Types of Support and Review Processes for Research and Career Development Activities

- Government Agencies -

Jaime S. Rubin, Ph.D.
Dept. of Medicine
College of Physicians and Surgeons
Columbia University

Course: “Funding and Grantsmanship for Research and Career Development Activities”

http://grantscourse.columbia.edu/
Course Policies:

Please, No:

- Recording of Presentation
- Screen Shots of Presentation
- Posting to Social Media
- Sharing of Course Material with those Outside of Course

Thanks, Jaime Rubin
Topics to be Discussed

- **Funding Agencies**
  - Federal
    - National Institutes of Health, Dept. of Defense
  - 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

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- **Funding Announcements**

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

Federal Agencies

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

DoD Congressionally Directed Medical Research Programs (CDMRP)

1992-2020: $15.9 Billion (appropriations)
1992-2019: 18,662 grants/contracts awarded

- Breast Cancer: $3.8179 B (1992-20)
- Peer Reviewed Medical: $2.7107 B (1999-06, 08-20)
- Prostate Cancer: $1.930 B (1997-20)

Additional Supported DoD Programs/Projects
- Psychological Health/Traumatic Brain Injury: $1,264.3 B

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

The CDMRP originated in 1992 via a Congressional appropriation to foster novel approaches to biomedical research in response to the expressed needs of its stakeholders - the American public, the military, and Congress.

Hallmarks of the CDMRP include:
- investing in groundbreaking research
- targeting critical gaps
- reviewing application using a two-tier formal review with no standing peer review panels and no "pay line"
- involving consumer advocates throughout the program cycle
- supporting both the next generation of researchers and established scientists.
- funding the full pipeline of research development, including basic, translational, and clinical research.
- fostering (or employing) collaboration and synergy
CDMRP Application Process Overview

Step 1

Submit Preapplication in eBRAP

Preproposal

Receive Invitation to Submit Full Proposal Application

Letter of Intent

Step 2

Submit Full Application to Grant.gov

BO

Step 3

Verify Application in eBRAP

BO

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https://cdmrp.army.mil/funding/apply

BO: Business official from applicant organization
Pi: Principal Investigator from the applicant organization
eBRAP: CDMRP's Electronic Biomedical Research Application Portal
SAM: System of Award Management
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) – FY2020
<table>
<thead>
<tr>
<th>Topic Areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis</td>
</tr>
<tr>
<td>Burn Pit Exposure</td>
</tr>
<tr>
<td>Chronic Migraine and Post-Traumatic Headache</td>
</tr>
<tr>
<td>Congenital Heart Disease</td>
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<tr>
<td>Constrictive Bronchiolitis</td>
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<tr>
<td>Diabetes</td>
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<tr>
<td>Dystonia</td>
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<tr>
<td>Eating Disorders</td>
</tr>
<tr>
<td>Emerging Viral Diseases</td>
</tr>
<tr>
<td>Endometriosis</td>
</tr>
<tr>
<td>Epidermolysis Bullosa</td>
</tr>
<tr>
<td>Familial Hypercholesterolemia</td>
</tr>
<tr>
<td>Fibrous Dysplasia</td>
</tr>
<tr>
<td>Focal Segmental Glomerulosclerosis</td>
</tr>
<tr>
<td>Food Allergies</td>
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<tr>
<td>Fragile X</td>
</tr>
<tr>
<td>Frontotemporal Degeneration</td>
</tr>
<tr>
<td>Guillain-Barré Syndrome</td>
</tr>
<tr>
<td>Hemorrhage Control</td>
</tr>
<tr>
<td>Hepatitis B</td>
</tr>
<tr>
<td>Hydrocephalus</td>
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<tr>
<td>Immunomonitoring of Intestinal Transplants</td>
</tr>
<tr>
<td>Inflammatory Bowel Diseases</td>
</tr>
<tr>
<td>Interstitial Cystitis</td>
</tr>
<tr>
<td>Metals Toxicology</td>
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<tr>
<td>Mitochondrial Disease</td>
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<tr>
<td>Musculoskeletal Health</td>
</tr>
<tr>
<td>Myalgic Encephalomyelitis/Chronic Fatigue Syndrome</td>
</tr>
<tr>
<td>Myotonic Dystrophy</td>
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<tr>
<td>Nutrition Optimization</td>
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<tr>
<td>Pancreatitis</td>
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<tr>
<td>Pathogen-Inactivated Blood Products</td>
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<tr>
<td>Plant-Based Vaccines</td>
</tr>
<tr>
<td>Polycystic Kidney Disease</td>
</tr>
<tr>
<td>Pressure Ulcers</td>
</tr>
<tr>
<td>Pulmonary Fibrosis</td>
</tr>
<tr>
<td>Resilience Training</td>
</tr>
<tr>
<td>Respiratory Health</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
</tr>
<tr>
<td>Sleep Disorders and Restriction</td>
</tr>
<tr>
<td>Spinal Muscular Atrophy</td>
</tr>
<tr>
<td>Sustained Release Drug Delivery</td>
</tr>
<tr>
<td>Vascular Malformations</td>
</tr>
<tr>
<td>Women’s Heart Disease</td>
</tr>
</tbody>
</table>
PRMRP (FY2020) – “Areas of Encouragement”

Diabetes

- Identification and/or evaluation of interventions to reduce metabolic dysregulation and the development of diabetes among individuals meeting the clinical criteria for prediabetes.
- Research on interventions to prevent or treat diabetes complications, including diabetic retinopathy, nephropathy, neuropathy, cardiomyopathy, and impaired wound healing.
- Research to better understand the heterogeneity of diabetes including the identification of novel biomarkers (especially the metabolomics biomarkers that are common between diabetes and post-traumatic stress disorder).
- Research on the transplantation of allogenic or autologous pancreatic islet cells for long-term natural insulin production, including current good laboratory/clinical/manufacturing practices (as needed) for cell line development.
- Research to design and implement improved or novel models (in vitro or in vivo) to model pancreatic islets to uncover pathogenesis and improve the efficiency of drug discovery.
- Development of an implantable biosensor system for glucose detection in real time.
NEWS RELEASE
Released: January 19, 2021

The Defense Health Program
Department of Defense Peer Reviewed Medical Research Program
Anticipated Funding Opportunities for Fiscal Year 2021 (FY21)

Congressionally Directed Topic Areas: Applications submitted to the FY21 PRMRP must address at least one of the FY21 PRMRP Congressionally directed topic areas. As of the release date of this pre-announcement, the FY21 PRMRP Topic Areas have not been finalized. This pre-announcement should not be construed as an obligation by the Government to include any of these Topic Areas or others in the FY21 PRMRP. The potential FY21 PRMRP Topic Areas are as follows:

- Arthritis
- Burn pit exposure
- Cardiomyopathy
- Congenital heart disease
- Diabetes
- Dystonia
- Eating disorders
- Emerging viral diseases
- Endometriosis
- Epidermolysis bullosa
- Familial hypercholesterolemia
- Fibrous dysplasia
- Focal segmental glomerulosclerosis
- Food allergies
- Fragile X
- Frontotemporal degeneration
- Hemorrhage control
- Hepatitis B
- Hydrocephalus
- Hypertension
- Inflammatory bowel diseases
- Malaria
- Metals toxicology
- Mitochondrial disease
- Myalgic encephalomyelitis/chronic fatigue syndrome
- Myotonic dystrophy
- Non-opioid therapy for pain management
- Nutrition optimization
- Pathogen-inactivated blood products
- Peripheral neuropathy
- Plant-based vaccines
- Platelet like cell production
- Polycystic kidney disease
- Pressure ulcers
- Pulmonary fibrosis
- Respiratory health
- Rheumatoid arthritis
- Sleep disorders and restriction
- Suicide prevention
- Sustained release drug delivery
- Vascular malformations
- Women’s heart disease

http://cdmrp.army.mil/
Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
<table>
<thead>
<tr>
<th>Condition</th>
<th>Research Program -</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol and Substance Abuse Disorders</td>
<td>$4.0 million</td>
</tr>
<tr>
<td>Amyotrophic Lateral Sclerosis</td>
<td>$40.0 million</td>
</tr>
<tr>
<td>Autism</td>
<td>$15.0 million</td>
</tr>
<tr>
<td>Bone Marrow Failure Disease</td>
<td>$7.5 million</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>$150.0 million</td>
</tr>
<tr>
<td>Chronic Pain Management</td>
<td>$15.0 million</td>
</tr>
<tr>
<td>Combat Readiness Medical</td>
<td>$10.0 million</td>
</tr>
<tr>
<td>Duchenne Muscular Dystrophy</td>
<td>$10.0 million</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>$12.0 million</td>
</tr>
<tr>
<td>Gulf War Illness</td>
<td>$22.0 million</td>
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<tr>
<td>Hearing Restoration</td>
<td>$10.0 million</td>
</tr>
<tr>
<td>Joint Warfighter Medical</td>
<td>$40.0 million</td>
</tr>
<tr>
<td>Kidney Cancer</td>
<td>$50.0 million</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>$20.0 million</td>
</tr>
<tr>
<td>Lupus</td>
<td>$10.0 million</td>
</tr>
<tr>
<td>Melanoma</td>
<td>$30.0 million</td>
</tr>
<tr>
<td>Military Burn</td>
<td>$10.0 million</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>$20.0 million</td>
</tr>
<tr>
<td>Neurofibromatosis</td>
<td>$20.0 million</td>
</tr>
<tr>
<td>Neurotoxin Exposure Treatment</td>
<td>$16.0 million</td>
</tr>
<tr>
<td>Orthotics and Prosthetics</td>
<td>$15.0 million</td>
</tr>
<tr>
<td>Ovarian Cancer</td>
<td>$35.0 million</td>
</tr>
<tr>
<td>Pancreatic Cancer</td>
<td>$15.0 million</td>
</tr>
<tr>
<td>Peer Reviewed Alzheimer’s</td>
<td>$15.0 million</td>
</tr>
<tr>
<td>Peer Reviewed Cancer</td>
<td>$115.0 million</td>
</tr>
<tr>
<td>Peer Reviewed Medical</td>
<td>$370.0 million</td>
</tr>
<tr>
<td>Peer Reviewed Orthopaedic</td>
<td>$30.0 million</td>
</tr>
<tr>
<td>Prostate Cancer</td>
<td>$110.0 million</td>
</tr>
<tr>
<td>Rare Cancers</td>
<td>$17.5 million</td>
</tr>
<tr>
<td>Reconstructive Transplant</td>
<td>$12.0 million</td>
</tr>
<tr>
<td>Sclerodema</td>
<td>$5.0 million</td>
</tr>
<tr>
<td>Spinal Cord Injury</td>
<td>$40.0 million</td>
</tr>
<tr>
<td>Tick-Borne Disease</td>
<td>$7.0 million</td>
</tr>
<tr>
<td>Traumatic Brain Injury and</td>
<td>$175.0 million</td>
</tr>
<tr>
<td>Psychological Health</td>
<td></td>
</tr>
<tr>
<td>Tuberous Sclerosis Complex</td>
<td>$8.0 million</td>
</tr>
<tr>
<td>Vision</td>
<td>$20.0 million</td>
</tr>
</tbody>
</table>
National Science Foundation

7 Directorates that support science and engineering research and education

- Biological Sciences
- Computer and Information Science and Engineering
- Education and Human Resources
- Engineering
- Geosciences
- Mathematical and Physical Sciences
- Social, Behavioral and Economic Sciences

Office of the Director (includes)

- Office of Integrative Activities
- Office of International Science and Engineering

https://www.nsf.gov/staff/orglist.jsp
National Science Foundation

Directorate for Biological Sciences
- Division of Molecular & Cellular Biosciences
- Division of Biological Infrastructure
- Division of Integrative Organismal Systems
- Division of Environmental Biology
- Emerging Frontiers Office

Directorate for Education & Human Resources
- Division of Research on Learning in Formal and Informal Settings
- Division of Graduate Education
- Division of Human Resource Development
- Division of Undergraduate Education

Directorate for Social, Behavioral & Economic Sciences
- Division of Social and Economic Sciences
- Division of Behavioral and Cognitive Sciences
- National Center for Science and Engineering Statistics
- SBE Office of Multidisciplinary Activities

https://www.nsf.gov/staff/orglist.jsp
U.S. Dept. of Health and Human Services
Agency for Healthcare Research and Quality (AHRQ)

“Mission is to produce evidence to make health care safer, higher quality, more accessible, equitable and affordable…”

- “invests in research on the Nation's health deliverysystem(13,10),(986,985) that goes beyond the "what" of health care to understand "how" to make health care safer and improve quality…

- creates materials to teach and train health care systems and professionals to put the results of research into practice…

- generates measures and data used by providers and policymakers.”

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https://www.ahrq.gov/cpi/about/mission/index.html
https://www.ahrq.gov/cpi/about/profile/index.html
Centers for Disease Control and Prevention (CDC)
Supports programs to “protect America from health, safety and security threats, both foreign and in the U.S.”

https://www.cdc.gov/about/organization/mission.htm
https://www.cdc.gov/about/pdf/organization/cdc-org-chart.pdf
Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Funds grants and cooperative agreements to support public health programs (national and international)

- National Institute for Occupational Safety and Health
  - Research Grants (R01, R21, R03)
  - Mentored Research Scientist Development Award (K01)
  - Cooperative agreements (U’s)
  - Workforce Development
  - Conference rants

- Center for Global Health
  - Division of Global HIV & TB
    - President's Emergency Plan for AIDS Relief (PEPFAR)

https://www.cdc.gov/niosh/oep/funding.html
https://www.cdc.gov/globalhealth/index.html
Food and Drug Administration (FDA)

- “ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.”

- “regulating the manufacturing, marketing, and distribution of tobacco products…”

- “helping to speed innovations that make medical products more effective, safer, and more affordable…”

- “plays a significant role in the Nation’s counterterrorism capability…”

Orphan Products Clinical Trials Grants Program

“Orphan products clinical trials grants are a proven method of successfully fostering and encouraging the development of new safe and effective medical products for rare diseases/conditions.” “prevalence of fewer than 200,000 persons in the US. Approximately 30 million Americans are affected by 7,000 known rare diseases” Budget: $15.5M/year

Orphan Products Natural History Grants Program

“A natural history study describes the course of a disease over time, identifying demographic, genetic, environmental, and other variables that correlate with its development and outcomes.”

https://www.fda.gov/industry/developing-products-rare-diseases-conditions/about-orphan-products-grants

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The Pediatric Device Consortia Grant Program

The nonprofit consortia provides a platform of experienced regulatory, business planning, and device development services (such as but not limited to intellectual property advising; prototyping; engineering; laboratory and animal testing; grant-writing; and clinical trial design) to help foster and guide the advancement of medical devices for pediatric patients.”

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Number of Consortia</th>
<th>Amount Awarded</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>5</td>
<td>$6 million</td>
</tr>
<tr>
<td>2017</td>
<td>7</td>
<td>$6 million</td>
</tr>
<tr>
<td>2016</td>
<td>7</td>
<td>$4 million</td>
</tr>
<tr>
<td>2015</td>
<td>8</td>
<td>$3.535 million</td>
</tr>
<tr>
<td>2014</td>
<td>8</td>
<td>$3.3 million</td>
</tr>
<tr>
<td>2013</td>
<td>7</td>
<td>$3.6 million</td>
</tr>
</tbody>
</table>

https://www.fda.gov/industry/developing-products-rare-diseases-conditions/pediatric-device-consortia-grants-program

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

“To improve health outcomes and address health disparities through access to quality services, a skilled health workforce, and innovative, high-value programs.”

Goals

- Goal 1: Improve Access to Quality Health Services
- Goal 2: Foster a Health Care Workforce Able to Address Current and Emerging Needs
- Goal 3: Achieve Health Equity and Enhance Population Health
- Goal 4: Optimize HRSA Operations and Strengthen Program Management

http://www.hrsa.gov/about/index.html
Health Resources & Services Administration

- **Bureau of Health Workforce**
  - “administers programs that are designed to strengthen the health workforce and connect skilled professionals to rural, urban, and tribal underserved communities nationwide.”

- **Bureau of Primary Health Care**

- **Healthcare Systems Bureau**

- **HIV/AIDS Bureau**
  - Ryan White HIV/AIDS Program: Parts A-F
  - Global HIV/AIDS: President's Emergency Plan for AIDS Relief (PEPFAR)

- **Maternal and Child Health Bureau**
  - health care/public health services: “mothers, children, and families across their lives”

To which programs can individuals apply?

Individuals can apply to these scholarship and loan repayment programs.

- National Health Service Corps (NHSC)
- Nurse Corps Loan Repayment Program
- Nurse Corps Scholarship Program
- Faculty Loan Repayment Program
- Native Hawaiian Health Scholarship Program

To which programs can schools apply?

Schools can apply to these scholarship and loan programs.

- Scholarships for Disadvantaged Students (SDS)
- Loans for Disadvantaged Students (LDS)
- Health Professions Student Loans (HPSL)
- Nursing Student Loans (NSL)
- Primary Care Loans (PCL)
Substance Abuse and Mental Health Services Administration (SAMHSA)

- "leads public health efforts to **advance the behavioral health** of the nation. SAMHSA's mission is to **reduce the impact of substance abuse and mental illness** on America's communities.

Centers for Medicare & Medicaid Services (CMS)

- Medicare, Medicaid, the Children’s Health Insurance Program (CHIP)
# NIH’s Frequent Federal Partners

<table>
<thead>
<tr>
<th>U.S. Department of Health and Human Services</th>
<th>Mission</th>
<th>Select Collaborations with NIH</th>
</tr>
</thead>
</table>
| **AHRQ**
Agency for Healthcare Research and Quality | Produces evidence to make health care safer, higher quality, more accessible, equitable, affordable. Partners with others to ensure such evidence is understood and used. | **U.S. Preventive Services Task Force (USPSTF)** |
| **CDC**
Centers for Disease Control and Prevention | Works to protect Americans from health, safety, security threats. Conducts science and provides health information to protect against such threats. | **SEARCH for Diabetes in Youth** |
| **CMS**
Centers for Medicare and Medicaid Services | Administers Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), and parts of the Affordable Care Act (ACA). | Data sharing between CMS and NCI’s SEER (Surveillance, Epidemiology, and End Results) Program, NIDDK’s U.S. Renal Data System, and NHLBI’s Research Cohorts |
| **FDA**
Food and Drug Administration | Protects public health by ensuring safety, efficacy, and security of drugs, biological products, medical devices, food, cosmetics, and radiation-emitting products. Helps speed innovations to make medical products safer, more affordable, and effective. | **Accelerating Medicines Partnership®** |

**NIH-Wide Strategic Plan Fiscal Years 2016-2020**


<table>
<thead>
<tr>
<th><strong>Health Resources and Services Administration</strong></th>
<th>Works to improve health and achieve equity through access to quality services, a skilled health workforce, and innovative programs.</th>
<th><strong>Maternal and Child Health Research Network Programs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indian Health Service</strong></td>
<td>Raises the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.</td>
<td><strong>Native American Research Center for Health (NARCH), (also with AHRQ, HRSA)</strong></td>
</tr>
<tr>
<td><strong>Assistant Secretary for Preparedness and Response</strong></td>
<td>Leads the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters by supporting our communities’ ability to withstand adversity, strengthening our health and response systems, and enhancing national health security.</td>
<td><strong>Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), (also with CDC, FDA, VA, DoD, USDA, Homeland Security, USDA)</strong></td>
</tr>
<tr>
<td><strong>Substance Abuse and Mental Health Services Administration</strong></td>
<td>Reduces the impact of substance abuse and mental illness on America’s communities.</td>
<td><strong>Patient-Reported Outcomes Measurement Information System® (PROMIS®), (also with CDC, CMS, FDA)</strong></td>
</tr>
<tr>
<td>Other Federal Agencies</td>
<td>Mission</td>
<td>Select Collaborations with NIH</td>
</tr>
<tr>
<td>------------------------</td>
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</tr>
<tr>
<td>Department of Defense</td>
<td>Provides the military forces needed to deter war and to protect the security of our country.</td>
<td>Federal Interagency Traumatic Brain Injury Research (FITBIR) database, (also with VA)</td>
</tr>
<tr>
<td>Defense Advanced Research Project Agency</td>
<td>Makes pivotal investments in breakthrough technologies for national security.</td>
<td>Tissue Chip for Drug Screening, (also with FDA)</td>
</tr>
<tr>
<td>Department of Energy</td>
<td>Ensures America’s security and prosperity by addressing its energy, environmental, and nuclear challenges through transformative science and technology solutions.</td>
<td>Structural biology with linear accelerator beam lines</td>
</tr>
<tr>
<td>Organization</td>
<td>Description</td>
<td>Collaboration</td>
</tr>
<tr>
<td>--------------</td>
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<td>---------------</td>
</tr>
<tr>
<td>Department of Veterans Affairs</td>
<td>Fulfills President Lincoln’s promise “to care for him who shall have borne the battle, and for his widow, and his orphan,” by serving and honoring the men and women who are America’s Veterans.</td>
<td>Interagency Pain Research Coordinating Committee (IPRCC), (also with AHRQ, CDC, DoD, FDA)</td>
</tr>
<tr>
<td>Environmental Protection Agency</td>
<td>Protects human health and the environment.</td>
<td>Toxicology Testing in the 21st Century (Tox21), (also with FDA)</td>
</tr>
<tr>
<td>National Science Foundation</td>
<td>Promotes the progress of science to advance the national health, prosperity, and welfare; to secure the national defense, and for other purposes.</td>
<td>BRAIN Initiative®, (also with DARPA)</td>
</tr>
<tr>
<td>Department of Agriculture</td>
<td>Provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and effective management.</td>
<td>National Collaborative on Childhood Obesity Research</td>
</tr>
</tbody>
</table>
National Institutes of Health

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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Examples of NIH Portfolio Analysis. Grant application content can be used to monitor overlap in research areas relevant to more than one NIH Institute/Center. Each dot above represents an R01 grant application; dot proximity is proportional to relatedness. Left image shows relatively high degree of overlap between areas considered for funding by the National Heart, Lung, and Blood Institute (NHLBI) and National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK), which focus on diseases with many biological synergies. Right image shows less overlap between areas considered for funding by the National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI), which focus on diseases with fewer biological synergies. Such analyses help to ensure NIH investments avoid overlaps and maximize synergies.
Typical NIH Institute/Center

National Advisory Council

Office of the Director

Board of Scientific Counselors

Extramural

Scientific Programs

Grants

Cooperative Agreements

Contracts

Intramural

Laboratory Studies

Clinical Studies

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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
NIH Extramural & Intramural Funding: FY 2019 Operating Plan

Spending at NIH
$6.4B (16.72%)

Spending Outside NIH
$31.8B (83.28%)
NIH Budget: 1983 – 2019

https://report.nih.gov/nihdatabook/
http://officeofbudget.od.nih.gov/

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Topics to be Discussed

- Funding Agencies
  - Federal
    - National Institutes of Health, Dept. of Defense
  - 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

## NIH Extramural Program

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant</td>
<td>Patron (Assistance, encouragement)</td>
</tr>
<tr>
<td>Cooperative</td>
<td>Partner (Assistance but substantial</td>
</tr>
<tr>
<td>Agreement</td>
<td>program involvement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser (Procurement)</td>
</tr>
</tbody>
</table>
**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

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
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

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

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
R01-Equivalent New (Type 1) Grants: Competing Applications, Awards, and Success Rates

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
# Success Rates – R01 vs. R21

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Competing Status (Type)</th>
<th>NIH Institutes / Centers</th>
<th>Activity Code</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>2019</td>
<td>New</td>
<td>NCI</td>
<td>R01</td>
<td>5,939</td>
<td>621</td>
<td>10.5%</td>
<td>$300,978,128</td>
</tr>
<tr>
<td>2019</td>
<td>New</td>
<td>NCI</td>
<td>R21</td>
<td>2,204</td>
<td>206</td>
<td>9.3%</td>
<td>$41,501,294</td>
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<tr>
<td>2019</td>
<td>New</td>
<td>NHLBI</td>
<td>R01</td>
<td>2,993</td>
<td>616</td>
<td>20.6%</td>
<td>$368,126,993</td>
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<tr>
<td>2019</td>
<td>New</td>
<td>NHLBI</td>
<td>R21</td>
<td>304</td>
<td>45</td>
<td>14.8%</td>
<td>$6,965,091</td>
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<td>2019</td>
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<td>NIDDK</td>
<td>R01</td>
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<td>374</td>
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<td>2019</td>
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<td>NIDDK</td>
<td>R21</td>
<td>334</td>
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<td>2019</td>
<td>New</td>
<td>NINDS</td>
<td>R01</td>
<td>2,163</td>
<td>388</td>
<td>17.9%</td>
<td>$203,639,931</td>
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<tr>
<td>2019</td>
<td>New</td>
<td>NINDS</td>
<td>R21</td>
<td>1,005</td>
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<td>17.7%</td>
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<td>2019</td>
<td>New</td>
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<td>2019</td>
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<td>NIAID</td>
<td>R21</td>
<td>2,533</td>
<td>532</td>
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<td>2019</td>
<td>New</td>
<td>NIAMS</td>
<td>R01</td>
<td>810</td>
<td>131</td>
<td>16.2%</td>
<td>$58,948,295</td>
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<td>2019</td>
<td>New</td>
<td>NIAMS</td>
<td>R21</td>
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<td>75</td>
<td>14.2%</td>
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<td>2019</td>
<td>New</td>
<td>NIMH</td>
<td>R01</td>
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<td>324</td>
<td>24.2%</td>
<td>$201,432,698</td>
</tr>
<tr>
<td>2019</td>
<td>New</td>
<td>NIMH</td>
<td>R21</td>
<td>643</td>
<td>135</td>
<td>21.0%</td>
<td>$31,137,885</td>
</tr>
</tbody>
</table>


**Success Rate:** Number of awards made divided by the sum of the applications reviewed (in a specific fiscal year). Resubmissions submitted in the same fiscal year are “combined” and counted as one application.

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

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

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

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

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

http://nexus.od.nih.gov/all/2014/03/05/comparing-success-award-funding-rates/fundingawardsuccess-rates_r01e/
Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
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)
Exploratory Grants (P20)

- **Planning** for new programs
- Expansion or modification of existing resources
- **Feasibility studies** to explore various approaches to the development of interdisciplinary programs
- May lead to specialized (P50) or comprehensive (P60) centers.

Center Core Grants (P30)

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

Specialized Center (P50)

- Full range of research, from the very basic to the clinical
- **Multidisciplinary** attack on a specific disease or biomedical problem area
- Usually in response to an announcement (e.g. RFA) of the programmatic needs of an NIH Institute
Comprehensive Center (P60)

- **Multi-purpose** unit designed to bring together into a common focus, divergent but related facilities.

- Usually includes basic and clinical research; community education, screening and counseling; and the education of medical and allied health professionals concerning the diagnosis and treatment of a specific disease.

- May include specialized centers, program projects, research projects as integral components.
<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant</td>
<td>Patron</td>
</tr>
<tr>
<td></td>
<td>(Assistance, encouragement)</td>
</tr>
<tr>
<td>Cooperative</td>
<td>Partner</td>
</tr>
<tr>
<td>Agreement</td>
<td>(Assistance but substantial program involvement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser</td>
</tr>
<tr>
<td></td>
<td>(Procurement)</td>
</tr>
</tbody>
</table>

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

Cooperative Agreements

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

Example RFA: “Following initial peer review, recommended applications will receive a second level of review… The following will be considered in making funding decisions:

- **Scientific and technical merit** of the proposed project as determined by scientific peer review.
- Availability of **funds**.
- Relevance of the proposed project to **program priorities**.
- **Complementarity** to and **synergy** with other funded projects.
- **Programmatic balance** among diseases to be studied, healthcare settings, and approaches to be implemented.”


Cooperative Agreements

- “Ability to work effectively in large collaborative efforts or research consortia
- Public health importance of conditions to be studied
- Diversity of study patients, particularly with respect to inclusion of minority or underserved populations in the U.S., and relevance of proposed research questions related to diversity and health disparities
- Ability to recruit and study large sample sizes efficiently and cost-effectively
- Applicability of the proposed approach to other healthcare settings”
Cooperative Agreements

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.”
Cooperative Agreements

- **U01: Research Project**
  - To support a discrete project

- **U10: Cooperative Clinical Research**
  - “To support clinical evaluation of various methods of therapy and/or prevention in specific disease areas… usually conducted under established protocols

- **U19: Research Program**
  - Supports “a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach

U54: Specialized Center

“To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area…Centers may also serve as regional or national resources for special research purposes, with funding component staff helping to identify appropriate priority needs.”
Training Programs

Institutional Training Award (T32)

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

Short-Term Research Training (T35)

- Short term (e.g. summer) support
- e.g., Medical students in summer after 1st year
Fellowship Programs

Predoctoral Individual Fellowship (F31)

Dual-Degree Predoctoral Individual Fellowship (F30)

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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Pre-doc Fellowships (F31’s)
Applications, awards, and success rates
## Pre-doc Fellowships (F31’s)
### Applications, awards, and success rates

<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 Rate¹</th>
<th>Total Funding²</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>F31</td>
<td>NCCIH****</td>
<td>15</td>
<td>6</td>
<td>40.0%</td>
<td>$226,155</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NCI</td>
<td>457</td>
<td>118</td>
<td>25.8%</td>
<td>$4,589,875</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NEI</td>
<td>70</td>
<td>17</td>
<td>24.3%</td>
<td>$677,820</td>
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<tr>
<td>2019</td>
<td>F31</td>
<td>NHGRI</td>
<td>17</td>
<td>5</td>
<td>29.4%</td>
<td>$182,994</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NHLBI</td>
<td>256</td>
<td>102</td>
<td>39.8%</td>
<td>$4,052,099</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NIA</td>
<td>143</td>
<td>37</td>
<td>25.9%</td>
<td>$1,403,885</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NIAAA</td>
<td>54</td>
<td>27</td>
<td>50.0%</td>
<td>$1,019,561</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NIAID</td>
<td>349</td>
<td>72</td>
<td>20.6%</td>
<td>$2,795,366</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NIAMS</td>
<td>93</td>
<td>17</td>
<td>18.3%</td>
<td>$694,203</td>
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<td>F31</td>
<td>NIBIB</td>
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<td>1</td>
<td>7.1%</td>
<td>$45,016</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NICHD</td>
<td>174</td>
<td>55</td>
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<tr>
<td>2019</td>
<td>F31</td>
<td>NIDA</td>
<td>102</td>
<td>26</td>
<td>25.5%</td>
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<tr>
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<td>NIDCD</td>
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<td>32</td>
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<tr>
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<td>F31</td>
<td>NIDCR</td>
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<td>21</td>
<td>70.0%</td>
<td>$797,017</td>
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<tr>
<td>2019</td>
<td>F31</td>
<td>NIDDK</td>
<td>189</td>
<td>55</td>
<td>29.1%</td>
<td>$2,190,246</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NEIHS</td>
<td>50</td>
<td>15</td>
<td>30.0%</td>
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<tr>
<td>2019</td>
<td>F31</td>
<td>NIGMS</td>
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<td>F31</td>
<td>NIH</td>
<td>232</td>
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<tr>
<td>2019</td>
<td>F31</td>
<td>NIMHD***</td>
<td>32</td>
<td>5</td>
<td>15.6%</td>
<td>$172,664</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NINDS</td>
<td>382</td>
<td>102</td>
<td>26.7%</td>
<td>$4,071,418</td>
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<tr>
<td>2019</td>
<td>F31</td>
<td>NIR</td>
<td>39</td>
<td>20</td>
<td>51.3%</td>
<td>$796,689</td>
</tr>
<tr>
<td>2019</td>
<td>F31</td>
<td>NLM</td>
<td>10</td>
<td>5</td>
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<tr>
<td><strong>2019</strong></td>
<td><strong>F31</strong></td>
<td><strong>ACTIVITY TOTAL</strong></td>
<td><strong>2,857</strong></td>
<td><strong>810</strong></td>
<td><strong>28.4%</strong></td>
<td><strong>$31,774,407</strong></td>
</tr>
</tbody>
</table>

¹ Success Rate: Number of Applications Awarded / Number of Applications Reviewed x 100
² Total Funding: Number of Applications Awarded x Average Funding per Award

### Pre-doc Fellowships (F31’s)
Applications, awards, and success rates

<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>2010</td>
<td>F31</td>
<td>NIDDK</td>
<td>24</td>
<td>12</td>
<td>50.0%</td>
<td>$401,646</td>
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<td>2011</td>
<td>F31</td>
<td>NIDDK</td>
<td>21</td>
<td>10</td>
<td>47.6%</td>
<td>$343,573</td>
</tr>
<tr>
<td>2012</td>
<td>F31</td>
<td>NIDDK</td>
<td>31</td>
<td>9</td>
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<td>2013</td>
<td>F31</td>
<td>NIDDK</td>
<td>29</td>
<td>9</td>
<td>31.0%</td>
<td>$312,742</td>
</tr>
<tr>
<td>2014</td>
<td>F31</td>
<td>NIDDK</td>
<td>51</td>
<td>15</td>
<td>29.4%</td>
<td>$490,924</td>
</tr>
<tr>
<td>2015</td>
<td>F31</td>
<td>NIDDK</td>
<td>137</td>
<td>45</td>
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<td>F31</td>
<td>NIDDK</td>
<td>152</td>
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<tr>
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<td>NIDDK</td>
<td>162</td>
<td>43</td>
<td>26.5%</td>
<td>$1,653,871</td>
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<tr>
<td>2018</td>
<td>F31</td>
<td>NIDDK</td>
<td>172</td>
<td>53</td>
<td>30.8%</td>
<td>$1,993,026</td>
</tr>
<tr>
<td><strong>2019</strong></td>
<td><strong>F31</strong></td>
<td><strong>NIDDK</strong></td>
<td><strong>189</strong></td>
<td><strong>55</strong></td>
<td><strong>29.1%</strong></td>
<td><strong>$2,190,246</strong></td>
</tr>
</tbody>
</table>

Sources:
- [http://grantscourse.columbia.edu](http://grantscourse.columbia.edu)

Postdoctoral Individual Fellowship (F32)

- Supports specific individual (e.g., PhD or MD trained)
- May be in degree program
- Stipend, tuition, institutional allowance

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Post-doc Fellowships (F32’s) 
Applications, awards, and success rates

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
NRSA Training Grants and Fellowships: Funding in Current and Constant Dollars

[Chart showing total funding in current and constant dollars from 1998 to 2019]
<table>
<thead>
<tr>
<th>Years of Experience</th>
<th>Stipend for FY 2016</th>
<th>Stipend for FY 2017</th>
<th>Stipend for FY 2018</th>
<th>Stipend for FY 2019</th>
<th>Stipend for FY 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>$43,692</td>
<td>$47,484</td>
<td>$48,432</td>
<td>$50,004</td>
<td>$52,704</td>
</tr>
<tr>
<td>1</td>
<td>$45,444</td>
<td>$47,844</td>
<td>$48,804</td>
<td>$50,376</td>
<td>$53,076</td>
</tr>
<tr>
<td>2</td>
<td>$47,268</td>
<td>$48,216</td>
<td>$49,188</td>
<td>$50,760</td>
<td>$53,460</td>
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<tr>
<td>3</td>
<td>$49,152</td>
<td>$50,316</td>
<td>$51,324</td>
<td>$52,896</td>
<td>$55,596</td>
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<tr>
<td>4</td>
<td>$51,120</td>
<td>$52,140</td>
<td>$53,184</td>
<td>$54,756</td>
<td>$57,456</td>
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<tr>
<td>5</td>
<td>$53,160</td>
<td>$54,228</td>
<td>$55,308</td>
<td>$56,880</td>
<td>$59,580</td>
</tr>
<tr>
<td>6</td>
<td>$55,296</td>
<td>$56,400</td>
<td>$57,528</td>
<td>$59,100</td>
<td>$61,800</td>
</tr>
<tr>
<td>7 or more</td>
<td>$57,504</td>
<td>$58,560</td>
<td>$59,736</td>
<td>$61,308</td>
<td>$64,008</td>
</tr>
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</table>
Training Grants and Fellowships: Pre- and Post-Doctoral Positions

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Training Grants and Fellowships: Pre- and Post-Doctoral Positions

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Training Grants and Fellowships: Pre- and Post-Doctoral Positions
Improving graduate student and postdoctoral training

- A. Put individual development plans in place for all trainees
- B. Reduce the length of graduate training
- C. Provide F30 and F31 awards from all Institutes/Centers
- D. Increase postdoctoral stipends and consider policies on benefits
- E. Increase support for K99/R00 and shorten eligibility period
- F. Increase support for Early Independence Awards

http://acd.od.nih.gov/bwf.htm

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship (Parent F31)

National Center for Complementary and Integrative Health (NCCIH)
National Cancer Institute (NCI)
National Eye Institute (NEI)
National Human Genome Research Institute (NHGRI)
National Heart, Lung, and Blood Institute (NHLBI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute on Minority Health and Health Disparities (NIMHD)
National Institute of Nursing Research (NINR)
National Institute of Neurological Disorders and Stroke (NINDS)
National Library of Medicine (NLM)
Office of Research Infrastructure Programs (ORIP)
National Institute on Drug Abuse (NIDA)
Ruth L. Kirschstein National Research Service Award (NRSA) Individual Predoctoral Fellowship to Promote Diversity in Health-Related Research (Parent F31-Diversity)

PA-21-052

National Center for Complementary and Integrative Health (NCCIH)
National Cancer Institute (NCI)
National Eye Institute (NEI)
National Human Genome Research Institute (NHGRI)
National Heart, Lung, and Blood Institute (NHLBI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
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National Library of Medicine (NLM)
Office of Research Infrastructure Programs (ORIP)
National Institute on Drug Abuse (NIDA)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
National Institute of General Medical Sciences (NIGMS)
“For the purpose of this announcement, institutions are encouraged to recruit potential student participants from diverse backgrounds, such as:

A. Individuals from racial and ethnic groups that have been shown by the National Science Foundation to be underrepresented in health-related sciences on a national basis (see data at http://www.nsf.gov/statistics/showpub.cfm?TopID=2&SubID=27 and the report Women, Minorities, and Persons with Disabilities in Science and Engineering). The following racial and ethnic groups have been shown to be underrepresented in biomedical research: Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders. In addition, it is recognized that underrepresentation can vary from setting to setting; individuals from racial or ethnic groups that can be demonstrated convincingly to be underrepresented by the grantee institution should be encouraged to participate in NIH programs to enhance diversity. For more information on racial and ethnic categories and definitions, see the OMB Revisions to the Standards for Classification of Federal Data on Race and Ethnicity https://www.govinfo.gov/content/pkg/FR-1997-10-30/html/97-28653.htm.

B. Individuals with disabilities, who are defined as those with a physical or mental impairment that substantially limits one or more major life activities, as described in the Americans with Disabilities Act of 1990, as amended. See NSF data at, https://www.nsf.gov/statistics/2017/nsf17310/static/data/tab7-5.pdf”.

C. **Individuals from disadvantaged backgrounds, defined as those who meet *two or more* of the following criteria:**

1. Were or currently are homeless, as defined by the McKinney-Vento Homeless Assistance Act (Definition: [https://nche.ed.gov/mckinney-vento/](https://nche.ed.gov/mckinney-vento/));
2. Were or currently are in the foster care system, as defined by the Administration for Children and Families (Definition: [https://www.acf.hhs.gov/cb/focus-areas/foster-care](https://www.acf.hhs.gov/cb/focus-areas/foster-care));
3. Were eligible for the Federal Free and Reduced Lunch Program for two or more years (Definition: [https://www.fns.usda.gov/school-meals/income-eligibility-guidelines](https://www.fns.usda.gov/school-meals/income-eligibility-guidelines));
4. Have/had no parents or legal guardians who completed a bachelor’s degree (see [https://nces.ed.gov/pubs2018/2018009.pdf](https://nces.ed.gov/pubs2018/2018009.pdf));
5. Were or currently are eligible for Federal Pell grants (Definition: [https://www2.ed.gov/programs/fpg/eligibility.html](https://www2.ed.gov/programs/fpg/eligibility.html));
6. Received support from the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) as a parent or child (Definition: [https://www.fns.usda.gov/wic/wic-eligibility-requirements](https://www.fns.usda.gov/wic/wic-eligibility-requirements)).
7. Grew up in one of the following areas: a) a U.S. rural area, as designated by the Health Resources and Services Administration (HRSA) Rural Health Grants Eligibility Analyzer ([https://data.hrsa.gov/tools/rural-health](https://data.hrsa.gov/tools/rural-health)), or b) a Centers for Medicare and Medicaid Services-designated Low-Income and Health Professional Shortage Areas (qualifying zipcodes are included in the file). Only one of the two possibilities in #7 can be used as a criterion for the disadvantaged background definition.
D. Literature shows that women from the above backgrounds (categories A, B, and C) face particular challenges at the graduate level and beyond in scientific fields. (See, e.g., From the NIH: A Systems Approach to Increasing the Diversity of Biomedical Research Workforce https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5008902/).

Women have been shown to be underrepresented in doctorate-granting research institutions at senior faculty levels in most biomedical-relevant disciplines, and may also be underrepresented at other faculty levels in some scientific disciplines (See data from the National Science Foundation National Center for Science and Engineering Statistics: Women, Minorities, and Persons with Disabilities in Science and Engineering, special report available at https://www.nsf.gov/statistics/2017/nf17310/ especially Table 9-23, describing science, engineering, and health doctorate holders employed in universities and 4-year colleges, by broad occupation, sex, years since doctorate, and faculty rank).

Upon review of NSF data, and scientific discipline or field related data, NIH encourages institutions to consider women for faculty-level, diversity-targeted programs to address faculty recruitment, appointment, retention or advancement.
Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship for Students at Institutions with NIH-Funded Institutional Predoctoral Dual-Degree Training Programs (Parent F30)

PA-21-049

National Center for Complementary and Integrative Health (NCCIH)
National Cancer Institute (NCI)
National Eye Institute (NEI)
National Heart, Lung and Blood Institute (NHLBI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Drug Abuse (NIDA)
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National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute on Minority Health and Health Disparities (NIMHD)
Office of Research Infrastructure Programs (ORIP)

Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32)

National Center for Complementary and Integrative Health (NCCIH)
National Cancer Institute (NCI)
National Eye Institute (NEI)
National Human Genome Research Institute (NHGRI)
National Heart, Lung and Blood Institute (NHLBI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of General Medical Sciences (NIGMS)
National Institute of Mental Health (NIMH)
National Institute of Nursing Research (NINR)
National Institute on Drug Abuse (NIDA)
National Institute on Minority Health and Health Disparities (NIMHD)
“The purpose of this award is to support outstanding scientific training of highly promising postdoctoral candidates with outstanding mentors. Candidates are eligible to apply for support from this program from ~12 months prior to the start of the proposed postdoctoral position to within 12 months after starting in the proposed postdoctoral position. This NINDS F32 seeks to foster early, goal-directed planning and to encourage applications for bold and/or innovative projects by the candidate that have the potential for significant impact. Inclusion of preliminary data is strongly discouraged; rather, this F32 seeks innovative research ideas and thoughtful plans for training and mentorship that will facilitate the development of the postdoctoral fellow into an outstanding scientist. Applications are expected to incorporate strong training in quantitative reasoning and the quantitative principles of experimental design and analysis. Support by this program is limited to the first 4 years of a candidate's activity in a specific laboratory or research environment, so as to further encourage early, thoughtful planning and timely completion of “mentored training” within a particular lab or environment.”
National Science Foundation: Graduate Research Fellowship Program

Eligibility:

- Citizenship:
  - US citizens, Nationals, Permanent Residents

- Degree Requirements:
  - Rules with regard to degree status (undergraduate vs. graduate student), joint degree programs, # of applications

- Research Areas not Eligible:
  - “goals are directly health-related, such as etiology, diagnosis, or treatment of physical or mental disease, abnormality, or malfunction in humans and other animals…”

https://www.nsfgrfp.org/

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National Science Foundation: Graduate Research Fellowship Program

**Fields of Study:** Chemistry, Computer and Information Science and Engineering, Engineering, Geosciences; **Life Sciences;** Materials Research; Mathematical Sciences; Physics and Astronomy; Psychology; Social Sciences; STEM Education and Learning Research

- **Life Sciences:** Biochemistry, Bioinformatics and Computational Biology, Biophysics, Cell Biology, Developmental Biology, Ecology, Environmental Biology, Evolutionary Biology, Genetics, Genomics, Microbial Biology, Neurosciences, Organismal Biology, Physiology, Proteomics, Structural Biology, Systematics and Biodiversity, Systems and Molecular Biology, Other (specify)

https://www.nsfgrfp.org/
National Science Foundation: Graduate Research Fellowship Program

**Application includes:**
- Personal, Relevant Background and Future Goals
- Graduate Research Plan
- Reference Letters
- Transcripts

**Funding:**
- Stipend
- Cost-of-education allowance

https://www.nsfgrfp.org/

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

Pathway to Independence Award

- 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
Pathway to Independence Award

“Eligibility Window”

“no more than 4 years of postdoctoral research experience as of the relevant application due date regardless of whether it is a new or resubmission application…

must be in mentored, postdoctoral training positions to be eligible”

“Parental, medical, or other well-justified leave for personal or family situations of generally less than 12 months duration is not included in the 4-year eligibility limit,

nor is clinical training with no research involvement (e.g., full-time residency training).

NIH will approve an extension of one year for childbirth within the 4 year K99 eligibility window...

Only time dedicated to research activities would count toward the 4-year limit.”

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“Candidates for the K99/R00 are strongly encouraged to obtain confirmation of their eligibility from the relevant IC before they begin to prepare their applications. It is incumbent upon the candidate to provide evidence that they meet all of the eligibility criteria…

Additional clarifications are provided under [Frequently Asked Questions](https://grants.nih.gov/faqs#/New-Investigators-Program).

Potential candidates are encouraged to discuss their individual situation with an [NIH Institute or Center Scientific Program Contact](https://grants.nih.gov/grants/guide/contacts/parent-K99-CT-not-allowed.html) before applying.

---

### Frequently Asked Questions (FAQs)

**New Investigators Program - Pathway to Independence Award**

<table>
<thead>
<tr>
<th>Table of IC-Specific Information, Requirements and Staff Contacts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Release Date:</strong> May 5, 2020</td>
</tr>
<tr>
<td><strong>Expiration Date:</strong> May 8, 2023</td>
</tr>
<tr>
<td><strong>NIH Institute or Center Contacts</strong></td>
</tr>
<tr>
<td><strong>Institute/Center Specific Information</strong></td>
</tr>
</tbody>
</table>

[https://grants.nih.gov/faqs#/New-Investigators-Program](https://grants.nih.gov/faqs#/New-Investigators-Program)

NIH remains strongly committed to enhancing biomedical research workforce diversity.. .

Applicants for the K99 awards listed in this NOT must have no more than 4 years of postdoctoral research experience at the time of the initial (new) or subsequent resubmission application. NIH considers requests for extension of the K99 eligibility window for various reasons, including medical concerns, disability, family care, extended periods of clinical training, natural disasters, and active duty military service. Each of these requests is reviewed on a case by case basis.

Consistent with the NIH Extension Policy for Early Stage Investigator Status (ESI), effective immediately, NIH will approve an extension of one year for childbirth within the 4 year K99 eligibility window.”
Under normal circumstances, individuals must have no more than four years of postdoctoral research experience to be eligible to apply for a K99/R00 Pathway to Independence award. The purpose of this notice is to inform the extramural community that due to disruptions caused by the COVID-19 pandemic, NIH will be providing up to a two-receipt cycle extension (roughly eight additional months) of eligibility for prospective applicants meeting the requirements for submission of a K99/R00 application from the time period covered by the June/July 2020 due dates through the February/March 2021 due dates.
Research Career Development Awards

Number of Awards

1.2K
1K
800
600
400
200
0


K01  K08  K23  K25  K99

NIH Data Book
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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 $^1$</th>
<th>Total Funding $^2$</th>
</tr>
</thead>
<tbody>
<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>
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<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>2018</td>
<td>K99</td>
<td>NHLBI</td>
<td>113</td>
<td>28</td>
<td>24.8%</td>
<td>$3,341,524</td>
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<tr>
<td>2019</td>
<td>K99</td>
<td>NHLBI</td>
<td>112</td>
<td>33</td>
<td>29.5%</td>
<td>$4,096,354</td>
</tr>
</tbody>
</table>


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Ph.D. (or equivalent research doctorate degree) candidates in positions other than postdoctoral fellow positions: It is recognized that some institutions appoint postdoctoral fellows in positions with other titles although they are still in non-independent, mentored training positions. Candidates in such positions are encouraged to obtain confirmation of their eligibility from the relevant IC before they begin to prepare their applications.…

Clinicians (including those with M.D., D.D.S, D.V.M…. ) in positions not designated as postdoctoral positions: Following clinical training or fellowship training periods, clinicians often obtain a clinical faculty position that denotes independence in clinical responsibilities but not in research. A clinical faculty member who does not hold an independent research faculty position may be eligible for the K99/R00 award,… Clinicians in such positions are encouraged to obtain confirmation of their eligibility before they begin to prepare their applications. Such individuals may also wish to consider other career awards (see K Kiosk) available for junior faculty development”
**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).

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 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.
Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00 - Independent Clinical Trial Not Allowed)

- National Institute of General Medical Sciences (NIGMS)
- National Institute of Biomedical Imaging and Bioengineering (NIBIB)
- National Institute of Nursing Research (NINR)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Human Genome Research Institute (NHGRI)
- National Institute on Aging (NIA)
- National Library of Medicine (NLM)
- National Institute of Mental Health (NIMH)
- National Institute on Drug Abuse (NIDA)
- National Institute on Alcohol Abuse and Alcoholism (NIAAA)
- National Heart, Lung and Blood Institute (NHLBI)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute of Dental and Craniofacial Research (NIDCR)
- National Center for Complementary and Integrative Health (NCCIH)
- National Institute of Allergy and Infectious Diseases (NIAID)
- National Institute of Neurological Disorders and Stroke (NINDS)

Career Transition Award (K22)

- **NCI, NIAID**: Transition from mentored, non-independent research position to independent faculty (or equivalent) position
- **NCI, NINDS**: Diversity candidates
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
Career Development (K) Support to Research Grant (R01)

K01/K08/K23 → R01
K12/KL2 → K23 → R01
K12/KL2 → K23 → R01
K01/K08/K23 → R01
K12/KL2 → R01

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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)

- For investigators just after specialty training; not renewable

Mid-Career Investigator In Patient-Oriented Research Career Development Award (K24)

- Support for clinicians to allow for time to devote to patient-oriented research and to mentor beginning clinical investigators

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Patient-oriented research:

- Research conducted with human subjects (or on material of human origin, i.e. tissues, specimens, and cognitive phenomena)
- Investigator directly interacts with human subjects

Research areas:

- Mechanisms of human disease
- Therapeutic interventions
- Clinical trials
- Development of new technologies
NCI will **no longer** be participating in PA-16-198, "Mentored Patient-Oriented Research Career Development Award (Parent K23)"

NCI will support training in Patient-Oriented Research through K08 Awards and increase K08 Salary and Research Support

**NCI K08 Career Development Awards** will support training in Basic, Translational, and Patient-Oriented Cancer Research, as well as combinations of Basic, Translational, and Patient-Oriented Research.

https://grants.nih.gov/grants/guide/notice-files/NOT-CA-17-043.html
Mentored Research Scientist Development Award (K01)

Not all NIH Institutes participate in program.

Participating Institutes may use for different purposes.

- Specific research areas
- Increase research workforce diversity
- Train in a new field
- Hiatus in research career
- Some Institutes support the parent funding announcement, some issue their own
Mentored Research Scientist Development Awards (K01)

- **NIMH:**
  - “Supports a 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… a strong, well-planned, thorough career development plan, in addition to development of an impactful research project, is a critical aspect of this K01”

Mentored Research Scientist Development Awards (K01)

- **NIDDK:**
  - For “experienced postdoctoral (two years minimum) and/or recently appointed junior faculty (usually with a Ph.D. degree) in biomedical, behavioral, or clinical sciences”

- **NIAID:**
  - Epidemiology and Data Science
  - includes “computational modeling, bioinformatics, big data and advanced statistical analyses”

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

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

Mentored Research Scientist Development Awards (K01)

- **NINR**: Supports “mentored patient-oriented research in the areas of symptom management, pulmonary, critical care, trauma, reproductive health, genetics, epigenetics, behavioral research, incorporation of advanced technology and end-of-life and palliative care”

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

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

- **NCI, NHLBI, NIDCR, NINDS:** Promote Faculty Diversity

Mentored Quantitative Research Career Development Award (K25)

For 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 primarily focused on NIH-relevant areas 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.

Details

View Current Funding Opportunities

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.

Details

View Current Funding Opportunities

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.

Details

View Current Funding Opportunities

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.

Details

View Current Funding Opportunities
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.

- Mentored Patient-Oriented Research Career Development Award (Parent K23 - Independent Basic Experimental Studies with Humans Required)
- Mentored Patient-Oriented Research Career Development Award (Parent K23 - Clinical Trial Required)
- Mentored Patient-Oriented Research Career Development Award (Parent K23 - Independent Clinical Trials Not Allowed)
Research Career Development Awards

![Graph showing the number of awards from 1997 to 2018, with categories K01, K08, K23, K25, and K99.](image-url)
Individual Research Career Development Awards – by NIH Institute

Awards for 2019

Institute / Center

Awards

FIC  NCCIH  NCI  NCRR  NEI  NHGRI  NHLBI  NIA  NIAAA  NIAID  NIAMS  NIBIB  NICHD  NIDA  NIDCD  NIDCR  NIDDK  NEHS  NIGMS  NIH  NIMHD  NINDS  NINR  NLM  OD

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

![Graph showing Research Career Development Awards](image-url)

<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>2013</td>
<td>K23</td>
<td>NHLBI</td>
<td>127</td>
<td>43</td>
<td>33.9%</td>
<td>$7,613,342</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIDCR</td>
<td>3</td>
<td>3</td>
<td>100.0%</td>
<td>$474,309</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIDDK</td>
<td>33</td>
<td>38</td>
<td>40.9%</td>
<td>$7,037,763</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NINDS</td>
<td>66</td>
<td>18</td>
<td>27.3%</td>
<td>$3,433,734</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIAID</td>
<td>50</td>
<td>22</td>
<td>44.0%</td>
<td>$4,230,498</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIGMS</td>
<td>6</td>
<td>5</td>
<td>83.3%</td>
<td>$971,559</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NICHD</td>
<td>51</td>
<td>24</td>
<td>47.1%</td>
<td>$3,810,589</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NEI</td>
<td>12</td>
<td>4</td>
<td>33.3%</td>
<td>$875,404</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIEHS</td>
<td>7</td>
<td>5</td>
<td>71.4%</td>
<td>$978,602</td>
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<tr>
<td>2013</td>
<td>K23</td>
<td>NIA</td>
<td>44</td>
<td>16</td>
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<td>$2,876,479</td>
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<tr>
<td>2013</td>
<td>K23</td>
<td>NIAMS</td>
<td>25</td>
<td>9</td>
<td>36.0%</td>
<td>$1,506,794</td>
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<tr>
<td>2013</td>
<td>K23</td>
<td>NIDCD</td>
<td>10</td>
<td>4</td>
<td>40.0%</td>
<td>$752,444</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIMH</td>
<td>97</td>
<td>25</td>
<td>25.8%</td>
<td>$4,454,570</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIDA</td>
<td>33</td>
<td>12</td>
<td>30.8%</td>
<td>$2,134,653</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIAAA</td>
<td>13</td>
<td>5</td>
<td>38.5%</td>
<td>$878,852</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NINR</td>
<td>18</td>
<td>8</td>
<td>44.4%</td>
<td>$1,177,027</td>
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<td>2013</td>
<td>K23</td>
<td>NIBIB</td>
<td>1</td>
<td>0</td>
<td>0.0%</td>
<td>$0</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NCCIH***</td>
<td>6</td>
<td>4</td>
<td>66.7%</td>
<td>$619,343</td>
</tr>
<tr>
<td>2013</td>
<td>K23</td>
<td>NIMHD***</td>
<td>9</td>
<td>6</td>
<td>66.7%</td>
<td>$363,191</td>
</tr>
</tbody>
</table>

2019 K23 ACTIVITY TOTAL  677  251  37.1%  $44,849,753
# NHLBI K23 Application Success Rate

<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>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>
<tr>
<td>2019</td>
<td>K23</td>
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<td>127</td>
<td>43</td>
<td>33.9%</td>
<td>$7,613,342</td>
</tr>
</tbody>
</table>

Agency for Healthcare Research and Quality

- **Portfolios of Research:** “Make health care safer, Increase accessibility, Improve health care affordability, efficiency and cost transparency”

- **Selected Areas of Research Interest:** Health Information Technology (Health IT), Healthcare-Associated Infections, Simulation in Healthcare

- **K08:** Mentored **Clinical Scientist** Research Career Development Award - for individuals with a clinical doctoral degree or Ph.D./other doctoral degree in a clinical discipline

- **K01:** Mentored **Research Scientist** Career Development Award - for individuals with a research doctoral degree


https://www.ahrq.gov/funding/fund-opps/index.html
https://www.ahrq.gov/funding/priorities-contacts/contacts/index.html
Centers for Disease Control and Prevention (CDC) K01

- National Institute for Occupational Safety and Health
  - Mentored Research Scientist Development Award
    - “career development experience in occupational health and safety research leading to research independence”


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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

Mentored Clinical Scientist Development Program Award (K12)

- **Multi-Institute:** Women’s Health

- **Institute specific**
  - NCI: Clinical oncology
  - NIDDK: Urology research
  - NIDDK: Diabetes research for endocrinologists
  - NICHD:
    - Child health
    - Pediatric scientists
    - Reproductive scientists

Mentored Clinical Scientist Development Program Award (K12)

- **Institute specific**
  - NIDA: Mentored clinical scientist development
  - NEI: Physician scientist award
  - NHLBI: Late stage (T4) translation research
  - NIDCR: Dental specialty and PhD program
  - NINDS: Neurosurgeons

- **CTSA - Clinical and Translational Scientist Award: KL2**
Administrative Supplements

- To promote **reentry** into biomedical and behavioral research careers
  - Individuals who have interrupted their research careers to care for children or parents or to attend to other family responsibilities

- To promote **diversity** in health-related research
  - Individuals from underrepresented racial and ethnic groups
  - Individuals with disabilities
  - Individuals from socially, culturally, economically, or educationally disadvantaged backgrounds that have inhibited their ability to pursue a career in health-related research

Administrative Supplements

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

<table>
<thead>
<tr>
<th>Form Number</th>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>FORMS-F (due dates on/after May 25, 2020)</td>
<td></td>
<td>Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional)</td>
<td>PA-20-272</td>
</tr>
<tr>
<td>FORMS-F (due dates on/after May 25, 2020)</td>
<td></td>
<td>Research Supplements to Promote Diversity in Health-Related Research (Admin Supp - Clinical Trial Not Allowed)</td>
<td>PA-20-222</td>
</tr>
<tr>
<td>FORMS-E (due dates before May 25, 2020)</td>
<td></td>
<td>Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (Admin Supp - Clinical Trial Not Allowed)</td>
<td>PA-18-592</td>
</tr>
</tbody>
</table>

https://grants.nih.gov/grants/guide/parent_announcements.htm

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)

Instrumentation

National Institutes of Health

- **High-End Instrumentation Grant Program (S10)**
  - “Purchase or upgrade a single item of expensive, specialized, commercially available instruments or integrated systems”
  - Grant provides $600,001 - $2,000,000
  - Major User Group of ≥3 PI’s of active NIH research grants
  - Major User Group: Minimum of 35% of the Accessible User Time (AUT) [or BRT]
  - NIH-funded projects: Minimum of 75% of the Accessible User Time (AUT) [or BRT]
  - Special Use Instruments: Biomedical Research Time (BRT) ≥50% of AUT

Instrumentation

National Science Foundation - Major Research Instrumentation Program (MRI)

- “Acquisition” or “Development” of multi-user research instrumentation
- Enhance research training of students
- Track 1: $100,000 to < $1 million
  - < $100,000 in mathematics or social, behavioral and economic sciences
- Track 2: $1 million - $4 million
- Cost-sharing required
  - 30% for Ph.D.-granting institutions

https://www.nsf.gov/od/oia/programs/mri/
https://www.nsf.gov/funding/pgm_summ.jsp?pims_id=5260

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Instrumentation

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

- Army Research Office, Office of Naval Research, and Air Force Office of Scientific Research
- Separate “Broad Agency Announcements” describing each agency’s areas of research interest
- “the acquisition of major equipment to augment current or develop new research capabilities in support of DoD-relevant research”
- $50,000 - $1,500,000
NIH CTSA Awards: A Home for Clinical and Translational Science

Source: Zerhouni (NIH) [9/06]
Institutional Clinical & Translational Science Award

- **National network** of medical research institutions (hubs)
- > 50 medical research institutions
- “Hubs collaborate locally and regionally to catalyze innovation in training, research tools and processes.”
- “Test and develop innovative approaches to barriers in clinical research”
- Enables research teams (e.g., scientists, patient advocacy organizations, community members) to address “system-wide scientific and operational problems in clinical and translational research”

[Map image of CTSA Program Hubs]


[https://ncats.nih.gov/ctsa/about](https://ncats.nih.gov/ctsa/about)
Program goals:

- **Train** and cultivate the translational *science workforce*;
- Engage *patients and communities* in every phase of the translational process;
- Promote the integration of *special and underserved populations* in translational research across the human lifespan;
- Innovate processes to increase the *quality and efficiency of translational research*, particularly of multisite trials; and
- Advance the use of cutting-edge *informatics*”

https://ncats.nih.gov/ctsa/about
## NIH Extramural Program

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant</td>
<td>Patron (Assistance, encouragement)</td>
</tr>
<tr>
<td>Cooperative Agreement</td>
<td>Partner (Assistance but substantial program involvement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser (Procurement)</td>
</tr>
</tbody>
</table>
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

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Review Criteria

- **Differs from that of grants**

- Offerors respond to a ‘Request for Proposal’ (RFP) or a ‘Broad Agency Announcement’ (BAA)

- Proposals evaluated against criteria specified in RFP

- Recommendations of peer reviewers, and the results of separate NIH staff reviews, provide the basis for discussions with offerors in the competitive range
Offeror is requested to submit Best And Final Offer (BAFO)

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

- Clinical trials
  - Separate funding announcements
- Direct Costs > $500,000 per year
- Role of international institutions
- Single IRB if >1 domestic site
- Investigator-initiated epidemiology studies
- Research with human fetal tissue
- Exceptions to the standard Feb/March, June/July, and Oct/Nov deadlines

NIH’s Extramural Loan Repayment Program

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

- Up to $50,000/year towards educational loan debt
- Conduct qualified research activities for an average of at least 20 hours per week
- Qualifying educational loan debt equals or exceeds 20% of the applicant's institutional base salary

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NIH’s Extramural Loan Repayment Program

- May competitively apply for one-year renewal
- Repayments are considered taxable income and a tax payment is also made to the IRS

Eligibility:

- U.S. citizen/National/Permanent Resident
- 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

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

Number of Applications: 24,576
Number of Awards: 12,355
Success Rate: 50%

Mean Award: $50,846
Mean Age of Awardees: 37 Years
Total Funding: $628,204,487

https://www.lrp.nih.gov/data-reports
Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
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.
Apply for Loan Repayment

We offer programs that repay school loan debt.

- Nurse Corps Loan Repayment Program
- National Health Service Corps Loan Repayment Programs
- Faculty Loan Repayment Program

Apply for a Scholarship

We offer scholarships to help pay for health professions’ education.

- Nurse Corps Scholarship Program
- Native Hawaiian Health Scholarship Program
- National Health Service Corps Scholarship Program
Topics to be Discussed

- Funding Agencies
  - Federal
    - National Institutes of Health, Dept. of Defense
  - 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
Funding Opportunity Announcement (FOA)

- Different types of FOA’s
- Published in the NIH Guide for Grants and Contracts (e.g., RFAs, PAs) and Grants.gov
NIH Guide for Grants and Contracts

Funding Opportunity Announcement (FOA)

Program Announcement (PA)
• Usually accepted on standard receipt dates on an on-going basis
• Parent and non-Parent Program Announcements
• Special Types
  • **PAR**: A PA with special *receipt, referral and/or review* considerations, as described in the PAR announcement
  • **PAS**: A PA that includes specific *set-aside funds* as described in the PAS announcement

Request for Application (RFA)
• Identifies a more narrowly defined area for which one or more NIH institutes have set aside funds for awarding grants
• Usually has a single receipt date
• Usually reviewed by a Scientific Review Group convened by the issuing Institute

Request for Proposal (RFP)
• Solicits *contract* proposals. Usually has one receipt date

Notice (NOT)
• Announces policy and procedures, changes to RFA or PA announcements, RFPs and other general information items
Funding Announcements – New Clinical Trials Policy

Policy on Funding Opportunity Announcements (FOA) for Clinical Trials

“NIH will require that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials. This means that the NIH will no longer accept clinical trial applications through "parent" FOA announcements or through other FOAs that are not specifically designed to accept clinical trials.”

Update on Clinical Trial Funding Opportunity Announcement Policy

“New Effective Date
Effective January 25, 2018, all grant applications with plans to conduct clinical trials must be submitted in response to an FOA which specifically states that clinical trials are allowed. After that date, applications planning a clinical trial that are submitted to a non-clinical trial FOA will be returned without review.”


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“new parent Funding Opportunity Announcement (FOAs) for basic science experimental studies involving humans [BESH], referred to in NOT-OD-18-212 as “prospective basic science studies involving human participants.” These studies fall within the NIH definition of a clinical trial and also meet the definition of basic research. Types of studies that should submit under this FOA include studies that prospectively assign human participants to conditions (i.e., experimentally manipulate independent variables) and that assess biomedical or behavioral outcomes in humans for the purpose of understanding the fundamental aspects of phenomena without specific application towards processes or products in mind.”

# Comparison of Funding Opportunity Announcement Types by Clinical Trial Allowability

<table>
<thead>
<tr>
<th>Clinical Trial Not Allowed FOA</th>
<th>Clinical Trial Required FOA</th>
<th>Basic Experimental Studies with Humans Required FOA</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Studies not involving humans as research participants</td>
<td>- Studies of the safety, efficacy, or effectiveness of an intervention on biomedical or behavioral outcomes or processes</td>
<td>- Studies that prospectively assign interventions or experimentally manipulate independent variables with human participants and assess biomedical or behavioral outcomes for the purpose of understanding the fundamental aspects of phenomena without specific application towards processes or products in mind</td>
</tr>
<tr>
<td>- Studies of biospecimens obtained from humans in which any experimental manipulation is performed on the biospecimens, not on the humans</td>
<td>- Studies that prospectively assign interventions intended or anticipated to change the health status of human participants even if not for the purpose of assessing the safety, efficacy or effectiveness of the intervention (e.g., to study the mechanisms or pathways by which the treatment produces its effect)</td>
<td>- Studies that use an experimental manipulation or intervention probe in order to understand normal functioning or the pathophysiology of a disorder</td>
</tr>
<tr>
<td>- Human observational studies in which no experimental manipulations of independent variables and no prospective assignment of interventions are performed</td>
<td>Interventions or experimentally manipulate independent variables to understand the fundamental aspects of phenomena with a specific application in mind (e.g., FDA Phase 0 or 1 trials, translational/applied studies in which fundamental processes are applied to a particular problem or health condition)</td>
<td>Note: Many ICs will continue to accept basic experimental studies with humans through existing FOAs that accept clinical trials (Clinical Trial Required or Clinical Trial Optional)</td>
</tr>
<tr>
<td>- Studies in which experimental</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Studies of tests (e.g., laboratory, biomarkers, patient-report, performance, observational) in which the purpose of the study is to assess the various properties of the test (reliability, validity, sensitivity/specificity, etc.), not to assess biomedical or behavioral outcomes or processes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Participation in Funding Opportunities will vary by NIH Institutes and Centers (ICs)
“FOAs can now have any of the following clinical trial (CT) classifications:

• CT Not Allowed
• CT Optional
• Mechanistic CT Only
• BESH Required [Basic Experimental Studies with Humans]
• CT Required

When you’re ready to submit your next application, you must select a FOA that accepts the type of research you wish to propose.”
Funding Announcements

- **RFA**
  - Targeted research

- **Institute-Specific PA**
  - Research in a stated area of scientific interest

- **Parent PA**
  - Investigator-initiated research in any area

Direction:
- Broad to narrow

Parent Funding Announcement

- Funding Opportunity Announcement (FOA) for unsolicited investigator-initiated grant applications [e.g., R’s (R01, R03, R21), K’s (K01, K08, K23, K99), F’s (F30, F31, F32)]

- Allows for the submission of grant applications that are not in response to specific Program Announcement or RFA

- Published in the *NIH Guide for Grants and Contracts* and Grants.gov

“Parent announcements are broad funding opportunity announcements allowing applicants to submit investigator-initiated applications for specific activity codes. They are open for up to 3 years and use standard due dates.

Not all NIH Institutes and Centers participate on all parent announcements. Before submitting your application, make sure the NIH Institute or Center that might be interested in your research is listed as a participating organization in the announcement.”
<table>
<thead>
<tr>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td><strong>NIH Research Project Grant</strong> (Parent R01 Clinical Trial Not Allowed)</td>
<td>PA-20-185</td>
</tr>
<tr>
<td>R01</td>
<td><strong>Research Project Grant</strong> (Parent R01 Basic Experimental Studies with Humans)</td>
<td>PA-20-184</td>
</tr>
<tr>
<td>R01</td>
<td><strong>Research Project Grant</strong> (Parent R01 Clinical Trial Required)</td>
<td>PA-20-183</td>
</tr>
</tbody>
</table>

https://grants.nih.gov/grants/guide/parent_announcements.htm
NIH Research Project Grant (Parent R01
Clinical Trial Not Allowed)

National Eye Institute (NEI)
National Heart, Lung, and Blood Institute (NHLBI)
National Human Genome Research Institute (NHGRI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of General Medical Sciences (NIGMS)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders and Stroke (NINDS)
National Institute of Nursing Research (NINR)
National Institute on Minority Health and Health Disparities (NIMHD)
National Library of Medicine (NLM)
National Center for Complementary and Integrative Health (NCCIH)
Division of Prog. Coord., Planning and Strategic Initiatives, Office of Research Infrastructure Prog. (ORIP)
National Cancer Institute (NCI)


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
The following Institutes/Centers only accept mechanistic studies that meet NIH's definition of a clinical trial.

National Heart, Lung, and Blood Institute (NHLBI)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
National Institute of Neurological Disorders and Stroke (NINDS)
National Center for Complementary and Integrative Health (NCCIH)
Release Date: May 05, 2020
Expiration Date: May 8, 2023

R01 Clinical Trial Required Participating Institutes and Centers:

- NIH Institutes and Centers that accept Investigator-Initiated R01 applications in response to the Parent R01 Clinical Trial Required Announcement - (PA-20-NNN): NHGRI, NEI, NIA, NIAAA, NIAID, NIDA, NIDCD, NIEHS, NIGMS, NIMHD, NINR

- NIH Institutes and Centers that only accept Investigator-Initiated R01 applications proposing mechanistic clinical trials in response to the Parent R01 Clinical Trial Required Announcement (PA-20-NNN): NCCIH, NHLBI, NIAMS, NIH, NINDS

- NIH Institutes and Centers that DO NOT ACCEPT applications in response to the Parent R01 Clinical Trial Required Announcement but ONLY accept R01 applications proposing clinical trial(s) in response to their specific funding opportunity announcements: NCI, NIBIB, NICHD, NIDCR, NIDDK (PA-18-330), NLM, FIC, NCATS

NIH Institute Or Center Contacts
Scientific/Research Contact
Institute/Center Specific Information

https://grants.nih.gov/grants/guide/contacts/parent-R01-CT-Required.html
Research Project Grant (Parent R01 Basic Experimental Studies with Humans Required)

National Eye Institute (NEI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute on Deafness and Other Communication Disorders (NIDCD)
National Institute of Dental and Craniofacial Research (NIDCR)
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders and Stroke (NINDS)
National Institute of Nursing Research (NINR)
National Institute on Minority Health and Health Disparities (NIMHD)
National Library of Medicine (NLM)
National Center for Complementary and Integrative Health (NCCIH)

“Not all NIH Institutes and Centers participate on all parent announcements. Before submitting your application, make sure the NIH Institute or Center that might be interested in your research is listed as a participating organization in the announcement.”

<table>
<thead>
<tr>
<th>R21</th>
<th>NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)</th>
<th>PA-20-195</th>
</tr>
</thead>
<tbody>
<tr>
<td>R21</td>
<td>NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)</td>
<td>PA-20-194</td>
</tr>
<tr>
<td>R21</td>
<td>NIH Exploratory/Developmental Research Grant Program (Parent R21 Basic Experimental Studies with Humans Required)</td>
<td>PA-20-196</td>
</tr>
</tbody>
</table>
National Human Genome Research Institute (NHGRI)
National Institute on Aging (NIA)
National Institute on Alcohol Abuse and Alcoholism (NIAAA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Drug Abuse (NIDA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute of Neurological Disorders and Stroke (NINDS)

# Parent Announcements (For Unsolicited or Investigator-Initiated Applications)

## Career Development (K) Announcements

<table>
<thead>
<tr>
<th>K08</th>
<th>Mentored Clinical Scientist Research Career Development Award (Parent K08 Independent Clinical Trial Not Allowed)</th>
<th>PA-20-203</th>
</tr>
</thead>
<tbody>
<tr>
<td>K08</td>
<td>Mentored Clinical Scientist Research Career Development Award (Parent K08 Independent Clinical Trial Required)</td>
<td>PA-20-202</td>
</tr>
<tr>
<td>K08</td>
<td>Mentored Clinical Scientist Research Career Development Award (Parent K08 Independent Basic Experimental Studies with Humans Required)</td>
<td>PA-20-201</td>
</tr>
<tr>
<td>K23</td>
<td>Mentored Patient-Oriented Research Career Development Award (Parent K23 Independent Clinical Trial Required)</td>
<td>PA-20-206</td>
</tr>
<tr>
<td>K23</td>
<td>Mentored Patient-Oriented Research Career Development Award (Parent K23 Independent Clinical Trial Not Allowed)</td>
<td>PA-20-205</td>
</tr>
<tr>
<td>K23</td>
<td>Mentored Patient-Oriented Research Career Development Award (Parent K23 Independent Basic Experimental Studies with Humans Required)</td>
<td>PA-20-204</td>
</tr>
</tbody>
</table>

In addition to the Parent Funding Opportunity Announcement, individual NIH Institutes/Center may issue “non parent” Program Announcements for specific areas of research or initiatives.

- e.g., Highlight Institute’s interest in funding a specific area of research.

- e.g., An Institute/Center may not support the Parent R21 or R03 Funding Announcements, but will support these funding mechanisms through Institute-issued funding announcements.
Program Announcement (PA)

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

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

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)

Program Announcement (PAR)

- Program Announcement for grant applications with “special” receipt/referral/review considerations

- Research area coincides with the programmatic interests of an NIH Institute

https://grants.nih.gov/grants/guide/description.htm

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Program Announcement (PAR):

Limited Competition: Small Grant Program for NIDDK K01/K08/K23/K25 Recipients (R03 Clinical Trial Optional)

Funding Opportunity Announcement (FOA) Number: PAR-19-365

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

Program Announcement (PAS)

- Program Announcement with dedicated funding
- “Set-aside funds”
- Research area coincides with the programmatic interests of an Institute

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

PAR “special review”
PAS “set-aside funds”
Request For Applications (RFA)

- Addresses an Institute’s initiative in a well-defined scientific area (may involve >1 Institute)
- Invitation to the scientific research community to submit applications for what is often a one-time “competition”
- Usually reviewed by a committee (Scientific Review Group) formed by the Institute(s)
- Set-aside of funds for a certain number of awards
- Published in the NIH Guide for Grants and Contracts and Grants.gov

Adapted from: NIH (DRG) - Peer Review of NIH Research Grants Applications
https://grants.nih.gov/grants/guide/description.htm

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
“NIH currently has a **large number of non-parent program announcements (PAs)**… **These PAs will be phased out over time and will be replaced with Notices of Special Interest**… We will continue to post full funding opportunity announcements (FOAs) for requests for applications (RFAs), program announcements with special receipt/referral/review considerations (PARs), and program announcements with set-aside funds (PASs).”

**Notices of Special Interest**
- Succinctly highlight a **specific topic of interest**, for example a specific area of research or program
- **Direct applicants** to one or more **active FOAs (often parent announcements)** for submission of applications for the initiative described…”

“…Applicants must also **adhere to any additional submission guidance** described in the Notice of Special Interest… Most Notices of Special Interest require applicants to **include the notice number** in the Agency Routing Identifier **field (4b)** of the **SF424 (R&R)** form…”

“NIH currently has a large number of non-parent program announcements (PAs)… These PAs will be phased out over time and will be replaced with Notices of Special Interest… We will continue to post full funding opportunity announcements (FOAs) for requests for applications (RFAs), program announcements with special receipt/referral/review considerations (PARs), and program announcements with set-aside funds (PASs).”

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Most Notices of Special Interest require applicants to include the notice number in the Agency Routing Identifier field (4b) of the SF424 (R&R)

Funding Announcements

PAR “special review”
PAS “set-aside funds”

NOSI

RFA
Targeted research

Institute-Specific
Research in a stated area of scientific interest

Parent PA
Investigator-initiated research in any area
Request For Proposals (RFP)

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

- Describes research areas of interest to a government agency
- Describes agency’s technical objectives
- Usually requests contract proposals that use creative and innovative approaches

Similar to RFPs, except:

- The applicant, not the government, develops the ‘Statement of Work’
- The applicant, not the government, develops the work requirements and performance specifications
Topics to be Discussed

- Funding Agencies
  - Federal
    - National Institutes of Health, Dept. of Defense
  - 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
<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


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
# RESUBMISSION AND COMPETITIVE RENEWAL APPLICATIONS

## 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>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>All Activity Codes Cited Above</th>
<th><strong>AIDS and AIDS-Related Applications</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Effective. Sept 5, 2015 - N/A for SBIR/STTR Applications using Standard Due Dates</em></td>
<td></td>
</tr>
</tbody>
</table>

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

<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>F Series Fellowships (including F31 Diversity – NOT-OD-17-029)</td>
<td><em>Individual</em> National Research Service Awards (Standard)* (see NRSA Training Page)</td>
<td>April 8</td>
<td>August 8</td>
<td>December 8</td>
</tr>
</tbody>
</table>

*new, renewal, resubmission*
### 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</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

- Assigns to Study Section & Institute

Study Section
- Evaluates for Scientific Merit
- Evaluates for Program Relevance

Institute
- Recommends Action

Advisory Councils and Boards
- Recommends Action

Institute Director
- Takes final action for NIH Director

Research Grant Application
- Initiates Research Idea
- Submits Application

School or Other Research Center
- Initiates Research Idea
- Allocates Funds

Research Grant Application

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
NIH REFERRAL AND REVIEW SYSTEM
REGULAR RESEARCH GRANT APPLICATIONS

PROGRAM & POLICY CONSIDERATIONS

NINDS  NIGMS  NIA

NIAID

NCI

NEI

NIAMS

NHLBI

NCHGR

NICHHD

NLM

NCRR

FIC

NIDDK

SCIENTIFIC MANAGEMENT

FUNDING DECISIONS

SCIENTIFIC REVIEW

REFERRAL

CSR
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

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<table>
<thead>
<tr>
<th>CSR</th>
<th>Institutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Research Grants (e.g., R01’s)</td>
<td>Multi-Project Grants (P01, P50, etc)</td>
</tr>
<tr>
<td>*Fellowships (F’s)</td>
<td>Career Development (K’s)</td>
</tr>
<tr>
<td>Small Business</td>
<td>Research Grants/Cooperative Agreements in response to “special” PA/PAR/PAS &amp; RFA’s</td>
</tr>
<tr>
<td></td>
<td>Training Grants (T’s)</td>
</tr>
<tr>
<td></td>
<td>Contracts – RFP’s</td>
</tr>
</tbody>
</table>

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

NIH: one round of applications
Application to CSR

CSR assigns to IRG, IC

Review by CSR IRG

Summary statement to applicant

Second level Council review

Fundable

NIAID negotiates award

Grant ends, renewal

Not funded

Applicant evaluates feedback

Revised application

Applicant can request IRG and IC

New RFAs, other*

RO1s, revised RFAs, other*

CSR sends to NIAID

Review by NIAID

Not funded

Applicant evaluates feedback

Revised application

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

Applicant can request IRG and IC

New RFAs, other*

Summary statement to applicant

CSR sends to NIAID

Review by NIAID

Applicant notified, sent feedback

# NIH R01-Equivalent Grants Success Rates - FY2019

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Competing Status (Type) and Submission Number²</th>
<th>R01-EQUIVALENT GRANTS⁴</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Number of Applications Reviewed</td>
<td>Number of Applications Awarded</td>
</tr>
<tr>
<td>2019</td>
<td>New First Submission (A0)</td>
<td>23,807</td>
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<tr>
<td>2019</td>
<td>New with Resubmissions (A1)</td>
<td>8,291</td>
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<tr>
<td>2019</td>
<td>Continuations (A0)</td>
<td>1,844</td>
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<tr>
<td>2019</td>
<td>Continuations with Resubmissions (A1)</td>
<td>1,076</td>
</tr>
<tr>
<td>2019</td>
<td>Supplements</td>
<td>67</td>
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<tr>
<td>2019</td>
<td>FY Total</td>
<td>35,085</td>
</tr>
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</table>

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**NIH R01-Equivalent Grants Success Rates - FY2019**

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Competing Status (Type)</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>New First Submission (A0)</td>
<td>14.8%</td>
</tr>
<tr>
<td>2019</td>
<td>New with Resubmissions (A1)</td>
<td>31.1%</td>
</tr>
<tr>
<td>2019</td>
<td>Continuations (A0)</td>
<td>41.7%</td>
</tr>
<tr>
<td>2019</td>
<td>Continuations with Resubmissions (A1)</td>
<td>44.7%</td>
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<tr>
<td>2019</td>
<td>Supplements</td>
<td>31.3%</td>
</tr>
<tr>
<td><strong>2019</strong></td>
<td><strong>FY Total</strong></td>
<td><strong>21.0%</strong></td>
</tr>
</tbody>
</table>

### NIH R01-Equivalent Grants Success Rates - FY2019

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Competing Status (Type)</th>
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<tr>
<td>2019</td>
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<td>Continuations (A0)</td>
<td>41.7%</td>
</tr>
<tr>
<td>2019</td>
<td>Continuations with Resubmissions (A1)</td>
<td>44.7%</td>
</tr>
<tr>
<td>2019</td>
<td>Supplements</td>
<td>31.3%</td>
</tr>
<tr>
<td><strong>FY Total</strong></td>
<td></td>
<td><strong>21.0%</strong></td>
</tr>
</tbody>
</table>

Center for Scientific Review
- Integrated Review Groups (IRG's) -

- AIDS and Related Research
- Biobehavioral and Behavioral Processes
- Biological Chemistry and Macromolecular Biophysics
- Biology of Development and Aging
- Bioengineering Sciences and Technologies
- Brain Disorders and Clinical Neuroscience
- Cardiovascular and Respiratory Sciences
- Cell Biology
- Digestive, Kidney, and Urological Systems
- Emerging Technologies and Training in Neurosciences
- Endocrinology, Metabolism, Nutrition and Reproductive Sciences
- Genes, Genomes and Genetics
- Healthcare Delivery and Methodologies

https://public.csr.nih.gov/StudySections/IntegratedReviewGroups
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- Immunology
- Infectious Diseases and Microbiology
- Integrative, Functional, and Cognitive Neuroscience
- Interdisciplinary Molecular Sciences and Training
- Molecular, Cellular, and Developmental Neuroscience
- Musculoskeletal, Oral and Skin Sciences
- Oncology 1 – Basic Translational
- Oncology 2 – Translational Clinical
- Population Sciences and Epidemiology
- Risk, Prevention and Health Behavior
- Surgical Sciences, Biomedical Imaging, and Bioengineering
- Vascular and Hematology
Oncology 2 - Translational Clinical IRG – OTC

The Oncology 2 – Translational Clinical Integrated Review Group (OTC IRG) will consider applications involving translational and clinical investigations that encompass cancer prevention, diagnosis and treatment.

Specifically, the OTC IRG reviews research grant applications related to mechanism of action of cancer therapeutic agents in both in vitro and in vivo model systems; development and evaluation of experimental therapies of neoplastic diseases; translation of basic research to clinical practice; development or optimization of treatment modalities; radiation biology and therapy; chemoprevention; and development of biomarkers/signatures for tumor detection and diagnosis.

https://public.csr.nih.gov/StudySections/DTCS/OTC
Oncology IRG 2 - Translational Clinical IRG

- Cancer Biomarkers [CBSS]
- Cancer Prevention [CPSS]
- Cancer Immunopathology and Immunotherapy [CII]
- Clinical Oncology [CONC]
- Drug Discovery and Molecular Pharmacology [DMP]
- Developmental Therapeutics [DT]
- Mechanisms of Cancer Therapeutics 1 [MCT1] and 2 [MCT2]
- Radiation Therapeutics and Biology [RTB]
- Small Business Special Emphasis Panels

In Oncology 1 IRG: Oncology Sciences Fellowship Panels [F09]
Radiation Therapeutics and Biology Study Section – RTB

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

Topics

Shared Interests and Overlaps

Membership Panel

The membership panel is a list of chartered members only.

View Membership Panel

Review Dates

- List of Reviewers on 02/22/2021
- List of Reviewers on 10/08/2020
- List of Reviewers on 06/08/2020

https://public.csr.nih.gov/StudySections/DTCS/OTC/RTB
“Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 and NOT-OD-15-106, including removal of the application from immediate review.”
## Project Details

<table>
<thead>
<tr>
<th>Agency/Institute/Center</th>
<th>NIH Spending Category</th>
<th>Funding Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Admin</td>
<td>AND OR</td>
<td></td>
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<tr>
<td>Award Type</td>
<td>Project Number/Application ID</td>
<td>Activity Code</td>
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<td>Radioterpematics and Biology Study Section [RTP]</td>
<td>5R01CA012345-04/ 8515397, semicolon &quot;;&quot; separated</td>
<td></td>
</tr>
<tr>
<td>1 R01 CA 811099 01 A1S1</td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Study Section</td>
<td>Program Officer (PO)</td>
<td>Project Start Date</td>
</tr>
<tr>
<td>Standing CSR study sections only</td>
<td>PO Names, semicolon &quot;;&quot; separated</td>
<td>Format: MM/DD/YYYY</td>
</tr>
</tbody>
</table>
How to Direct a Grant Application to the Appropriate Study Section

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

PHS Assignment Request Form

Funding Opportunity Number: Pre-populated from announcement information.

Awarding Component Assignment Suggestions (optional)

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment suggestions can be honored.

Information about Awarding Component can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Suggested Awarding Components: Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Study Section Assignment Suggestions (optional)

If you have a suggestion for a study section assignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section in the boxes for "Suggested Study Sections." Remove all hyphens, parentheses, and spaces. All suggestions will be considered; however, not all assignment suggestions can be honored.

For example, enter "CAMP" if you wish to suggest assignment to the NIH Cancer Molecular Pathobiology study section, or "ZRG1HDMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Suggested Study Sections: Suggestions are considered with other assignment factors. Not all suggestions can be honored.

Only 20 characters allowed

Rationale for assignment suggestions (optional)

Entry is limited to 1000 characters.

Up to 1000 characters.
PHS Assignment Request Form

List individuals who should not review your application and why (optional)

Provide sufficient information (e.g., name organization affiliation) to correctly identify each individual. Provide specific reason why an individual should not review your application. Information will be considered, but listing an individual does not guarantee they will not be on review panel.

Identify scientific areas of expertise needed to review your application (optional)

Note: Do not provide names of individuals

Expertise: Each entry is limited to 40 characters

Limit your answers to expertise. DO NOT enter the names of individuals you’d like to review your application.
How are Assignments Made?

To Study Sections Based on:
- Specific review guidelines of each Study Section

To Institutes Based on:
- Overall mission of the Institute
- Specific programmatic mandates and interests of the Institute

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

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

**Referral Officers** – Trained as scientists, most of whom serve as Scientific Review Officers (SROs) of Study Sections

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

Scientific Review Officers

- Performs administrative and technical review of applications
- Selects reviewers
- Manages Study Sections
- Prepares summary statements
- Provides any requested information about Study Section recommendations

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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Criteria for Selection of Peer Reviewers

- Demonstrated scientific expertise
- Doctoral degree or equivalent
- Mature judgment
- Balanced perspective and objectivity
- Ability to work effectively in a group context
- Interest in serving
- Adequate representation of women and diverse scientists

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

Jaime S. Rubin, Ph.D.; http://grantcourse.columbia.edu
Pink Sheet: Reviewers’ Comments
Initial Review Group or Study Section

Actions

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

- **Not Discussed:**
  - Receives Scores for individual core review criteria

- **Not Recommended for Further Consideration (NRFC)**

- **Other:** e.g. Deferred

“current criteria derive from multiple regulations; changes that conform to them well are more feasible than those that don’t. The Code of Federal Regulations (42 C.F.R. Part 52h.8) requires that research project applications be evaluated based on significance, investigators, innovation, approach, and environment. Protections for humans, animals, and the environment, adequacy of inclusion plans, and budget must be evaluated. The “21st Century Cures” Act (Public Law 114-255) requires attention to rigor and reproducibility and aspects of clinical trials. That said, there is room for improved implementation.”
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

---

For Research Project Grant (Parent R01 Clinical Trial Not Allowed) (PA-20-185)
Check individual funding announcement if applying to another


Impact Score

- **Preliminary Impact Scores** determine which applications discussed at study section

- **Impact Score given by each member** of the study section

- **Overall Impact Score** (for discussed applications): Mean of reviewers’ Impact Scores \( \times 10 \)

- 81 possible overall Impact Scores
  
  \( (10 - 90, \text{ whole numbers}) \)

http://enhancing-peer-review.nih.gov/timelines.html

http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/7payline.aspx

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
NIH's Review Criteria

Core Review Criteria
A separate score is given for each 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>
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<tbody>
<tr>
<td>Strengths</td>
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NIH Research Grant Applications: Changes

Applications deadlines **on/after January 25, 2019**

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<thead>
<tr>
<th>Form</th>
<th>Section</th>
<th>Heading</th>
<th>Current language</th>
<th>Revised language</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Plan</td>
<td>Research Strategy</td>
<td>Significance</td>
<td>Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.</td>
<td>Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.</td>
</tr>
<tr>
<td>Research Plan</td>
<td>Research Strategy</td>
<td>Approach</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Human Subjects and Clinical Trials Information</td>
<td>Section 2 – Study Population Characteristics</td>
<td>2.4 Inclusion of Women, Minorities, and Children</td>
<td>2. Inclusion of Children [References to the Inclusion of Children in Clinical Research policy]</td>
<td>2. Inclusion Across the Lifespan [References to Inclusion of Children replaced with Inclusion Across the Lifespan]</td>
</tr>
</tbody>
</table>

Notice Number: NOT-OD-18-228


NIH's Review Criteria

(A) Significance:

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

(2) Is the prior research that serves as the key support for the proposed project rigorous?

(3) If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

(4) How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?”

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(B) Investigators:

1. “Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project?
2. If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training?
3. If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
4. If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?”


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NIH's Review Criteria

(C) Innovation:

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

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

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

(D) Approach:

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

(2) Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?

(3) Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”

NIH's Review Criteria

(D) Approach:

(4) “Are potential problems, alternative strategies, and benchmarks for success presented?

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

(6) Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?”

NIH's Review Criteria

(D) Approach:

“If the project involves human subjects and/or NIH-defined clinical research, are the plans to address

1) the protection of human subjects from research risks, and

2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?”

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NIH's Review Criteria

(E) "Environment:

(1) "Will the scientific environment in which the work will be done contribute to the probability of success?"

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

(3) Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?"
Additional Review Criteria & Considerations

**Additional Review Criteria** – Evaluated 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 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


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Guidance for NIH Reviewers

- Rigor and Transparency
- Sex as a Biological Variable
- Vertebrate Animals
- Human Subjects Section
- Clinical Trials
- Single IRB for multi-site studies
- Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research
- Human Embryonic Stem Cells
- Authentication of Key Biological and/or Chemical Resources
- Select Agents
- Resource Sharing Plans
- Budget Information
- Revision Applications


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
### Guidelines for NIH Reviewers


<table>
<thead>
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<th>Letter</th>
<th>Description</th>
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<tr>
<td>R</td>
<td>R and U Awards (Research Project Grants; R01, R03, R21, SBIR/STTR, etc. and Cooperative Agreements: U01, etc.).</td>
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</tr>
<tr>
<td>K</td>
<td>K Awards (Career Development)</td>
<td>+</td>
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<tr>
<td>F</td>
<td>F Awards (Fellowships)</td>
<td>+</td>
</tr>
<tr>
<td>S</td>
<td>S10 Awards (Shared Instrumentation)</td>
<td>+</td>
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<tr>
<td>T</td>
<td>T Awards (Training)</td>
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# Guidelines for NIH Reviewers


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<tr>
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<tr>
<td>KATZ R01 GUIDE FOR REVIEWERS (01/19/2021)</td>
<td><a href="#">NEW</a></td>
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<td>R01 GUIDE FOR REVIEWERS (08/20/2019)</td>
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<td>R15 GUIDE FOR REVIEWERS (08/14/2020)</td>
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<td>R34 GUIDE FOR REVIEWERS (08/20/2019)</td>
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<td>U01 BRP GUIDELINES FOR REVIEWERS (08/20/2019)</td>
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<td>R13/U13 GUIDE FOR REVIEWERS (08/20/2019)</td>
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<td>R41, R42, R43, R44 GUIDE FOR REVIEWERS (04/05/2016)</td>
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<td>Guide for Reviewers for 1R44 SBIR Direct Phase II applications (03/18/2019)</td>
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 NIH Research Grant Review Criteria: Changes

- Application deadlines on/after January 25, 2019

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<th>Section</th>
<th>Criteria</th>
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<th>Revised language</th>
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<tr>
<td>Scored Review Criteria</td>
<td>Significance</td>
<td>Is there a strong scientific premise for the project?</td>
<td>Is the prior research that serves as the key support for the proposed project?</td>
</tr>
<tr>
<td>Scored Review Criteria</td>
<td>Approach</td>
<td>Not Applicable</td>
<td>Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?</td>
</tr>
</tbody>
</table>

Notice Number: NOT-OD-18-228


# NIH Research Grant Review Criteria: Changes

- **Application deadlines on/after January 25, 2019**

| Scored Review Criteria | Approach | If the project involves human subjects and/or NIH-defined clinical research, are the plans to address: 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed? | If the project involves human subjects and/or NIH-defined clinical research, are the plans to address: 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children and older adults, justified in terms of the scientific goals and research strategy proposed? |

**Notice Number: NOT-OD-18-228**


## NIH Research Grant Review Criteria: Changes

- **Applications deadlines** on/after January 25, 2019

| Additional Review Criteria | Inclusion of Women, Minorities, and Individuals Across the Lifespan | When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. | When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. |

**Notice Number:** NOT-OD-18-228

Clinical Trial-Specific Review Criteria

FOAs that accept clinical trials will include additional review criteria questions in Section V. Application Review Information.

The NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials

Scored Review Criteria

Significance
Investigator(s)
Innovation
Approach
Study Design
Data Management and Statistical Analysis
Environment
Additional Review Criteria
Study Timeline

Notice Number: NOT-OD-17-118

Key Dates
Release Date: September 21, 2017

https://grants.nih.gov/policy/clinical-trials/review-criteria.htm

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

Notice Number: NOT-OD-16-011

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

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

Updates include:

• Revisions to application guide instructions for preparing your research strategy attachment
• Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
• Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications.

https://grants.nih.gov/grants/peer/critiques/rpg.htm
Implementing Rigor and Transparency in NIH & AHRQ Career Development Award Applications

Notice Number: NOT-OD-16-012

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

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

Updates include:

- Revisions to application guide instructions for preparing your research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications.

https://grants.nih.gov/grants/peer/critiques/k.htm
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
<table>
<thead>
<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rigor of the Prior Research</td>
<td>A careful assessment of the <em>rigor of the prior research</em> that serves as the key support for a proposed project will help applicants identify any weaknesses or gaps in the line of research. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.</td>
<td><em>See related FAQs, blog post</em></td>
</tr>
<tr>
<td>Scientific Rigor (Design)</td>
<td><em>Scientific rigor</em> is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results.</td>
<td><em>See related FAQs, blog post, examples from pilots</em></td>
</tr>
</tbody>
</table>

See: [Related FAQs](https://grants.nih.gov/grants/Rigor-and-Reproducibility-Chart-508.pdf)

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<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
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</thead>
<tbody>
<tr>
<td>Biological Variables</td>
<td>Biological variables, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex. <em>See related FAQs, blog posts, article</em></td>
<td>Research Strategy&lt;br&gt;➢ Approach</td>
</tr>
</tbody>
</table>
| Authentication | Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These resources may or may not have been generated with NIH funds and: • may differ from laboratory to laboratory or over time; • may have qualities and/or qualifications that could influence the research data; • are integral to the proposed research. The authentication plan should state in one page or less how you will authenticate key resources, including the frequency, as needed for your research. Note: Do not include authentication data in your plan. *See related FAQs, blog post, examples* | Other Research Plan Section<br>➢ Include as an attachment<br>➢ Do not include in the Research Strategy.
NIH's Evaluation/Scoring System

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

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
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<tr>
<td>High Impact</td>
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<td>Exceptional</td>
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<td>2</td>
<td>Outstanding</td>
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<td></td>
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<td>Excellent</td>
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<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
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<td>6</td>
<td>Satisfactory</td>
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<td>Low Impact</td>
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<td></td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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</table>

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


Research Applications

Overall Impact:
The likelihood for a project to exert a **sustained, powerful** influence on research field(s) involved

**Evaluating Overall Impact:**
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer’s judgment) and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

- **High Impact**
  - e.g. Applications are addressing a problem of **high importance/interest** in the field. May have some or no weaknesses.
  - 5 is a good medium-impact application, and the entire scale (1-9) should always be considered.

- **Medium Impact**
  - e.g. Applications may be addressing a problem of **high** importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
  - e.g. Applications may be addressing a problem of **moderate** importance in the field, with some or no weaknesses.

- **Low Impact**
  - e.g. Applications may be addressing a problem of **low** or **no importance** in the field, with some or no weaknesses.

FELLOWSHIPS & CAREER AWARDS

Overall Impact:
The likelihood that the proposed training (F) or career development (K) will enhance the candidate's potential for a productive, independent scientific research career in a health-related field.

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
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<tbody>
<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
</tbody>
</table>

Evaluating Overall Impact
Consider the 5 criteria (weighting based on reviewer’s judgment):

**Fs**
- Applicant
- Sponsor(s)
- Research Training Plan
- Training Potential
- Institutional Environment & Commitment

**Ks**
- Candidate
- Career Development Plan/Goals*
- Research Plan
- Mentor(s)**
- Environment & Institutional Commitment

and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards

*K05 and K24: Plan to Provide Mentoring
**K02: Consultants/Collaborators

5 is a good, medium-impact application. The entire scale (1-9) should always be considered.

e.g. Proposes training or career development of high or moderate value/benefit for the candidate who has high potential for developing into a productive, independent scientist. May have some or no weaknesses in the criteria.

e.g. Proposes training or career development of high or moderate value/benefit for the candidate who has high or moderate potential for further development, but weaknesses in the criteria reduce the overall impact to medium.

e.g. Proposes training or career development of moderate value/benefit for the candidate who shows moderate potential. May have some weaknesses in the criteria.

e.g. Proposes training or career development of low value/benefit for the candidate who shows low potential. May have some weaknesses in the criteria.
Impact Score

- Preliminary Impact Scores determine which applications discussed at study section
- Impact Score given by each member of the study section
- **Overall Impact Score** (for discussed applications): Mean of reviewers’ Impact Scores \( \times 10 \)
- 81 possible overall Impact Scores
  
  \( 10 - 90 \), whole numbers

http://enhancing-peer-review.nih.gov/timelines.html
http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/7payline.aspx

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
# Calculating Percentile

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

- Relative rank for each priority score on a scale from 10 to 90.

- Follows NIH convention: Inverse relationship of priority score to scientific merit - lowest percentile value represents the highest scientific merit.

- Specifies the percent of applications with scores equal to or better than (lower impact score) the application

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

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

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

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

// // //

80

Rank = 3

\[ P = \frac{100}{80} \times (3^{\frac{1}{2}}) = 3.1 \]

* Study section’s last three review cycles

NIAID: Payline

From: National Institute of Allergy and Infectious Diseases (NIAID) <naiid@se
Sent: Wednesday, January 27, 2021 4:33 PM
To: jsr9@columbia.edu
Subject: [EXTERNAL] NIAID Alert: Fiscal Year Paylines for R01, R03, and R21

Fiscal Year Paylines for R01, R03, and R21

We posted the following new fiscal year NIAID Paylines:

- Research projects (R01)—14 percentile for non-new PIs, 18 percentile for new PIs.
- Small grants (R03)—31 overall impact score.
- Exploratory/developmental grants (R21)—31 overall impact score.

FY2021 (1/27/2021 e-mail)
<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>
</tbody>
</table>
What’s the problem?

Payline

Study Section A

Study Section B

Great application

Not great application

Courtesy of Dr. Jon Lorsch, NIGMS
What’s the problem?

Payline

Study Section A

Study Section B

Great application

Not great application

Courtesy of Dr. Jon Lorsch, NIGMS
Post Initial Review Group Actions

- Calculations of priority scores and percentile rankings
- Removal of applications from Council/Board consideration

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

- Concurrence with Study Section action
- Modification of Study Section action based on program or policy considerations
- Deferral for further review

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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
What Determines which Awards are Made?

- Scientific Merit
- Program Considerations
- Availability of Funds
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
The Opinion Pages

OP-ED CONTRIBUTOR

Young, Brilliant and Underfunded

By ANDY HARRIS

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

Comments

The New York Times

OCT. 2, 2014

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
    - (e.g., medical, clinical training, military service, disability)
  - “effective immediately, NIH will approve an ESI extension of one year for childbirth within the ESI period”

Early Stage Investigator (ESI) Status

ESI status may give you special funding consideration when applying for certain grants.

Early Stage Investigator (ESI)

- New and Early Stage Investigator Policies

- Frequently Asked Questions
  https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm

- Extension to the Early Stage Investigator Period
  - Request submitted (with justification) via the Education section of an investigator’s Personal Profile in NIH Commons.
Extension Policy for Early Stage Investigator Status (ESI)

- “NIH considers requests for extension of the ESI period for various reasons, including medical concerns, disability, extended periods of clinical training, natural disasters, active duty military service.”

- “Because close to 50% of the ESI extension requests are related to childbirth, effective immediately, NIH will approve an ESI extension of one year for childbirth within the ESI period.”

# Early Stage Investigators: NHLBI

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>R01</td>
<td>Research Project Grant</td>
<td>16</td>
</tr>
<tr>
<td>R01 ESI</td>
<td>Early Stage Investigators</td>
<td>26</td>
</tr>
</tbody>
</table>

## FY2020

https://www.nhlbi.nih.gov/current-operating-guidelines

R01-Equivalent grants, New (Type 1): Funding rates, by career stage of investigator
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”. NIH must encourage successful, independent careers for Early Stage Investigators (ESIs) in a way that enhances workforce diversity, and must create a sustainable workforce across all career stages to ensure the long term stability of the biomedical research enterprise.
“at-risk” investigators -- applicants with meritoriously-scored applications who would not have major NIH research funding if the application under consideration is not awarded. In addition, an “at-risk” investigator would not have significant research support from other sources.

A cited benefit of looking at using an “at-risk” definition as characterized above is that it would support both ESI applicants (with no history of prior, major independent research funding) and mid-career applicants (both New Investigators/those with no history of prior major independent research funding, and those who may have has a prior major award such as an R01, but are now at risk for losing funding).”
“The overarching goal of this pilot program is to enhance the retention of investigators facing critical life events who are transitioning to the first renewal of their first independent research project grant award or to a second new NIH research project grant award… This program supports “at-risk” investigators as identified in the NIH Next Generation Researchers Initiative (see https://grants.nih.gov/ngri.htm).”

“Qualifying Critical Life Events: The PD/PI must demonstrate a critical life event such as childbirth or adoption during the parent grant project period; or primary caregiving responsibilities of an ailing spouse, partner, or a member of the immediate family. In circumstances in which the critical life event is pending and is expected to occur during the project period, the supplement period may be submitted in advance of the event.”
“The overarching goal of this program is to support the transition and retention of investigators from mentored career development to research independence and to minimize departures from biomedical research workforce at this critical juncture. This supplement program is intended to ensure continuity of research among recipients of mentored career development (K) awards by providing supplemental research support to help sustain the investigator’s research during critical life events.

For the purposes of this program, childbirth, adoption, and primary caregiving responsibilities of an ailing spouse, child, partner, or a member of the immediate family during the project period are critical life events that would qualify for consideration.”
Next Generation Researchers Initiative Working Group

ACD Working Group on Biomedical Workforce

ACD Physician-Scientist Workforce

ACD Working Group on Diversity

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