Extramural Support for the Career Development of Physician-Scientists and Best Practices for Competitive Grant Applications

- Howard Hughes Medical Institute -
- Medical Research Fellows Program -

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Dept. of Medicine
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Course: “Funding and Grantsmanship for Research and Career Development Activities”
http://grantscourse.columbia.edu/
ACD Physician-Scientist Workforce

Working Group Reports

- Physician-Scientist Workforce Working Group Report, June 2014 (PDF – 6.2MB)
- Executive Summary of the Physician-Scientist Workforce Working Group Report (June 2014) (PDF – 408KB)
- Physician Scientist Workforce Working Group Presentation at the ACD meeting on June 6, 2014 (PDF – 1.65MB)
Topics to be Discussed

- **Funding Agencies**
  - Federal
    - National Institutes of Health
  - Voluntary Health Organizations, Professional Societies, Foundations, Industry, Other

- **Types of Awards**
  - Fellowships (F’s), Training grants (T’s), Career Transition Awards, Research grants,

- **Planning & Organizing a Research Proposal**
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- Planning & Organizing a Research Proposal
Types of Awards

- Individual fellowships
- Training grants
- Career transition awards
- Career development awards
- Research grants
- Program Projects
- Administrative supplements

- Cooperative agreements
- Institutional Clinical & Translational Science Award (CTSA)
- Subcontracts
- Contracts
- Loan Repayment Program

Types of Awards

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

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)

- **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 years - 5 years (R01) each competitive period
Timeline of Funding for Junior Investigators

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

Short term Training

Timeline of Funding for Junior Investigators

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

Short term Training

HHMI Year-long Enhancement Program

Timeline of Funding for Junior Investigators

- Short term Training
- Research Support
- Medical School
- Internship/Residency
- Fellowship – Research Years
- Instructor/Assistant Professor

HHMI Year-long Enhancement Program

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Residents - Research

- American Medical Association Foundation
  - Seed Grant Research Program - Supports research in: Cardiovascular/Pulmonary Diseases, HIV/AIDS, Pancreatic Cancer, and Neoplastic Diseases

- American College of Gastroenterology/ACG Institute for Clinical Research & Education
  - Clinical Research Awards

- American Academy of Pediatrics
  - Resident Grant
Residents - Research

- American Society of Hematology
  - HONORS (Hematology Opportunities for the Next Generation of Research Scientists)

- American College of Surgeons
  - Resident Research Scholarship

- American Academy of Otolaryngology - Head and Neck Surgery Foundation
  - Resident Research Award
Residents - Travel

American Heart Association: Travel Stipends to Scientific Sessions

- Council on:
  - Arteriosclerosis, Thrombosis and Vascular Biology (ATVB)
  - Basic Cardiovascular Sciences (BCVS)
  - Cardiopulmonary, Critical Care, Perioperative and Resuscitation (3CPR)
  - Cardiovascular Disease in the Young (CVDY)
  - Cardiovascular Radiology and Intervention (CVRI)
  - Cardiovascular Surgery and Anesthesia (CVSA)
  - Clinical Cardiology (CLCD)
  - Functional Genomics and Translational Biology (FGTB)
  - Peripheral Vascular Disease (PVD)

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Residents - Research

Stimulating Access to Research in Residency (StARR)

National Heart, Lung, and Blood Institute (NHLBI)
National Cancer Institute (NCI)
National Institute of Allergy and Infectious Diseases (NIAID)

The purpose of this program is to recruit and retain outstanding, postdoctoral-level health professionals who have demonstrated potential and interest in pursuing careers as clinician-investigators. To address the growing need for this critical component of the research workforce, this funding opportunity seeks applications from institutional programs that can provide outstanding mentored research opportunities for Resident-Investigators and foster their ability to transition to individual career development research awards. The program will support institutions to provide support for up to 2 years of research conducted by Resident-Investigators in structured programs for clinician-investigators with defined program milestones.

Residents - Research

National Institute of Neurological Disorders and Stroke

NINDS Research Education Programs for Residents and Fellows in Neurology, Neurosurgery, Neuropathology, Neuroradiology and Emergency Medicine (R25)

“Research education and preparation of clinical residents and fellows that will foster careers as physician-scientists…. Participants in the research education program must be residents or fellows, typically in neurology, neurosurgery, neuropathology, neuroradiology, anesthesiology or emergency medicine, who will conduct research within the mission of NINDS.”

Timeline of Funding for Junior Investigators

Short term Training

Medical School

HHMI Year-long Enhancement Program

Research Support

Internship/Residency

Fellowship – Research Years

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

Instructor/Assistant Professor

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Post-doc: Institutional Training Grant (NIH-T32)

- Post-docs selected by institution
- Research training in specific area
- Defined number of slots
- Stipend, health fees, tuition, travel

Do your fellowship programs of interest have a T32?

Post-doc: Individual Fellowship

- Supports specific individual
- Stipend, health fees, tuition, travel
- NIH: F32

Review criteria:
- Individual fellow
- Mentor
- Research project
- Research environment

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Post-doc Fellowships (F32’s) Applications, awards, and success rates

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

- American Cancer Society
- American Heart Association
- American Kidney Fund
- American Liver Foundation
- Helen Hay Whitney Foundation
Timeline of Funding for Junior Investigators

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

- Medical School
- Internship/Residency
- HHMI Year-long Enhancement Program
- Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot
- 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.

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
5. **NIH should establish a new physician-scientist-specific granting mechanism to facilitate the transition from training to independence.** This program should be similar to the K99/R00 program whose funding currently goes almost exclusively to individuals holding a PhD degree. This new grant program could serve either as a replacement or transition from existing K Awards for physician scientists, and should provide a longer period of support, potentially lengthening the R00 phase to 5 years (with an interim staff review at year 3). This new grant series, as well as K and all other training awards, should rigorously enforce protected time of at least 75 percent effort and provide sufficient salary support to make that possible.
The purpose of the NIH Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented, NIH-supported, independent investigators. This program is designed to facilitate a timely transition of outstanding postdoctoral researchers with a research and/or clinical doctorate degree from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions. The program will provide independent NIH research support during this transition in order to help awardees to launch competitive, independent research careers.

Prospective candidates are encouraged to contact the relevant NIH staff for IC-specific programmatic and budgetary information: Table of IC-Specific Information, Requirements and Staff Contacts.

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Additional Information for Physician-Scientists

For the purposes of this program, physician-scientists include individuals with an MD, DO, DDS/DMD, DVM/VMD, or nurses with research doctoral degrees who devote the majority of their time to biomedical research. The K99/R00 is intended for those physician-scientists who already have substantial research training and are dedicated to initiating a strong, research-intensive career as physician-scientists. The K99/R00 program is designed to facilitate a timely transition of outstanding physician-scientists from mentored, research positions to independent, tenure-track or equivalent faculty positions, and to provide independent NIH research support during the transition. Individuals who need a longer period of mentored career development before they are prepared to begin the transition to research independence should consider the K08 or K23 program (see: K Kiosk).
The purpose of the NIAID Physician-Scientist Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented independent physician-scientists. This program is designed to facilitate a timely transition of outstanding postdoctoral researchers with a clinical doctorate degree from mentored, postdoctoral research positions to independent, tenure-track or equivalent faculty positions. The program will provide independent NIAID research support during this transition to help awardees launch competitive, independent research careers in biomedical fields and thereby help to address the national physician-scientist workforce shortage.
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.O., 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**: Years 3-5
      - Annual Total: $170,000

Career Transition Awards

- **American Heart Association**

  **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

Career Transition Awards

- **JDRF: Advanced Postdoctoral Fellowships**
  - Supports full-time research training and assist awardees “in transitioning from a fellowship to an independent (faculty-level) position”
  - Generally, the most recent doctoral degree (PhD, MD, DMD, DVM, or equivalent) received no more than 6 years before application
  - No citizenship requirements
  - $95,000 per year for up to 3 years
  - **Transition Award:** “Optional transition year in which the awardee may request funding support in their **first year as a faculty member**” (up to $110,000 for one year)

Timeline of Funding for Junior Investigators

- Short term Training
- Medical School
- HHMI Year-long Enhancement Program

- Research Support
- Internship/Residency

- Fellowship – Research Years
- Individual Post-doc Fellowship or Institutional T32 Post-doc Training Grant slot
- Career Transition Awards

- Instructor/Assistant Professor
- 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
- 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
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.

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)

- **NIMH:**
  - Supports “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”

- **NINDS:**
  - Supports “postdoctoral researchers… Candidates are encouraged to apply for support… between the second through fourth year of cumulative mentored postdoctoral research experience…”

- **NCI, NHLBI, NINDS:** Promote Faculty Diversity
Mentored Research Scientist Development Awards (K01)

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

- **NLM:** Biomedical Informatics and Data Science

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

- **FIC:**
  - International Research Scientist Development Award (IRSDA)

Mentored Research Scientist Development Awards (K01)

- **NHGRI:**
  - (a) Genomic Sciences
  - (b) Ethical, legal and social issues (ELSI)

- **NHLBI:**
  - (a) Epidemiology
  - (b) Biostatistics
  - (c) Outcomes Research
  - (d) Implementation Research

Research Career Development Awards

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<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>2016</td>
<td>K08</td>
<td>NCI</td>
<td>64</td>
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<td>31.3%</td>
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<td>K08</td>
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<td>6</td>
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<td>K08</td>
<td>NICHD</td>
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<td>K08</td>
<td>NIBIB</td>
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<td>1</td>
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<td><strong>2016</strong></td>
<td><strong>K08</strong></td>
<td><strong>Activity Total</strong></td>
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<td><strong>162</strong></td>
<td><strong>37.8%</strong></td>
<td><strong>$27,198,434</strong></td>
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## NCI K08 Application Success Rate

<table>
<thead>
<tr>
<th>Fiscal Year</th>
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<th>NIH Institute / Center</th>
<th>Number of Applications Reviewed</th>
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<th>Success Rate $^2$</th>
<th>Total Funding $^3$</th>
</tr>
</thead>
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<td>K08</td>
<td>NCI</td>
<td>77</td>
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<td>2009</td>
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<td>2010</td>
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<td>22</td>
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<td>2014</td>
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<td>18</td>
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<td>2015</td>
<td>K08</td>
<td>NCI</td>
<td>72</td>
<td>18</td>
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<td>2016</td>
<td>K08</td>
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<td>$3,392,677</td>
</tr>
</tbody>
</table>


Research Career Development/Scholar Programs

- AGA Research Foundation
  - Research Scholar Awards
- American Heart Association
  - Career Development Award
- Robert Wood Johnson Foundation
  - Harold Amos Medical Faculty Development Program
- Damon Runyon Cancer Research Foundation
  - Damon Runyon-Rachleff Innovation Award
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
- Institutional K12 Career Development Slot

- HHMI Year-long Enhancement Program
- Career Transition Awards
- Individual Mentored K Career Development Award

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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, Emergency Care

- Institute specific
  - NCI: Clinical oncology
  - NEI: Vision scientists
  - NIDDK: Pediatric diabetes research
  - NICHD:
    - Child health, Pediatric scientists, Reproductive scientists

Mentored Clinical Scientist
Development Program Award (K12)

- **Institute specific**
  - **NHLBI:**
    - Late stage (T4) translation research, HIV-related
  - **NIDA:** Drug abuse and addiction
  - **NINDS**
    - Child Neurologists, Neurosurgeons

- **CTSA - Clinical and Translational Scientist Award:** KL2
NIH CTSA Awards: A Home for Clinical and Translational Science

Clinical Research Ethics
Biomedical Informatics
Clinical Resources
CTSA HOME
Trial Design
Advanced Degree-Granting Programs
Participant & Community Involvement
Biostatistics
Regulatory Support

Source: Zerhouni (NIH) [9/06]

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Specialty Training and Advanced Research (STAR): “Unique curriculum designed for optimal training of physician-scientists… this program offers the opportunity to combine clinical fellowship or residency training with formal, advanced research training leading to a graduate degree, coordinated with clinical training.” 4 Tracks: Track 1. Physician-Scientist - Basic Science, Track 2. Physician-Scientist - Health Services/Outcomes Research; Track 3. Clinician-Investigator - Clinical Research; Track 4. Physician-Scientist - Postdoctoral Research

Advanced Residency Training at Stanford (ARTS): “Opportunity to combine clinical training with advanced research training to complete a PhD degree during or upon completion of residency or clinical fellowship. The program begins with one or more years of postgraduate clinical training, followed by research training in a graduate program”

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“The ASCI Council Young Physician-Scientist Awards, initiated in 2013, recognize young physician-scientists who are supported by NIH K or similar significant career-development awards, are early in their first faculty appointment, and have made notable achievements in their research.”
NIH’s Extramural Loan Repayment Program

http://www.lrp.nih.gov/

- Up to $35,000/year towards educational loan debt
- Conduct qualified research activities for at least 50% of professional effort (or 20 hours per week) for 2 years
- Qualifying educational loan debt equals or exceeds 20% of the applicant's institutional base salary
NIH’s Extramural Loan Repayment Program

- May competitively apply for one-year renewal
- Repayments represent taxable income and are paid in addition to loan

Eligibility:

- U.S. citizen/Permanent residence
- Recipient of M.D., Ph.D., D.D.S. D.M.D., or other specified equivalent doctoral degree

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NIH’s Extramural Loan Repayment Program

Extramural Programs

- Clinical Research
- Pediatric Research
- Health Disparities Research
- Clinical Researchers from Disadvantaged Backgrounds
- Contraception and Infertility Research

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<table>
<thead>
<tr>
<th>All LRP</th>
<th>New</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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<tr>
<td>Number of Applications</td>
<td>1,554</td>
<td></td>
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<tr>
<td>Number of Awards</td>
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<tr>
<td>Success Rate</td>
<td>39%</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Mean Award</td>
<td>$67,680</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean Age of Awardees</td>
<td>35 Years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Funding</td>
<td>$41,149,389</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
6. NIH should expand Loan Repayment Programs and the amount of loans forgiven should be increased to more realistically reflect the debt burden of current trainees. This program should also be made available to all students pursuing biomedical physician-scientist researcher careers, regardless of particular research area or clinical specialty.
Faculty Loan Repayment Program

- “Pursuing a career as a faculty member at a health professions school…”
- Loan payment assistance up to $40,000…
- From a disadvantaged background, based on environmental and/or economic factors”
National Health Service Corps (NHSC)

- “Primary care medical, dental and mental/behavioral health clinicians…"
- Up to $50,000 to repay their health profession student loans…
- Two-year commitment to work at an approved NHSC site in a high-need, underserved area”

https://nhsc.hrsa.gov/loanrepayment/loanrepaymentprogram.html

Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
Career Development (K) Support to Research Grant (R01)

- Individual K to R01
- KL2/K12 to Individual K to R01
- KL2/K12 to R01

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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)
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

Research Project Grants: Applications, Awards, and Success Rates
## 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

Percent of PIs

Age

Sources: IMPAC II Current and History Files
Age Distribution of NIH RPG Investigators: 2006

Average Age
New R01 Investigator: 42.2

Sources: IMPAC II Current and History Files

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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
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.

Young scientists go for fresh ideas.

Callaway E.

Age and the Trying Out of New Ideas

Mikko Packalen, Jay Bhattacharya

NBER Working Paper No. 20920

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

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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%

Source: M. Packalen & J. Bhattacharya Preprint at http://doi.org/2015
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 Investigator (ESI)

ESI status gives you special consideration and enhanced benefits when applying for certain grants. Young investigators have this status for 10 years after they receive a PhD.

See more Information on ESI

Your Status
Not eligible: No completed terminal degree has been indicated.
Early Stage Investigator (ESI)

- **New and Early Stage Investigator Policies**

- **Frequently Asked Questions**
  [https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm](https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm)

- **Extension to the Early Stage Investigator Period**

  Form for Requesting an Extension in the Early Stage Investigator (ESI) Period.

  ESI extensions will be considered only after the terminal research degree and/or the residency end date has been added to the eRA Commons Profile

  Sample requests for extension of the ESI period

# Early Stage Investigators: NHLBI

<table>
<thead>
<tr>
<th>Grant Program</th>
<th>Grant Program Description</th>
<th>Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>Research Project Grant</td>
<td>15</td>
</tr>
<tr>
<td>R01 ESI</td>
<td>Early Stage Investigators</td>
<td>25</td>
</tr>
</tbody>
</table>

**FY17**


R01-Equivalent grants, New (Type 1): Success rates, by career stage of investigator
Next Generation Researchers Initiative

The 21st Century Cures Act, enacted December 13, 2016, includes a section entitled, “Investing in the Next Generation of Researchers” that requires the Director to “Develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity”. To ensure the long term stability of the biomedical research enterprise, NIH must encourage successful independent careers for Early Stage Investigators (ESIs), and retain them as they become Early Established Investigators (EEIs) in a way that enhances workforce diversity.
Early Stage Investigator (ESI): “Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award…. Under the Next Generation Researchers policy, meritorious R01-equivalent applications with ESI PD/PIs will be prioritized for funding.”

Early Established Investigator (EEI): “PD/PI who is within 10 years of receiving their first substantial, independent competing NIH R01-equivalent research award as an ESI. A meritorious application with a designated PD/PI EEI may be prioritized for funding if:

1. The EEI lost or is at risk for losing all NIH research support if not funded by competing awards this year, OR
2. The EEI is supported by only one active award.”
ADVISORY COMMITTEE TO THE DIRECTOR

Next Generation Researchers Initiative Working Group

ACD Physician-Scientist Workforce

ACD Working Group on Diversity

ACD Working Group on Biomedical Workforce

https://acd.od.nih.gov/

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Topics to be Discussed

Funding Agencies

- Federal
  - National Institutes of Health
- Voluntary Health Organizations, Professional Societies, Foundations, Industry, Other

Types of Awards

- Fellowships (F’s), Training grants (T’s), Career Transition Awards, Research grants,
Approaches for Competitive Applications

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

General Resources

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

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

- **Foundation Center**
  - [http://foundationcenter.org/](http://foundationcenter.org/)
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
      - Able to save queries and have “ongoing” results e-mailed as funding alerts

Approaches for Competitive Applications

- Identify Funding
- Prepare to Write 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

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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?
Approaches for Competitive Applications

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

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Complete the Grant Application

- Review the application instructions
- Identify the different components
- Create a checklist
- 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
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 (“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 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 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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
# 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>
<td></td>
</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>
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</tbody>
</table>
Anticipate Questions and Answer them before they are asked
Quote Investigator suggests crediting sociologist William Bruce Cameron
http://quoteinvestigator.com/2010/05/26/everything-counts-einstein/
Investigator

- Competent
- Enthusiastic
- Thorough
- Professional
# 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>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
<td>Strengths</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td></td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td></td>
</tr>
<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
<td>Weaknesses</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td></td>
</tr>
</tbody>
</table>


<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
**Overall Impact** Write a paragraph summarizing the factors that informed your Overall Impact score.
Separate Scores for the Individual Criteria

1. **Candidate**

   **Strengths**
   - 
   **Weaknesses**
   - 

2. **Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring**

   **Strengths**
   - 
   **Weaknesses**
   - 

3. **Research Plan**

   **Strengths**
   - 
   **Weaknesses**
   - 

4. **Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s)**

<table>
<thead>
<tr>
<th>Strengths</th>
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<tbody>
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</table>

<table>
<thead>
<tr>
<th>Weaknesses</th>
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<tbody>
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</table>

5. **Environment and Institutional Commitment to the Candidate**

<table>
<thead>
<tr>
<th>Strengths</th>
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<td></td>
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</table>

<table>
<thead>
<tr>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
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 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 Awards

Institution

- Limited scientific/technical resources
- Limited career development opportunities
- Limited opportunities for career advancement
Elements of a Good Proposal

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

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

Great

Definitely do not fund

Fine

Definitely fund

Great

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