Outline for the Presentation

- Overview of NIH Peer Review Process
- New and Early Stage Investigators
- Preparation of your NIH grant applications
- The Role of Scientific Review Officers (SROs)
- Study Section Meetings
- Follow-Ups after Review Meetings
- Early Career Reviewer Program
Your Application Could Be Funded by One of 24 NIH Institutes or Centers

- Office of the Director
  - National Institute on Aging
  - National Institute on Alcohol Abuse and Alcoholism
  - National Institute of Allergy and Infectious Diseases
  - National Institute of Arthritis and Musculoskeletal and Skin Diseases
  - National Cancer Institute
  - Eunice Kennedy Shriver National Institute of Child Health and Human Development
  - National Institute on Deafness and Other Communication Disorders
  - National Institute of Dental and Craniofacial Research
  - National Institute of Diabetes and Digestive and Kidney Diseases
  - National Institute on Drug Abuse
  - National Institute of Environmental Health Sciences
  - National Eye Institute
  - National Institute of General Medical Sciences
  - National Heart, Lung, and Blood Institute
  - National Human Genome Research Institute
  - National Institute of Mental Health
  - National Institute of Neurological Disorders and Stroke
  - National Institute of Nursing Research
  - National Institute of Allergy and Infectious Diseases
  - John E. Fogarty International Center
  - National Center for Advancing Translational Sciences
  - National Library of Medicine
  - National Institute on Minority Health and Health Disparities
  - National Institute of Biomedical Imaging and Bioengineering
  - National Center for Complementary and Integrative Health
  - Clinical Center
  - Center for Information Technology
  - Center for Scientific Review
Overall Timeframe from Submission to Award

There are three main overlapping cycles per year

http://grants1.nih.gov/grants/funding/submissionschedule.htm
New and Early Stage Investigators

- **New Investigator (NI)**
  - PD/PI who has not yet *competed successfully* for a substantial NIH independent research award

- **Early Stage Investigator (ESI)**
  - PD/PI who qualifies as a New Investigator AND is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency (or equivalent)

The NI/ESI status is only relevant to R01 submission.

http://grants.nih.gov/grants/new_investigators/
# Timetable for New Investigator R01 Grant Applications

<table>
<thead>
<tr>
<th>Due Dates for New R01 (A0)</th>
<th>Summary Statement Release</th>
<th>Due Date for Next Round Resubmission (A1)</th>
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</thead>
<tbody>
<tr>
<td>February 5</td>
<td>July 10</td>
<td>August 10</td>
</tr>
<tr>
<td>June 5</td>
<td>November 10</td>
<td>December 10</td>
</tr>
<tr>
<td>October 5</td>
<td>March 10</td>
<td>April 10</td>
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Choose a Funding Opportunity Announcement (FOA)

• An application must be submitted in response to a FOA
• FOAs are classified by clinical trials not allowed, optional, or required
• The parent R01 program announcement
  • PA-18-484 (Clinical trial not allowed)
  • PA-18-345 (Clinical trial required)
• What to look for:
  • Participating institutes
  • Receipt dates
  • Specific requirements (e.g., applicant, research components, review criteria)
• Tip: Get guidance from an appropriate IC Program Officer before submission of your application
Assignment Request Form (ARF)

- Requests for IC assignment
- Requests for review group assignment
- Identify conflicts
- Suggest expertise

You should never suggest specific reviewers
Help Your Application Get to the Right Institute

Match your application to NIH:

- Projects: related research on the same scientific topic
- FOAs: Funding Opportunity Announcements for the topic area
- Institutes: Programs that are funding research in this topic area

http://ProjectRePORTER.NIH.gov
Help Your Application Get to the Right Study Section

Study Sections

Applications are reviewed in study sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of study sections based on scientific discipline.

Find a Study Section

Enter Keyword or Title

- or -

Use our Guided Study Section Selector

https://public.csr.nih.gov/StudySections
Quantitative Biology and Informatics Study Sections at CSR

• **Biodata Management and Analysis** [BDMA]
  – Computational methods for data acquisition, management, querying, sharing and analysis
  – Design and engineering of computing hardware and software systems

• **Modeling and Analysis of Biological Systems** [MABS]
  – Computational biology: analytical methods and modeling
  – Systems level analysis of biological processes

• **Genomics, Computational Biology and Technology Study Section** [GCAT]
  – Generation, analysis, mining, and simulation of omics datasets and genetic/genomic systems
  – Emerging genomic and epigenomic technologies
  – New computational algorithms and software as applied to omics/genetic data

• **Macromolecular Structure and Function D** [MSFD]
  – Computational molecular modeling and simulation
  – Bioinformatics on the structure, dynamics, folding pathways and function of macromolecules

• **Biomedical Computing and Health Informatics** [BCHI]
  – Collection, integration, and analysis of clinical and biological data to support clinical decisions
  – Clinical informatics, translational bioinformatics, consumer health informatics

• **Biostatistical Methods and Research Design** [BMRD]
  – Statistical quantitative methods to aid in the design, analysis, and interpretation of clinical, genomic, and population-based research studies
Assisted Referral Tool (Art)

Enter application text and get a list of relevant study sections

https://art.csr.nih.gov
Before the Study Section Meeting

- The Scientific Review Officer (SRO) performs administrative review of applications and selects and assigns reviewers.
- Each application is assigned to 3 or more reviewers 5-6 weeks in advance.
- Reviewers assess each application by providing:
  - A preliminary overall impact score (1-9).
  - Criterion scores (1-9) for each of the 5 core review criteria:
    - Significance
    - Investigator(s)
    - Innovation
    - Approach
    - Environment
  - A written critique.
At the Meeting

Discussion is done by clusters

• New Investigator R01 applications are clustered
• Clinical applications & other mechanisms may be clustered (n ≥ 20)

Not all applications are discussed

• The average of the preliminary Overall Impact score from the assigned reviewers determines the review order
• About half of the applications will be discussed
• Discussions start with the application with the best average preliminary Overall Impact score
• Applications unanimously judged by the review committee to be in the lower half are not discussed
<table>
<thead>
<tr>
<th>Rigor and Transparency Element</th>
<th>Which applications?</th>
<th>Where in the application?</th>
<th>Which Criteria?</th>
<th>What’s added to the review criteria?</th>
<th>Affect overall impact score?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Foundational) Scientific Premise</strong></td>
<td>All</td>
<td>Research Strategy (Significance)</td>
<td><strong>Significance</strong></td>
<td>Is there a strong scientific premise or foundation for the project?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Scientific Rigor</strong></td>
<td>All</td>
<td>Research Strategy (Approach)</td>
<td><strong>Approach</strong></td>
<td>Are there strategies to ensure a robust and unbiased approach?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Consideration of Relevant Biological Variables, Such as Sex</strong></td>
<td>Projects with vertebrate animals and/or human subjects</td>
<td>Research Strategy (Approach)</td>
<td><strong>Approach</strong></td>
<td>Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Authentication of Key Biological and/or Chemical Resources</strong></td>
<td>Project involving key biological and/or chemical resources</td>
<td>New Attachment</td>
<td>Additional review considerations</td>
<td>Comment on plans for identifying and ensuring validity of resources.</td>
<td>No</td>
</tr>
</tbody>
</table>
Additional Criteria Contribute to Overall Impact Scores

- Study timeline (for clinical trial applications)
- Protections for human subjects
  - Inclusions of women, minorities, and children
- Appropriate use of vertebrate animals
  - Power calculation to justify the number of animals is evaluated as scientific rigor (Approach)
  - SABV is justified as scientific rigor (Approach)
- Management of biohazards
Scoring

- Discussed applications receive an overall score from each eligible (i.e., without conflicts of interest) panel member, and these scores will be averaged to one decimal place, and multiplied by 10. The 81 possible priority scores will thus range from 10-90.

- All applications will receive scores: Not discussed applications will receive initial criterion scores from the three assigned reviewers.
After the Meeting—Your Summary Statement

- Available in eRA Commons within 30 days after the meeting (or 10 working days for ESI/NI R01s)
- Scores for each review criterion
- Critiques from assigned reviewers
- Administrative notes if any

If your application is discussed, you also will receive:

- An overall impact/priority score and percentile ranking
- A summary of review discussion
- Budget recommendations
Early Career Reviewer Program Goals

- Train and educate qualified scientists to become critical and well-trained reviewers
- Expose investigators to the peer review experience to help make them more competitive as applicants
- Enrich the existing pool of NIH reviewers
How Can I Become an Early Career Reviewer?

Apply! Instructions at
https://public.csr.nih.gov/ForReviewers/BecomeARReviewer/ECR

If you are accepted, we will:

• Place your name in our ECR database
• Invite you to serve if your expertise is needed to review particular applications
Who Can Answer Your Questions?

Before You Submit Your Application
• A Program Officer at an NIH Institute or Center
• Scientific Review Officer

After You Submit
• Your Scientific Review Officer

After Your Review
• Your Assigned Program Officer

GrantsInfo: GrantsInfo@nih.gov – 301 435-0714
CSR and NIH Information Sources
Key NIH Review and Grants Web Sites

NIH Center for Scientific Review  http://www.csr.nih.gov

NIH Office of Extramural Research  http://grants.nih.gov/
NIH Mission

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-Wide Strategic Plan: Fiscal Years 2016 - 2020
  • FY2018 budget = $26.9 B

• The 21st Century Cures Act (December 13, 2016)
  • [https://www.nih.gov/research-training/medical-research-initiatives/cures](https://www.nih.gov/research-training/medical-research-initiatives/cures)
  • $4.5 B over 10 years (FY 2017 – 2026)
  • All of Us Research Program (aka Precision Medicine Initiative)
  • BRAIN Initiative
  • Cancer Moonshot (FY 2017 – 2023)
  • Regenerative Medicine Innovation (FY 2017 – 2020; FDA + NIH)
Resources: Rigor and Transparency of Research policy

- **Key NIH Guide Notices:**
  - **NOT-OD-15-102:** Consideration of Sex as a Biological Variable in NIH-funded Research
  - **NOT-OD-15-103:** Enhancing Reproducibility through Rigor and Transparency
  - **NOT-OD-16-011:** Implementing Rigor and Transparency in NIH and AHRQ Research Grant Applications

- **Applicant and Reviewer Resources:**
  - General overview and background on the policy (video module):
    https://grants.nih.gov/reproducibility/module_1/presentation.html
  - Reviewer Guidance on Rigor and Transparency:
Your Application Was Reviewed
What Do You Do Next?

Visit NIH’s Next Steps Website

http://grants.nih.gov/grants/next_steps.htm