</td>
<td>NHLBI</td>
<td>167</td>
<td>40</td>
<td>24%</td>
<td>$4,590,006</td>
</tr>
<tr>
<td>2015</td>
<td>K99</td>
<td>NHLBI</td>
<td>111</td>
<td>27</td>
<td>24.3%</td>
<td>$3,094,830</td>
</tr>
<tr>
<td>2016</td>
<td>K99</td>
<td>NHLBI</td>
<td>124</td>
<td>32</td>
<td>25.8%</td>
<td>$4,066,065</td>
</tr>
<tr>
<td>2017</td>
<td>K99</td>
<td>NHLBI</td>
<td>99</td>
<td>24</td>
<td>24.2%</td>
<td>$3,072,290</td>
</tr>
<tr>
<td><strong>2018</strong></td>
<td><strong>K99</strong></td>
<td><strong>NHLBI</strong></td>
<td><strong>113</strong></td>
<td><strong>28</strong></td>
<td><strong>24.8%</strong></td>
<td><strong>$3,341,524</strong></td>
</tr>
</tbody>
</table>


Timeline of Funding for Junior Investigators

- **Short term Training**
  - Medical School
  - Year-long Enhancement Programs
  - MD/PhD Fellowship or Institutional T32

- **Research Support**
  - Internship/Residency

- **Fellowship – Research Years**
  - Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot

- **Instructor/Assistant Professor**
  - Career Transition Awards
  - Individual Mentored K Career Development Award

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
- US citizen/permanent resident.
- Can reduce effort to 50% in last 2 years if PI of NIH research grant
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
- Some Institutes support the parent funding announcement, some issue their own

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Mentored Quantitative Research
Career Development Award (K25)

- To attract investigators with expertise in quantitative science and engineering research (e.g., mathematics, statistics, economics, computer science, imaging science, informatics, physics, chemistry), but whose research has not been focused on NIH-relevant questions of health and disease.

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Mentored Research Scientist Career Development Award
For support of a postdoctoral or early career research scientists committed to research, in need of both advanced research training and additional experience.

Mentored Clinical Scientist Research Career Development Award
To provide the opportunity for promising clinician scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research, and aid in filling the academic faculty gap in health profession’s institutions.

Mentored Patient-Oriented Research Career Development Award
To provide support for the career development of clinically trained professionals who have made a commitment to patient-oriented research, and who have the potential to develop into productive, clinical investigators.

Pathway to Independence Award
To support both an initial mentored research experience (K99) followed by independent research (R00) for highly qualified, postdoctoral researchers, to secure an independent research position. Award recipients are expected to compete successfully for independent R01 support during the R00 phase.
# NHLBI K23 Application Success Rate

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<tr>
<th>Fiscal Year</th>
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<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>K23</td>
<td>NHLBI</td>
<td>93</td>
<td>46</td>
<td>49%</td>
<td>$6,408,599</td>
</tr>
<tr>
<td>2010</td>
<td>K23</td>
<td>NHLBI</td>
<td>90</td>
<td>38</td>
<td>42%</td>
<td>$5,466,560</td>
</tr>
<tr>
<td>2011</td>
<td>K23</td>
<td>NHLBI</td>
<td>89</td>
<td>39</td>
<td>44%</td>
<td>$5,486,852</td>
</tr>
<tr>
<td>2012</td>
<td>K23</td>
<td>NHLBI</td>
<td>86</td>
<td>18</td>
<td>21%</td>
<td>$2,635,891</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NHLBI</td>
<td>107</td>
<td>32</td>
<td>30%</td>
<td>$4,639,354</td>
</tr>
<tr>
<td>2014</td>
<td>K23</td>
<td>NHLBI</td>
<td>77</td>
<td>29</td>
<td>38%</td>
<td>$4,147,948</td>
</tr>
<tr>
<td>2015</td>
<td>K23</td>
<td>NHLBI</td>
<td>94</td>
<td>36</td>
<td>38.3%</td>
<td>$5,393,783</td>
</tr>
<tr>
<td>2016</td>
<td>K23</td>
<td>NHLBI</td>
<td>101</td>
<td>45</td>
<td>44.6%</td>
<td>$8,086,510</td>
</tr>
<tr>
<td>2017</td>
<td>K23</td>
<td>NHLBI</td>
<td>138</td>
<td>52</td>
<td>37.7%</td>
<td>$9,311,596</td>
</tr>
<tr>
<td>2018</td>
<td>K23</td>
<td>NHLBI</td>
<td>137</td>
<td>50</td>
<td>36.5%</td>
<td>$8,957,091</td>
</tr>
</tbody>
</table>


Research Career Development Awards

![Graph showing trends in Research Career Development Awards from 1997 to 2017 for different types of awards: K01, K08, K23, K25, K99.](http://grantscourse.columbia.edu)
Individual Research Career Development Awards – by NIH Institute
Timeline of Funding for Junior Investigators

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

Internship/Residency
- Research Support
- Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot

Fellowship – Research Years
- Institutional K12 Career Development Slot

Instructor/Assistant Professor
- Career Transition Awards
- Individual Mentored K Career Development Award

Mentored Clinical Scientist
Development Program Award (K12)

- Support to an institution for career development experiences for junior investigators 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, NIDDK, NIDDK, NICHD, NIDA, NEI, NHLBI, NIDCR, NINDS

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

K01/K08/K23 → R01

K12 → K23 → R01

K01/K08/K23 → R01

K12 → R01

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# NIH Extramural Program

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
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<tr>
<td>Grant</td>
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<tr>
<td>Contract</td>
<td>Purchaser</td>
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<td>(Procurement)</td>
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Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications

Research Grant (NIH R01)

- Supports a discrete, specified project
  - Specific Aims
- “Comprehensive” funding
- Modular budgets up to $250,000/year
- Multi-year
- Flexibility
- Most NIH-supported investigator-initiated research is through this funding mechanism

Research Grant (NIH R01)

- Funds research project
  - Salaries of PI and other research personnel
  - Supplies, reagents, etc
  - Animal costs
  - Patient care costs
  - Core facilities
  - Travel to national meetings

- Multi-Year (4yrs – 5yrs)

- Renewable
  - e.g. original grant + 2 renewals = 15yrs

R01-Equivalent Grants: Competing Applications, Awards, and Success Rates
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 accepts applications in response to their specific funding opportunity announcements

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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
New (Type 1) R01 and R21 Success Rates over Time

Success Rate (%)

Fiscal Year

R01
R21

https://nexus.od.nih.gov/all/2016/11/04/nih-r01-r21//

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Research Program Projects
and Centers

Research Program Projects (P01)

- Broadly-based, multidisciplinary, often long-term research program
- Specific major objective or a basic theme
- Directed toward a range of problems having a central research focus
- Usually 3 or more Research Projects (“R01-like”) and Cores (administrative and technical)
**NIH Extramural Program**

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Cooperative Agreements (U’s)

Since cooperative agreement funding frequently involves a “network” of awards, there may be NIH Institute funding considerations [e.g., programmatic priorities, diversity of research subjects in clinical research (ethnicity, socioeconomic status, age, gender, disease-related, geographic)] that are in addition to the “usual” NIH review criteria (e.g., Significance, Investigators, Innovation, Approach, Environment).
Cooperative Agreements (U’s)

Example Notice of Grant Award (NGA): “This award is issued as a cooperative agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity.”
## NIH Extramural Program

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</tr>
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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
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

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Instrumentation

National Institutes of Health

- **Shared Instrumentation Grant Program (S10)**
  - “Purchase or upgrade a single item of expensive, specialized, commercially available instruments or integrated systems”
  - Grant provides $50,000 - $600,000
  - Major User Group of ≥3 PI’s of active NIH research grants
  - Major User Group: Minimum of 35% of the Accessible User Time (AUT)
  - NIH-funded projects: Minimum of 75% of the Accessible User Time (AUT)

NIH CTSA Awards: A Home for Clinical and Translational Science

Source: Zerhouni (NIH) [9/06]
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Funding Announcements

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

[Diagram showing the hierarchy of funding announcements]

## Research (R) Announcements

<table>
<thead>
<tr>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R01</strong></td>
<td>NIH Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)</td>
<td>PA-19-091</td>
</tr>
<tr>
<td><strong>R01</strong></td>
<td>Research Project Grant (Parent R01 Clinical Trial Required)</td>
<td>PA-19-055</td>
</tr>
<tr>
<td><strong>R01</strong></td>
<td>Research Project Grant (Parent R01 Clinical Trial Not Allowed)</td>
<td>PA-19-056</td>
</tr>
</tbody>
</table>

Program Announcement (PA): [not a Parent Announcement]

Maternal Nutrition and Pre-pregnancy Obesity: Effects on Mothers, Infants and Children (R01 Clinical Trial Optional)

Funding Opportunity Announcement (FOA) Number
PA-18-776

Components of Participating Organizations
National Institute of Nursing Research (NINR)


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Program Announcement (PAR):

Limited Competition: Small Grant Program for NIDDK K01/K08/K23 Recipients (R03 Clinical Trial Optional)

Funding Opportunity Announcement (FOA) Number PAR-18-103

Components of Participating Organizations
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

- Program Announcement Reviewed in an Institute (PAR) Mechanism
  - Grant applications are reviewed at the Institute and not the Center for Scientific Review (CSR)
  - Usually some applications are funded
  - Specific focus or mission

Request For Applications (RFA)

- Formal announcement describing an institute initiative in a well-defined scientific area
- Invitation to the field to submit research grant applications for 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

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## Application Due Dates

<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</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</td>
<td>Research Grants</td>
<td>February 5</td>
<td>June 5</td>
<td>October 5</td>
</tr>
<tr>
<td>K series</td>
<td>Research Career Development</td>
<td>February 12</td>
<td>June 12</td>
<td>October 12</td>
</tr>
<tr>
<td>R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3</td>
<td>Other Research Grants and Cooperative Agreements</td>
<td>February 16</td>
<td>June 16</td>
<td>October 16</td>
</tr>
</tbody>
</table>

NEW APPLICATIONS


## Application Due Dates

### Activity Codes

<table>
<thead>
<tr>
<th>Activity Codes</th>
<th>Program Description</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</td>
<td>Research Grants</td>
<td>March 5</td>
<td>July 5</td>
<td>November 5</td>
</tr>
<tr>
<td>K series</td>
<td>Research Career Development</td>
<td>March 12</td>
<td>July 12</td>
<td>November 12</td>
</tr>
<tr>
<td>R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3</td>
<td>Other Research Grants and Cooperative Agreements</td>
<td>March 16</td>
<td>July 16</td>
<td>November 16</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Activity Codes Cited Above</th>
<th>AIDS and AIDS-Related Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>new, renewal, resubmission, revision</td>
<td>*Effective. Sept 5, 2015 - N/A for SBIR/STTR Applications using Standard Due Dates</td>
</tr>
</tbody>
</table>

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

## Review and Award Cycles

<table>
<thead>
<tr>
<th></th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Due Dates</td>
<td>January 25 - May 7</td>
<td>May 25 - September 7</td>
<td>September 25 - January 7</td>
</tr>
<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>

Review Process for a Research Grant Application

National Institutes of Health

Ctr for Scientific Review

Research Grant Application 
School or Other Research Center

• Initiates Research Idea
• Submits Application

Study Section

• Evaluates for Scientific Merit

Institute

• Evaluates for Program Relevance

Advisory Councils and Boards

• Recommends Action

Institute Director

• Takes final action for NIH Director
NIH Referral and Review System
Regular Research Grant Applications

CSR

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
<table>
<thead>
<tr>
<th>CSR</th>
<th>Institutes</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td></td>
<td>• Conference Grants (R13)</td>
</tr>
<tr>
<td></td>
<td>• Research Grants in response to RFAs</td>
</tr>
<tr>
<td></td>
<td>• Contracts</td>
</tr>
</tbody>
</table>

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants 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
Application to CSR

CSR assigns to IRG, IC

Review by CSR IRG

Second level Council review

Fundable

NIAID negotiates award

Grant ends, renewal

Not funded

Applicant evaluates feedback

Revised application

New RFAs, other*

Application can request IRG and IC

CSR sends to NIAID

Review by NIAID

Summary statement to applicant

RO1s, revised RFAs, other*
## NIH R01-Equivalent Grants

### Success Rates - FY2018

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Competing Status (Type) and Submission Number</th>
<th>Number of Applications Reviewed</th>
<th>Number of Applications Awarded</th>
<th>Success Rate</th>
<th>Total Funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>New First Submission (A0)</td>
<td>23,326</td>
<td>3,516</td>
<td>15.1%</td>
<td>$2,236,194,239</td>
</tr>
<tr>
<td>2018</td>
<td>New with Resubmissions (A1)</td>
<td>8,099</td>
<td>2,632</td>
<td>32.5%</td>
<td>$1,449,684,312</td>
</tr>
<tr>
<td>2018</td>
<td>Continuations (A0)</td>
<td>1,841</td>
<td>768</td>
<td>41.7%</td>
<td>$443,483,489</td>
</tr>
<tr>
<td>2018</td>
<td>Continuations with Resubmissions (A1)</td>
<td>1,241</td>
<td>582</td>
<td>46.9%</td>
<td>$303,402,673</td>
</tr>
<tr>
<td>2018</td>
<td>Supplements</td>
<td>77</td>
<td>19</td>
<td>24.7%</td>
<td>$10,341,325</td>
</tr>
<tr>
<td>2018</td>
<td><strong>FY Total</strong></td>
<td><strong>34,584</strong></td>
<td><strong>7,517</strong></td>
<td><strong>21.7%</strong></td>
<td><strong>$4,443,106,038</strong></td>
</tr>
</tbody>
</table>

# NIH R01-Equivalent Grants Success Rates - FY2018

<table>
<thead>
<tr>
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<th>Competing Status (Type) and Submission Number</th>
<th>Success Rate</th>
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</tr>
<tr>
<td><strong>2018</strong></td>
<td><strong>FY Total</strong></td>
<td><strong>21.7%</strong></td>
</tr>
<tr>
<td>Fiscal Year</td>
<td>Competing Status (Type)</td>
<td>Success Rate</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------</td>
<td>--------------</td>
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</tbody>
</table>

https://report.nih.gov/fundingfacts/index.cfm
Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
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Applicant can request IRG and IC

New RFAs, other*

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Summary statement to applicant

Second level Council review

Fundable

NIAID negotiates award

Grant ends, renewal

Not funded

Applicant evaluates feedback

Revised application

Applicant notified, sent feedback

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Pink Sheet: Reviewers’ Comments
<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>

**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

NIH's Review Criteria

■ **Overall Impact Score**
  - “Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project 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.

■ **Core Review Criteria**
  A separate score is given for each
NIH's Review Criteria

Core Review Criteria
A separate score is given for each.

(A) Significance
(B) Investigators
(C) Innovation
(D) Approach
(E) Environment
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>

Additional Review Criteria & Considerations

**Additional Review Criteria** – Considered for the overall impact score, but not given an individual score

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Individuals Across the Lifespan
- Vertebrate Animals
- Biohazards
- **Resubmissions**
  - Response to previous reviewers’ comments and subsequent changes made to the proposal
- Renewals
  - Progress made in the last funding period

Additional Review Criteria & Considerations

Additional Review Considerations - Not given an individual score and not considered for the overall impact score

- Select Agent Research
- Resource Sharing Plans
  - 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genomic Data Sharing Plan (GDS)
- Authentication of Key Biological and/or Chemical Resources
  - Plans for identifying and ensuring the validity of resources
- Budget and Period of Support

Guidance: Rigor and Reproducibility in Grant Applications

NIH research grant and career development award application instructions and review language focus on four key areas:

1. The rigor of the prior research
2. Rigorous experimental design for robust and unbiased results
3. Consideration of relevant biological variables
4. Authentication of key biological and/or chemical resources

Number of Scored Applications from First-time Investigators are Dropping

- From Established Investigators
- From First-time Investigators

+339 Applications

-535 Applications
## 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>

*RO1 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
Age Distribution of NIH RPG Investigators: 2006

Average Age
New R01 Investigator: 42.2

Percent of PIs

Age

Sources: IMPAC II Current and History Files

http://enhancing-peer-review.nih.gov/meetings/Peer%20Review%20Implementation%20FINAL%20DRAFT%20update%20-

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.

The New York Times

OCT. 2, 2014

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

<table>
<thead>
<tr>
<th>Payline</th>
<th>Grant Program Description</th>
<th>Percentile</th>
<th>Priority Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Research Project Grant</td>
<td>16</td>
<td>N/A</td>
</tr>
<tr>
<td>R01 ESI</td>
<td>Early Stage Investigators</td>
<td>26</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**FY18**


R01-Equivalent grants, New (Type 1): Funding rates, by career stage of investigator

![Graph showing funding rates over fiscal years for first-time and established investigators.](image-url)
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**

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
HRA AWARD CHARACTERISTICS IN 2012

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
Non-Government Funding Agencies

Non-profit agencies
- Voluntary Health Organizations
- Professional Societies
- Private Foundations

For profit agencies
- Biotechnology Companies
- Pharmaceutical Companies
Research Career Development/Scholar Programs

- American Heart Association
  - Career Development Award

- Harold Amos Medical Faculty Development Program
  - “Physicians, dentists, or nurses from historically disadvantaged backgrounds (ethnic, financial, or educational)”
  - Partners: American Society of Hematology, American Society of Nephrology, American Heart Association

- Damon Runyon Cancer Research Foundation
  - Clinical Investigator Award

- Doris Duke Charitable Foundation
  - Clinical Scientist Development Award

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
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 strategic interests and giving rationale
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
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    - e.g. Research grants, fellowships, career development awards

- Funding Announcements

- Grant Review Processes: National Institutes of Health

- Identifying Funding

- Approaches for Competitive Applications
Identify Funding

- Identify appropriate funding agencies
  - Government
  - Non-government

- Identify appropriate funding mechanisms
  - Research
  - Training

- Create a calendar of application deadlines for identified funding programs
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.

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
### Type of Funding Opportunity Announcement
- All FOAs
- PA
- PAR
- PAS
- RFA
- Parent Announcements

### Type of Research
- All
- Clinical trials
- Not clinical trials

### Activity Code
- K01
- K02
- K07
- K08
- K12
- K18
- K22
- K23
- K24
- K25
- K43

### Organizations
- NCI
- NCID
- NCMHD
- NCRR
- NEI
- NHGRI
- NHLBI
- NIA
- NIAAA
- NIAID


PIVOT Funding Database

https://pivot.cos.com/funding_main

Save your search
Choose a name for your search: pancreatic cancer

Would you like to receive a weekly email containing new or updated opps from this query?

Save
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
Training

Courses: Proposal Writing Workshop and Bootcamp
Webinars
Self-Paced eLearning

The Foundation Directory Online

140,000 Grantmakers
12 million grants
Tax statements (990’s) showing previous awards
Access via Columbia University

http://www.columbia.edu/cgi-bin/cul/resolve?clio3328966
The Congressionally Directed Medical Research Programs (CDMRP) has expanded their social media presence!

Like us on Facebook:
www.facebook.com/TheCDMRP

Follow CDMRP on Twitter at:
twitter.com/CDMRP

View CDMRP research on YouTube:
www.youtube.com/user/CDMRP

Bookmark the CDMRP website:
cdmrp.army.mil
Identify Funding

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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Approaches for Competitive Applications

- Identify Funding
- Prepare to Complete the Grant Application
- Complete the Grant Application
It’s not the will to win, but the will to prepare to win that makes the difference.

Bear Bryant, University of Alabama
Prepare to Complete the Grant Application

- Speak with Agency Program Officer
- Speak with colleagues who are/were awardees
- Review funded applications if possible
- Review agency’s review criteria
- Identify what will make the application more competitive
  - Research and/or career development arrangements
  - Access to core facilities/research resources
- Strengthen “Preliminary Work/ Pilot Data”
- Who will write confidential letters of reference?

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Research and Career Development Arrangements

- Multiple Principle Investigators (research awards)
- Multiple Mentors (mentored awards)
- Advisors (mentored awards)
- Co-investigators/Collaborations
- Subcontracts to other institutions
- Multidisciplinary/Interdisciplinary

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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Approaches for Competitive Applications

- Identify Funding
- Prepare to Complete the Grant Application
- Complete the Grant Application
Complete the Grant Application

- Review the application instructions
- Identify the different components
- Create a checklist (sequence/date of completion)
- Create an outline
  - Content, Length of section (vis a vis page limits)
- Identify and delegate responsibilities for the different components
  - Technical/Scientific
  - Administrative – e.g. budget
  - Regulatory
  - Draft letters of collaboration/support

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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 (e.g., by version # or date)
  - 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 (“**the hypothesis of my study is...**”)
- Discuss **limitations** and potential “**challenges**” and how these will be addressed (e.g., “**alternate approaches**”)
- Include well-designed **tables and figures**
- Present an **organized**, lucid write-up (use an **outline**)
- Ask colleagues (“**pseudo reviewers**”) to **review** and **comment**
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 (“the hypothesis of my study is…”)
- Discuss limitations and potential “challenges” and how these will be addressed (e.g., “alternate approaches”)
- Include well-designed tables and figures
- Present an organized, lucid write-up (use an outline)
- Ask colleagues (“pseudo reviewers”) to review and comment
Include Well-Designed Tables and Figures

- Include explanatory caption with the figure (not buried in text)
- Not overly complicated
- Informative, even if printed in black and white
- Easy for the reviewers to read

Tips:
- Bold label in text (e.g., Fig. 4) so it’s easier for reviewers to locate relevant text for individual Figure
- Try to have Figure and relevant text on the same page
## Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

<table>
<thead>
<tr>
<th>Benchmarks / Milestones</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of Specific Aim 1a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 1b</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Summary of Specific Aim 2a</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 2b</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Elements of a Good Proposal

- Feasible
- Relevant
- Unique
- Innovative
- Clear
- Brief
- Consistent
Anticipate Questions
and
Answer them before they are asked
Don’t Do the Minimum

“Optional”: Does not mean don’t do

- PHS Assignment Request Form
  - e.g., Request an Institute, specific Study Section, reviewers’ areas of expertise

- PHS Human Subjects and Clinical Trials Information Form: “3.5 Overall Structure of the Study Team” - Required if “Yes” for all questions in the “Clinical Trial Questionnaire.” Optional for all other human subjects research
  - Use the “extra” space to further describe your study team

- When appropriate, **fill the page** – ½ of page of text means you have nothing more to say

- K awards: “10. Description of Institutional Environment”
Avoid the 3 D’s!!

Day of Deadline Drama!!

- Missing/Incomplete required component
- Missing/Incomplete component that makes the application more competitive
- Just realized that research involves human subjects
- Problems with the budget
- Missing signature
- Component does not meet formatting requirements
Quote Investigator suggests crediting sociologist William Bruce Cameron
http://quoteinvestigator.com/2010/05/26/everything-counts-einstein/

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Investigator

- Competent
- Enthusiastic
- Thorough
- Professional

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Personal Statement/
Candidate’s Background

When describing a previous research experience:

- What was the hypothesis/scientific question?
- Why was the study important?
- What were the findings and conclusions?
- What were your role and responsibilities?
- What did you learn and accomplish?
  - “Intellectual aspects”
  - Do not focus on technical aspects
- Cite any resulting publications
- Describe any honors/awards and conference/workshop presentations

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Possible Problems Specific for Mentored Fellowship & 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

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Possible Problems Specific for Mentored Fellowship & Career Development Awards

Institution

- Limited scientific/technical resources
- Limited career development opportunities
- Limited opportunities for career advancement

Besides Funding....

- Role Models are Important
- Mentors are Important
- Colleagues are Important
- Be Open to New Ideas and Challenges
- Take Advantage of Unique Opportunities
- Networking – whether by accident or on purpose - is Important
Common Problems with Grant Applications from New Investigators

- Does not address/follow funding agency’s mission, specific instructions, budget limits, etc.
- Overly ambitious
  - e.g., $, time, expertise, career level, resources
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- No or insufficient preliminary data
  - Demonstrates feasibility of project, scientifically as well as by investigator’s team

Common Problems with Grant Applications from New Investigators

- Study design
  - e.g., Control groups(s), Unfocussed

- Issues with Statistical aspects/Power analysis/Data analysis

- Does not adequately describe access to “research resources”

- Unrealistic budget (too large or too small)

- Methodologies beyond the expertise of investigator or research team

- Not independent of previous mentor’s research

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NIH: one round of applications
Pink Sheet: Reviewers’ Comments
Bell Curve of Reviewer’s Grant Applications

Definitely do not fund

Fine

Definitely fund

Great

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

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Next Generation Researchers Initiative Working Group

ACD Working Group on Biomedical Workforce

ACD Physician-Scientist Workforce

ACD Working Group on Diversity