McALLISTER & QUINN
Winning Strategies. Proven Track Record.

Positioning yourself for success with the NIH R03 & R15

13 NOVEMBER 2024

Today's Speaker

Elizabeth Festa, Ph.D.
Managing Director
Research Universities Practice

Overview

About McAllister & Quinn

Washington, DC-based consulting firm

Founded in 2004.

Specialize in securing funding for a wide range of organizations.

Team of grants experts

100+ staff from Legislative and Executive branches, academia, non-profits, & industry.

400+ grant writers, consultants & subject matter experts.

Agenda

PART I: Presentation on the Agency and the R03/R15 mechanisms

1. Overview of NIH and the ICs
2. Understanding & searching for funding opps
3. Overview of R03 and R15 mechanisms
4. Communicating with Program Officers
5. Preparing Key Sections of your Proposal

PART II : R15 panel discussion

Dr. Mike Gawrysiak
Dr. Liz Grillo
Dr. Kristen Breit

Overview of NIH & the ICs

Overview of NIH

Clinical Center (Building 10), NIH Campus

- NIH is the largest public funder of biomedical research in the world
- NIH Budget: $47.683 billion (FY23)
- 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*

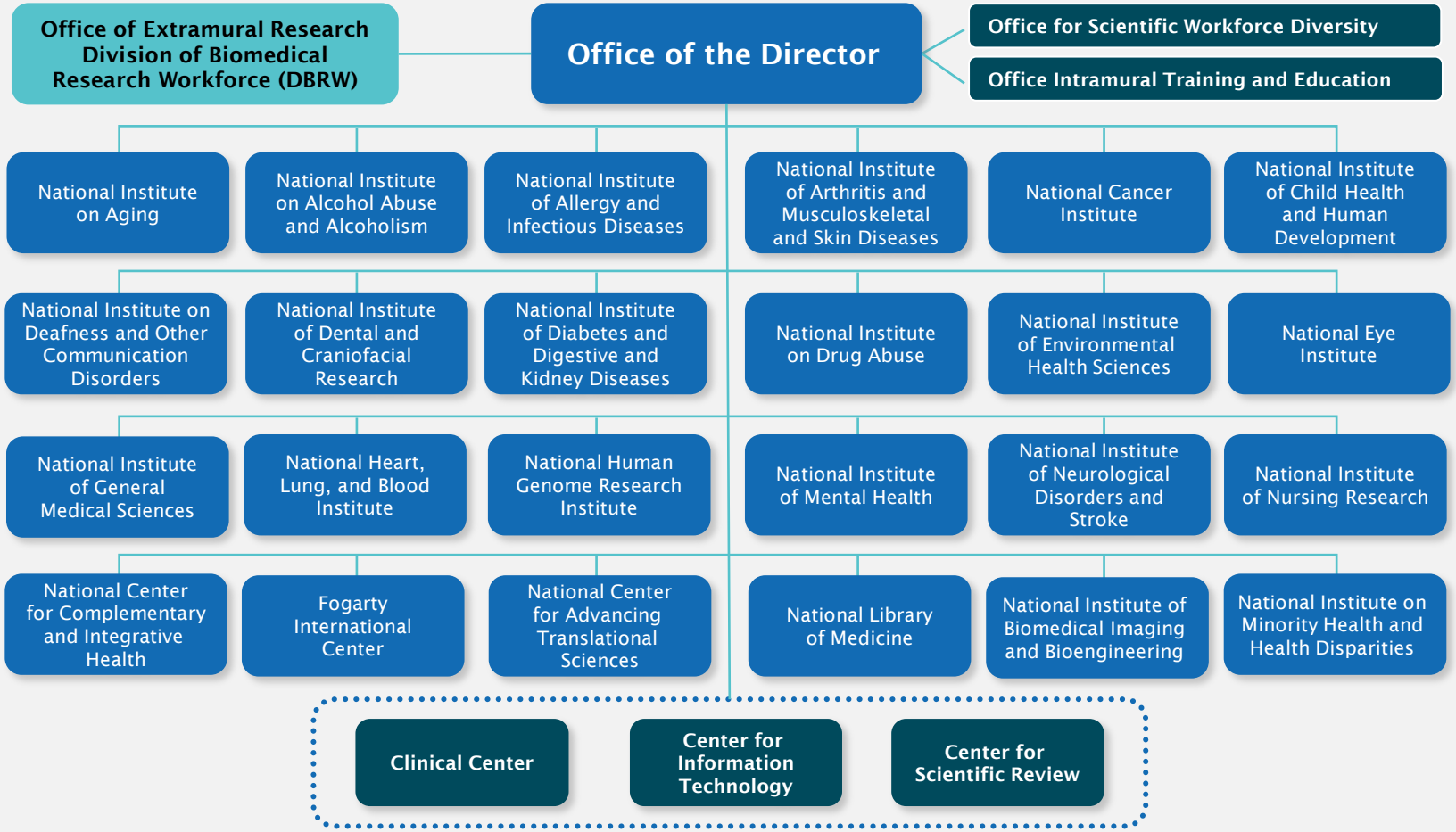
Key Acronyms

IC	Institute/Center	**RPG**	Research Project Grant
PO	Program Officer	**PPG**	Program Project Grant
SRO	Scientific Review Officer	**PA**	Program Announcement
CSR	Center for Scientific Review	**RFA**	Request for Application
FOA	Funding Opportunity Announcement	**NoA**	Notice of Award
NOFO	Notice of Funding Opportunity	**NOSI**	Notice of Special Intent

NIH Institutes & Centers (ICs)

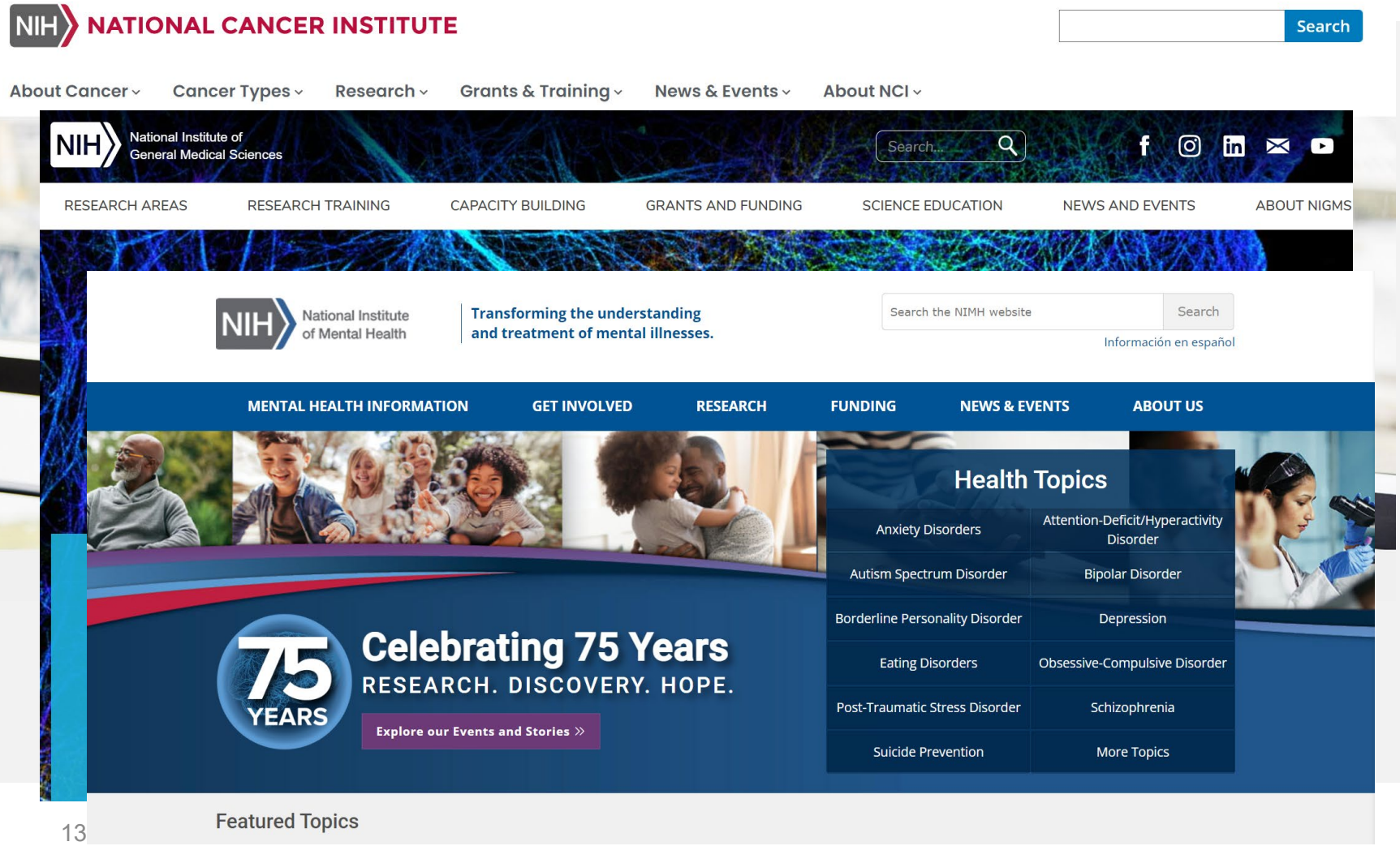
27 ICs (24 of which fund extramural research)

Each IC has its own
- mission
- priorities
- budget
- funding strategy



NIH and the ICs

Using Institute Webpages

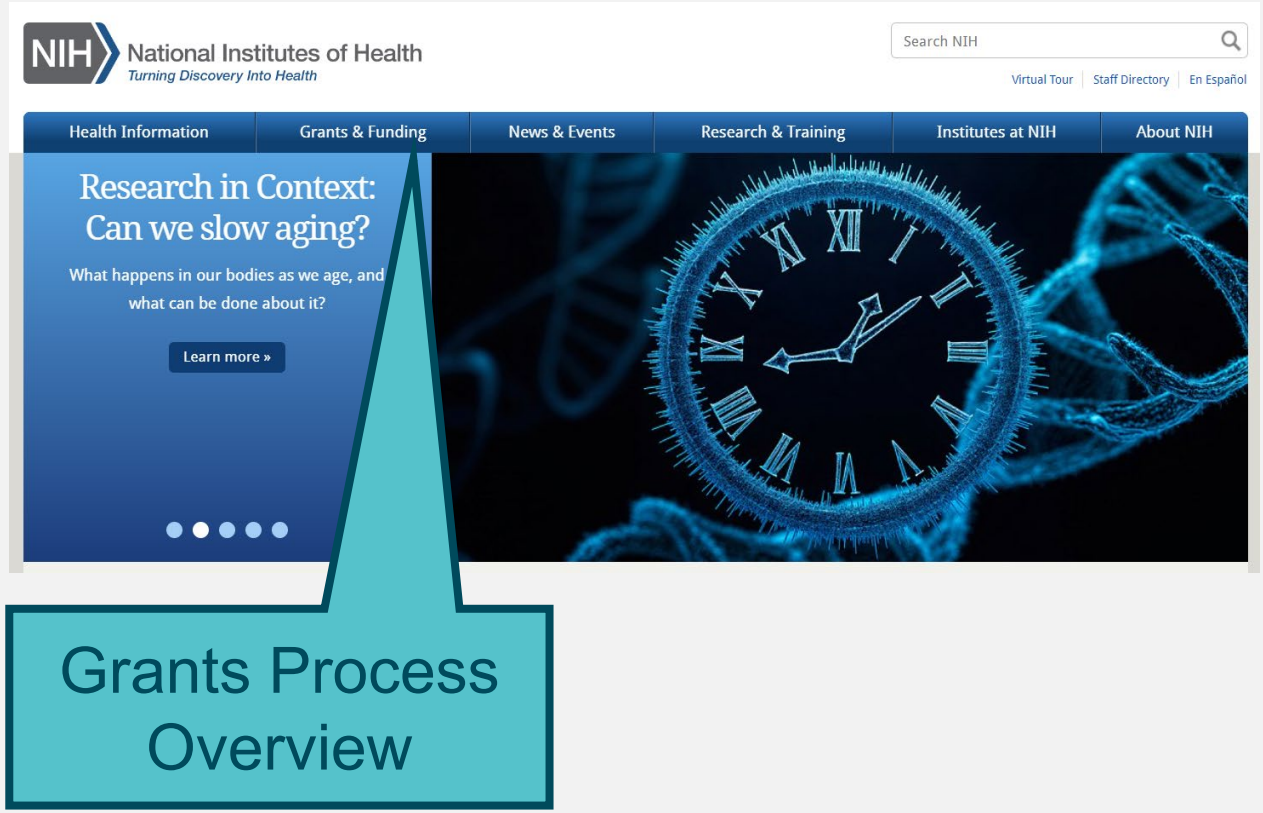


- Learn more about the institute's mission and active programs
- Review summaries of research projects previously funded by the institute
- Peruse current, future, and past funding solicitations in which the institute participates
- Find Program Officers
- Sign up for the Listserv and notifications

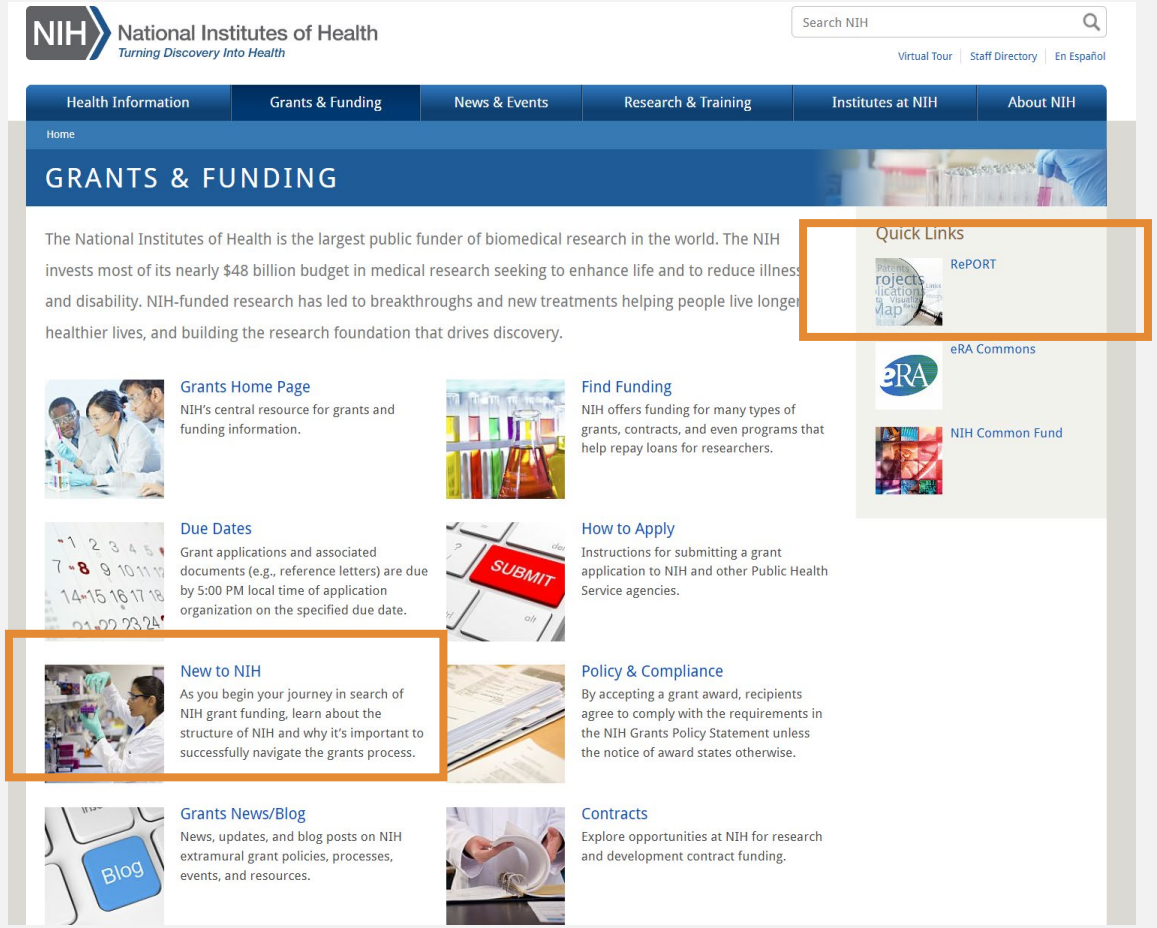
Understanding and searching for funding at the NIH

Understanding Funding

NIH Main Page



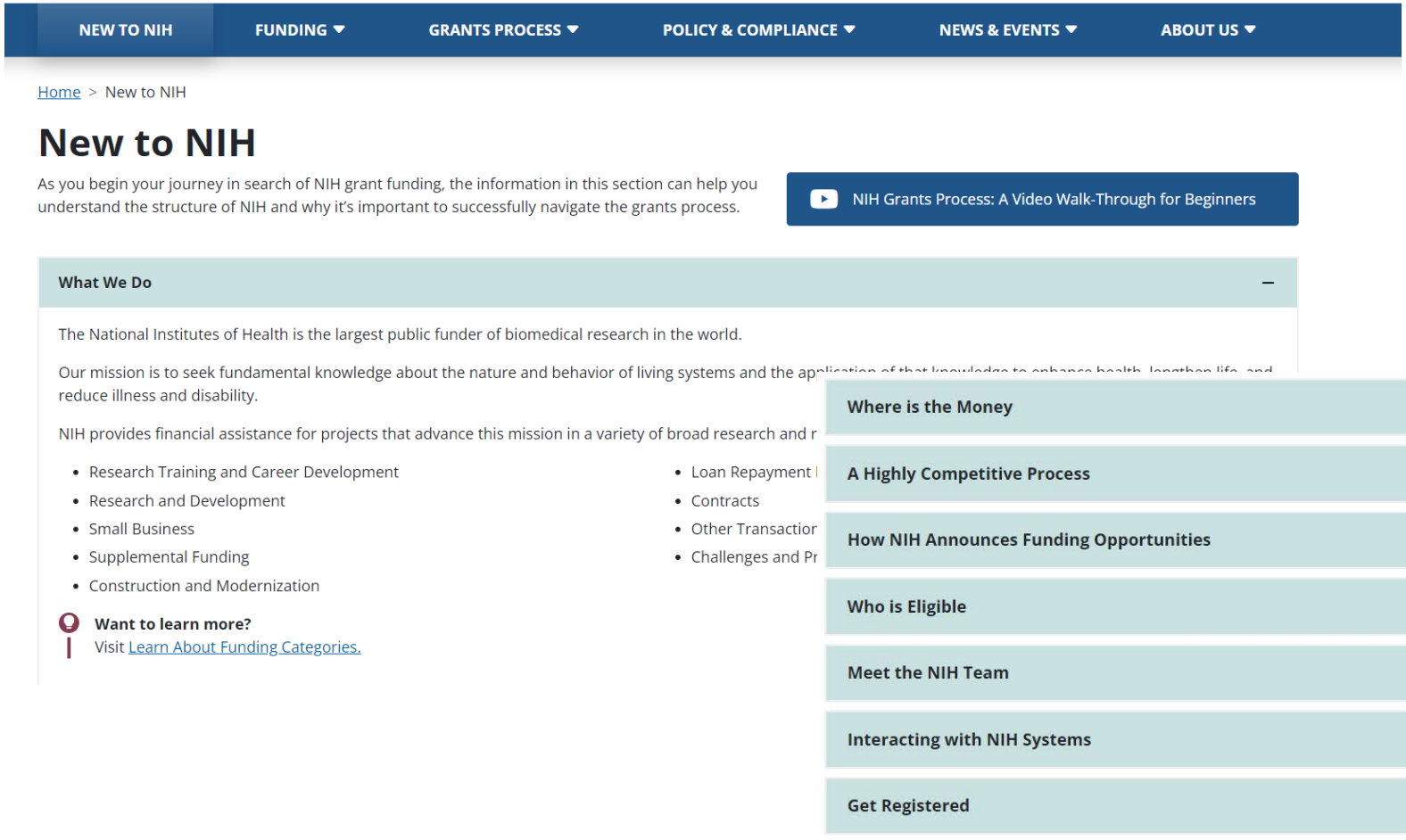
Grants Process Overview



Understanding funding

New to NIH page

New to NIH | Grants & Funding



Understanding funding

Resources, documents, utility links

Resources

General

Information For pages – links and resources of interest to specific audiences

- Researchers
- Research Administrators
- Reviewers
- Small Business
- Foreign Grants
- Media and the Public

See Also

Documents

- How to Apply – Application Guide — Use these general application instructions along with the guidance in funding opportunities to submit grant applications to NIH.
- NIH Grants Policy Statement (GPS) — The NIH GPS outlines the policy requirements that serve as the terms and conditions of NIH grant awards.
  - New policies or updates to existing policies are announced through the NIH Guide for Grants and Contracts and later incorporated into the NIH GPS on a yearly basis.

Utility links

We have several handy utility links in the upper right corner of every page.

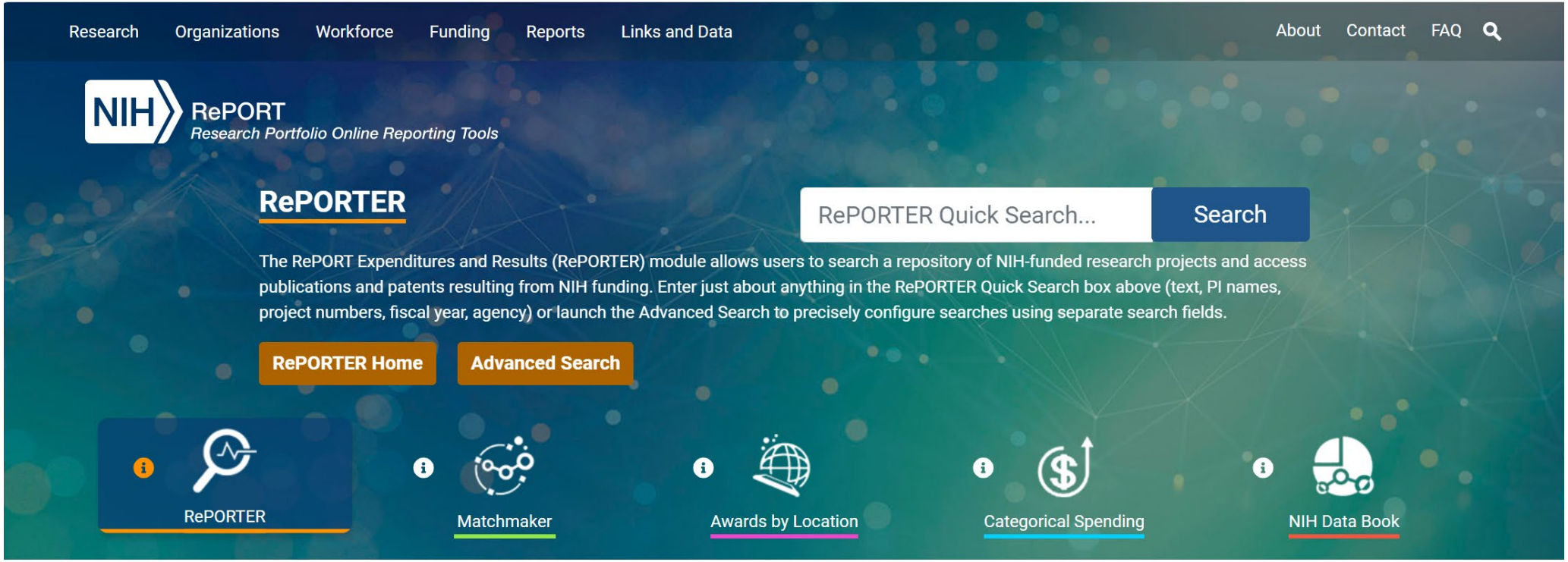
- Glossary — NIH, like most organizations, uses a lot of acronyms and nuanced terminology. Refer to our glossary to find acronym expansions and the meaning of many grant terms. A link to the glossary can be found at the top of each page under the search box.
- Frequently Asked Questions (FAQs) — Find the answers to questions on a wide range of grants administration policies, programs, and processes. The main FAQ page is a compilation of the topic-specific FAQ sets you'll find towards the bottom of our topic pages.

Contact

Check online guidance and direct your questions to your sponsored programs office or grants administrators. If you still need assistance, find NIH contacts at Need Help?

Understanding Funding

RePORT



Welcome to

Research Portfolio Online Reporting Tools (RePORT)

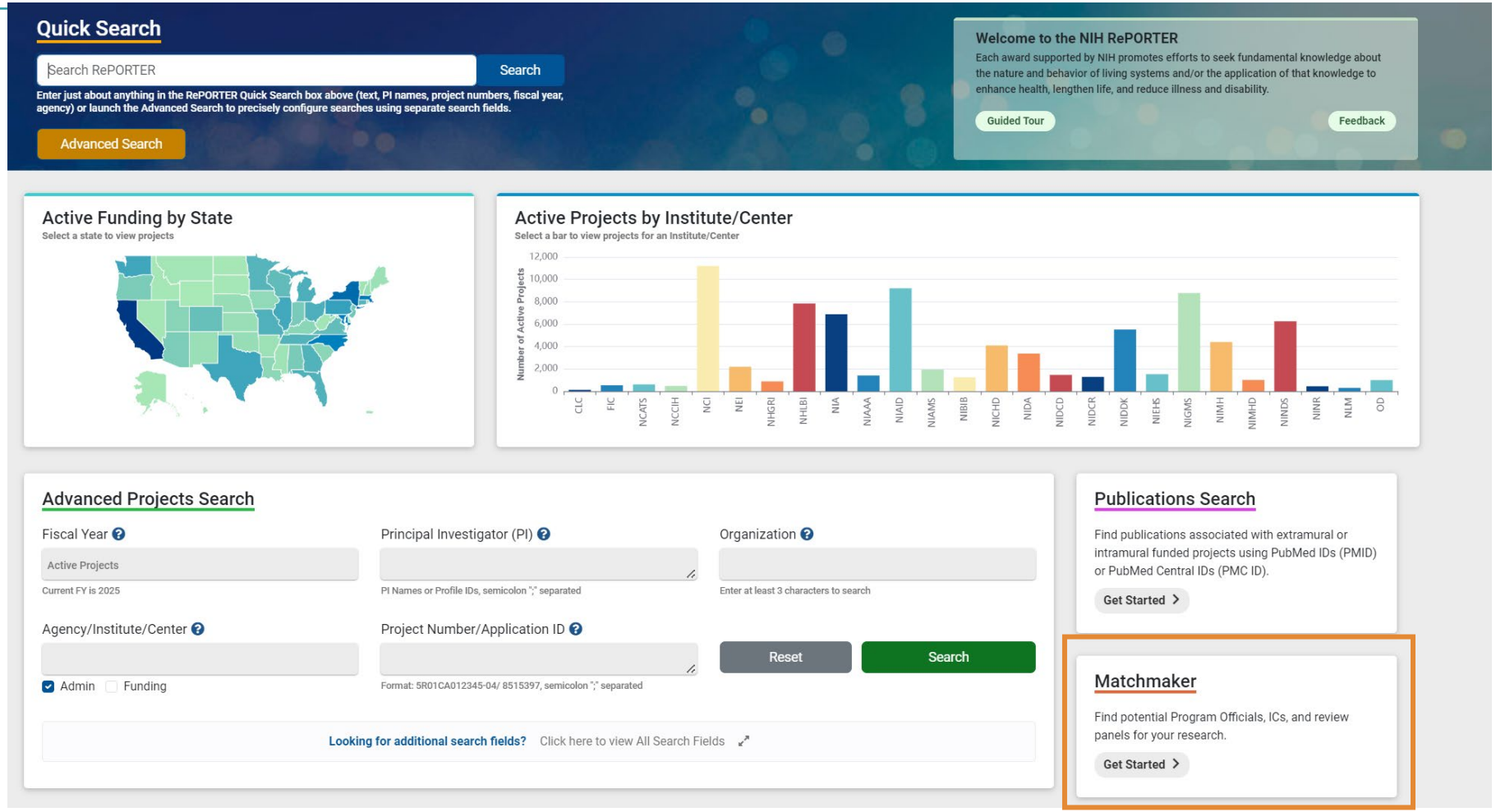
Spotlight

NIH COVID-19 Research

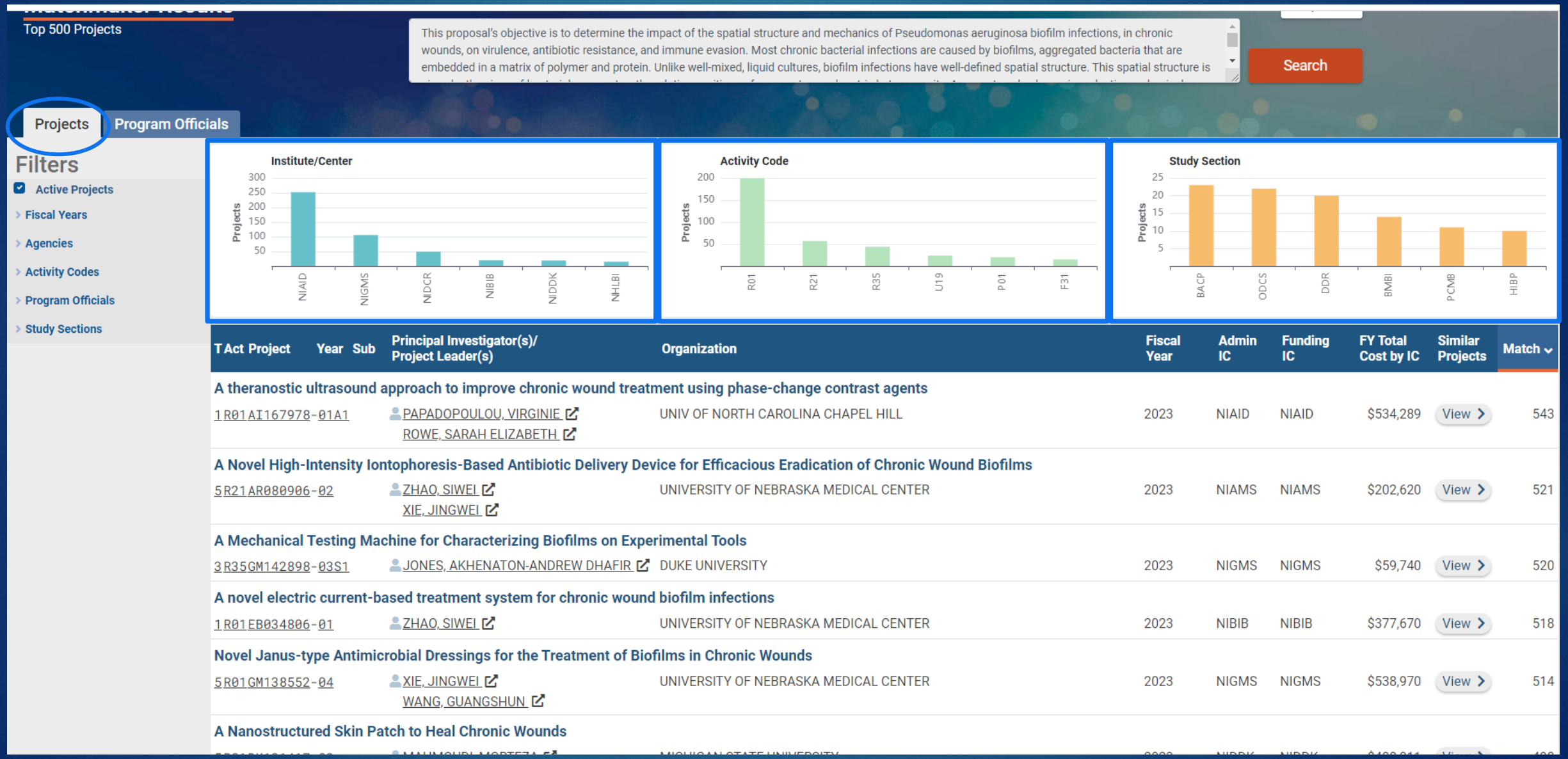
Explore NIH's comprehensive summary of ongoing COVID-19 research, including funding, clinical trials,

Understanding Funding

RePORTER

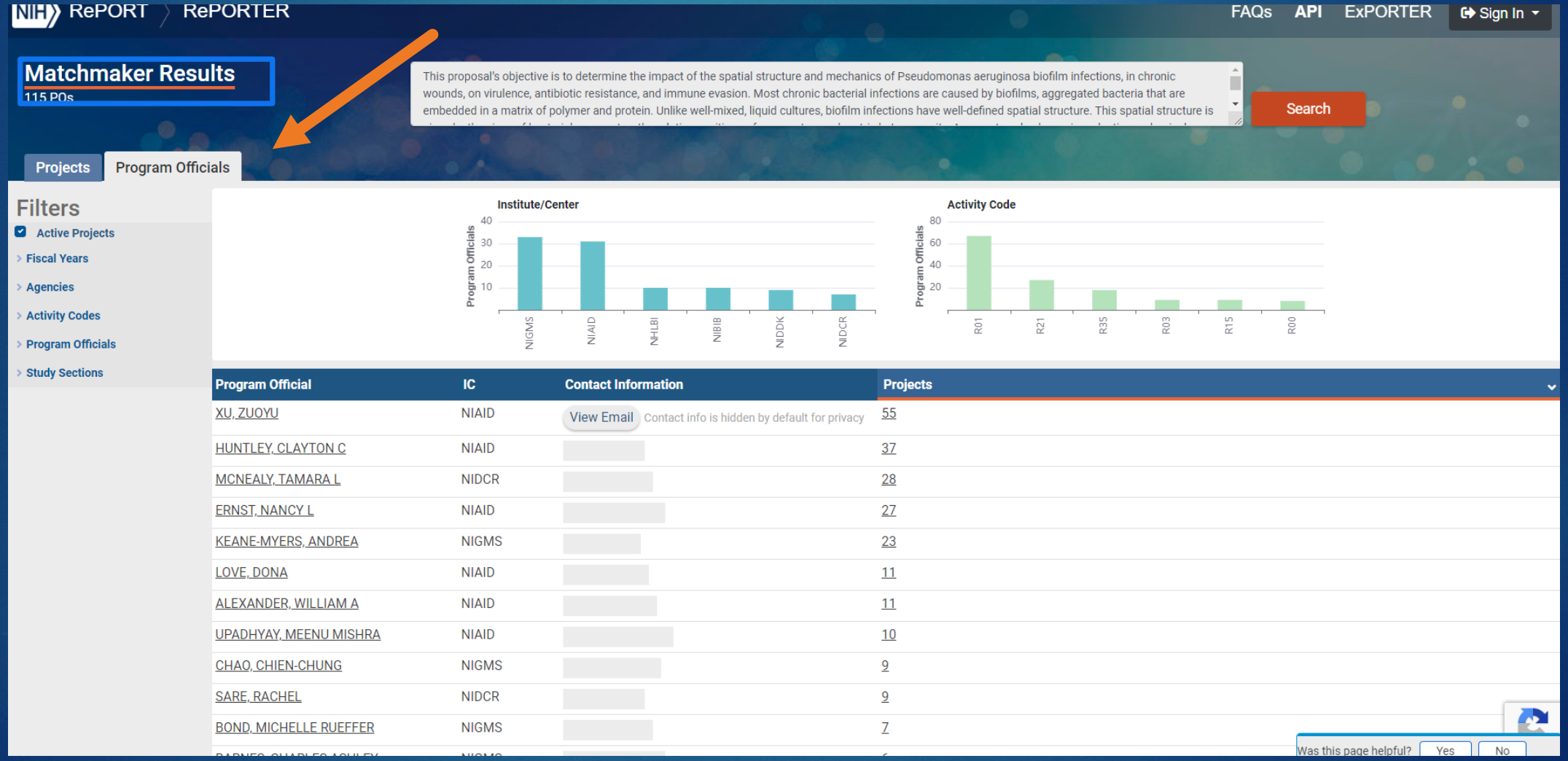


RePORTER - Matchmaker



T Act Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects	Match
A theranostic ultrasound approach to improve chronic wound treatment using phase-change contrast agents										
1 R01 AI167978-01A1			PAPADOPOULOU, VIRGINIE ROWE, SARAH ELIZABETH	UNIV OF NORTH CAROLINA CHAPEL HILL	2023	NIAID	NIAID	$534,289	View	543
A Novel High-Intensity Iontophoresis-Based Antibiotic Delivery Device for Efficacious Eradication of Chronic Wound Biofilms										
5 R21 AR080906-02			ZHAO, SIWEI XIE, JINGWEI	UNIVERSITY OF NEBRASKA MEDICAL CENTER	2023	NIAMS	NIAMS	$202,620	View	521
A Mechanical Testing Machine for Characterizing Biofilms on Experimental Tools										
3 R35 GM142898-03S1			JONES, AKHENATON-ANDREW DHAFIR	DUKE UNIVERSITY	2023	NIGMS	NIGMS	$59,740	View	520
A novel electric current-based treatment system for chronic wound biofilm infections										
1 R01 EB034806-01			ZHAO, SIWEI	UNIVERSITY OF NEBRASKA MEDICAL CENTER	2023	NIBIB	NIBIB	$377,670	View	518
Novel Janus-type Antimicrobial Dressings for the Treatment of Biofilms in Chronic Wounds										
5 R01 GM138552-04			XIE, JINGWEI WANG, GUANGSHUN	UNIVERSITY OF NEBRASKA MEDICAL CENTER	2023	NIGMS	NIGMS	$538,970	View	514
A Nanostructured Skin Patch to Heal Chronic Wounds										

RePORTER - Matchmaker



Matchmaker Results

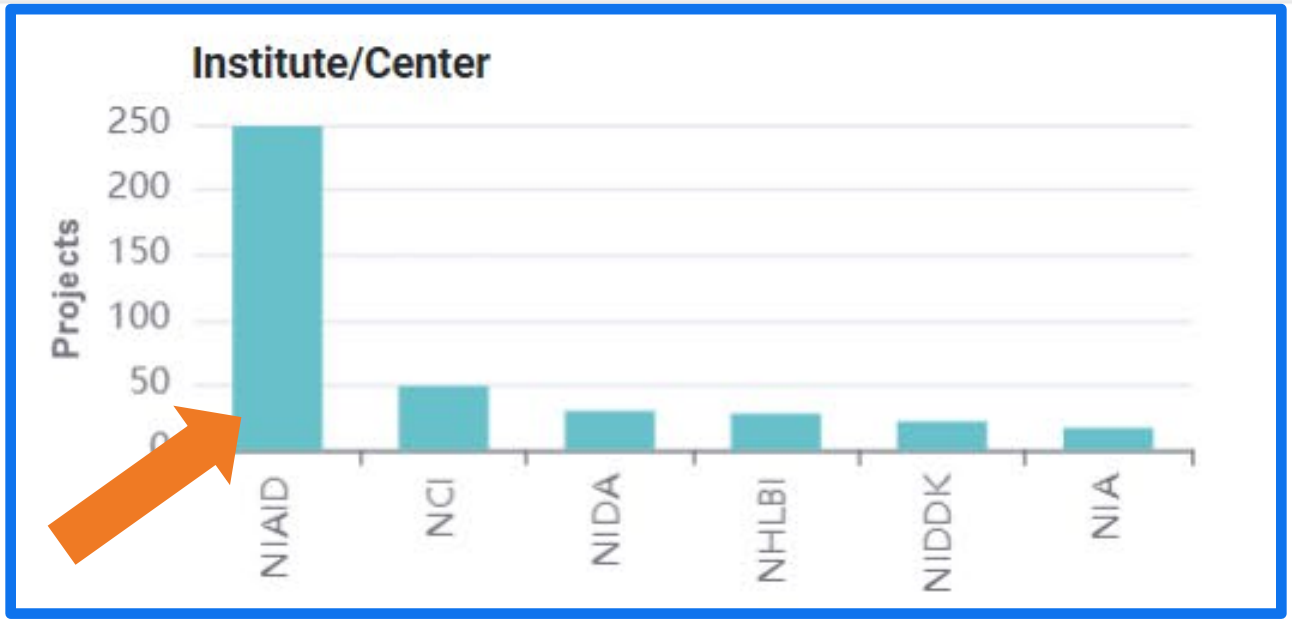
Top 500 Projects

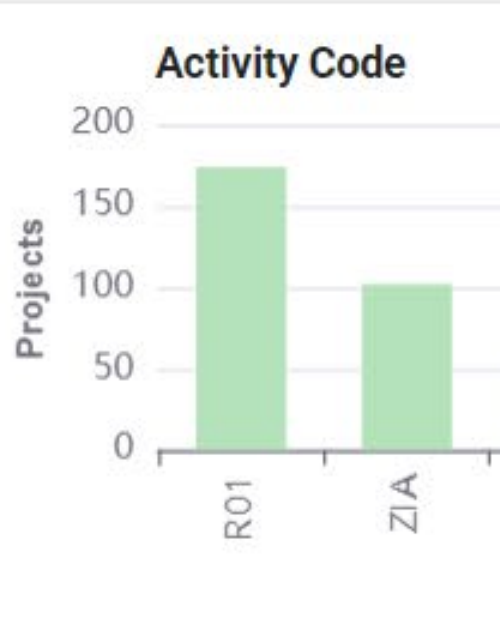
PROJECT SUMMARY Tregs and MDSCs have emerged as key suppresso
the TB granuloma. In addition, Tregs have been implicated in the mainten
generated two selective biologic agents for potent depletion of Tregs and

Projects | Program Officials

Filters

- [x] Active Projects
- Fiscal Years
- Agencies
- Activity Codes
- Program Officials
- Study Sections





T Act	Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization

Understanding NIH Funding Opportunity Types

NIH Issues Notices of Funding Opportunity (NOFOs)

Parent Announcements

- **Broad/'umbrella' NOFO** allowing investigators to submit "investigator initiated" or "unsolicited" research ideas in 'areas of choice' for a given activity code (e.g., parent R01, R03)
- Usually ongoing opportunity (3 years); standard receipt dates (you have flexibility)
- Most applications to NIH = investigator initiated

Program Announcements (PAR, PAS)

- **Identifies specific priority areas and/or areas of science**
- PAS: PA with set aside funds; PAR: has a special receipt, referral and/or review considerations (described in PA)
- Usually ongoing (3 years); standard receipt dates (you control when you apply)
- Most (but not all) NIH ICs participate

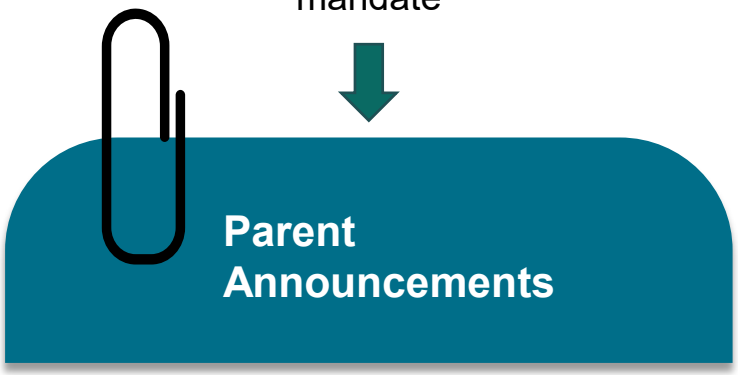
Requests for Applications (RFA)

- Special NOFO **identifying ('soliciting') research in specific, pre-defined scientific areas**
- Predetermined amount of set-aside funds, anticipated # of awards
- Usually, single receipt date; IC usually convenes review panel

Investigator- vs. Agency-Initiated Proposals

Investigator-Initiated

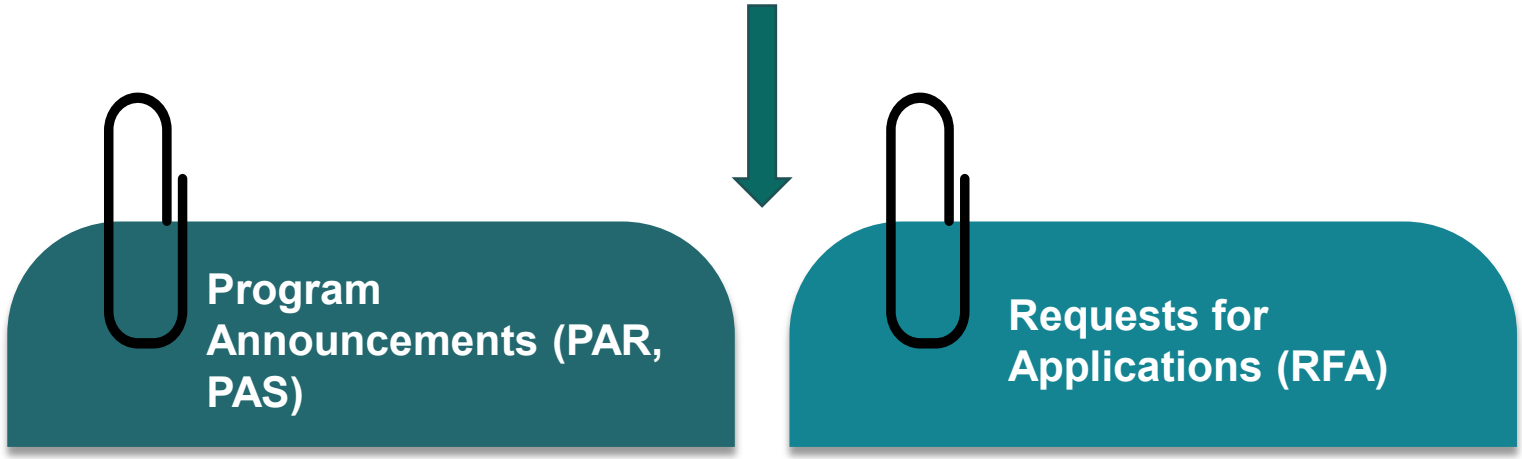
You go to the institute with an idea to solve a problem of **your choosing** that falls within the realm of the institute's mandate



- Often on the standard NIH submission cycle (3x/yr)
- Wider, more diverse applicant pool & concepts

Agency-Initiated

The agency tells you the problem they're seeking solutions to



- Focused applications with specific criteria for responsiveness
- Sometimes standard due dates, sometimes unique

Understanding Funding

Notices of Special Interest (NOSIs)

Notice of Special Interest (NOSI): Fundamental Mechanisms and Functions of Co-transmission in the Brain

Notice Number:
NOT-MH-24-105

Key Dates

Release Date:	January 3, 2024
First Available Due Date:	February 05, 2024
Expiration Date:	February 04, 2027

Issued by

National Institute of Mental Health (NIMH)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

National Institute on Drug Abuse (NIDA)

NOFO	Title	First Available Due Date	Participating ICs
PAR-22-155	Silvio O. Conte Centers for Basic Neuroscience or Translational Mental Health Research (P50 Clinical Trial Optional	June 7, 2024	NIMH
PA-21-219	Joint NINDS/NIMH Exploratory Neuroscience Research Grant (R21 Clinical Trial Optional)	February 16, 2024	NIMH
PA-21-235	NIMH Exploratory/Developmental Research Grant (R21 Clinical Trial Not Allowed)	February 16, 2024	NIMH
PA-20-195	NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)	February 16, 2024	NIDA, NIAAA
PAR-21-155	Academic Research Enhancement Award for Undergraduate-Focused Institutions (R15 Clinical Trial Not Allowed	February 25, 2024	NIMH, NIAAA, NIDA
PA-20-200	NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)	February 16, 2024	NIMH, NIAAA, NIDA
PA-20-185	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	February 5, 2024	NIMH, NIAAA, NIDA

Set of NOFOs this NOSI is pointing to

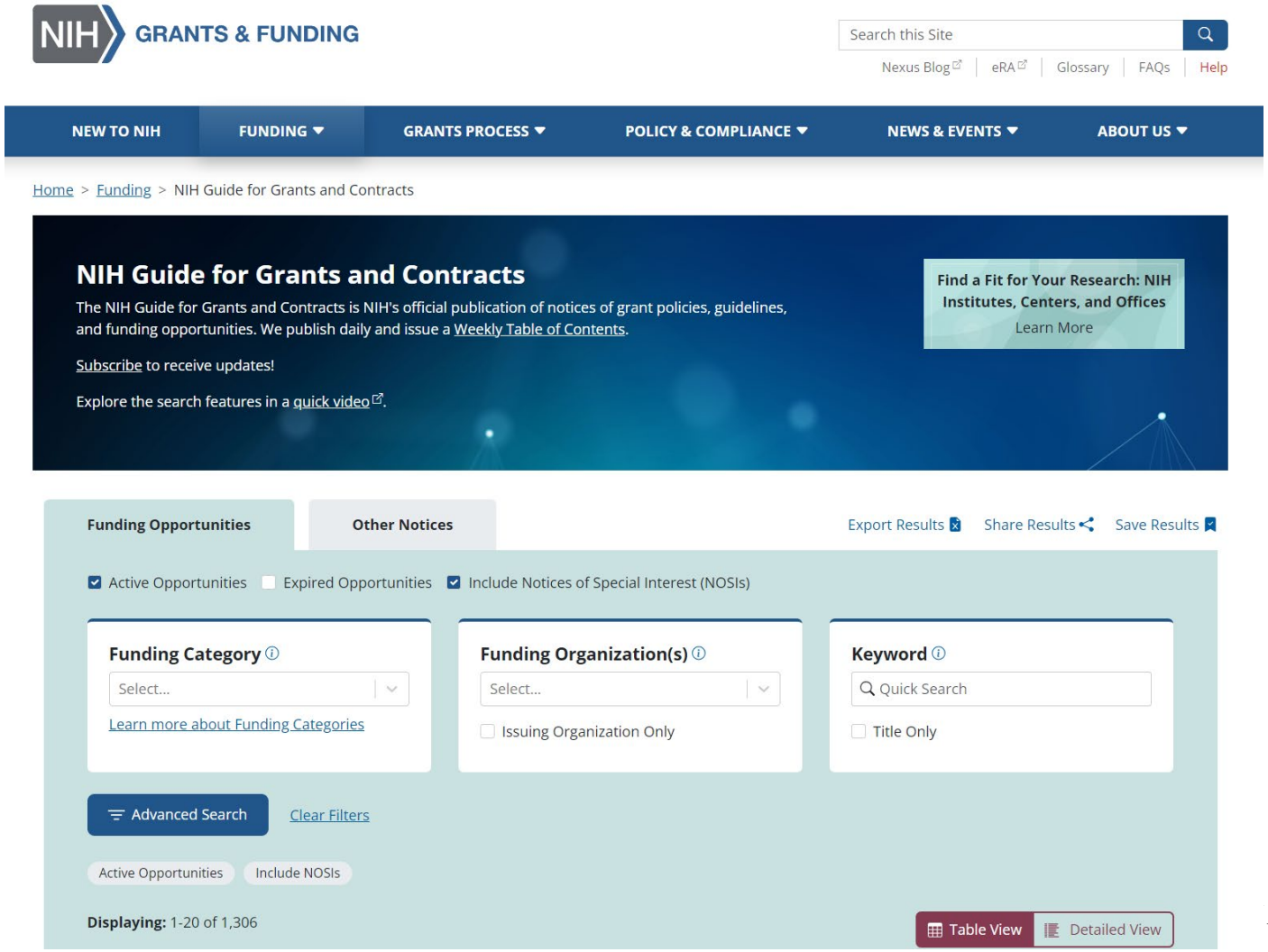
Increasingly used instead of IC-issued program announcements

Highlight areas of scientific interest

Designate existing NOFOs to use for application submission

Searching for grants

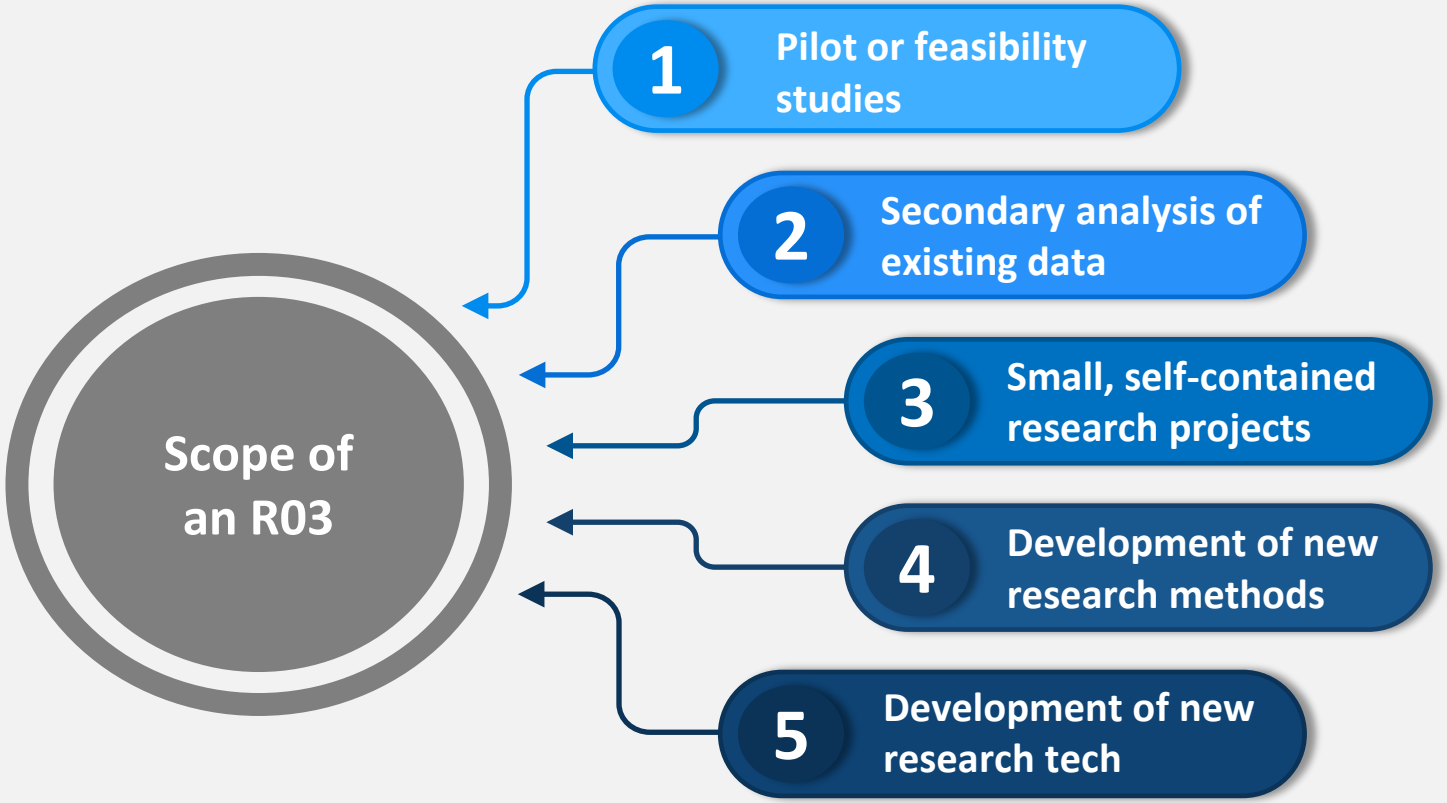
[NIH Guide for Grants and Contracts | Grants & Funding]



Overview of R03 & R15 mechanisms

What is an R03 grant?

An R03 is a grant for small projects that can be carried out in a limited time and with limited resources



R03 *at a glance*

Type of Grant	**Research Grant**
Type of Announcement	**Follows Parent Announcement, Program Announcement, or Request for Applications depending on IC**
IC participation	**24 or 26 ICs (note: not all ICs allow applications through the Parent Announcement)**
Required data	**No preliminary data required**
Clinical trial	**Not allowed**
Funding/length	**2 years, 50 K per year in direct costs per year, 100 K total, non-renewable**

R03: Participating ICs

Participating in Parent announcement

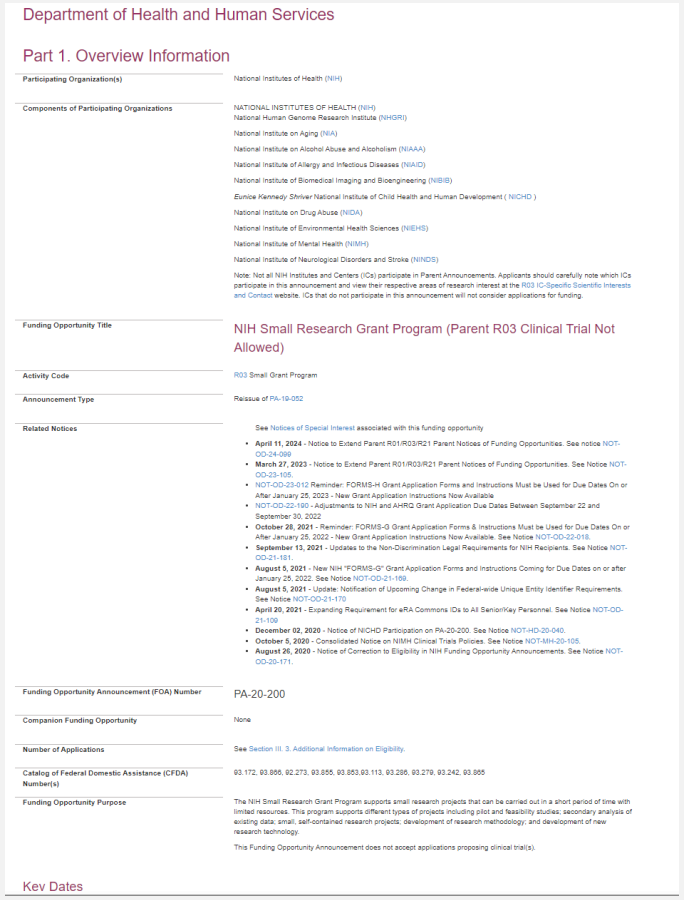
- National Human Genome Research Institute
- National Institute on Aging
- National Institute on Alcohol Abuse & Alcoholism
- National Institute of Biomedical Imaging and Engineering
- National Institute on Drug Abuse
- National Institute of Environmental Health Sciences
- National Institute of Mental Health
- National Institute on Minority Health & Health Disparities
- National Institute on Neurological Issues & Stroke
- National Institute on Child Health and Development

Do not Participate in PA
(may participate in RFA or Program Announcement)

- Fogarty International Center
- National Center for Advancing Translation Sciences
- National Center for Complementary & Alterative Medicines
- National Cancer Institute
- National Eye Institute
- National Heart Lung, and Blood Institute
- The National Institute of Arthritis & Musculoskeletal &Skin Diseases
- National Institute on Deafness & Other Communication Disorders
- National Institute of Diabetes & Digestive & Kidney Diseases
- National Institute of General Medical Sciences
- National Institute of Nursing Research
- National Library of Medicine
- Office of Research Infrastructure Programs

R03 and R15

Current Parent Announcement



Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	NATIONAL INSTITUTES OF HEALTH (NIH) 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 Biomedical Imaging and Bioengineering (NIBIB) *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of Mental Health (NIMH) National Institute of Neurological Disorders and Stroke (NINDS) 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 R03 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 Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)
Activity Code	R03 Small Grant Program
Announcement Type	Reissue of PA-19-052
Related Notices	See Notices of Special Interest associated with this funding opportunity • **April 11, 2024** - Notice to Extend Parent R01/R03/R21 Parent Notices of Funding Opportunities. See notice NOT-OD-24-099. • **March 27, 2023** - Notice to Extend Parent R01/R03/R21 Parent Notices of Funding Opportunities. See Notice NOT-OD-23-105. • NOT-OD-23-012 Reminder: FORMS-H Grant Application Forms and Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available • NOT-OD-22-190 - Adjustments to NIH and AHRQ Grant Application Due Dates Between September 22 and September 30, 2022 • **October 28, 2021** - Reminder: FORMS-G Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2022 - New Grant Application Instructions Now Available. See Notice NOT-OD-22-018. • **September 13, 2021** - Updates to the Non-Discrimination Legal Requirements for NIH Recipients. See Notice NOT-OD-21-181. • **August 5, 2021** - New NIH "FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022. See Notice NOT-OD-21-169. • **August 5, 2021** - Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements. See Notice NOT-OD-21-170. • **April 20, 2021** - Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel. See Notice NOT-OD-21-109. • **December 02, 2020** - Notice of NICHD Participation on PA-20-200. See Notice NOT-HD-20-040. • **October 5, 2020** - Consolidated Notice on NIMH Clinical Trials Policies. See Notice NOT-MH-20-105. • **August 26, 2020** - Notice of Correction to Eligibility in NIH Funding Opportunity Announcements. See Notice NOT-OD-20-171.
Funding Opportunity Announcement (FOA) Number	PA-20-200
Companion Funding Opportunity	None
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.172, 93.866, 92.273, 93.855, 93.853,93.113, 93.286, 93.279, 93.242, 93.865
Funding Opportunity Purpose	The NIH Small Research Grant Program supports small research projects that can be carried out in a short period of time with limited resources. This program supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. This Funding Opportunity Announcement does not accept applications proposing clinical trial(s).

Kev Dates

PA-20-200: NIH Small Research Grant Program (Parent R03 Clinical Trial Not Allowed)

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	NATIONAL INSTITUTES OF HEALTH (NIH) 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 Biomedical Imaging and Bioengineering (NIBIB) *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of Mental Health (NIMH) National Institute of Neurological Disorders and Stroke (NINDS) 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 R03 IC-Specific Scientific Interests and Contact website. ICs that do not participate in this announcement will not consider applications for funding.

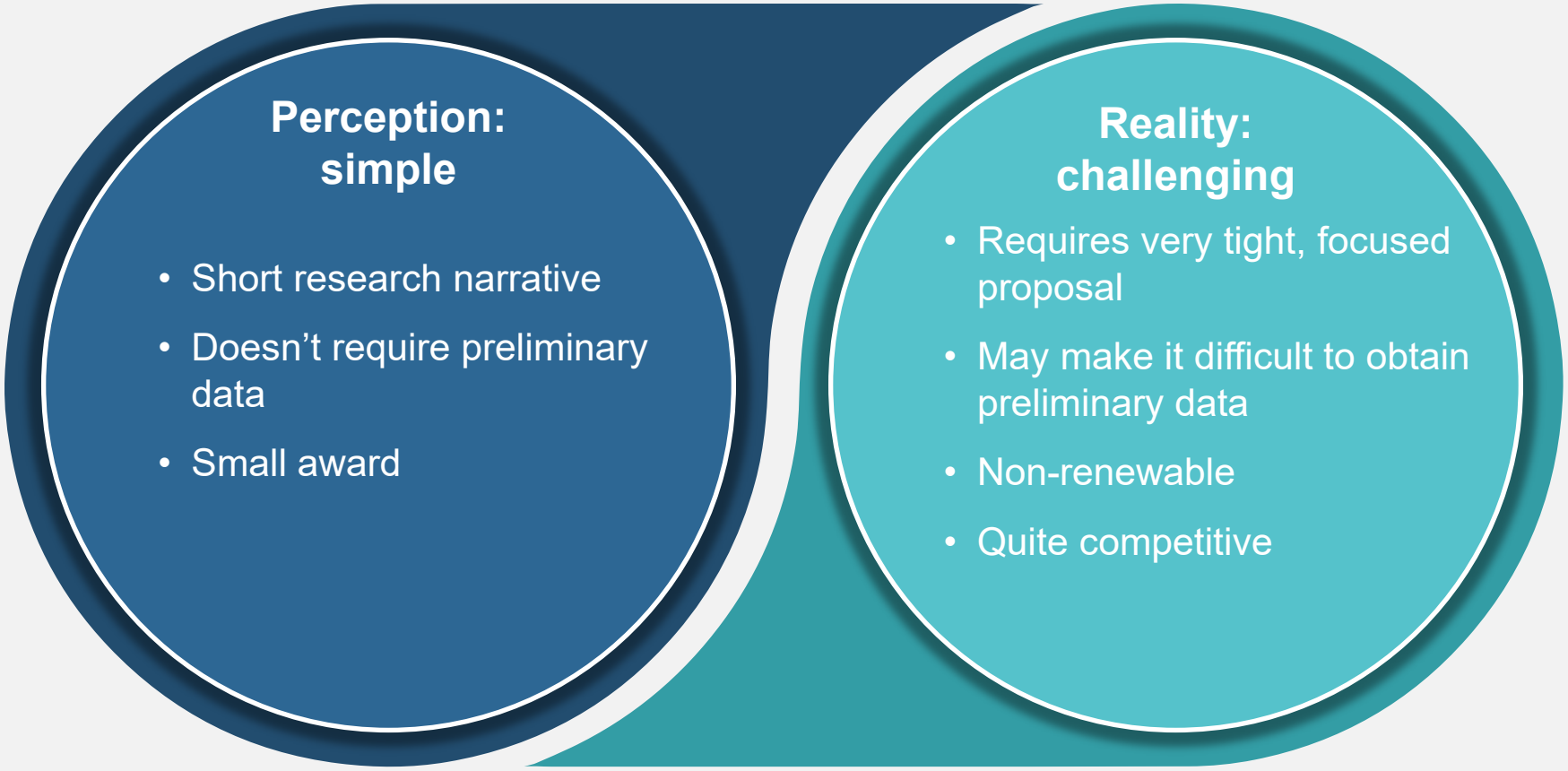
PARs, RFAs, and NOSIs for the R03

NIH Guide for Grants and Contracts | Grants & Funding

Title	Notice Number ⓘ	Issuing Organization ⓘ	Participating Organization(s) ⓘ	Release ▼ Date ⓘ	Expiration Date ⓘ	Activity Codes ⓘ
Pilot projects to enhance utility and usage of data sets from the Molecular Transducers of Physical Activity Consortium (MoTrPAC) (R03 Clinical Trials Not allowed)	RFA-RM-24-011	RMOD	N/A	October 23, 2024	December 27, 2024	R03
NCI Small Grants Program for Cancer Research (NCI Omnibus) (R03 Clinical Trial Optional)	PAR-25-078	NCI	N/A	October 18, 2024	January 8, 2026	R03
Imaging - Science Track Award for Research Transition (I/START) (R03 Clinical Trial Optional)	PAR-24-297	NIDA	N/A	September 17, 2024	January 8, 2028	R03
Notice of Special Interest (NOSI): Consequences of Prenatal Fentanyl Exposure	NOT-DA-26-003	NIDA	N/A	September 13, 2024	September 8, 2028	R21, R01, R03
Notice of Special Interest (NOSI): Application of Artificial Intelligence in Treatment Development for Substance Use Disorders	NOT-DA-26-005	NIDA	N/A	September 13, 2024	September 8, 2028	R03, R01, R21
Small Research Grant Program for the Next Generation of Researchers in Low- and Middle-Income Countries (LMICs) for Aging and Alzheimers Disease (AD) and AD-Related Dementias (ADRD) Research (R03 Clinical Trial Not Allowed)	RFA-AG-25-031	NIA	N/A	September 6, 2024	February 15, 2025	R03

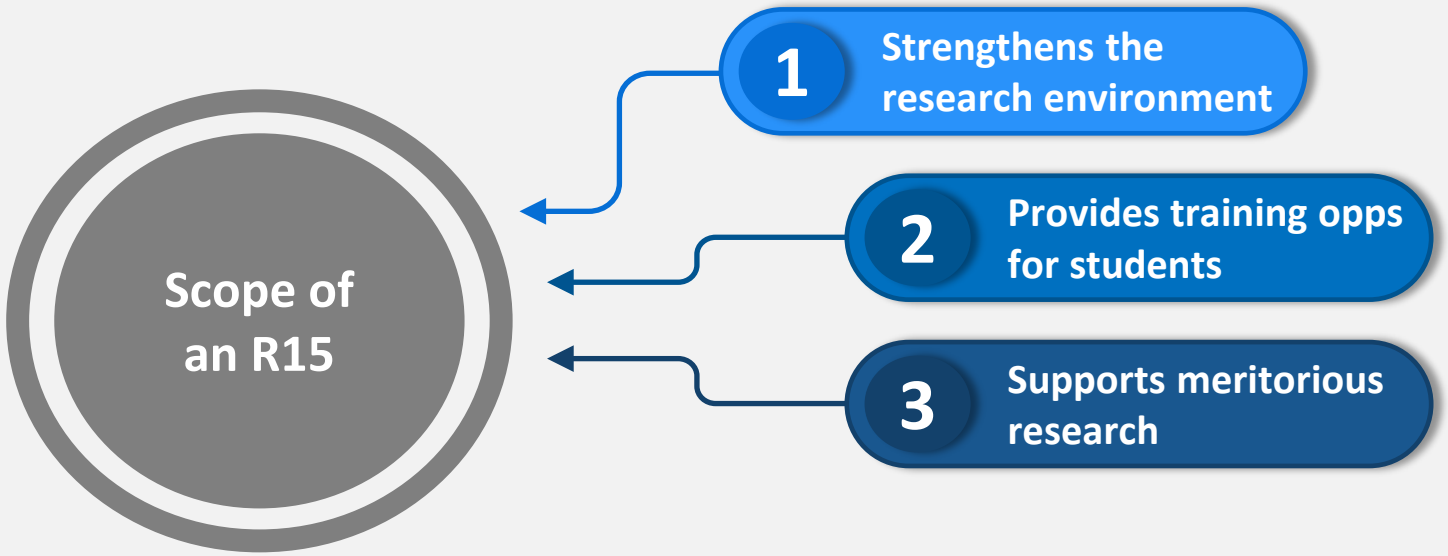
R03 & R15

Challenges of the R03



Purpose of the R15

An R15 supports small-scale research at institutions with limited NIH funding



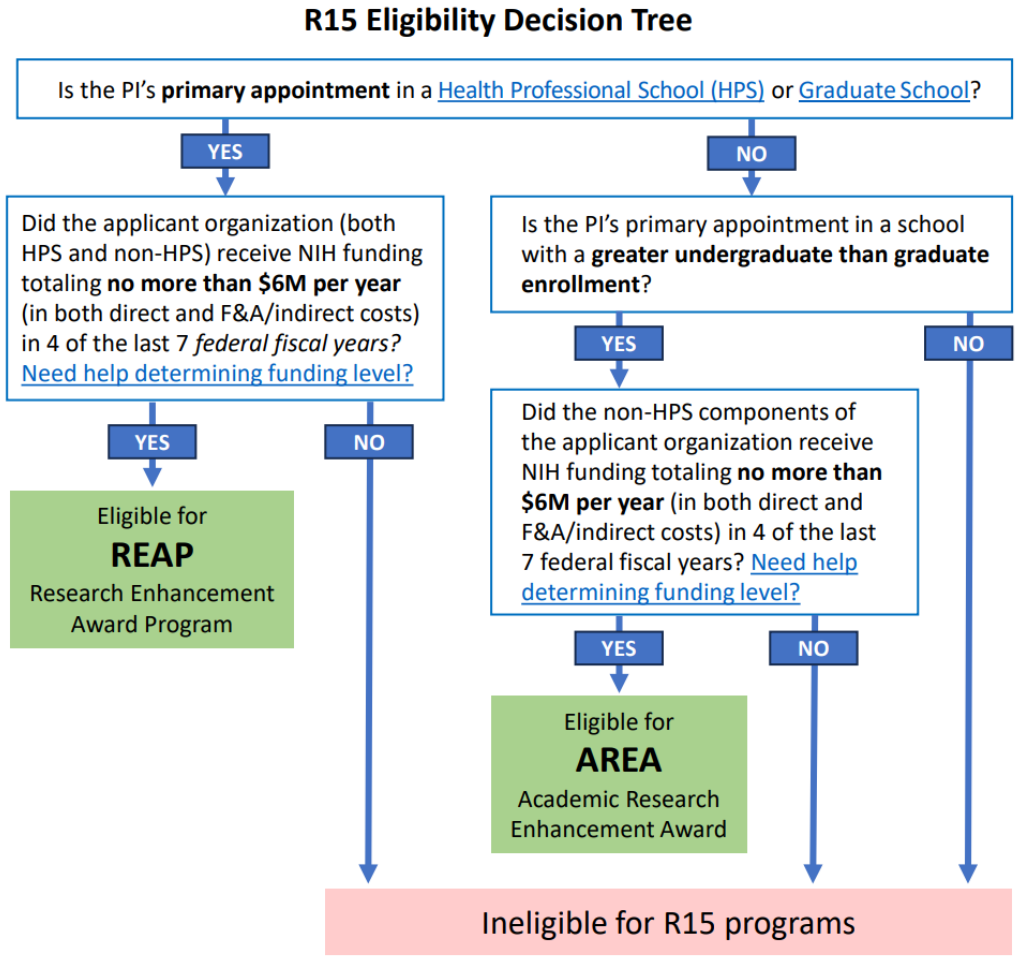
Two R15 Mechanisms: AREA & REAP

Academic Research Enhancement Award

For undergraduate focused institutions

Research Enhancement Award Program

For eligible health professionals schools and graduate schools



R03 and R15

R15 AREA *at a glance*

Type of Grant	**Research Grant**
Type of Announcement	**Program announcement, Request for Applications, NOSI---no parent program announcement**
IC participation	**25 of 26 ICs participating**
Required data	**No preliminary data required**
Clinical trial	**Clinical trial allowed**
Funding/length	**3 years, 300K in direct costs over the period; is renewable**
Eligibility	**For schools with greater undergraduate than graduate enrollment; Cannot exceed $6M (in direct and F&A indirect) from NIH in 4 of last 7 years; requires letter to confirm; all PIs on the grant must be from qualifying institutions**

R03 and R15

R15 REAP *at a glance*

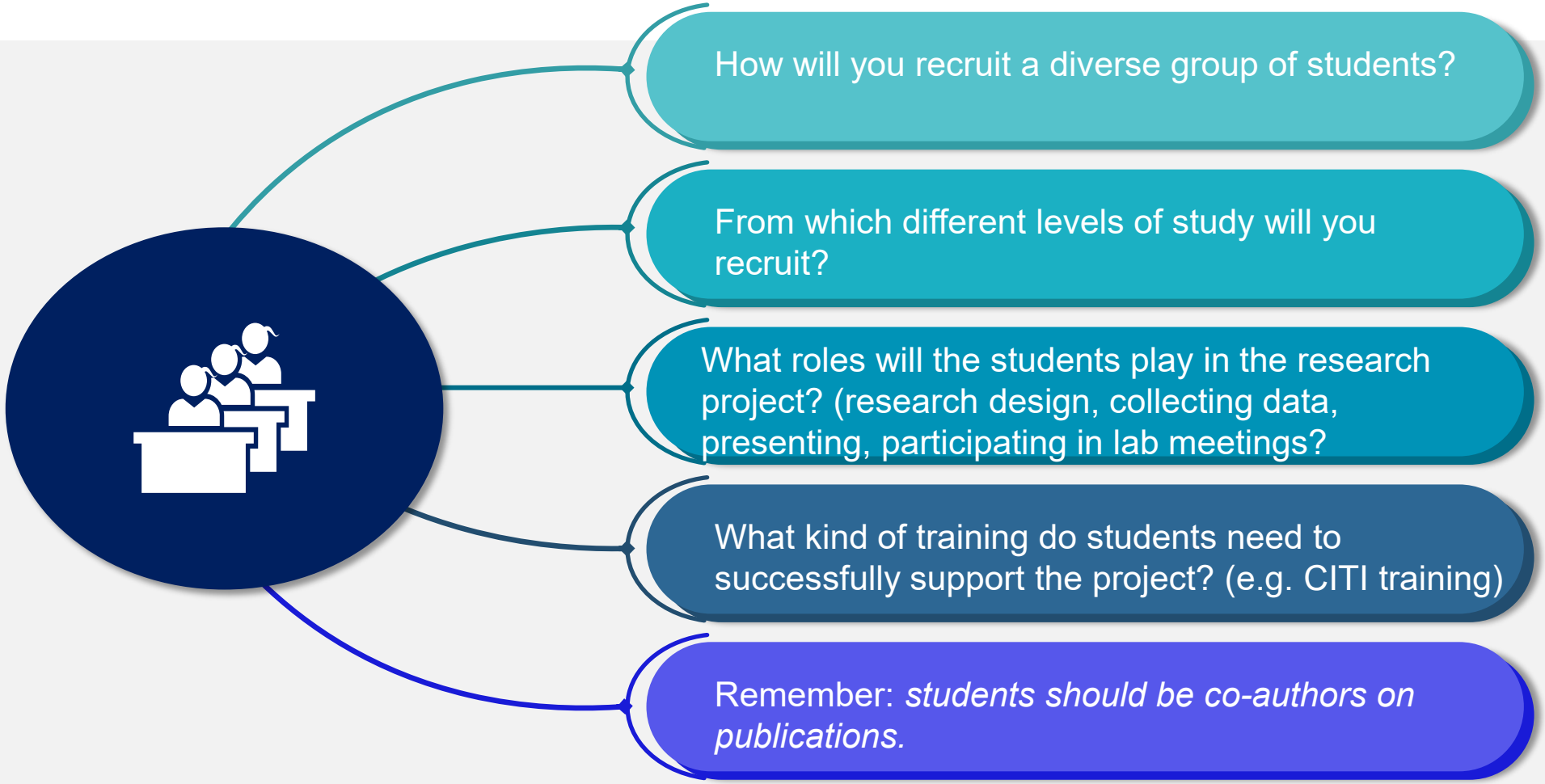
Type of Grant	**Research Grant**
Type of Announcement	**Program announcement, Request for Applications, NOSI---no parent program announcement**
IC participation	**20 ICs participating**
Required data	**No preliminary data required**
Clinical trial	**Yes, depending on NOFO**
Funding/length	**3 years, 300K in direct costs over the period; is renewable**
Eligibility	**Eligible institutions must award baccalaureate or advanced science degrees and have received no more than $6 million dollars per year of NIH support (in both direct and F&A/indirect costs) in 4 of the last 7 fiscal years. For institutions composed of multiple schools and colleges, the $6 million funding limit is based on the amount of NIH funding received by all the schools and colleges within the institution as a whole.**

How is the R15 different from the R01?

R15	R01
Impact: Publishable, disseminated and important scientific contribution to the research field(s) involved	Impact: A sustained, powerful influence on the research field(s) involved
Scope: Could be limited due to limitations of facilities and personnel	Scope: Broader, could extend across one or multiple fields
Must describe research opportunities for students	Not relevant
Must describe how the award will strengthen the research environment at the institution	Not relevant
Foreign institutions: Not eligible but foreign partners are allowed	Foreign institutions: Non-domestic (non-US) entities and non-domestic (non-US) components of US organizations are eligible

From NIH Research Enhancement Award (R15)... What You Need to Know! - Video | Grants & Funding

Crafting a strong training component for the R15



R03 and R15

Plan for student compensation

Facilities & Resources for R15

01 **Data**
 # students who have gone on to doctorates or careers in the biomedical sciences in last 5 years

02 **Recruiting plans**
Plans to inform undergrads from diverse backgrounds about research opportunities

03 **Institutional description**
Special characteristics of applicant institution that make it especially well-suited to the AREA

04 **Impact**
Likely impact of an award on the PI

05 **Impact**
Likely impact on the institutional environment

06 **Impact**
Likely impact on ability of undergrads to gain biomedical research experience

07 **Resources**
Resources of the applicant institution

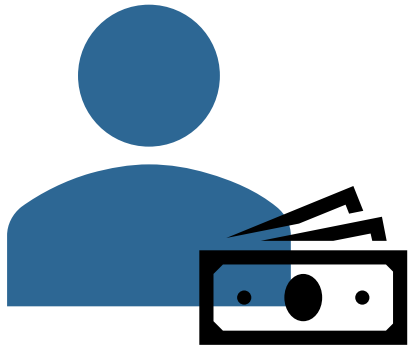
08 **Resources**
Resources and access to resources at other institutions where research will be conducted

Your extramural funding team & communicating with program officers

NIH Extramural Funding Staff: Key Team Members

Program Officer (PO)

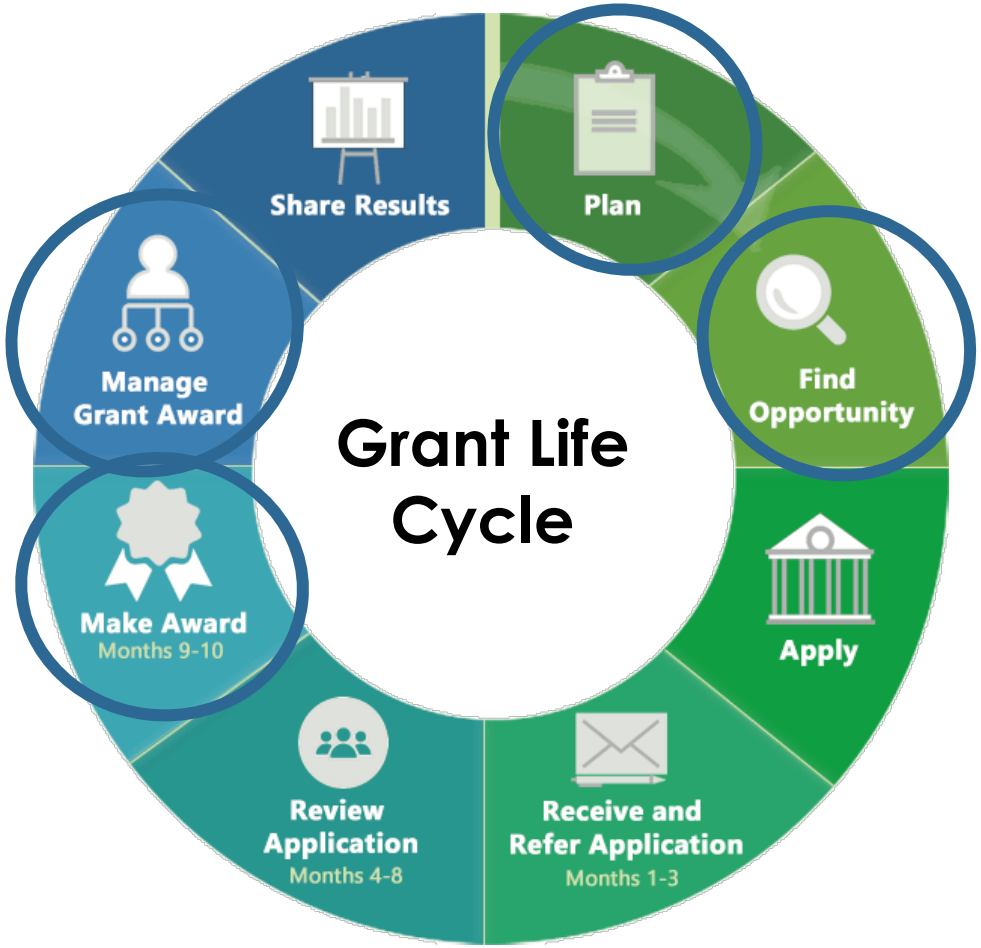
Scientific Review Officer (SRO)



Grants Management Officer (GMO)

NIH Funding Staff

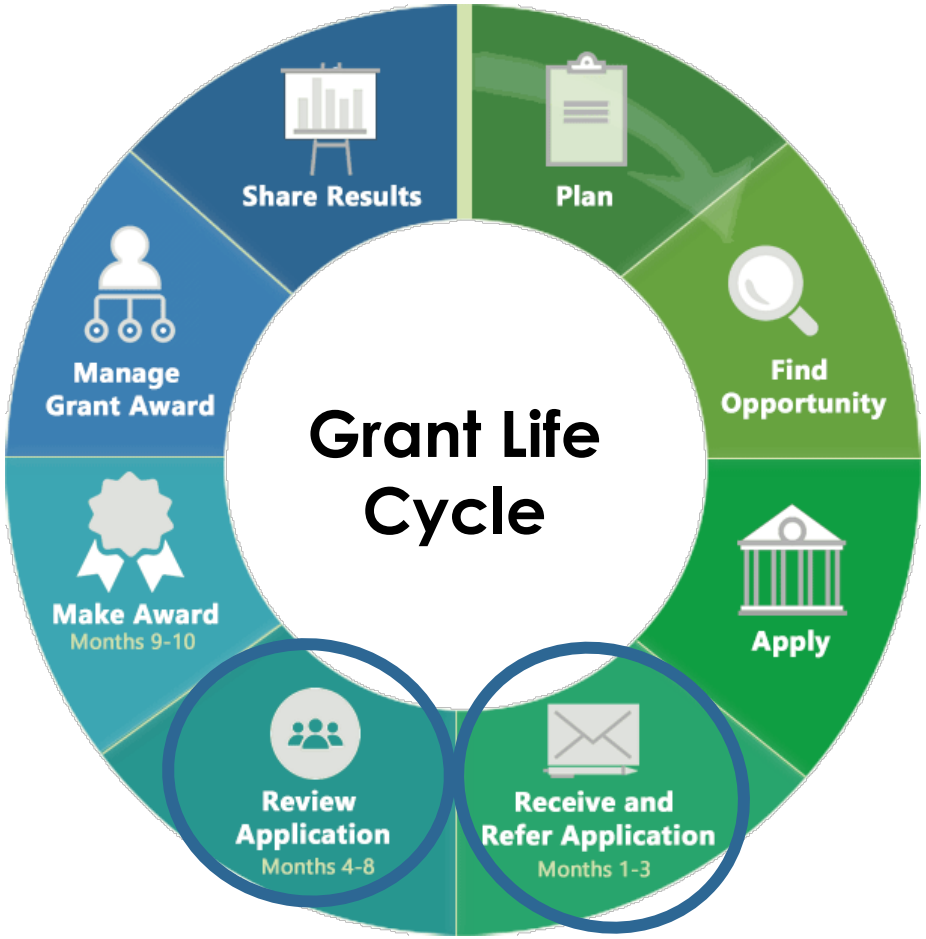
Roles of the Program Officer



- Scientific portfolio of awards within the mission of an institute
- Initiative development
- Recommends applications to be considered for award to the IC director
- Programmatic, scientific, and/or technical guidance pre- and post-award
- Post-award oversight by monitoring research progress

NIH Funding Staff

Roles of the Scientific Review Officer



- Recruits reviewers and assigns applications
- Manages the study section meeting and reviewer conflicts
- Prepares summary statements
- Tools to identify SROs:
  - Typically listed in RFAs
  - Center for Scientific Review study sections
  - CSR Assisted Referral Tool (ART)

Need Help? Know Who, When, and What to Ask!

Program Officer (PO)

Before applying

Concept paper aims & fit with NIH priorities

Appropriate funding mechanism

Responsiveness to review criteria

After review

Next steps

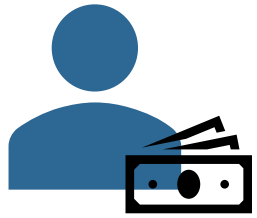
Scientific Review Officer (SRO)

After application is assigned to a review committee until review is complete

Review committee selection

Missing info

Supplemental info



Grants Management Officer (GMO)

Before or after review

NIH grants policy

Budget

Change of institutions

Grant start dates

Basic Components of an NIH Proposal

A standard NIH Research Project Grant

"Major Narrative"

Component	Space Limit
Introduction *(only resubmissions)*	1 page
Specific Aims	1 page
Research Strategy	6 or 12 pages
References Cited	No limit
Project Summary/Abstract	30 lines
Project Narrative	3 sentences
Facilities & Other Resources	No limit
Biographical Sketches (for each key person)	5 pages, NIH format
Budget & Justification	No limit
Letters of Support (see NOFO)	No limit

Component	Space Limit
Equipment	No limit
Data Management and Sharing (DMS) Plan	2 pages
Resource Sharing Plan	No limit
Authentication of Key Biological/Chemical Resources	1 page
Human study documents (multiple attachments)	N/A
Vertebrate animal protections	No limit

NOFO instructions always supersede general instructions

Writing to the Review Criteria

For due dates *before* Jan 25, 2025

Significance (scored)

Innovation (scored)

Approach (scored)

Investigators (scored)

Environment (scored)

All considered in overall impact score

For due dates *on/after* Jan 25, 2025

Factor 1: Importance of the Research

- Significance, Innovation
- Scored 1-9

Factor 2: Rigor and Feasibility

- Approach (also includes Inclusion and Clinical Trial Study Timeline)
- Scored 1-9

Factor 3: Expertise and Resources

- Investigators, Environment
- Either rated as sufficient for the proposed research or not (gaps require explanation); no individual score

Application Package Components

	Factor 1		Factor 2	Factor 3	
Application Component	**Significance**	**Innovation**	**Approach**	**Investigators**	**Environment**
Abstract	✓	✓	✓		
Project Narrative	✓				
Specific Aims	✓				
Research Strategy	✓	✓	✓		
Biosketch(es)	✓	✓	✓	✓	
Equipment				✓	✓
Facilities & Other Resources					✓

Budget Questions – Modular or Detailed?

Modular Budget	Detailed Budget
Used in **Research Grants** or **Cooperative Agreements**	Used in any NIH Grant; based on total budget/mechanism
Presented in modules of $25K	Presented in total numbers
Justification includes personnel (name, role, person-months), consortium and additional narrative	Justification is more involved; includes personnel with salary and fringe, equipment, travel, supplies, costs, tuition, services
Budget is limited to $250K	**Must be used when budget exceeds $250K**

Best Practices for Developing Key Proposal Components

Optimizing Impact: Focus on Specific Sections

- Specific Aims
- Research Strategy
- Abstract
- Biosketches

Specific Aims

- The Specific Aims page is arguably **the most important** section of your grant application. This is because it:
  - Serves as the “elevator pitch” for your research
  - Is likely the first thing your assigned reviewers will read
  - Is likely one of the two documents that every member of the study section will read (Biosketch is the other)
- Limited to one page – **must be compelling**!

Developing Key Proposal Components

What makes strong NIH *specific aims*?

STRONG PREMISE

Designed in response to a pressing need that the NIH cares about.

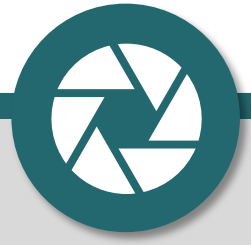
Well-rationalized.

WELL FOUNDED

Evidence-based and either:

(1) Hypothesis-driven; or

(2) Objective-driven



STABLE

Aims are complementary but ***not dependent upon*** one another

One aim can fail, but not the entire project

HIGH IMPACT

Each aim has clear expected outcomes that will have a measurable impact on the research program and field

Specific Aims: Rhetorical Patterns

- There is no template for a strong Specific Aims page, but there are established **rhetorical patterns** apparent in Specific Aims pages from successful proposals.
- The Specific Aims page should clearly demonstrate to the reviewers:
  - The ***importance of the research*** and *the* ***critical barrier to progress/gap in knowledge*** being addressed
  - That the Aims will ***address the stated barrier/gap in knowledge*** and ***test a central hypothesis***
  - That the ***approach is innovative*** and the ***investigative team is uniquely qualified*** to conduct the proposed research
  - That the outcomes of the research will ***advance current knowledge***

Developing Key Proposal Components

Anatomy of a Specific Aims page

SPECIFIC AIMS

The inhospitable environment within a lysosome-derived vacuole is the preferred growth medium for *Coxiella burnetii*, the etiological agent of human Q fever. The unique ability of *C. burnetii* to thrive in this acidic vacuole that contains noxious cationic peptides, reactive oxygen species, and lysosomal hydrolases is the key to its virulence. However, metabolic pathways critical to the pathogen's intracellular growth are *unknown*, mainly due to the unavailability of appropriate genome-scale approaches. This gap in knowledge is an important problem because it has *hindered* both the understanding of *C. burnetii*'s basic biology and pathogenesis, and the development of better therapies. Long-term combinatorial treatment with doxycycline and hydroxychloroquine (≥1.5 years) is the best available option; however, strains resistant to this treatment are prevalent. This select agent is found worldwide and can occasionally cause epidemics; e.g., a recent outbreak in the Netherlands involved ~4,000 human cases and caused the culling of over 50,000 goats (a reservoir).

Our *long-term goal* is to understand the molecular details of *Coxiella*'s distinctive physiology, and to apply this knowledge to developing novel therapeutic strategies. Towards attaining this goal, the *overall objective* of this application is to identify metabolic pathways that are vital to *C. burnetii*'s intracellular growth. Our *central hypothesis* is that *C. burnetii* evolved from a tick-associated ancestor by acquiring critical metabolic genes through horizontal gene transfer (HGT). Our hypothesis was formulated based on our previous work (Smith et al. 2015), which showed that the closest relatives of *C. burnetii* are avirulent bacteria with reduced metabolic capabilities present in ticks. The work by Duron et al. (2015) also supports this hypothesis. Based on these insights, we will use a *novel evolutionary genomics approach that will overcome the current technical difficulties* to identify metabolic processes critical to *C. burnetii*. The proposed research will be *impactful* because once metabolic processes important to *C. burnetii*'s intracellular growth are identified, new pharmacological agents that block these pathways can be developed to treat chronic Q fever more effectively.

To test our central hypothesis, in Specific Aims 1 and 2 we will use two complementary genome-scale approaches to define critical metabolic processes in *C. burnetii*, and in Specific Aim 3, as a proof of principle, we will experimentally validate the importance of heme biosynthesis to *Coxiella*'s physiology.

1. Identify metabolic pathways that distinguish *C. burnetii* from tick-associated *Coxiella*. Because *Coxiella* species present in ticks do not replicate within a lysosome-derived vacuole, our *working hypothesis* is that genes critical to *C. burnetii*'s unique intracellular physiology will not be present in tick-associated *Coxiella*. We will sequence the complete genome of *C. burnetii*'s closest known relative—a *Coxiella* species present in the soft tick *Ornithodoros rostratus*, and by comparative genome analyses, we will identify metabolic genes and pathways unique to *C. burnetii*.

2. Define metabolic pathways that are critical to *C. burnetii*'s intracellular growth. Superfluous genes are lost from obligate intracellular bacteria such as *C. burnetii*. This is especially true for genes acquired via HGT, which will be retained only if they improve *C. burnetii*'s fitness. Consequently, we *hypothesize* that horizontally derived genes are critical to *C. burnetii*'s physiology. We will utilize phylogenetic approaches to identify HGT-derived metabolic genes among those identified in Aim 1. Using RNA-seq and transposon-insertion libraries, we will validate their importance to *C. burnetii*'s intracellular growth.

3. Determine the importance of heme biosynthesis to *C. burnetii's* intracellular growth. *C. burnetii*'s heme biosynthesis pathway contains HGT-derived genes, and this pathway is not present in *Coxiella* symbionts, and we established that *C. burnetii* could not use external heme. We therefore *hypothesize* that heme biosynthesis is crucial to *C. burnetii*'s intracellular growth and can serve as an example for the efficacy of our novel approach. We will confirm the importance of heme biosynthesis to *Coxiella* by assaying heme production and intracellular growth in wild-type and heme pathway-deficient strains.

At the successful completion of this project, *expected outcomes* include elucidation of the evolutionary history of this enigmatic pathogen, and identification of metabolic pathways that are important to *Coxiella*'s intracellular growth and virulence. Results are expected to have a *positive impact* because it will provide a *useful model for identifying key metabolic* processes in other human pathogens with closely related symbionts such as *Rickettsia* and *Francisella*. Additionally, non-redundant proteins in critical metabolic pathways, e.g. HemA and HemL in heme biosynthesis, are ideal *candidates for developing new anti-Coxiella agents.*

Introductory paragraph

- Brief background/orientation
- Hook (gap in knowledge)

Secondary paragraph

- Introduce solution
- Hypotheses/objectives
- Introduce team & prelim work

Aims/approach

- (Bold) Specific aim titles
- Brief rationale for aim
- Brief description of approach
- (Optional) Brief outcomes

Final paragraph

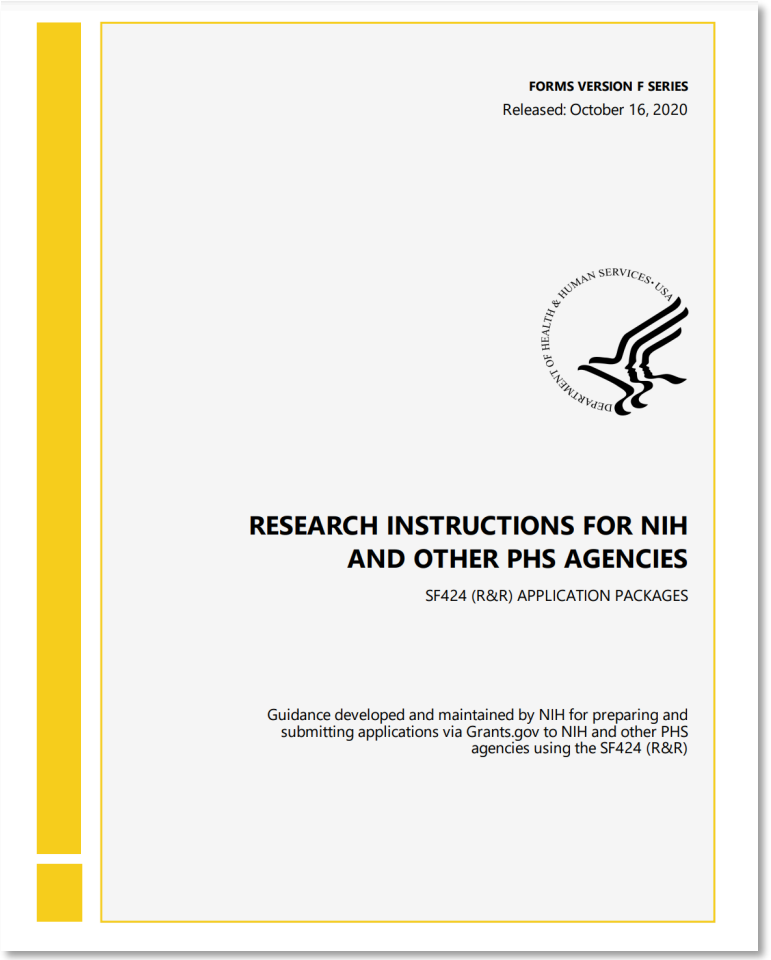
- Reiterate innovation
- Summarize outcomes and impact on field

Common Specific Aims Pitfalls

- Idea is not original
- Aims are descriptive; no *measurable* outcome
- Aims are not hypothesis-driven
- Aims are not cohesive
- Aims are dependent on each other
- Aims do not present an impact on the field

Research Strategy: Know the guidelines

- **Page limit**: 6 or 12 pages, depending on the solicitation
- **Research Strategy Sections** (unless specified in the NOFO):
  - ***Significance***
  - ***Innovation***
  - ***Approach***
- Must address all requirements for **rigor & reproducibility**



Research Strategy Sections

A. Significance

- Relevant background
- **Research premise:** *Must address the strengths and weaknesses in the rigor of the prior research that serves as key support*
- Impact

B. Innovation

- Conceptual
- Technical

C. Approach

- Introduce team
- Overview of the Approach
- Hypotheses
- Aims: methodology, analyses, outcomes, potential pitfalls
- Overall project timeline and future directions paragraph

Significance

Official guidance

"Explain the importance of the problem or critical barrier to progress that the proposed project addresses. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields."

Key tips

- Describe *the importance of the problem, gap, or critical barrier to progress* that is addressed in the proposal. **Start broad with the links to human health—incidence, prevalence, impacts, etc.**
- Include a discussion of the *strengths and weaknesses in the rigor of the prior research* that serves as key support for the proposed project. **Cite seminal work, as well as recent findings (yours and others) to frame the premise of the proposed work and hypotheses**
- Explain how the proposed project will *improve scientific knowledge, technical capability, and/or clinical practice* in one or more broad fields. **State the expected outcomes and knowledge that will result from the project**

Innovation – Example

Was the Apple Watch novel?

No. The first Smartwatches were introduced in the 1990s. The first Apple Watch was released in 2015.

Is electrocardiography novel?

No. Commercial electrocardiography devices were available in the early 1900s.

Is fall detection novel?

No. Medical alert systems were conceived and developed in Germany in the early 1970s.

Apple Watch Series 4 offered **FDA-cleared ECG and fall detection.** The refinement of the existing Smartwatch technology to serve as a medical device is ***innovation.***

Approach – Organizational Strategies

- A common tactic is to organize the Approach section of the research strategy around the Specific Aims
- **Strong strategies**: Lead off the Approach with a description of the Investigative Team (brief roles and responsibilities). Include a Figure that depicts an overview of the study
- **Be consistent in your organization**:
  - **Use the same subheadings under each Specific Aim.** Common subheadings: Rationale, Methods, Expected Outcomes; Do not forget Potential Pitfalls and Alternative Approaches section!
  - If there are certain sections that apply to all Aims, you can describe before or after the description of each Aim (e.g. statistical analyses or rigor and reproducibility)

Approach: *Human and/or animal studies*

Official guidance

"Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans.."

"For trials that randomize groups or deliver interventions, describe how your methods for analysis and sample size are appropriate and your plans for participant assignment and intervention delivery."

Key tips

- Clearly describe how "relevant biological variables" will be experimentally included, with strong justification for proposing to study only one type or subset of variables.
- Give enough detail to demonstrate experimental rigor (power calculations, sample sizes, control groups) but **leave the in-depth details for the associated human or animal study attachments and documents.**

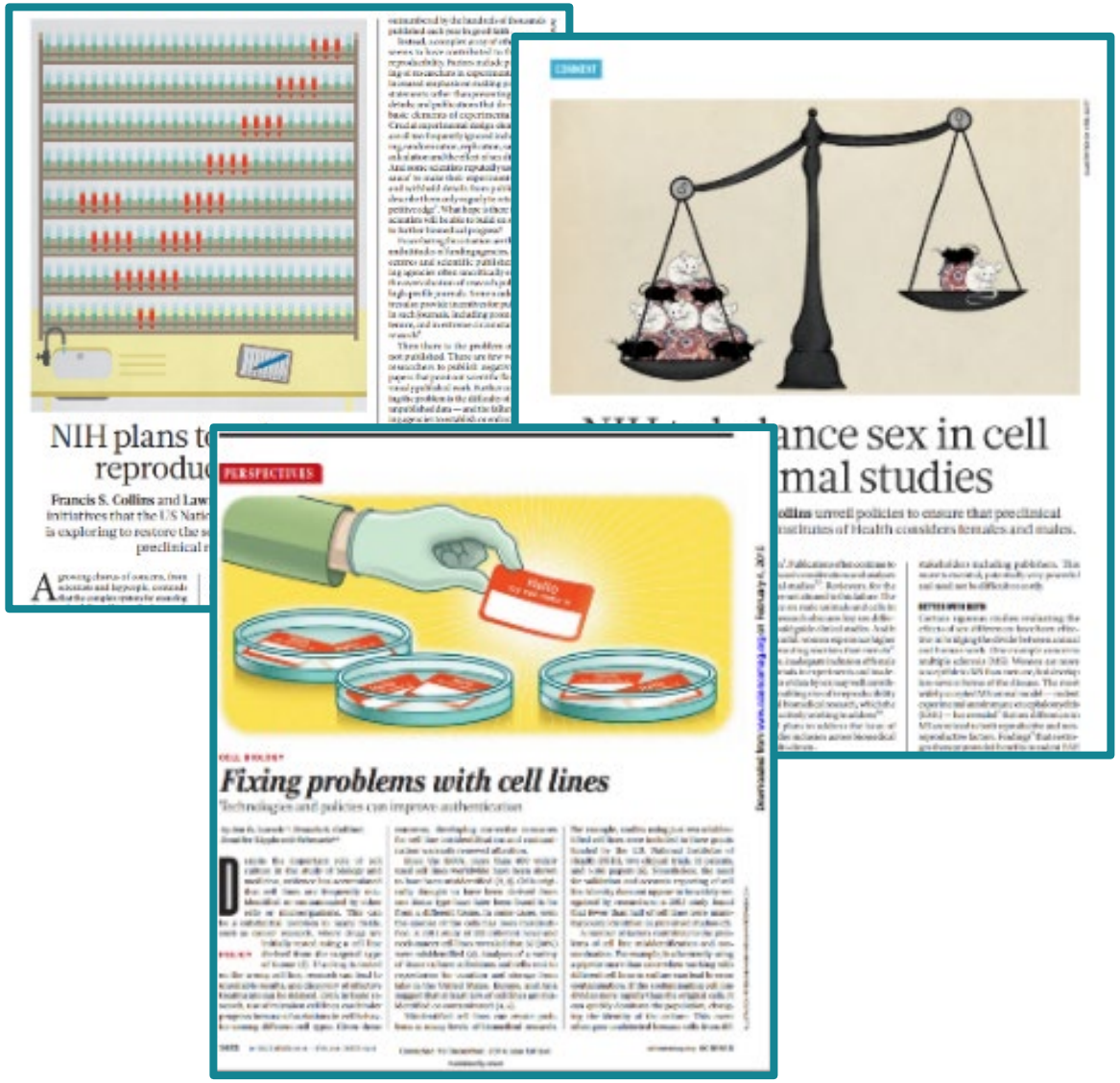
Significance ≠ Rigor of Prior Research ≠ Rationale

Separate but equally important concepts!

	Significance	Rigor of Prior Research	Rationale
What	A demonstration of the "importance" of the project and how the field, the world, and existing knowledge will be improved or changed if the research is performed.	The strengths and weaknesses in the rigor of prior research that serve as key support for the proposed project	A reason, based on supporting scientific evidence that a particular action is chosen (e.g., one method over another).
	PROSPECTIVE	**RETROSPECTIVE**	**PROSPECTIVE**
Where	Aims, Significance, Approach	Significance	Aims, Approach

Rigor and Reproducibility

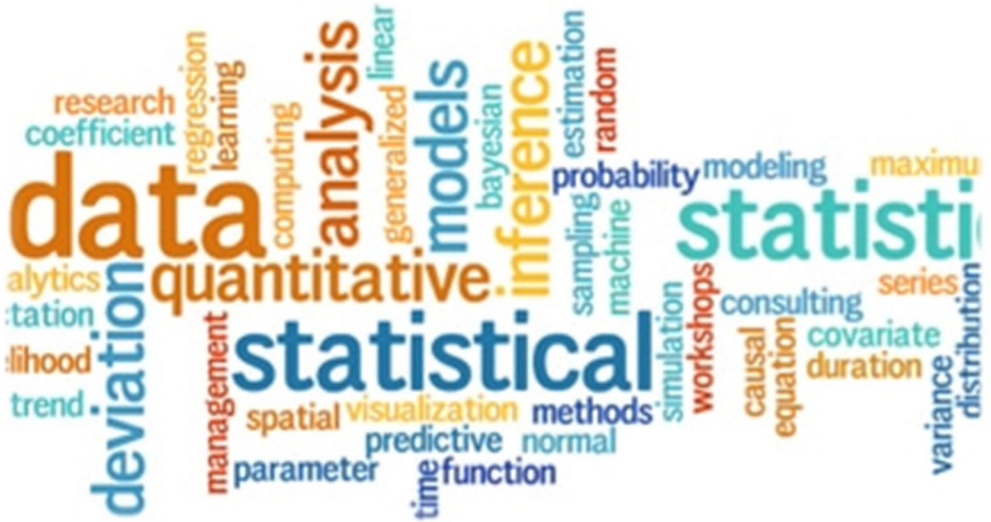
- Rigor of Prior Research (*scientific premise*)
- Rigor of the Proposed Research (*experimental design*)
- Consideration of Relevant Biological Variables
- Authentication of Key Biological and/or Chemical Resources



Rigor of the Prior AND Current Research

When discussing the *strengths and/or weaknesses in the* ***rigor of the prior research*** as well as demonstrating the rigor of the proposed research, consider elements of rigor including:

- Sample sizes
- Control groups
- Power calculations
- Technical and Biological Replicates
- Measures to control bias
- Statistical analyses
- Relevant biological variables



Rigor and Reproducibility: Where Does It Go?

	Rigor of Prior Research	Rigor of the Proposed Research	Relevant Biological Variables	Authentication of Key Resources
Where to address?	Significance & Approach	Approach	Approach	Attachment
Scored?	Yes- both	Yes	Yes	No, but….

This will be very important when the review criteria shift to the new format!

Preliminary Data: *Where Does It Go?*

Official guidance

Include information on preliminary studies. Discuss the preliminary studies, data, and or experience pertinent to the application.

Requirement as to ***where*** to present the preliminary data: **NONE**

Key tips

- Unless prohibited, preliminary data should always be included, *even for activity codes that claim preliminary data is not needed*
- General guidance: ***Put your best cards forward!***
  - If preliminary data serves as **key support** for the concepts underlying the proposed research, present the preliminary data in the **Significance section**.
  - If preliminary data demonstrates the **feasibility** of an analytical approach, present the preliminary data in the **Approach section**.

Abstract

- Limited to 30 lines
- Concisely describes project
- Provides importance and relevance of the project
- Briefly describes approach
- *Does not contain jargon* and can be understood by a non-scientific audience

Structure of Abstract

Background: First sentence should provide background on the problem, not the disease.

Problem Statement: Where is the field lacking knowledge?

Preliminary Data: What have you done to address the problem to date?

Objective: Provide overall hypothesis or objective of project

Aims: How do you plan to test the hypothesis/achieve the objective?

Significance: If successful, how will this move the field forward/ provide new knowledge?

Biosketches

For the R15, be sure to discuss your mentorship experience

- Each Biosketch should be specific to the application being submitted!
- Current format NIH for Biosketches (5-page limit):
  - **Section A**: **Personal Statement** that describes why you are well-suited for your role(s) in the project, including your training, prior experience, research, etc.
    - You may cite up to four publications or research products that highlight your experience and qualifications for the project after the Personal Statement
  - **Section B**: **Positions, Scientific Appointments and Honors**
  - **Section C**: **Contributions to science**
    - Each of these sections are allowed 4 “research products”. Junior faculty likely will only highlight 2-3 major contributions.
  - A URL is allowed for reviewers to see all your publications.

SciENcv is a tool you can use to develop and automatically format your Biosketch according to NIH requirements

Figures – Best Practices

Be judicious with Figures and make sure Figure captions are readable!

Use Figures to show data that supports key concepts underlying your study

An Overview Figure at the beginning of the Approach section can be used to provide a snapshot of the full study

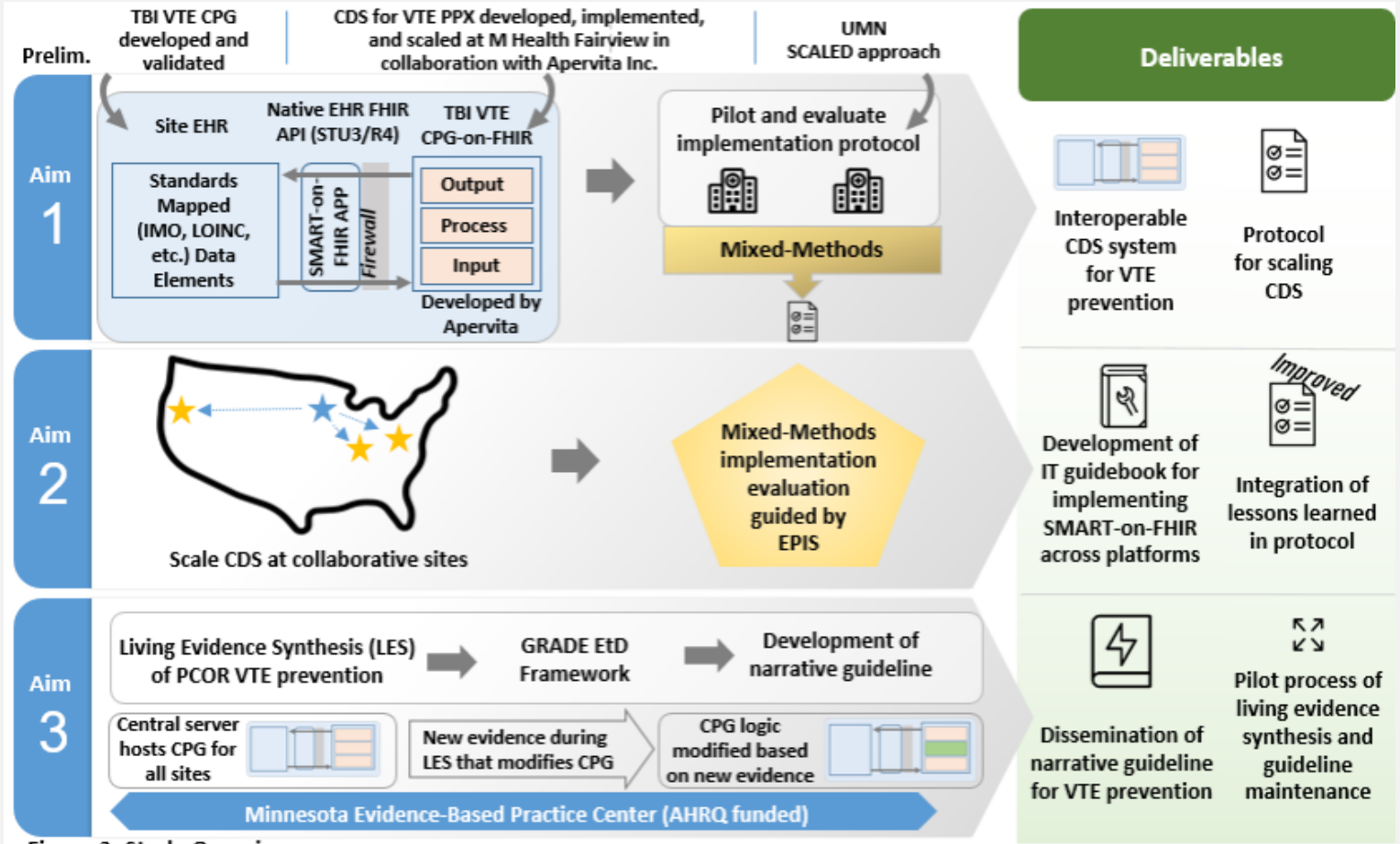


Figure 3. Study Overview

General Advice

- Use the tools available to you (Matchmaker, RePORTER, etc.)
- Keep up on publications
- Study successful grant applications
- Engage with your program officer
- Make life easy for your reviewers
  - Leave white space, concise writing, proofread, write for a broad audience

Panel discussion

Today's panelists

Mike Gawrysiak, Ph.D.
Asst. Prof. of Psychology

Liz Grillo, Ph.D. CCC-SLP, CHSE, EMT
Prof. of Communication Sciences & Disorders

Kristen Breit, Ph.D.
Asst. Prof. of Biopsychology

Panel questions

1. Tell us briefly about the research you proposed to NIH, how it aligned with your IC's mission, and a bit about the significance and innovation of your work.
2. R15s do not require preliminary data, but many applicants include it—did you have preliminary data?
3. Tell us about how you recruited a diverse group of students and involved students in your research? What kind of roles did students play in the research?
4. How did you address your mentoring experience in your application?
5. Did you connect to your program officer or another mentor during the writing process?
6. Tell us about your timeline? How long did your proposal production process take from conception to submission?

Resources

Resources: **Tools**

- **RePORTER**
  https://reporter.nih.gov/
- **Matchmaker**
  https://reporter.nih.gov/matchmaker
- Annotated NOFO:
  https://grants.nih.gov/grants/Annotated_FOA.pdf

Resources: **Application Process**

- **Grants Process Overview**
  https://grants.nih.gov/grants/grants_process.htm
- **How to Submit Track and View Your Application**
  https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/submit-track-view.htm
- https://public.csr.nih.gov/ForApplicants/SubmissionAndAssignment
- https://public.csr.nih.gov/ForApplicants/InitialReviewResultsAndAppeals
- **Pre-Award and Award**
  https://grants.nih.gov/grants/pre-award-process.htm
- https://grants.nih.gov/grants/post-award-monitoring-and-reporting.htm

Resources: **Application Preparation**

- **How to Apply – Application Guide**
  https://grants.nih.gov/grants/how-to-apply-application-guide.htm
- **Submission Options**
  https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/submission-options.htm
- **Write Your Application**
  https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/write-your-application.htm
- https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

Resources: **Funding Opportunities & Programs**

- **Understand Funding Opportunity Announcements**
  https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/understand-funding-opportunities.htm
- **NIH Guide for Grants & Contracts**
  https://grants.nih.gov/searchGuide/
- **Grants.gov Search Grants**
  https://www.grants.gov/web/grants/search-grants.html
- **Types of Grant Programs**
  https://grants.nih.gov/Grants/funding/funding_program.htm

Resources: **General**

- **NIH Grants and Funding** https://grants.nih.gov/grants/oer.htm
- **NIH Grants Policy Statement** https://grants.nih.gov/policy/nihgps/index.htm