

THE NIH: AN OVERVIEW

A Webinar Presented by Hanover Research George Washington University January 15, 2025

WEBINAR LOGISTICS





~55 minutes plus additional time for moderated Q&A $% \left(A_{1}^{2}\right) =0$



Ask questions at the end of today's presentation.



All attendees will receive a copy of the recording, including the slides.

TODAY'S PRESENTER



MELISSA A. CORNISH MANAGING GRANTS CONSULTANT



AGENCY EXPERTISE



plus, other federal agencies (AHRQ, HRSA) and nonfederal foundations

- MSPH (Health Policy)
- Joined Hanover in 2017
- Health policy background
- Health services research, STEM programming, clinical research





TODAY'S AGENDA



- \checkmark A basic introduction to the NIH
- ✓ Key funding mechanisms and finding funding opportunities
- \checkmark Preparing a competitive proposal
- ✓ Proposal review process
- ✓ Resources to leverage

A BASIC INTRODUCTION



LARGEST FUNDER OF MEDICAL RESEARCH IN U.S.

NIH BY THE NUMBERS:



~50,000

COMPETITIVE

APPLICATIONS



300,000+ RESEARCHERS



2,500+ INSTITUTIONS GLOBALLY

NEARLY \$48B INVESTED ANNUALLY IN MEDICAL RESEARCH



Budget | National Institutes of Health (NIH)

NIH GOALS

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."

- Discoveries, innovative research, and applications
- Scientific human and physical resources
- Knowledge base in medical and associated sciences
- Highest level of scientific integrity, public accountability, and social responsibility in the conduct of science





NIH ORGANIZATION BY INSTITUTE/CENTER/OFFICE (ICO)



Generally organized by either medical condition (NCI) or body part (NEI).



Source: https://oma.od.nih.gov/IC_Organization_C hart/NIH%20Organizational%20Chart.pdf

KEY FUNDING MECHANISMS

Types of Mechanisms	Purpose
R series	Research
K series	Career Development
 T & F series	Research Training and Fellowships
P series	Program Project and Center Grants
 U series	Cooperative Agreements
 Other	Resource Grants, Trans-NIH Programs, etc.

Detailed descriptions: http://grants.nih.gov/grants/funding_program.htm





COMMON RESEARCH (R) AWARDS



Activity codes: https://grants.nih.gov/funding/activity-codes





Designation	Eligibility	Priority
Early Stage Investigator (ESI)	A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously <u>competed successfully</u> as PD/PI for a substantial NIH independent research award. **A list of NIH grants that a PD/PI can hold and still be considered an ESI can be found at <u>https://grants.nih.gov/policy/early- investigators/list-smaller-grants.htm</u>	ESI applications with meritorious scores will be prioritized for funding.
New Investigator (NI)	An investigator who has not previously received substantial, independent funding from NIH.	NIH ICOs fund New Investigators according to the ICOs' programmatic and strategic interests.



NOTICES OF FUNDING OPPORTUNITIES (NOFOs)

PARENT ANNOUNCEMENTS

PROGRAM ANNOUNCEMENTS (PAs)

REQUESTS FOR APPLICATIONS (RFAs)

- Allows applicants to submit an investigator-initiated application for specific activity code (unsolicited research)
- Centrally managed, broadly issued, most NIH ICOs participate
- Usually on-going (every 3 years)
- Issued by one or more ICO to highlight areas of scientific interest
- Encourage applications for a new/on-going program
- PA<u>S</u> have set-aside funds; PA<u>R</u> have special receipt, referral and/or review considerations
- Issued by one or more ICO to highlight well-defined areas of scientific interest to accomplish specific program objectives
- Uses set-aside funds
- Typically has single due date; ICO usually convenes review panel

Formerly called "FOAs"

NOTICES OF SPECIAL INTEREST (NOSI)



- Not a type of NOFO but an expanded opportunity
- Published in the NIH Guide for Grants and Contracts
- Statement of scientific priorities that encourages investigators to apply using a particular NOFO
 - Typically a parent NOFO
 - Consists of a topic of concern or area of scientific interest for the sponsoring institute.
- These notices designate existing NOFOs to use for application submission.
- Sample NOSIs NIEHS: https://www.niehs.nih.gov/funding/grants/announcements/sp ecial-interest



OPPORTUNITY DATABASE: GRANTS.GOV <u>WWW.GRANTS.GOV</u>



NIH GRANTS & FUNDING

SPONSOR DATABASE
<u>GRANTS.NIH.GOV</u>

NIH Guide for Grants and Contracts

The NIH Guide for Grants and Contracts is NIH's official publication of notices of grant policies, guidelines, and funding opportunities. We publish daily and issue a <u>Weekly Table of Contents</u>.

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PREPARING A COMPETITIVE PROPOSAL

NIH REPORT AND REPORTER







Get Started >

USING MATCHMAKER

	RePORTER			•	FAQs A	PI EY JRTER (Bet	a) 🕒 Sign In ◄
Matchmaker Res Top 500 Projects Projects Program 04	sults fficials	Cortella burnetii is the etiological ag aoult 1999). CDC has classified Co extremely low infectious dose [ID50 the U.S. since 1999, however the tru associated with biob mortality rate (gent of a flu-like illness (acute Q fever) and a chronic dise oxiella as a select agent due to its past use as a bioweap of one to ten bacteria in a guinea pig model (Tigertt et a le rate of infection is not known due to widespread under (>60%) (Karakousis et al. 2006), and Coviella is one of the	ase commonly manifested as endocarditis on, environmental stability, aerosol transmi I. 1961)]. Human Q fever is a nationally not reporting (CDC 2002). Untreated chronic C a commonest causes of culture negative in	s (Maurin and ission and tifiable disease in c fever is offective	Export T	
Filters C Active Projects Fiscal Years Agencies Activity Codes Program Officials	Institute/Center 400 200 100 0 UPIN	N N N N N N N N N N N N N N N N N N N	Activity Code	ZIA PO1 R44	Study Section	C C RFS	HBP - MAN
 Study Sections 	TAct Project Year Sub Coxiella burnetii immune 1ZIAAI001331-02 Exploiting a cyclic dinuc 5R01AI139051-03	Principal Investigator(s)/ Project Leader(s) obiology, host-pathogen modeling & LONG, CARRIE leotide-mediated immune respons & GOODMAN, ALAN GABRIEL	Organization , and countermeasure development NATIONAL INSTITUTE OF ALLERGY AND INF se to reduce the burden of Coxiella burnetii WASHINGTON STATE UNIVERSITY	ECTIOUS DISEASES	Fiscal YearAdmin IC2021NIAID2021NIAID	Funding IC FY Total Cost by IC NIAID \$1,027,713 NIAID \$466,870	Similar Projects Match
	<u>Genetics of Coxiella burn</u> <u>1ZIAAI000946-18</u>	netii ▲ <u>HEINZEN, ROBERT A</u> I	NATIONAL INSTITUTE OF ALLERGY AND INF	ECTIOUS DISEASES	2021 NIAID	NIAID \$381,40	7 View > 90



GET ORGANIZED



When you are ready to begin, prepare thoroughly.

- Read all <u>competition</u> materials, e.g., the NOFO, the NOSI (if applicable), the Application Guide.
- Identify all required application elements. Create a checklist!
- Note required timelines and deadlines.
- Create a grant development plan, including a <u>timeline</u>.
- Start an Aims page draft.
- Create a <u>narrative outline</u> (or "skeleton").
- Gather required information.
- Reach out to your sponsored programs office to understand their process.

SAMPLE CHECKLIST



After reviewing competition parameters, develop a checklist:

- SF 424 Form
- Cover Sheet
- Project Summary/Abstract
- Project Narrative
- PHS 398 Research Plan Form
 - Specific Aims
 - Research Strategy
- Bibliography & References Cited
- Biographical Sketch(es)
- Data Management & Sharing Plan
- Facilities and Other Resources
- Equipment (optional)
- Other Attachments
- Budget

- Budget Justification
- Progress Report Publication List
- Multiple PD/PI Plan (if applicable)
- Consortium/Contractual Arrangements (if applicable)
- Letters of Support
- Resource Sharing Plan
- Authentication of Key Chemical and/or Biological Resources
- Appendix
- Human Subjects and Clinical Trials Information
- Study Records/Delayed Onset
- PHS Assignment Request Form (optional)

WRITE THE AIMS PAGE & RESEARCH STRATEGY



Do not add/remove/change the order of these sections.

Follow the guidelines!

KEYS TO SUCCESS



- Talk to a PO about your ideas
- Share an Aims page (if the PO is open to reviewing it)
- Review the additional resources provided throughout this webinar
- Complete a first full draft at least 6-12 weeks before the deadline
- Get feedback on your draft from others
- Revise, revise, revise
- Submit early, in case you've missed something that can be identified by the sponsor in time for you to correct it
- If your application is not funded, review the summary statement and request a conversation with the PO to discuss it.

PROPOSAL REVIEW PROCESS

NIH REVIEW PROCESS: KNOW YOUR AUDIENCE





CSR ASSISTED REFERRAL TOOL (ART): CHOOSING A STUDY SECTION

	PHS Assignment Request Form	OMB Number: 0925-0001 Expiration Date: 01/31/2026
Funding Opportunity Number:		
Funding Opportunity Title:		
Awarding Component Assignment Sugges	stions (optional)	
If you have a suggestion for an awarding com Cancer Institute) and enter it below in the box	nponent (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (ses for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment s	on (e.g., "NCI" for National uggestions can be honored.
Information about Awarding Component can I	be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents	
Suggested Awarding Components:		
Study Section Assignment Suggestions (o	optional)	
If you have a suggestion for a study section a Study Sections." Remove all hyphens, parent	ssignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section the section short and spaces. All suggestions will be considered; however, not all assignment suggestions can be hone	in the boxes for "Suggested red.
For example, enter "CAMP" if you wish to sug Healthcare Delivery and Methodologies SBIR	ggest assignment to the NIH Cancer Molecular Pathobiology study section, or "ZRG1HDMR" if you wish to sur /STTR panel for informatics.	ggest assignment to the NIH
Information about Study Sections can be foun	nd here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection	
Suggested Study Sections: Each entry is limited to 20 characters		
Rationale for assignment suggestions (opt	tional)	Entry is limited to 1000 characters





NIH REVIEW PROCESS: KNOW YOUR AUDIENCE

- First Level of Review:
 - Scientific Review Group (SRG)
 - Managed by NIH Scientific Review Officers (SROs)
 - Composed primarily of non-federal scientists with relevant expertise
 - Can be requested by the PI
 - All proposals individually reviewed by [typically] 3-4 reviewers
 - Top ~40-50% are typically discussed in the group

Significance – scored Investigator(s) – scored Innovation – scored Approach – scored Environment – scored

+ few additional review criteria, e.g., human subjects

Second Level of Review: IC Advisory Council/Board

- Composed of both scientific and public representatives
- Do not strictly fund based on SRG scores







SIMPLIFIED REVIEW FRAMEWORK FOR MOST RPGS

Current

Significance – scored

Investigator(s) - scored

Innovation - scored

Approach – scored

Environment - scored

Simplified Framework (for RPGs submitted on or after 1/25/2025)

(all considered in Overall Impact Score)

Factor 1: Importance of the Research

Significance, Innovation Scored 1-9

Factor 2: Rigor and Feasibility

Approach (also includes Inclusions for Human Subjects and Clinical Trial Study Timeline) Scored 1-9

Factor 3: Expertise and Resources

Investigators, Environment Evaluated as appropriate or additional expertise / resources needed; gaps require explanation No individual score



NIH Simplified Review Framework for Research Project Grants (RPGs), <u>webinar presented by the NIH, 17 Apr 2024</u>. Applicant Guidance: <u>https://grants.nih.gov/policy-and-compliance/policy-topics/peer-review/simplifying-review/applicant-guidance</u>

MORE RESOURCES TO LEVERAGE

OPEN MIKE

U.S. Department of Health & Human Services | National Institutes of Health





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January 7, 2025

0 Comments

HOME OPEN MIKE MORE TOP STORIES NEW RESOURCES TIPS BEFORE YOU SUBMIT YOU ASK, WE ANSWER



Helping connect you with the NIH perspective, and helping connect us with yours.

A Brief Look Back at 2024, With a Glimpse Into 2025

By Mike Lauer

As we start 2025, we are taking a brief look back at 2024 and our efforts to support and inform the extramural biomedical research community on NIH grant policies and initiatives.

Biomedical Research Workforce, Funding data, Grants policy

Introducing the New NIH Public Access Policy



Dr. Michael Lauer is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

https://nexus.od.nih.gov/all/category/open-mike/

EARLY CAREER REVIEWER PROGRAM



- Gain reviewer experience
- An opportunity for qualified individuals to get to know the review process by serving as a reviewer
- Enables individuals to become more competitive as applicants themselves

Early Career Reviewer (ECR) Program | NIH Center for Scientific Review

To apply:

- A full and up-to-date CV is needed (no biosketch)
- A list of terms that describes your areas of scientific expertise
- NIH Commons ID
- Up to 4 CSR study sections that match your expertise
- ECR application
- If accepted, then you are invited to stay in the program until your qualifications no longer meet the eligibility criteria
- Updates to your qualifications are needed annually.



A FEW MORE...

- New to the NIH: <u>https://grants.nih.gov/new-to-nih</u>
- Data Management and Sharing Policy: https://sharing.nih.gov/data-management-and-sharing-policy
- Center for Scientific Review Infographic: <u>https://public.csr.nih.gov/sites/default/files/2022-</u> 06/CSR_ResourceInfographic_v21.pdf
- NIH Research Training and Career Development: Research Career Goal toward Becoming a Physician-Scientist: <u>https://researchtraining.nih.gov/infographics/physician-scientist</u>
- Changes Coming to NIH Applications and Peer Review in 2025: <u>https://grants.nih.gov/policy-and-compliance/changes-coming-2025</u>
- Sample applications: <u>https://www.niaid.nih.gov/grants-contracts/sample-applications</u>







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Hanover's **Grant Rant** podcast is available on Apple's iTunes for a variety of grant-seeking topics.



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