National Institute of Neurological Disorders and Stroke

The Life of the Grant

Dr. Svetlana Kotliarova
Program Director
National Institute of Neurological Disorders and Stroke
National Institutes of Health

Goals of todays webinar

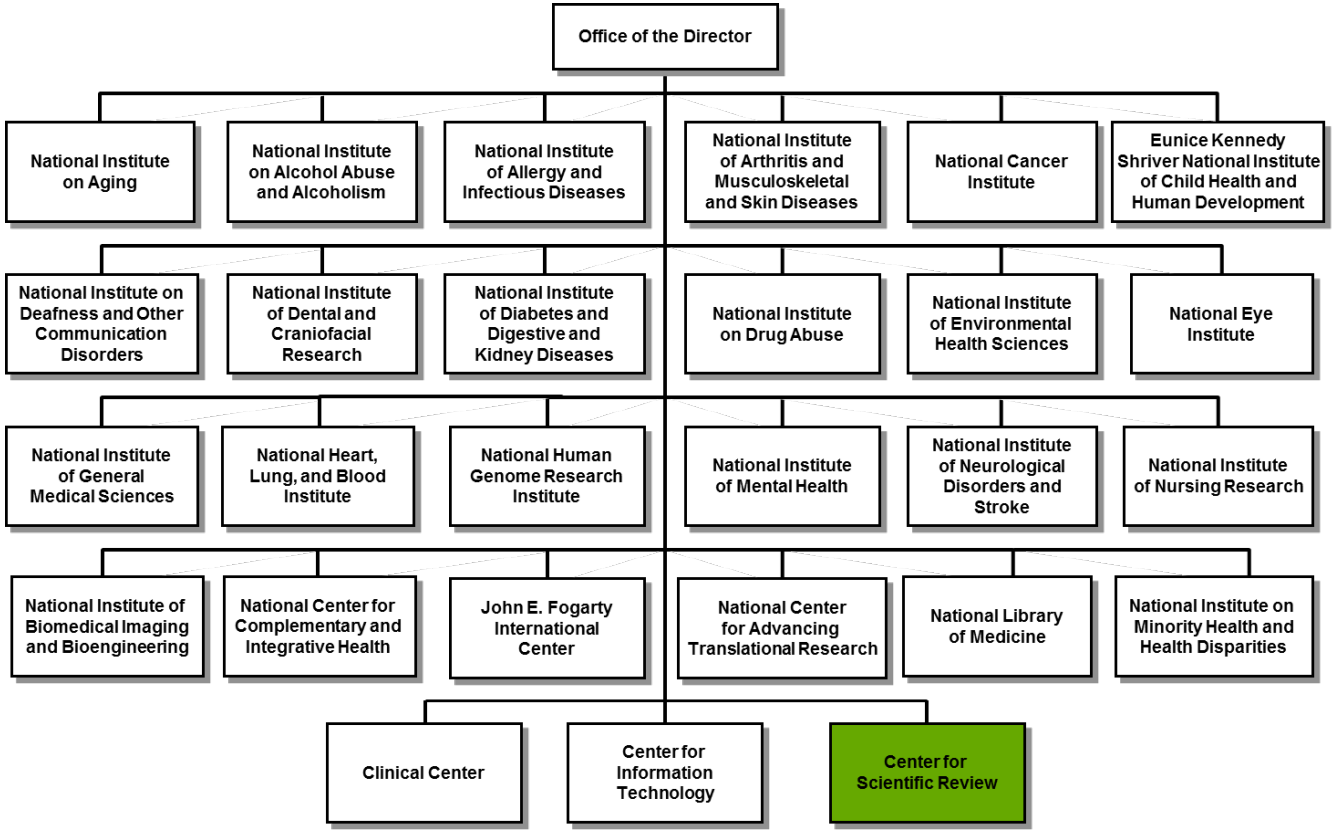
- To understand the basics of the NIH Application and Peer Review Process
- To gain insight into preparing your own application
- To learn who you can contact at NIH at all stages in the process
- To learn about NIH resources and programs
  - R15 program
  - Early Career Reviewer (ECR) program

National Institutes of Health…. turning discovery into health

Much of the biomedical research in the United States is supported by the Federal Government, primarily the National Institutes of Health (NIH).

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 application could be funded by one of NIH Institutes or Centers (ICs)



The Gateway for NIH Grant Applications

The Center for Scientific Review

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

Review and Funding of NIH Grant Applications

Center for Scientific Review

Division of Receipt and Referral

Assigns to Institute(s) and Review Group	2 weeks

Level I Review: Study Section

Recruits and Assigns Reviewers	2-4 weeks
Reviews for Scientific Merit	4-6 weeks
Meets	1-2 days
Releases Score	~3 days
Produces Summary Statement	~ 30 days

CSR's role

Level II Review: Institute or Center

Evaluates Relevance to Research Priorities	2-4 Months
Council Recommends Action	
Decision	

Funding Institute's role

NIH Peer Review System for Grant Applications

Jan-May May-Sept Sept-Jan	**Receipt Dates**
May-July Sept-Nov Jan-Mar	**Review Dates**
Sept-Oct Jan-Feb May-June	**National Advisory Council/Board Dates**
Dec Apr July	**Earliest Possible Beginning Date**

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

Standard Due Dates

R01 *new*	**Research Grants**	February 5	June 5	October 5
U01 *new*	**Research Grants - Cooperative Agreements**	February 5	June 5	October 5
K series *new*	**Research Career Development**	February 12	June 12	October 12
R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3 *new*	**Other Research Grants and Cooperative Agreements**	February 16	June 16	October 16
R15 *All - new, renewal, resubmission, revision*	**Academic Research Enhancement Award (AREA)**	February 25	June 25	October 25
R01 *renewal, resubmission, revision*	**Research Grants**	March 5	July 5	November 5
U01 *renewal, resubmission, revision*	**Research Grants - Cooperative Agreements**	March 5	July 5	November 5

https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

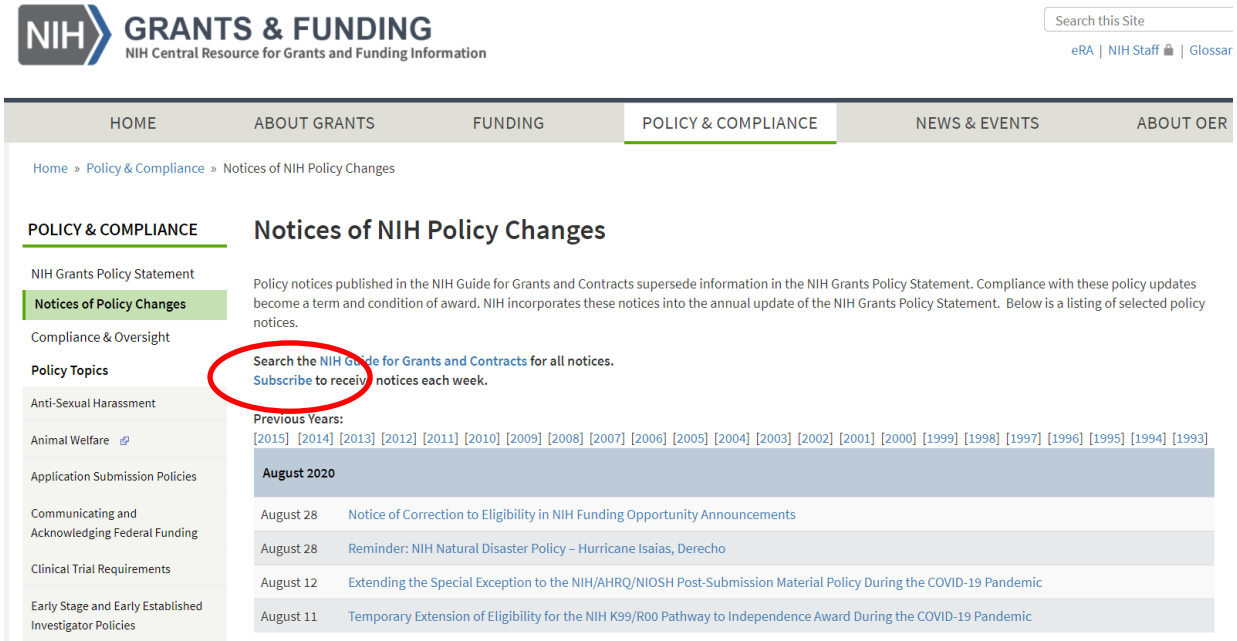
How can researchers navigate the NIH?

- Subscribe to the NIH Guide Notice.
- Find a notice of funding opportunities (NOFO).
- Talk to program officers.
- Prepare the application well in advance of the deadline.
- Learn about the review process so you can put together a competitive application.

What is the NIH Guide Notice?

This is how NIH communicates changes in policy, such as changes to submission deadlines, changes to requirements for grants, etc.

Subscribe so that you are in the know!



https://grants.nih.gov/policy/notices.htm

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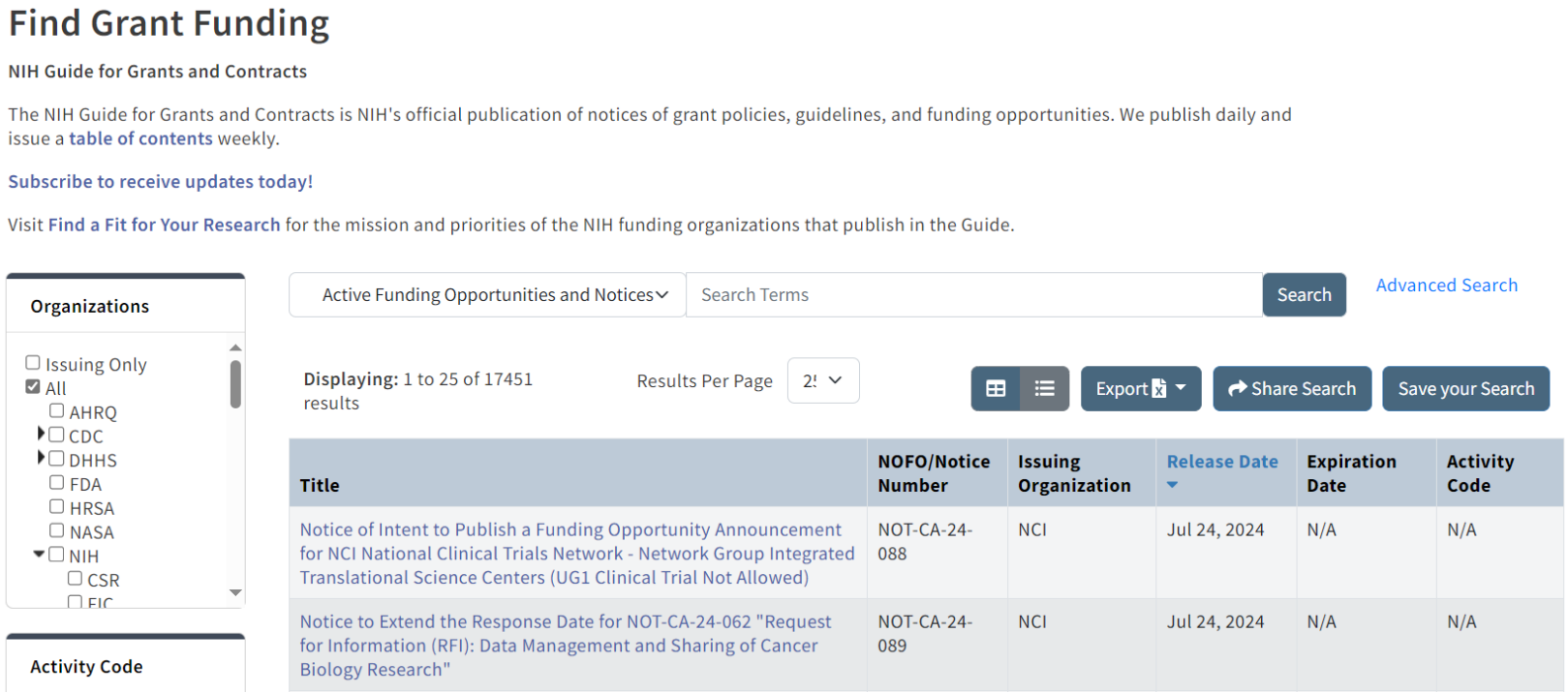
How NIH lets you know what it wants to support - NOFOs

Notice of funding opportunities (NOFO).

- **Program Announcements (PA)** Identifies priority areas and/or funding mechanisms for an area.
  - **PAR:** a PA with special receipt, referral and/or review considerations.
  - **PAS:** a PA with set-aside funds.
- **Request for Applications (RFA):** Identifies a focused area where NIH award grants with set aside funds.
- **Request for Proposal (RFP):** Solicits contract proposals, usually with one receipt date.
- **Notices of Special Interest (NOSI):** Simplified notices of specific research interests.
- **Notice (NOT):** Announces policy and procedures, changes to earlier NOFOs and general info.

How can researchers find NOFOs?



https://grants.nih.gov/funding/searchguide/index.html

Parent Announcements: https://grants.nih.gov/grants/guide/pa-files/PA-19-056.html

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI) 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 of Dental and Craniofacial Research (NIDCR) National Institute on Deafness and Other Communication Disorders (NIDCD) 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 Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP) Note: Not all NIH Institutes 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 R01 IC-Specific Scientific Interests and Contact website. ICs that do not participate in this announcement will not consider applications for funding.
Funding Opportunity Title	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
Activity Code	R01 Research Project Grant

Read these announcements in detail!

- It tells you which institutes participate (might fund you).
- Specifics here trump general application instructions (the SF424).

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- Prepare the application well in advance of the deadline.
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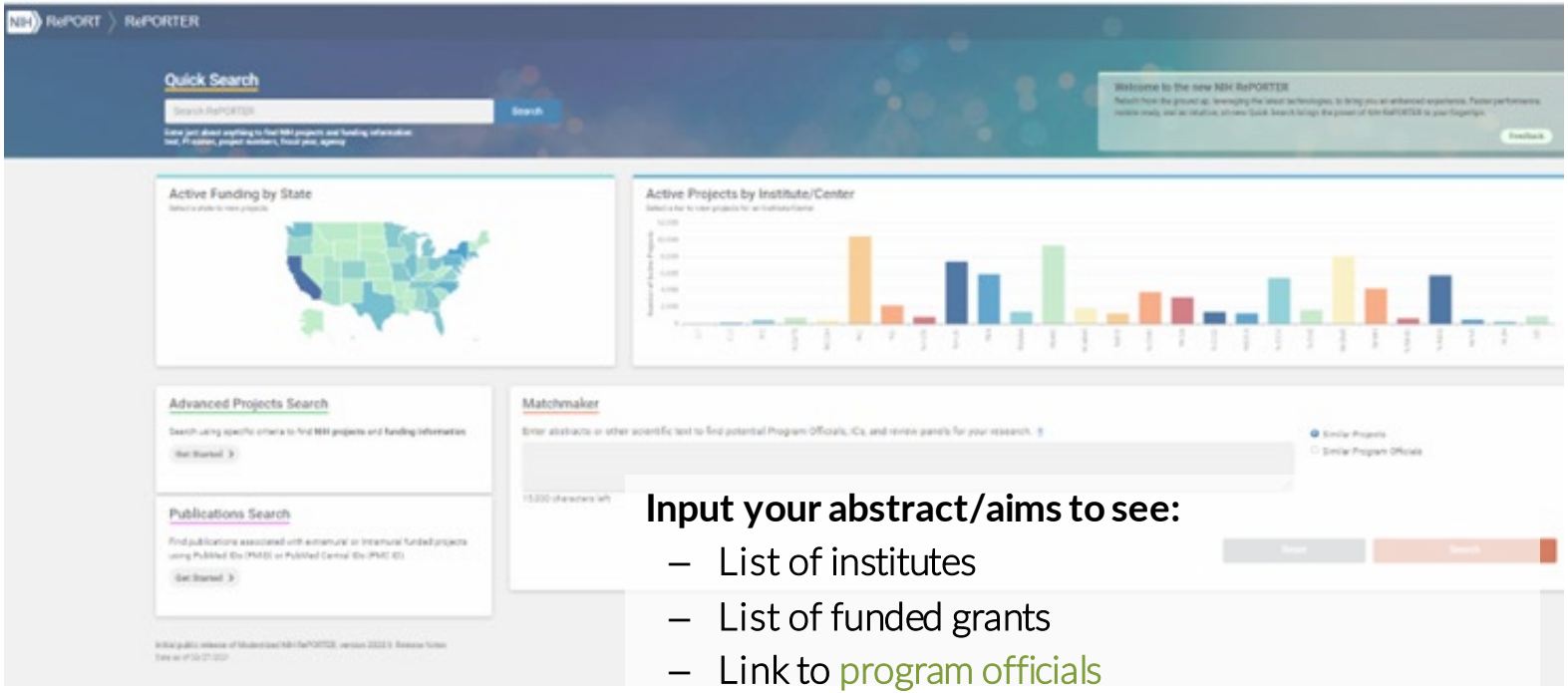
Talk to a program officer

- They can tell you whether your research fits the institute's priorities.
- They can help you identify funding opportunities.
- They can help you figure out a study section (= review panel) to request for the review.
- They can offer advice if you need to resubmit your application after the initial review.

How can you find a program officer?

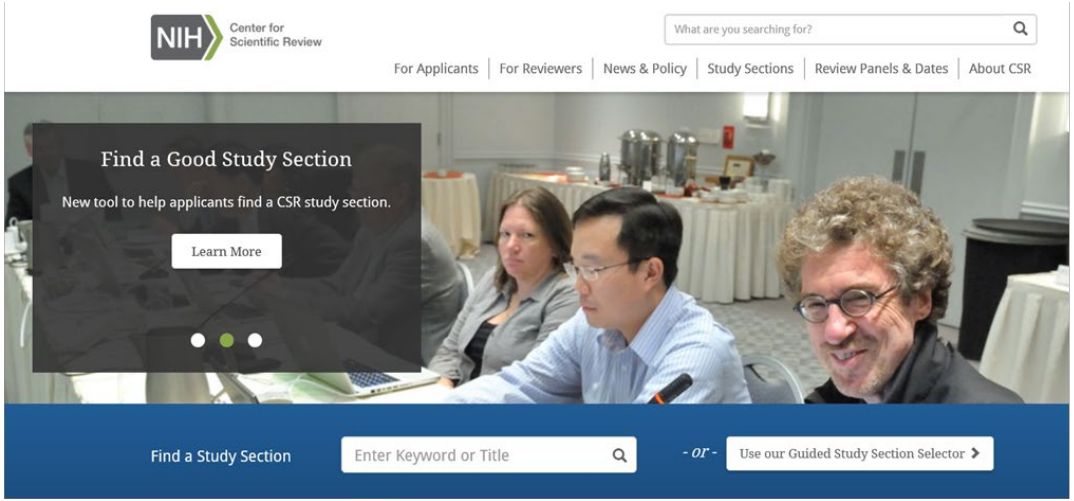
Use NIH RePORTER: https://projectreporter.nih.gov/reporter.cfm



Input your abstract/aims to see:

- List of institutes
- List of funded grants
- Link to program officials
- Study section that reviewed the funded grant

Help your application get to the right study section



Key Word **Search**

Assisted Referral Tool **Search**

http://www.csr.nih.gov

Output from the Assisted Referral Tool

Relevance	SRG	RB	Membership	Name
Strong	CMGC	CCHI	Roster	Clinical Management in General Care Settings Study Section
Strong	CNBT	CN	Roster	Clinical Neuroimmunology and Brain Tumors Study Section
Strong	LCBH	CCHI	Roster	Lifestyle Change and Behavioral Health Study Section
Possible	ASPA	EPH	Roster	Analytics and Statistics for Population Research Panel A Study Section
Possible	CIDH	HSS	Roster	Clinical Informatics and Digital Health Study Section
Possible	HSQE	HSS	Roster	Health Services: Quality and Effectiveness Study Section
Possible	ODHS	HSS	Roster	Organization and Delivery of Health Services Study Section
Possible	TIO	CDPT	Roster	Translational Immuno-oncology Study Section

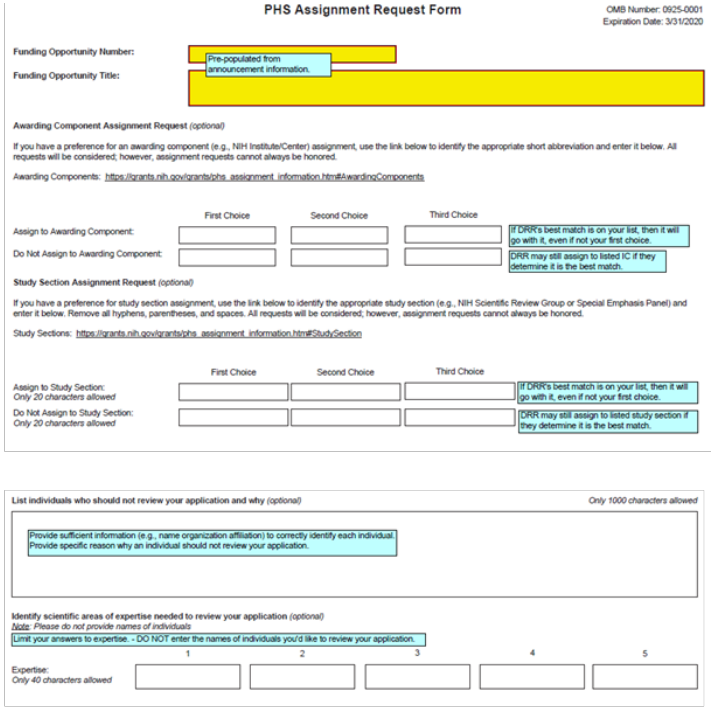
If you've identified a potential funding institute and study section, how do you let us know? Use the Assignment Request Form.

Requests for IC assignment

Requests for review group assignment

Identify conflicts

Suggest expertise



PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 3/31/2020

Funding Opportunity Number:

Funding Opportunity Title:

Pre-populated from announcement information.

Awarding Component Assignment Request *(optional)*

If you have a preference for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation and enter it below. All requests will be considered; however, assignment requests cannot always be honored.

Awarding Components: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

	First Choice	Second Choice	Third Choice	
Assign to Awarding Component:				If DRR's best match is on your list, then it will go with it, even if not your first choice.
Do Not Assign to Awarding Component:				DRR may still assign to listed IC if they determine it is the best match.

Study Section Assignment Request *(optional)*

If you have a preference for study section assignment, use the link below to identify the appropriate study section (e.g., NIH Scientific Review Group or Special Emphasis Panel) and enter it below. Remove all hyphens, parentheses, and spaces. All requests will be considered; however, assignment requests cannot always be honored.

Study Sections: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

	First Choice	Second Choice	Third Choice	
Assign to Study Section: *Only 20 characters allowed*				If DRR's best match is on your list, then it will go with it, even if not your first choice.
Do Not Assign to Study Section: *Only 20 characters allowed*				DRR may still assign to listed study section if they determine it is the best match.

List individuals who should not review your application and why *(optional)* — *Only 1000 characters allowed*

Provide sufficient information (e.g., name organization affiliation) to correctly identify each individual.
Provide specific reason why an individual should not review your application.

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

Note: Please do not provide names of individuals

Limit your answers to expertise. - DO NOT enter the names of individuals you'd like to review your application.

	1	2	3	4	5
Expertise: *Only 40 characters allowed*					

Never list names of recommended reviewers!

How can researchers navigate the NIH?

- Subscribe to the NIH Guide Notice.
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- Talk to program officers.
- Prepare the application well in advance of the deadline.
- Learn about the review process so you can put together a competitive application.

Submit your application ahead of the deadline

Start early!

- Application must be accepted **TWICE**: Grants.gov and NIH

Check eRA Commons for your submitted application - automated 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
- **Errors** cause rejection
- **Warnings** are error-free and accepted but could be cause for withdrawal at a later stage.
- 2-day viewing window does not extend the deadline

How can you take advantage of the 2-day viewing window? Submit early!

There is a 2-day viewing window during which the application can be rejected, changed, submitted again.

The final version must be in the system before the application deadline.

- If you submit 3 days early, you get 2 days to view the application and fix it.
- If you submit 2 days early, you get 2 days to view the application and fix it.
- If you submit 4 hrs early, you get 4 hrs to view the application and fix it.

Grants.gov will allow you to submit it late (because there are acceptable reasons for late applications). But, **if you submit it late without an acceptable reason, it will be caught and withdrawn.**

A window to your application: eRA Commons

eRA Commons is an online interface where a grant applicant can:

- Check submitted grant application for errors and warnings and view final image
- Track review assignment, view review outcomes (score, summary statements), find contact info for scientific review officers (SRO) and program officers (PO)
- Update Personal Profile to ensure Early Stage Investigator eligibility is in place
- Submit pre-award information (just in time)
- View Notice of Award and other key documents

And much more!

https://commons.era.nih.gov/commons/

Track your application

- An Authorized Organizational Representative (AOR) in your sponsored research office must submit your application.
- The Principal Investigator (PI) is responsible for accuracy of submission.
- Again, submit early to give yourself time to make corrections if needed.
- Do not wait for e-mails; proactively check eRA Commons.
- If you cannot see your application in eRA Commons, neither can we!

How can researchers navigate the NIH?

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- Prepare the application well in advance of the deadline.
- Learn about the review process so you can put together a competitive application.

How can you learn more about the review process?

Visit NIH Center for Scientific Review

For Applicants

Application Process

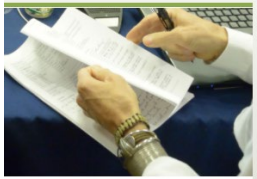
CSR does not award funding but instead handles review of proposals. Please visit the NIH for an overview of the grant process or view our video What Happens to Your Grant Application.

Planning & Writing

Guidance to assist you in planning and preparing a proposal.

Application Deadlines

Standard receipt dates for grant proposals



Submission & Assignment

How proposals are assigned to a review group

Initial Review, Results, & Appeals

What happens in the review process?

Frequently Asked Questions (FAQs)

Top 10 and Top 100 Peer Review Q&As for NIH Applicants

For Reviewers

Become a Reviewer

We welcome researchers who volunteer to serve on our peer review groups. Explore the ways you can do this.

Meeting Overview

Explore orientation materials and resources to get you started.

Guidelines & Templates

Learn about review criteria, scoring and possible conflict of interest information.

Tools & Technology

Looking for guidance on the technology we use? Explore our online tutorials and tools.

Travel & Reimbursement

Explore all you need to know to about getting reimbursed for travel and

Frequently Asked Questions (FAQs)

Top Peer Review Q&As for NIH Reviewers

Your Scientific Review Officer

- Recruits reviewers and assigns applications
- Manages the meeting and conflicts
- Prepares summary statements
- Provides information to NIH Institutes and Centers

Before the Study Section Meeting

Each application is assigned to 3 or more reviewers 5-6 weeks in advance

Reviewers Assess Each Application by Providing:

- Preliminary Overall Impact score
- Criterion scores for each of the 5 core review criteria
- Comment on appropriateness of your budget
- A written critique

What Do Reviewers Look for in Applications?

- Significance and impact
- Exciting ideas, Compelling hypotheses
- Strong preliminary data
- Exceptional, rigorous science
- Clarity
- Ideas they can understand -- Don't use jargon
- Realistic aims and timelines -- Don't be overly ambitious
- Brevity with things that everybody knows
- Noted limitations of the study
- A clean, well-written application

Insider's Guide to Peer Review for Applicants:
http://www.csr.nih.gov/applicantresources/insider

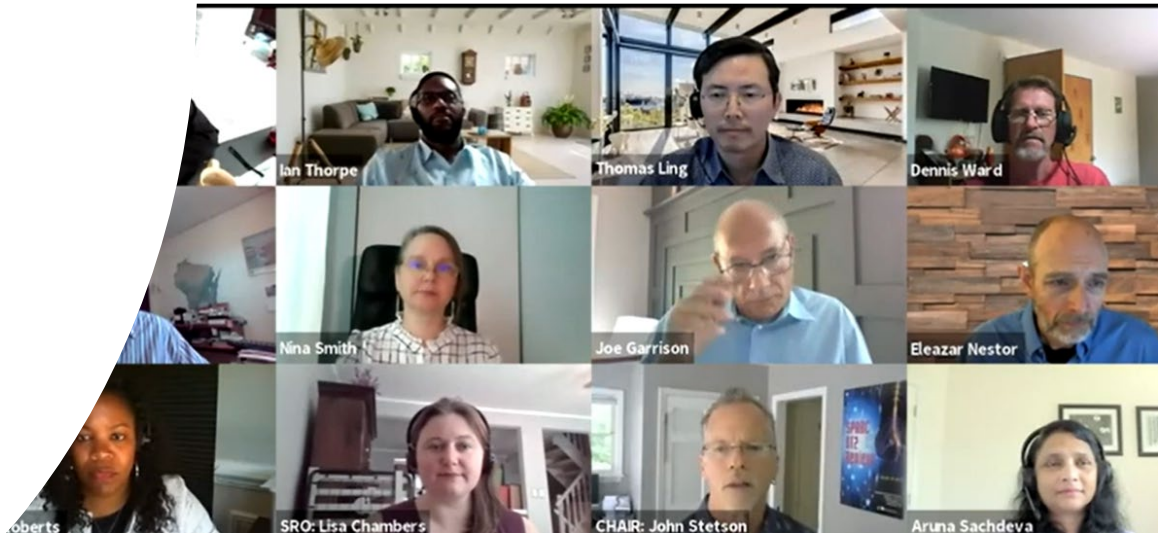
Common Problems in Applications

- Lack of a strong scientific foundation
- Lack of new or original ideas
- Lack of knowledge of published relevant work
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Uncritical approach; lack of scientific rigor
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Unrealistically large amount of work
- Uncertainty concerning future directions

CSR Study Sections: The Meeting

- Each CSR standing study section (review group) has ~12-22 regular members plus temporary reviewers from the scientific community

- About 70-100 applications are reviewed by each study section in 1-2 day meetings



At the Meeting

Discussion of Applications

- About half the applications will be discussed
- Applications unanimously judged by the review committee to be in the lower half are not discussed

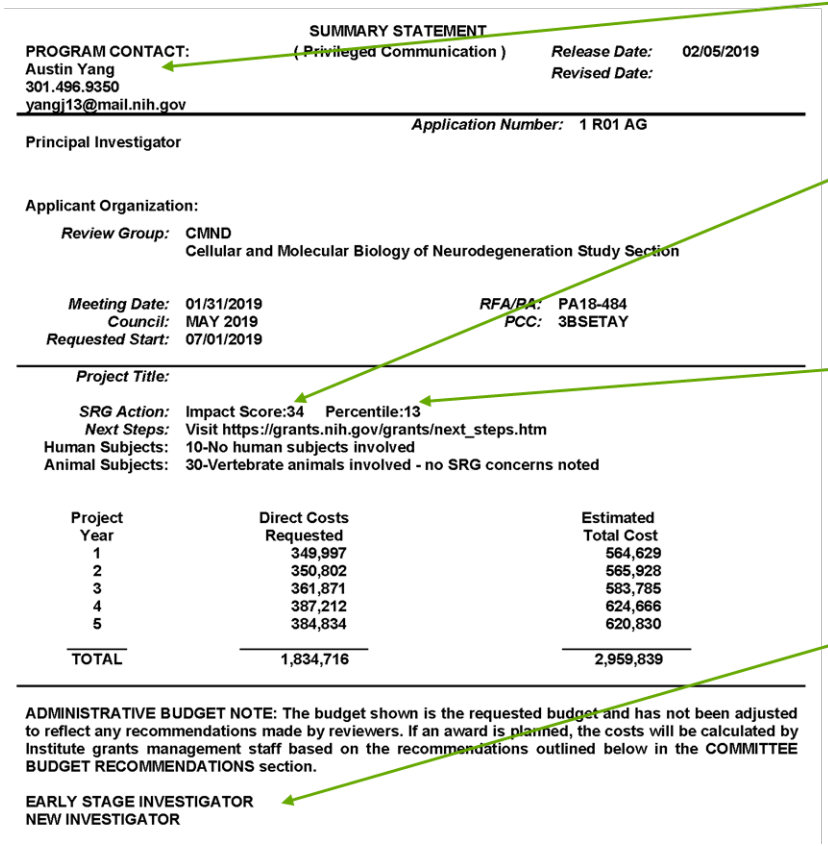
Clustering of Review

- New Investigator R01 & some types of applications are often reviewed together

Order of Review

- Applications to be discussed are reviewed in random order within each cluster.

Summary Statement



SUMMARY STATEMENT

PROGRAM CONTACT:
Austin Yang
301.496.9350
yangj13@mail.nih.gov

(Privileged Communication)

Release Date: 02/05/2019
Revised Date:

Application Number: 1 R01 AG

Principal Investigator

Applicant Organization:

Review Group: CMND
Cellular and Molecular Biology of Neurodegeneration Study Section

Meeting Date: 01/31/2019
Council: MAY 2019
Requested Start: 07/01/2019

RFA/PA: PA18-484
PCC: 3BSETAY

Project Title:

SRG Action: Impact Score:34 Percentile:13
Next Steps: Visit https://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved - no SRG concerns noted

Project Year	Direct Costs Requested	Estimated Total Cost
1	349,997	564,629
2	350,802	565,928
3	361,871	583,785
4	387,212	624,666
5	384,834	620,830
TOTAL	1,834,716	2,959,839

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

EARLY STAGE INVESTIGATOR
NEW INVESTIGATOR

Program Officer

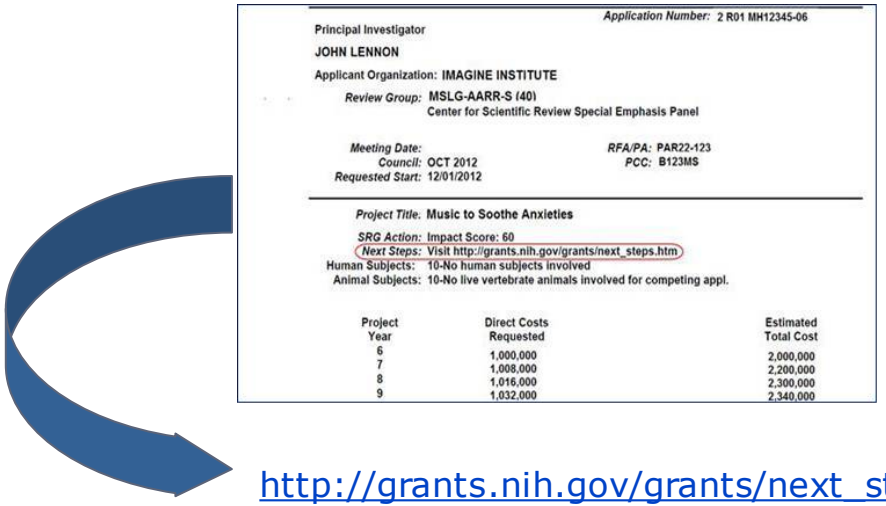
Impact/Priority Score 10-90 range

Percentile in whole numbers

Indicator for Early Stage Investigators/New Investigator eligibility

Your Application Was Reviewed What Do You Do Next?

Visit NIH's Next Steps Website



Application Number: 2 R01 MH12345-06

Principal Investigator
JOHN LENNON

Applicant Organization: IMAGINE INSTITUTE

Review Group: MSLG-AARR-S (40)
Center for Scientific Review Special Emphasis Panel

Meeting Date:
Council: OCT 2012
Requested Start: 12/01/2012

RFA/PA: PAR22-123
PCC: B123MS

Project Title. Music to Soothe Anxieties

SRG Action: Impact Score: 60
Next Steps: Visit http://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested	Estimated Total Cost
6	1,000,000	2,000,000
7	1,008,000	2,200,000
8	1,016,000	2,300,000
9	1,032,000	2,340,000

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

Resources: Who should you talk to? When?

Before you submit – identify and talk to a program officer

After you submit and before the review – your scientific review officer (SRO)

After the review – program officer

If you have trouble finding these contacts, email CSR – we'll put you in touch with the right people: askexperts@csr.nih.gov

Road to Success….

- Go where the data and your interests take you
- Take advantage of grant writing workshops/seminars
- Start early with grant preparations
- Spend ample time on Abstract & Specific Aims
- Engage collaborators if needed
- Presentation counts!
  - What's your "hook" or "sparkle"?
  - Edit if dense/overly-ambitious
  - Good grammar, font size, figure legends?
- Contact program director
  - Mechanism? Initiative? Potential Study Section?
- Share proposal with senior colleagues
  - Some institutions require prior to submission
- Put your best, RIGOROUS science in ONE application/cycle
- Get your critical publication(s) out first
- Prepare the application well in advance of the deadline.

NIH Research Training and Development Site

https://researchtraining.nih.gov/

Learn about the new Simplified Review Framework

NIH is implementing a simplified framework for the peer review of the majority of competing research project grant (RPG) applications, beginning with submissions with due dates of January 25, 2025. The simplified peer review framework aims to better facilitate the mission of scientific peer review – identification of the strongest, highest-impact research – by:

1. **Enabling peer reviewers to better focus on answering the key questions necessary to assess the scientific and technical merit of proposed research projects:**
    1. Should the proposed research project be conducted?
    2. Can the proposed research project be conducted?
2. **Mitigating the effect of reputational bias** by refocusing the evaluation of investigator/environment to within the context of the proposed research.
3. **Reducing reviewer burden** by shifting policy compliance activities to NIH staff.

Simplifying Review of Research Project Grant Applications | grants.nih.gov

NIH Simplified Peer Review Framework Webinar

R15 Programs

NIH Research Enhancement Award (R15) | grants.nih.gov

R15 Programs

Goals of R15 are to:

- support meritorious research
- expose students to research
- strengthen the research environment of the institution

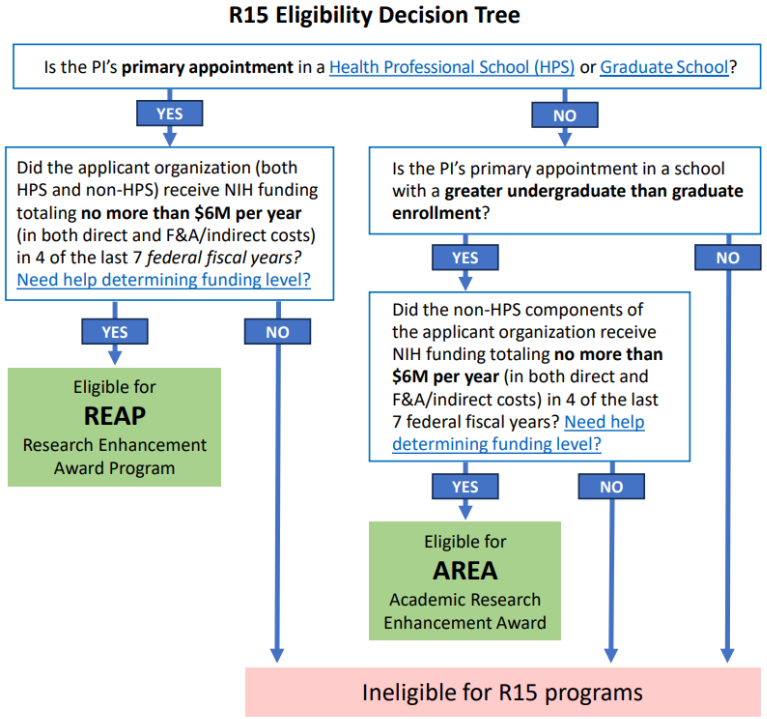
Key Features

- **Research Grant** mechanism with 12-page Research Strategy (**Not a training grant!**)
- 3-year project period
- Up to $300,000 direct cost over 3 years
- Grants are renewable
- Five review criteria (as in R01), but different emphasis on R15 program

NIH Research Enhancement Award (R15) | grants.nih.gov

R15: AREA vs REAP Programs

Academic Research Enhancement Award (AREA)	Research Enhancement Award Program (REAP)
Undergraduate-Focused Institutions	Health Professional and Graduate Schools
Award baccalaureate science degrees **Undergraduate students must be part of the research team.** PAR-24-152 and PAR-24-214	**Award baccalaureate or advanced degrees in health professions.** **Any type of students (graduate and/or undergraduate) is allowed.** PAR-21-357 and PAR-22-060



Is one of the R15 programs (REAP or AREA) right for me? (nih.gov)

Jumpstart Your Career:
CSR Early Career Reviewer (ECR) Program

Jumpstart Your Career: CSR Early Career Reviewer (ECR) Program

ECR Program goals:

- Train qualified scientists to become critical and well-trained reviewers
- Expose investigators to the peer review experience so that they can write more competitive grant applications of their own
- Enrich the existing pool of NIH reviewers

Benefits of ECR program:

- Work side-by-side with some of the most accomplished researchers in your field to help NIH identify the most promising grant applications
- Learn how reviewers determine overall impact scores
- Improve your own grant writing skills by getting an insider's view of how grant applications are evaluated
- Serve the scientific community by participating in NIH peer review
- Develop research-evaluation and critique-writing skills

ECR Qualifications

Employment

- You have at least **1 year of experience as a fulltime faculty member** (Assistant Professor) or a researcher in a similar role. Associate Professors and Postdoctoral Fellows are not eligible.

Grant & Review History

- You have not served on an NIH study section aside from being a mail reviewer.
- You have not held an R01 or equivalent grant as a PI/PD. (R35, R37, RF1, R23, R29, DP1, DP2, DP5, U01, RL1) in the PD/PI role.
- You have submitted a grant application to NIH and received the summary statement.

Research

- You have evidence of an active, independent research program.
- You have at least 2 senior-authored research publication in peer-reviewed journals – 1 since doctoral degree, 1 in the last 2 yrs.

45

Visit https://public.csr.nih.gov/ForReviewers/BecomeAReviewer/ECR for qualifications and application process.

ECR Success Stories

Michelle M. Martínez Montemayor, PhD

Associate Professor, Department of Biochemistry
Universidad Central del Caribe-School of Medicine, Bayamón, Puerto Rico

President and co-Founder
Dynamiko Pharmaceutics, LLC, San Juan, Puerto Rico
mmmtz92@gmail.com

- University of Puerto Rico - AD, BS, MS studies, Michigan State University – PhD studies.
- Former EAC – NCI, NIMHD. Currently, standing member CPSS – CSR.
- Research interests:
  - Development of selective, less toxic and affordable therapeutics for aggressive breast cancers (i.e. inflammatory breast cancer and triple negative breast cancer)
  - Increasing knowledge about inflammatory breast cancer biology to improve diagnosis, treatment and overall survival rates, and increasing representation and diversity in research.
- Funding

NIH National Institutes of Health
USDA NIFA United States Department of Agriculture National Institute of Food and Agriculture
Susan G. Komen
Puerto Rico Science, Technology & Research Trust
PRINBRE IDeA Network of Biomedical Research Excellence
The Alliance
Título 5 Coop RCM-UCC

Chiba I. Ene MD PhD

CEne@mdanderson.org

- **2004-2013: MD PhD**
  - 2004: MD Indiana University School of Medicine
  - 2006: Howard Hughes Medical Institute (HHMI) Research Scholar (with Dr. Howard Fine, Neuro-oncology Branch, NCI)
  - 2007-2013: PhD Cambridge University, NIH-Oxford Cambridge Research Scholars Program (Dr. Howard Fine/NCI and Dr. Rick Livesey/Cambridge University, U.K)

- **2013-2020: Clinical Neurosurgery Residency, University of Washington, Seattle**
  - 2016-2018: NINDS R25 post-doctoral research fellowship, Fred Hutch Cancer Research Center. Seattle, WA (with Dr. Eric Holland)

- **2020-2022: 2year Neurosurgical Oncology Fellowship, MD Anderson Cancer Center**
  - 1st year: Post-doctoral Research Fellowship (with Dr. Fred Lang)
  - 2nd year: Clinical Neurosurgery subspecialty training in oncology

- **2022-Present: Assistant Professor (Tenure track) and Physician Scientist in the Department of Neurosurgery, MD Anderson Cancer Center.**

- Field of Study- Genetically engineered macrophages as cell therapy for primary and metastatic brain tumors.
- Served as ECR in 2023-10 review cycle

Sergei Grivennikov, PhD

Professor/ Research Scientist II,
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Sergey.Grivennikov@cshs.org

- Earned Ph.D from Engelhardt Institute of Molecular Biology, Moscow, Russia
- Trained at National Cancer Institute/National Institutes of Health and University of California, San Diego
- Joined Fox Chase Cancer Center in 2012 and was Adjunct Assistant and Associate Professor at Temple University
- Established Grivennikov Lab at Cedars-Sinai in 2020.

Field of Study: genetic and inducible animal models of colitis and colorectal cancer and the role of cytokine milieu, microbiota, and inflammatory signaling in tissue regeneration, autoimmunity and cancer.

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Discussion

Thank You!