Navigating the NIH for Early Career Researchers

October 29, 2019
Research Development Services provides a variety of services for faculty seeking support for research, creative work, public service and scholarly projects.
Agenda

• Overview of NIH
  • Mission
  • Budget
  • Organizational structure

• Funding Opportunities
  • How to find
  • How to comprehend

• NIH for Early Career Researchers
  • Early career mechanisms
  • ESI vs. NI

• Timeline for successful submission

• Peer Review Process
  • Opportunities to serve on peer-review
NIH Mission

NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
NIH Goals

• to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
• to develop, maintain, and renew scientific human and physical resources that will ensure the Nation's capability to prevent disease;
• to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
• to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.
NIH Budget Allocation

FY 2018 NIH Budget
$25.8 Billion - Estimated Percent Total by Mechanism

- Research Project Grants: 53%
- Research Centers: 8%
- Intramural Research: 11%
- Research & Development Contracts: 9%
- Research Management & Support: 6%
- Buildings and Facilities: 10%
- Other Research, Superfund, Office of the Director, PCORTF: 10%
- Research Training: 3%
NIH Structure

Comprised of 27 institutes and centers, each with different:

- Mission & priorities
- Budget
- Funding strategy
Extramural Organizational Structure
Extramural Organizational Structure

Program

Review

Grants Management
Program Officer

• Responsible for the programmatic, scientific, and/or technical aspects of a grant

• Provides scientific guidance to investigators pre- and post-award

• Develops initiatives

• Provides post-award oversight
Scientific Review Officer

• Responsible for scientific and technical review
  • Ensures fair and unbiased evaluation of scientific and technical merit
  • Provides a summary of the evaluation
  • Reviews applications for completeness and conformance with application requirements

• Point of contact for applicants during the review process
Grants Management Officer

• Responsible for completion of business management requirements
  • Evaluates applications for administrative content and compliance with policy
  • Negotiates awards
  • Interprets grants administration policies
Finding Funding Opportunities

• **Pivot**
  - Search by funder
  - Weekly updates based on your keyword

• **NIH Guide Listserv**
  - Receive weekly updates on Friday
  - [https://grants.nih.gov/grants/guide/listserv.htm](https://grants.nih.gov/grants/guide/listserv.htm)

• **Grants.gov**
<table>
<thead>
<tr>
<th>Type of FOA</th>
<th>Description</th>
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| **Program Announcements (PA, PAR, PAS)**            | • Highlights areas of focus  
• Usually ongoing (3 years)  
• Often use standard receipt dates                                                                                                                                                                         |
| **Requests for Applications (RFA)**                 | • Narrowly defined scope  
• Usually single receipt date  
• Set aside funds  
• Institutes & Centers (IC) usually convenes review panel                                                                                                                                                  |
| **Parent Announcements**                            | • Type of program announcement  
• Generally span the breadth of NIH mission  
• By activity code (R01, R03, etc.)  
• For “investigator initiated” or “unsolicited” research ideas                                                                                                                                              |
Understanding Funding Opportunities

Department of Health and Human Services
Part 1. Overview Information

Participating Organization(s)
National Institutes of Health (NIH [http://www.nih.gov])

Components of Participating Organizations
National Cancer Institute (NCI [http://www.nci.nih.gov])
National Eye Institute (NEI [http://www.nei.nih.gov])
National Heart, Lung, and Blood Institute (NHLBI [http://www.nhlbi.nih.gov])
National Human Genome Research Institute (NHGRI [https://www.genome.gov])
National Institute on Aging (NIA [http://www.nia.nih.gov])
National Institute on Alcohol Abuse and Alcoholism (NIAAA [http://www.niaaa.nih.gov])
National Institute of Allergy and Infectious Diseases (NIAID [http://www.niaid.nih.gov])
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS [http://www.niams.nih.gov])
National Institute of Biomedical Imaging and Bioengineering (NIBIB [http://www.nibib.nih.gov])
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD [http://www.nichd.nih.gov])
National Institute of Dental and Craniofacial Research (NIDCR [http://www.nidcr.nih.gov])
National Institute on Deafness and Other Communication Disorders (NIDCD [https://www.nidcd.nih.gov])
National Institute on Drug Abuse (NIDA [http://www.nida.nih.gov])
National Institute of Environmental Health Sciences (NIEHS [http://www.niehs.nih.gov])
National Institute of General Medical Sciences (NIGMS [http://www.nigms.nih.gov])
National Institute of Mental Health (NIMH [http://www.nimh.nih.gov])
National Institute of Neurological Disorders and Stroke (NINDS [http://www.ninds.nih.gov])
National Institute of Nursing Research (NINR [http://www.ninr.nih.gov])
National Institute on Minority Health and Health Disparities (NIMHD [http://www.nimhd.nih.gov])
National Center for Complementary and Integrative Health (NCCIH [http://www.nccam.nih.gov])
Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP [http://dpccps.nih.gov/orip/index.shtml])

Note: Not all NIH Institute and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the B01 IG- Specific Scientific Interests and Contact [https://grants.nih.gov/grants/guide/contacts/parent-b01-ig-specific-scientific-interests-and-contact.html].
Understanding Funding Opportunities

Announcement Type

Related Notices
Understanding Funding Opportunities

Application Due Date(s)

Standard dates (https://grants.nih.gov/grants/guide/url_redirect.htm?id=11111) apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.

Review and Award Cycles

<table>
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<tr>
<th></th>
<th>Cycle I</th>
<th>Cycle II</th>
<th>Cycle III</th>
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<tbody>
<tr>
<td>Application Due Dates</td>
<td>January 25 - May 7</td>
<td>May 25 - September 7</td>
<td>September 25 - January 7</td>
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<tr>
<td>Scientific Merit Review</td>
<td>June - July</td>
<td>October - November</td>
<td>February - March</td>
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<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>
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Funding Mechanism by Career Stage

- Graduate/Clinical Training: T32, T35, F30, F31
- Postdoctoral Training/Clinical Residency: T32, F32, R25, K12
- Early Research Career: K01, K07, K25, K08, K23, K22, K99, K22, R00
- Established Investigator: R03, R21, R01, DP2, K02, K24, P01, P50

- Loan Repayment Programs
- Diversity Supplements
- Re-Entry Supplements
<table>
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<tr>
<th>Mechanism</th>
<th>Description</th>
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| **R01**  | - Used to support a discrete, specified, circumscribed research project  
           - Need extensive preliminary data  
           - Utilized by all ICs |
| **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.**  
           - No preliminary data is generally required***  
           - Most ICs utilize |
| **R03**  | - Provides limited funding for a short period of time to support a variety of types of projects, including: pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small, self-contained research projects, etc.  
           - Utilized by more than half of the NIH ICs  
           - Consider UO INTERNAL funding |
| **DP2**  | - To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research. |
| **K-Series** | - For support of a scientist/clinician, committed to research, in need of both advanced research training and additional experience  
              - Transition between career stages |
Funding Opportunities for Early Career Researchers

DP2: NIH Director’s New Innovator Award

• Supports early-stage investigators of exceptional creativity who propose bold and highly innovative new research approaches that have the potential to produce a major impact in biomedical and behavioral research
• Awardees are required to commit at least 25% of their research effort each year to activities supported by the New Innovator Award
• $1.5M in direct costs over 5 years
• Typically due late August/early September
Funding Opportunities for Early Career Researchers

NIGMS MIRA for Early Stage Investigators (R35)

• Improve the efficiency and effectiveness of its support for basic biomedical research
• Increase the stability of investigator funding
• Enhance investigators’ ability to take on ambitious scientific problems creatively
• Increase the flexibility for investigators to follow important new research directions
• Improve the distribution of funding to improve overall scientific productivity and the chances for important breakthroughs
• Reduce the time spent by researchers writing and reviewing grant applications
NI vs. ESI

NI: New Investigator

An investigator who has not previously received substantial, independent funding from NIH. Following awards are NOT considered substantial:

- R00, R03, R21, R56, etc.
- Any training mechanism (F, T)
- Institutional or individual K series for mentorship
- Loan repayment
NI vs. ESI

ESI: Early Stage Investigator
Any NI investigator who is also within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency

ESI Applying for R01 or DP2 grants:

- Receive special attention at Review (career stage) and at National Advisory Council (high program priority)
- No imposed reductions in duration and amount of awards (beyond the recommendations of the initial review group)
- Increased payline for scored R01 applications from Early-Stage Investigators
Extending ESI status

• Some researchers may have lapses in their research or research training, or have experienced periods of less than full-time effort. NIH will consider requests to extend the ESI status period for reasons that can include: medical concerns, disability, family care responsibilities, natural disasters, and active duty military service, determined on a case by case basis at the sole discretion of NIH.

• Principal investigators can submit a request for an ESI extension via an ESI Extension Request link found in the Education section of the PI's Personal Profile in eRA Commons. For step-by-step instructions, see the ESI Extension Request online help and the ESI Status Extension Request video tutorial.
Preparing your submission

When is the right time to submit?
Balance between:

• Getting your lab started/keeping the work going
• Submitting at the most optimal time
  • Submit when you think the application will be the most competitive

Consider:

• Your publication record
  • Papers must be published/in press (not submitted)
  • Do they pertain directly to the aims?
• Your preliminary data
Preparing your submission

Heilmeier Catechism

- What are you trying to do? Articulate your objectives using absolutely no jargon.
- How is it done today, and what are the limits of current practice?
- What is new in your approach and why do you think it will be successful?
- Who cares? If you are successful, what difference will it make?
- What are the risks?
- How much will it cost?
- How long will it take?
- What are the mid-term and final “exams” to check for success?
Preparing your submission

<table>
<thead>
<tr>
<th>Months Prior</th>
<th>PLANNING</th>
<th>WRITING</th>
<th>SUBMITTING</th>
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<tbody>
<tr>
<td>8</td>
<td>7</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1 mo.</td>
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Assess yourself, field, & resources

8
Brainstorm; research idea; call NIH staff

7
Set up own review committee; determine human & animal subject requirements

6
Outline application structure; write your application

5
Meet institutional deadlines

4
Get feedback; edit & proofread

3
 Receipt Date

2
Preparing your submission

NIH funds well-operationalized studies

Will you be in trouble if the study is…?

Discovery-driven? No, but you need to:
  • Describe the rationale for the aim and how it will provide the foundation to follow up with more mechanistic questions
  • Have a defined plan for prioritizing large amounts of data

Uses a model system? No, but you need to:
  • Place the work in context as to how it will propel the field forward
  • Emphasize its significance

Not immediately translational? No,
  • But if you discuss the potential translatability of a study it becomes fair game for reviewers to disagree
Next Workshop

NIH Part 2: Preparing Your First R-Series Submission

- Developing your outline
  - Components of a proposal and resources to help prepare
- Anatomy of an aims page
- Grant review with NIH peer-reviewers

Tuesday, November 19, 12-1pm
EMU Cedar (231)
Peer Review Process

Great Research Idea!

Investigator
Performs the Research

Institution
Submits Application
Allocates Funds

National Institutes of Health
Center for Scientific Review
Assigns to IC & IRG / Study Section

Study Section
Reviews for Scientific Merit

Institute
Evaluates for Relevance

Advisory Councils & Board
Recommends Action

Institute Director
Makes Funding Decision
Peer Review Process

Center for Scientific Review (CSR) vs. Institute/Center Review:
- CSR is most R01s, some PA/RFA
- IC review is for specific program projects, training grants, career development awards, RFAs

Study Sections:
- Do NOT make funding decisions
- Evaluate and make recommendations based on review criteria
- Provide priority scores (or not discussed) and written critiques (summary statements)

Reviewer assignments:
- Minimum of 3 reviewers per proposal
- Based on scientific content, expertise and consider COI
Review Process

Top 50% of proposals are discussed in study section:
  • 9 hour day of review; each proposal gets ~13-14 minutes

In discussion:
  • Reviewers with conflicts leave room
  • Assigned reviewers present initial scores
  • Primary reviewer explains project; strengths/weaknesses
  • Other assigned reviewers follow
  • Open discussion
  • Assigned reviewers present score following discussion
    • Indication of voting out of range
Scoring Criteria

Review FOA: relevant criteria listed here
  • Sent to reviewers; guides discussions; format for critiques in summary statement

Standard Criteria: 1-9
  • Significance
  • Approach
  • Innovation
  • Investigator(s)
  • Environment
  • Protection of human subjects/Vertebrate Animals/Biohazard*

Overall Impact/Priority Score: 1-9
Priority/Impact Score

Overall Impact:
The likelihood that a project will have a sustained and powerful influence on science (and/or clinical practice and/or technological developments?)

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
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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: significance, investigator, innovation, approach, environment (weighted based on reviewer’s judgment)

- e.g. Applications are addressing a problem of high importance in the field. May have some or no technical weaknesses.
- 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 technical weaknesses.
- e.g. Applications may be addressing a problem of moderate/high importance in the field, but weaknesses in the criteria bring down the overall impact to low.
- e.g. Applications may be addressing a problem of low or no importance in the field, with some or no technical weaknesses.

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

PROGRAM CONTACT: Stuart Moss
(301) 435-6979 mossstua@mail.nih.gov

SUMMARY STATEMENT (Privileged Communication)
Release Date: 03/27/2016

Application Number: 1 R21 HDXXXXX-01
Principal Investigator: CURIE, MARIE, PHD
Applicant Organization: University of Paris
Review Group: CMIR Meeting Date: 03/23/2016
RFA/PA: PA11-261
Council: MAY 2014 PCC: RS-SM
Requested Start: 07/01/2016
Project Title: The Effect of Radium on the Testis

SRG Action: Impact/Priority Score: 30 Percentile: 22 #
Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved –no SRG concerns noted
Summary Statement

RESUME AND SUMMARY OF DISCUSSION:
Written by the SRO based on the final outcome of the discussion, summarizes strengths & weaknesses mentioned by all reviewers, highlights areas of concurrence & disagreement between reviewers.

CRITIQUE 1
Significance: 3
Investigator: 1
Innovation: 1
Approach: 4
Environment: 1

Overall Impact:
Written by the individual reviewer to summarize their opinion on the overall strengths and weaknesses of the application.
Early Career Reviewer Program

• Help emerging researchers advance their careers by exposing them to experience in peer review that may make them more competitive as applicants

• Train and educate qualified scientists without prior CSR review experience to develop critical and well-trained reviewers

• Enrich the existing pool of reviewers by including scientists from less research-intensive institutions
Work with RDS

Contact us for supporting the development of your proposals.

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