



Grants 101: Navigating NIH Peer Review

RCMI Consortium National Conference Investigator Development Workshop

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NIH/CSR

Scope

- Who would find this useful?
 - The Applicant / PI (i.e. ESI, NI)
- Why would this be useful?
 - For a PI (Understand the peer review process, Reduce uncertainty, Submit a competitive application)
- What I cannot talk about
 - Funding related questions
 - A previously reviewed application
 - An application that is currently under review.

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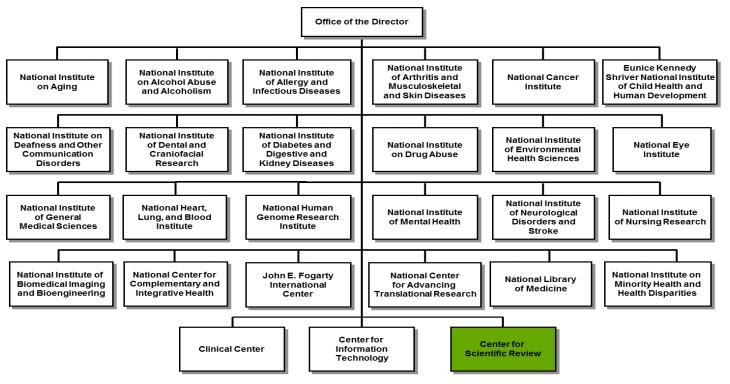
NIH... Turning Discovery Into Health



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.



Your NRSA Application Could Be Funded by One of 24 NIH Institutes (IC)



- Reviews ~75 % of ~ 85,000 applications submitted to NIH for peer review
- ~ 250 scientific review officers

The Gateway for NIH Grant Applications

The Center for Scientific Review



- Receives all NIH grant applications
- Assigns applications to one or more NIH
 Institute or Center for potential funding
- Assigns applications to CSR or NIH Institute review groups
- Conducts initial scientific merit review of most NIH research applications



CSR Mission

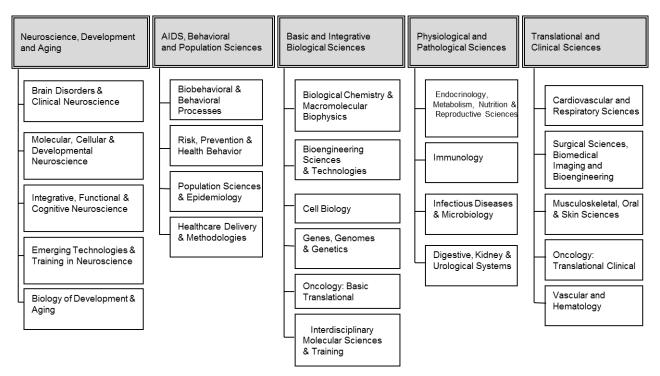


Ensure that NIH grant applications receive

fair, independent, expert, and timely scientific reviews –

free from inappropriate influences – so the NIH can fund
the most promising research.

Divisions and Integrated Review Groups (IRGs)



240 Study Sections and Recurring Special Emphasis Panels



Division of AIDS, Behavioral and Population Sciences

Integrated Review Groups

Biobehavioral & Behavioral Processes

Risk, Prevention & Health Behavior

Population Sciences and Epidemiology

Healthcare Delivery & Methodologies

Social Sciences and Population Studies

Behavioral Genetics and Epidemiology

Cardiovascular and Sleep Epidemiology

Epidemiology of Cancer

Kidney, Nutrition, Obesity, & Diabetes Epidemiology

Infectious Diseases, Reproductive Health, Asthma and Pulmonary Epidemiology

Neurological, Aging and Musculoskeletal Epidemiology



Two-level process of review and funding of NIH grant applications



Center for Scientific Review

Level I Review: Study Section

Scientific Review Officer (SRO)

- <u>Reviewers</u> assess scientific, technical, training merits of an application
- Assess merit in the form of critiques and an overall impact score to the NIH council.
- Do not make funding recommendations

~3 months

Level II Review: Institute or Center

Considers recommendations from level 1 and makes funding decision based on research priorities.

2 - 4 months

Two-level process of review and funding of NIH grant applications



Center for Scientific Review

Level I Review: Study Section

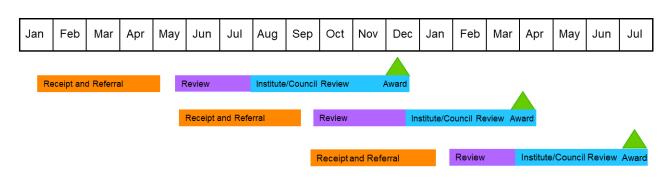
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3 - 4 months

Timeframe from Submission to Award

There are three main overlapping cycles per year



http://grants1.nih.gov/grants/funding/submissionschedule.htm



The timeline for the first level of peer review

Presubmission
(PI – PO / SRO)

Review
(PI –SRO)

Post Review
(PI – PO)



Presubmission – some pointers

Presubmission (PI – PO / SRO)

Funding Announcement

- ✓ Select appropriate FOA
- ✓ Read Details (Eligibility, Review Criteria)
- ✓ Is institute part of FOA?
- ✓ Follow Instructions, use current forms

Prepare Application

- ✓ Identify the right institute
- ✓ Study section fit? Email SRO
- ✓ Cover letter
- ✓ Submit on time (better yet early!)

Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)

Components of Participating Organizations

National Institutes of Health (NIH)

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)



Help your application get to the right <u>funding institute</u>



NIH RePORTER: Find NIH projects and funding information using text searches.

NIH Matchmaker: Copy abstract/aims

Search returns: List of Institutes, List of funded grants and Link to Program

Officials

https://report.nih.gov/



Help your application get to the right study section

- Browse CSR's list of study sections: https://public.csr.nih.gov/StudySections
- Use CSR Assisted Referral Tool (ART) https://art.csr.nih.gov/ART/selection.jsp



Help Your Application Get to the Right Study Section



http://www.csr.nih.gov



Help your application get to the right study section

- Browse CSR's list of study sections: https://public.csr.nih.gov/StudySections
- Use CSR Assisted Referral Tool (ART): https://art.csr.nih.gov/ART/selection.jsp
- Use the Assignment Request Form to suggest a specific study section
 - Make assignment requests (study section and institute)
 - Identify potential conflicts of interest
 - > List areas of expertise needed to evaluate the application
 - You should never suggest specific reviewers.

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.600-phs-assignment-request-form.htm



Submitting a Cover Letter

The cover letter conveys important information:

- Explain why your application is late (NOT-OD-15-039)
- Provide notice of plans to submit a video
- Identify your project as generating large-scale genomic data
- Provide pre-approvals (\$500K, conference grants)

You should NOT use a cover letter to:

- Make assignment requests or indicate potential conflicts of interest with reviewers (use the Assignment Request Form!)
- Suggest specific reviewers (never do this?)



How to avoid submitting a late application

Start early!

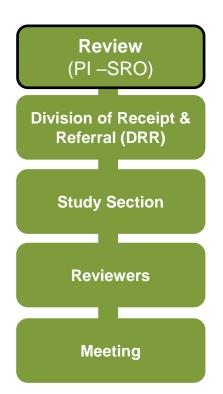
- You prepare the application, your Authorized Organization Representative (AOR) submits it
- Application must be accepted TWICE: by Grants.gov and by NIH.
- Grants.gov : non-compliant applications generates errors / warnings
- Errors cause rejection Warnings let the application move forward, but check warnings to prevent NIH rejection
- Ensure reference letter writers have submitted before deadline!

Check eRA Commons for your submitted application

- E-mails are sent but can be caught in SPAM filters
- High volume at deadlines slows processing/validation time
- On-time application = submitted error-free by 5 PM local time on due date
- > The error correction window does NOT extend the deadline
- Give yourself time to fix errors, warnings, or omissions before the deadline.



Review – How your application is handled



Due Date	Scientific Review	Council Review
June 5	Oct. – Nov	January
Oct 5	February - March	May
Feb 5	June - July	August

AIDS and AIDS Related Fellowship Deadlines:

September 7 | January 7 | May 7

Due dates that fall on weekends or federal holidays roll to the next business day. https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm



Compliance & Assignment

CSR's Division of Receipt and Referral (DRR) Determines if your application is

- On time
- Formatted correctly
- Complete
- Compliant with NIH policy

Assigns your application to

- Review group (= Study section)
- Institute(s) or Center for funding consideration



Assignment to CSR Study Sections

Within an IRG, applications are assigned to:

Standing Study Sections

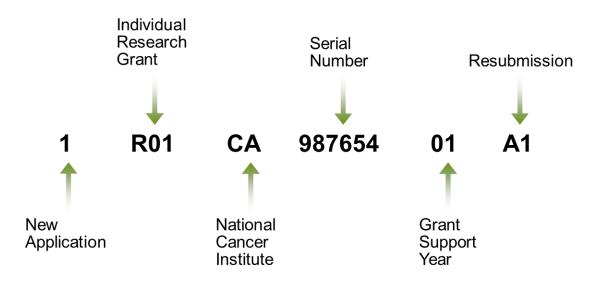
 When subject matter of application matches the referral guidelines for the study section or

Special Emphasis Panels (SEPs)

- When the subject matter does not fit into any study section—recurring or for onetime conflicts or initiatives.
- When assignment of an application to the most appropriate study section creates a conflict of interest
- When certain types of grants are sought (e.g., fellowships, SBIRs, AREAS)

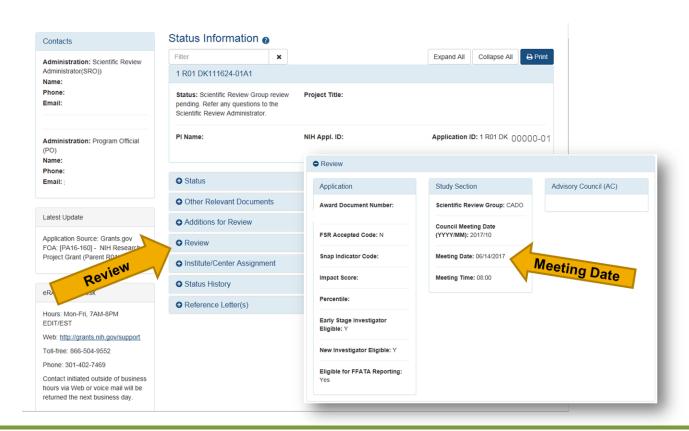


Sample Application Number





Check the Status of Your Application in NIH eRA Commons







How SROs prepare for reviewing your application

After your application is assigned to a study sections, the SRO:

Reads it to determine:

- Appropriate fit for the focus of the study section
- Problems in the application (i.e., with biosketches, human subjects, compliance)
- Scope and focus of the project
- Expertise needed to evaluate it

Sends a "welcome" email to you

- Deadline for receiving post submission materials.
- E.g.: accepted manuscript, prelim data, sponsor funding
- Initiates search for appropriate reviewers







Reviewer Recruitment



We seek reviewers with:

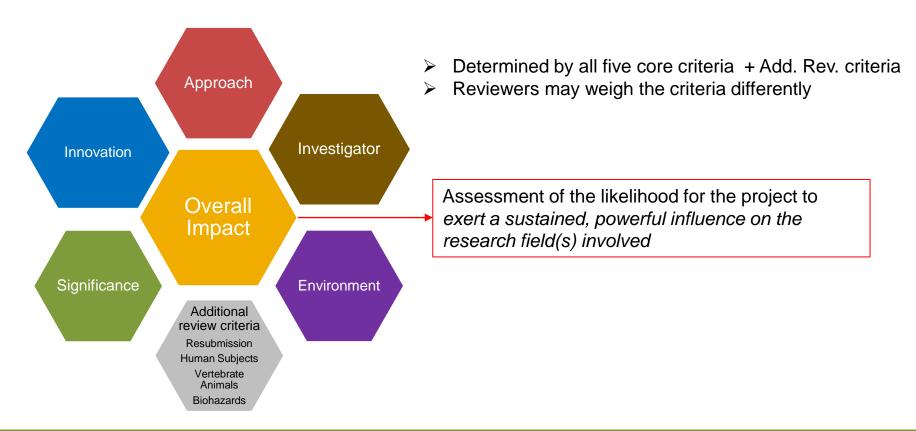
- Demonstrated scientific and technical expertise
- Research support
- Mature judgment and breadth of perspective
- Impartial, work effectively in a group context

We aim to assemble panels with:

- Institutional diversity
- Representation of women and minority scientists
- Wide geographic distribution
- Fresh perspectives (continually bring in reviewers who are new to the panel)



Train reviewers on review criteria and scoring





Reviewers

SRO assigns applications to reviewers

- 3 reviewers per application
- Match reviewer expertise and application content

Reviewers assess each application:

- Use 9-point scoring scale
- Criterion scores for each of the 5 core review criteria
- Preliminary overall impact score Not an average of criterion scores
- Impact summary & a written critique
- Comment on appropriateness of additional review criteria and considerations







Based on preliminary scores, the top 50% will be discussed



Meeting Format

- > SRO is the designated federal official, allowed to communicate the discussion
- The chair runs the meeting, ensures all opinions are heard
- Reviewers articulate their score driving points.
- The whole panel (minus conflicts) scores
- About half the applications will NOT be discussed.
- Reviewers are given the opportunity to bring up any application on the not-discussed list for discussion.

Clustering of Review

- Applications are clustered by activity code (e.g., R01, R21 etc).
- Discussed in random order, within each cluster.





Elements of a strong application

Significance and Impact

Exciting Ideas

Ideas they can understand – don't assume too much

Brevity with things everyone knows

Realistic aims and timeline

- Don't be overly
ambitious



Rigor of prior research, Rigor of proposed research

<u>Clarity</u>

Consideration of biological variables

Noted limitations of the study

Insider's Guide to Peer Review for Applicants:

http://www.csr.nih.gov/applicantresources/insider



Scores



Priority scores/percentile

- Final scores from <u>ALL panel members</u> are averaged and multiplied by 10 to give the final priority score.
- A percentile ranks your application relative to the other applications reviewed by your study section at its last three meetings.
- Percentiles range from 1 to 99. A lower number indicates a better score.

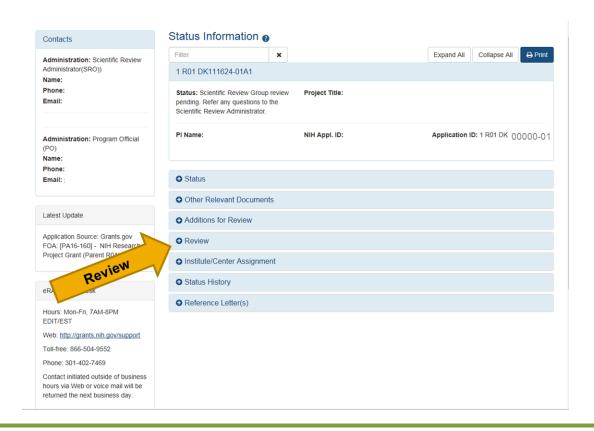
Summary Statements



After the review

Releases your score within 3 business days of the meeting.

Check the status of your application in NIH eRA Commons





Summary Statements



After the review

- Releases your score within 3 business days of the meeting.
- Prepares summary statements and releases them within ~ 30 days.
- Summary statement = resume of discussion + 3 critiques & criterion scores + administrative notes
- Resume (written by the SRO) captures the score driving points discussed during the meeting between reviewers and the panel at large.
- Critiques for not-discussed applications will not include resume.
- Includes any administrative notes (budget, human subjects etc.).
- Provides information to NIH Institutes and Centers when needed.

Summary statement

Human Subjects: 10-No human subjects involved

Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

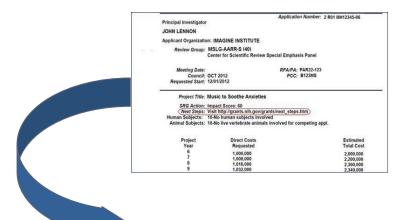
Questions?

- Contact your program officer
- Answer questions about your review
- Provide guidance in preparing a resubmission

Program Officer SUMMARY STATEMENT (Privileged Communication) PROGRAM CONTACT: Release Date: 02/05/2019 **Austin Yang** Revised Date: 301.496.9350 yangj13@mail.nih.gov Application Number: 1 R01 AG **Principal Investigator** Impact/Priority Score 10-90 range **Applicant Organization:** Review Group: CMND Cellular and Molecular Biology of Neurodegeneration Study Section RFA/BA: PA18-484 Meeting Date: 01/31/2019 MAY 2019 3BSETAY Council: Requested Start: 07/01/2019 Percentile in whole Project Title: numbers Impact Score:34 Percentile:13 Visit https://grants.nih.gov/grants/next_steps.htm

Your Application Was Reviewed What Do You Do Next?

Visit NIH's Next Steps Website



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



NIH's Resubmission Policy

After an unsuccessful new (A0) application or an unsuccessful resubmission (A1) application, you may submit a new (A0) application with the same idea as long as your summary statement has been issued.

The NIH Will Not Accept

- An AO or A1 application that overlaps a funded application
- Simultaneous submissions of overlapping applications
- An AO or A1 application before NIH issues the summary statement of an earlier, overlapping application.

Resubmission FAQs

http://grants.nih.gov/grants/policy/resubmission_q&a.htm



Your New Application Must Be Written as New

Your new (A0) application should not contain information that might bias the review or provide a competitive advantage:

You Cannot Refer to a Previous Review

- No mention of previous score
- No mention of previous reviewer comments
- No mention of how the AO is responsive to previous review
- No marks in text to indicate changes

You Cannot Submit Elements of a Renewal

- No Progress Report
- No Progress Report Publication List



Your Career Stage Is Considered...







- If you are a New Investigator or Early Stage Investigator on an RO1 application
- If NIH has the correct info on the applicant's career stage

Larger Factor in Second Level Review by Institutes/Centers

http://grants.nih.gov/grants/new_investigators/



Jumpstart Your Career: CSR Early Career Reviewer Program

- Work side-by-side with some of the most accomplished researchers in your field
- Learn how reviewers evaluate and score applications
- Develop research-evaluation and critique-writing skills
- Serve the scientific community by helping NIH identify the most promising grant applications







www.csr.nih.gov/ecr



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
- Your program officer has the prime responsibility to answer questions about your review and preparing a new application.

GrantsInfo: GrantsInfo@od.nih.gov - 301 945-7573



NIH peer review information on the Web

National Institutes of Health: http://www.nih.gov

- Office of Extramural Research https://grants.nih.gov/grants/oer.htm
- Grants Policy
 http://www.nih.gov/grants/policy/policy.htm
- Electronic Submission
 http://era.nih.gov/ElectronicReceipt
- NIH Next Steps Website
 https://grants.nih.gov/faqs#/next-steps.htm

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

- Resources for Applicants
 http://www.csr.nih.gov/ResourcesforApplicants
- CSR Study Section Descriptions
 http://public.csr.nih.gov/StudySections
- CSR Rosters and Meeting Dates
 http://public.csr.nih.gov/RosterAndMeetings
- CSR Helpful Handouts
 https://public.csr.nih.gov/NewsAndPolicy/OutreachResources

For issues related to respectful interactions, bias or anything else that could affect the fairness of the review process, contact your SRO or the CSR Associate Director of Diversity & Workforce Development, Dr. GabrielFosu, at G.Fosu_AssocDir@csr.nih.gov.

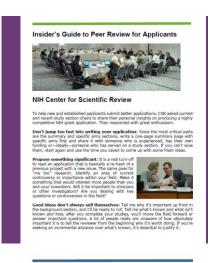


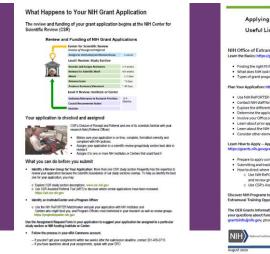
Helpful Handouts

Insider's Guide to Peer Review

What Happens to Your Grant Application

NIH Grant Application Useful Web Links







http://www.csr.nih.gov/publications/



Top 10 NIH Peer Review Q&As



Top 100 NIH Peer Review Q&As www.csr.nih.gov/faq



Thank you for your attention

Questions / Comments?

