Strategies for Success with NIH Funding

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National Institutes of Health
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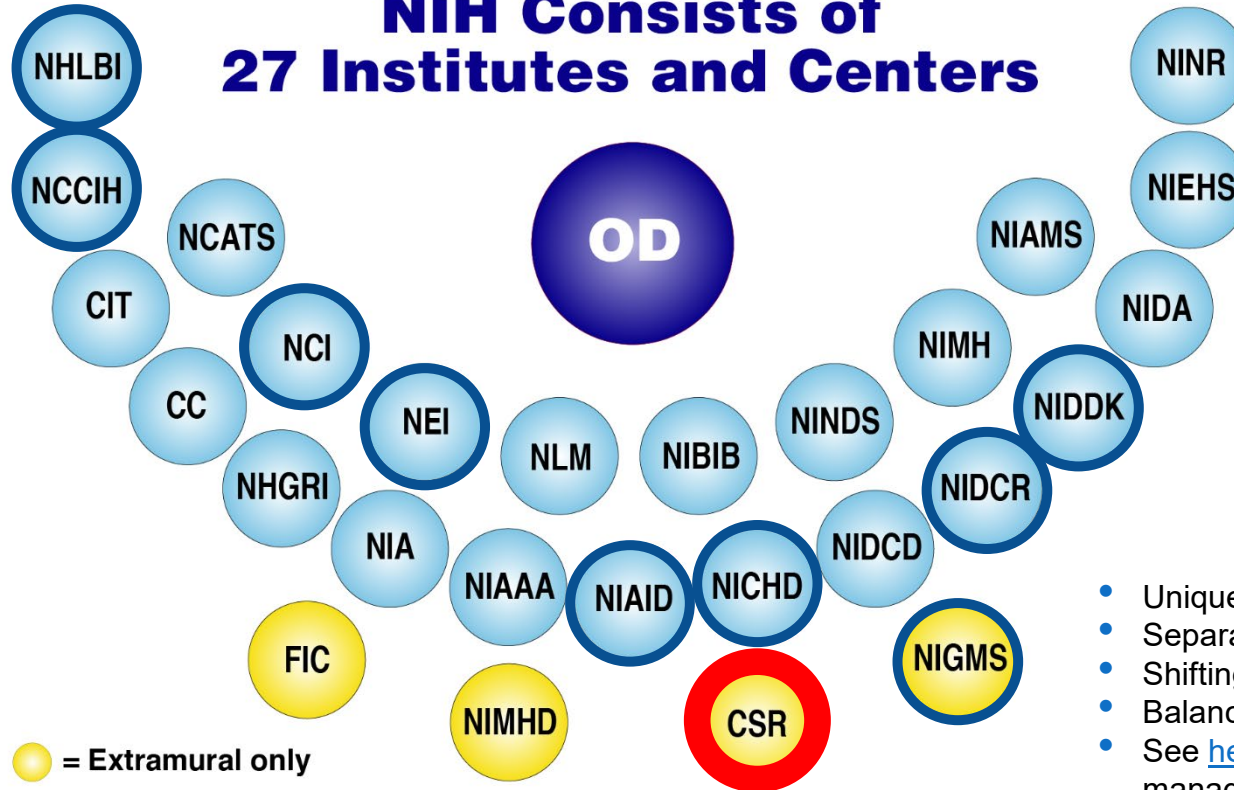NIAID

NIH 101
Demystifying the NIH grant process

- Introduction to NIH
- Finding a fit for your research
- How to improve your NIH application
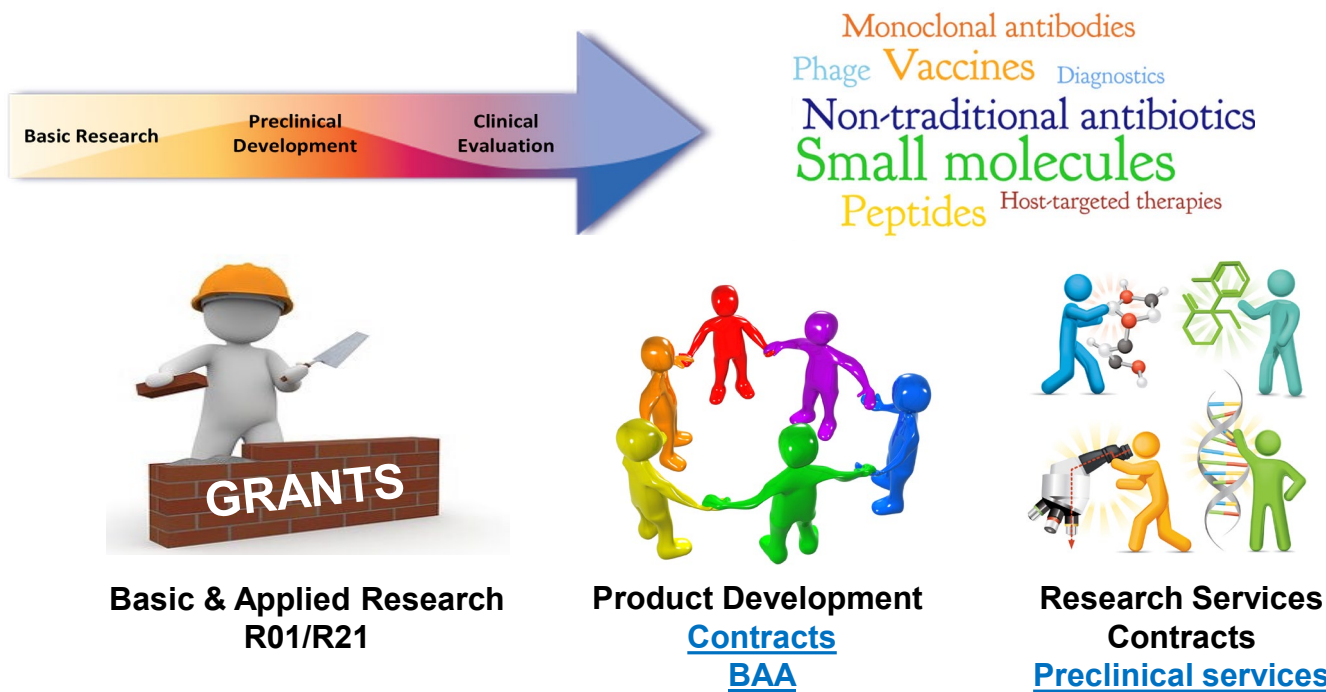- Free support for your research

NIH Organization

NIH Consists of 27 Institutes and Centers

Circles: NHLBI, NCCIH, NCATS, CIT, CC, NHGRI, NIA, NIAAA, FIC, NIMHD, NCI, NEI, NLM, NIAID, NICHD, CSR, NIBIB, NINDS, NIDCD, NIDCR, NIDDK, NIMH, NIAMS, NIDA, NIEHS, NINR, NIGMS, OD
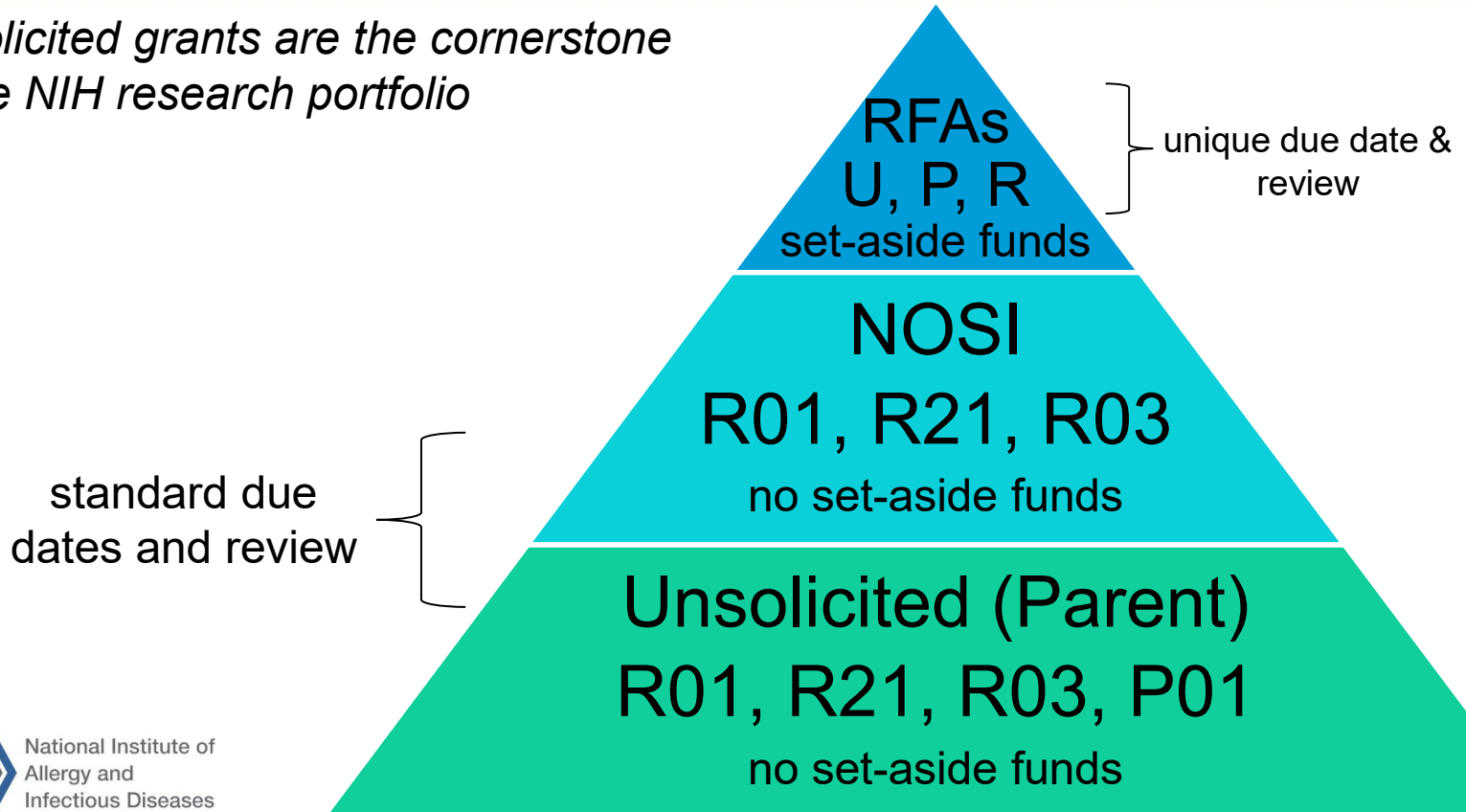
= Extramural only

- Unique missions
- Separate budgets
- Shifting priorities
- Balance portfolios differently
- See here for NIAID financial management plan
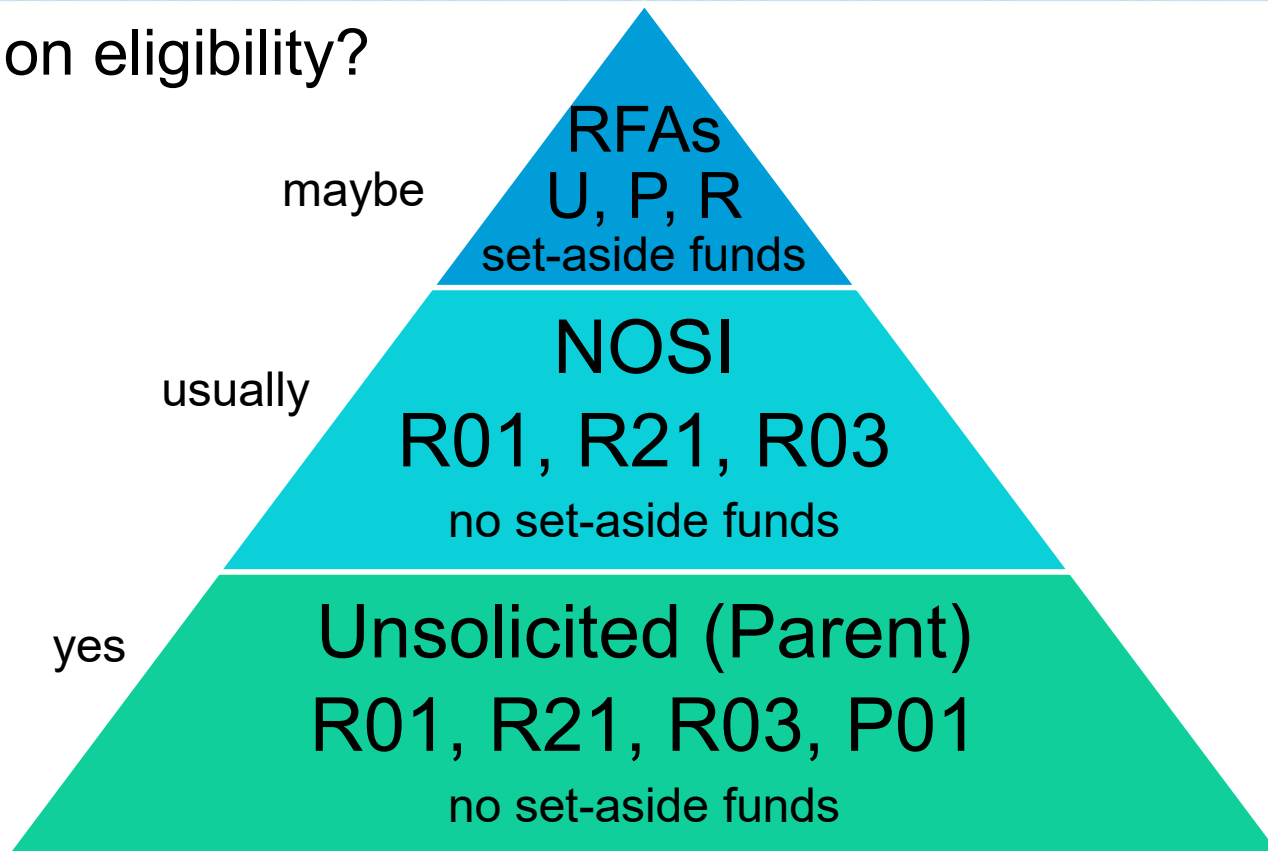
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Funding and resources available from NIAID

Monoclonal antibodies
Phage Vaccines Diagnostics
Non-traditional antibiotics
Small molecules
Peptides Host-targeted therapies

Basic & Applied Research
R01/R21

Product Development
Contracts
BAA

Research Services
Contracts
Preclinical services

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Types of NIH funding mechanisms

Unsolicited grants are the cornerstone of the NIH research portfolio

RFAs
U, P, R
set-aside funds

unique due date & review

NOSI
R01, R21, R03
no set-aside funds

standard due dates and review

Unsolicited (Parent)
R01, R21, R03, P01
no set-aside funds

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Types of NIH funding mechanisms

Foreign institution eligibility?

maybe — RFAs U, P, R set-aside funds

usually — NOSI R01, R21, R03 no set-aside funds

yes — Unsolicited (Parent) R01, R21, R03, P01 no set-aside funds

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Types of NIH funding mechanisms

R01 Most commonly used grant program

- Utilized by all Institutes, special consideration for New Investigators
- Up to 5 years; $500K direct costs/year; renewable
- PA-20-185 (no IICT), PA-20-183 (clinical trial required)

R21 Exploratory/Developmental award

- Support for early stages of project
- 2 years; $275K total direct costs; not renewable
- PA-20-195, …look carefully in Part 1 of NOFO

R03 Small grant program

- Pilot, feasibility studies, collection of data, secondary analysis
- 2 years; $50K per year7; not renewable
- Utilized by most Institutes, PA-20-200

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Description of NIH grant mechanisms

Flow chart of NIH grant application
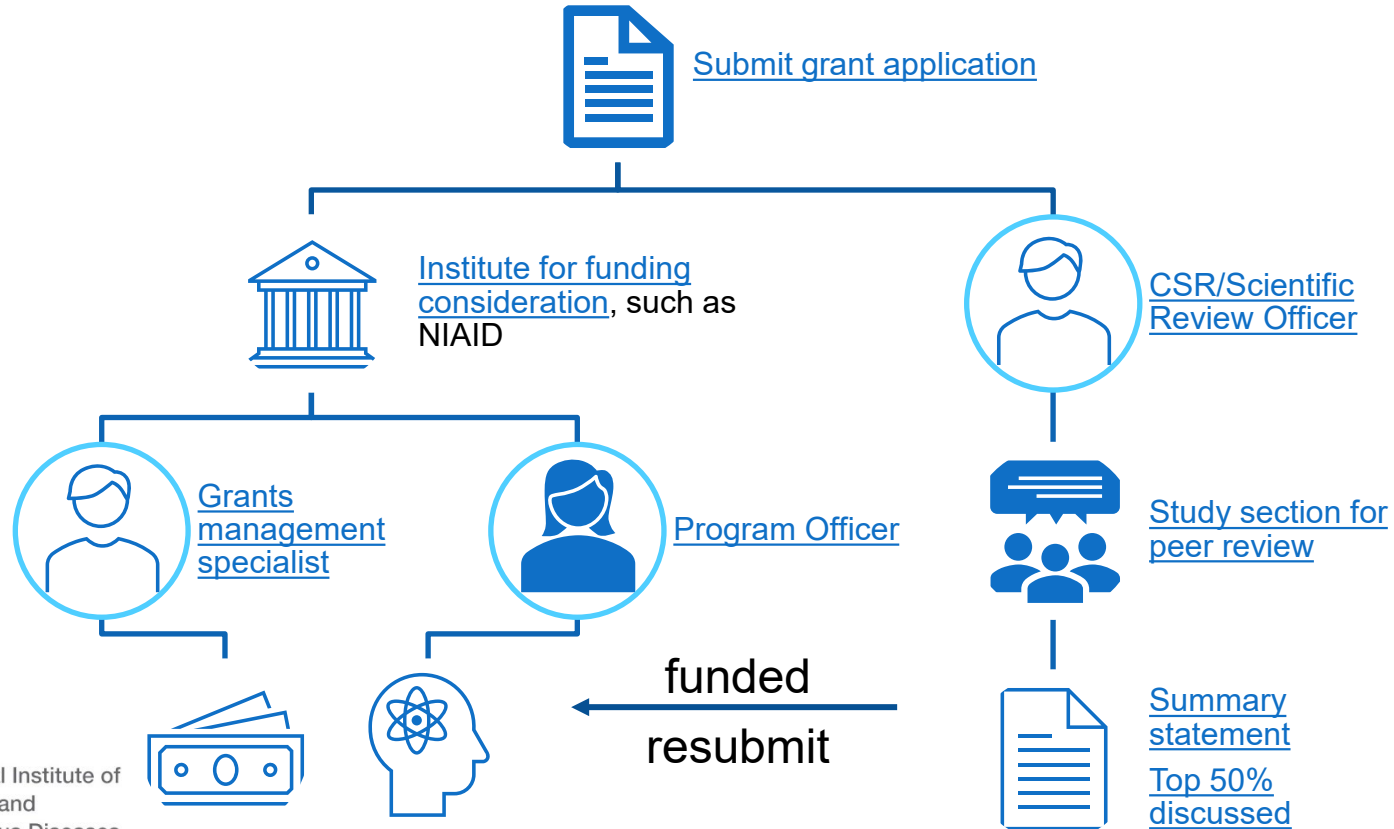
NIH grant applications…finding a fit

- [Research Portfolio Online Reporting Tools (RePORT)](#)

- [NIH Grants and Funding](#)

- [Sign up for NIH funding news](#)

- [Cleared Council Concepts](#)

Example of Approved Council Concepts

Table of Contents

Fiscal Year (FY) 2024 Division of Microbiology and Infectious Diseases (DMID) Concepts

FY 2025 DMID Concepts

NIAID

NIH grant applications…getting started

- [NIH web resources](#)

- [NIAID web resources](#)

- [Sample applications](#)

- [Unsolicited research](#)

- [Individual Fellowships](#)

- [Career transition awards](#)

Preparing an NIH grant application

- **Learn NIH institutes' priorities & goals**
- **Know the literature and the gaps you're filling**
- **Propose your best ideas with passion and commitment**
- **Be familiar with the NIH application and review process**
- **Learn what reviewers look for in applications**
- **Be familiar with the criteria that affect Overall Impact**

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Know how to decode the "NOFO"

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID
Funding Opportunity Title	Novel approaches to understand diagnose coccidioidomycosis (V select endemic fungal infections Allowed)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	• **December 19, 2018** - Notice of Changes to PA-19-
Funding Opportunity Announcement (FOA) Number	PA-19-082

Table of Contents

Part 1. Overview Information
    Key Dates
Part 2. Full Text of Announcement
    Section I. Funding Opportunity Description
    Section II. Award Information
    Section III. Eligibility Information
    Section IV. Application and Submission Information
    Section V. Application Review Information
    Section VI. Award Administration Information
    Section VII. Agency Contacts
    Section VIII. Other Information

Tour an annotated FOA

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…Responsive, eligible, special review criteria…..

International applications

- Many NIH funding mechanisms allow foreign applicants

- Check Section III of NOFO for eligibility

- Foreign justification is required and discussed after application is scored
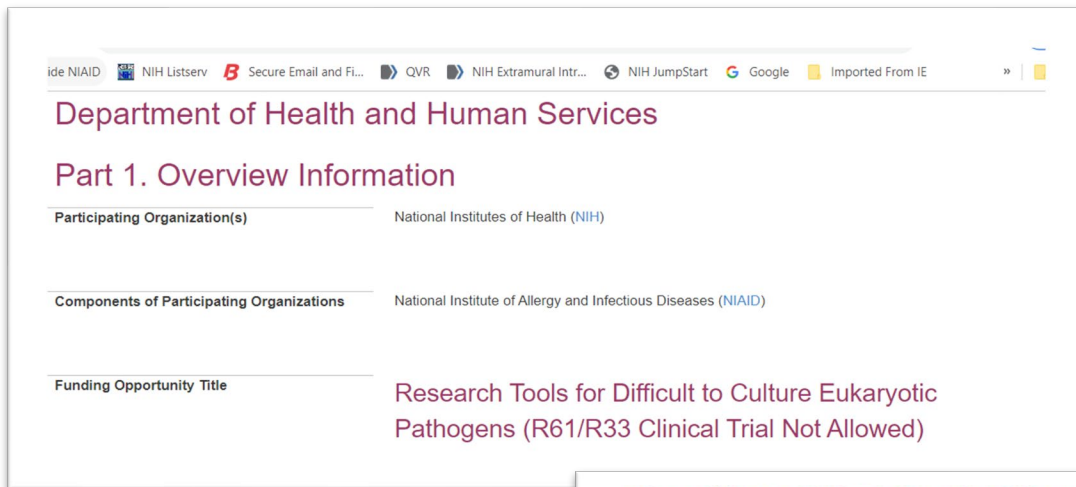
- US collaborators are not required

- Collaborative team should support the science proposed

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See here and here for more information

International Eligibility

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Institute of Allergy and Infectious Diseases (NIAID)
Funding Opportunity Title	Research Tools for Difficult to Culture Eukaryotic Pathogens (R61/R33 Clinical Trial Not Allowed)

Section III. Eligibility Information

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Required Registrations

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Preparing an NIH application

Specific Aims: put your best foot forward

- **Include objective and/or hypothesis**

- **If application is not hypothesis-driven, explain why the work is important**

- **Describe the gap your application will fill**

- **Aims should be inter-related without being too co-dependent**

- **Be realistic: do not propose too much for the time available**

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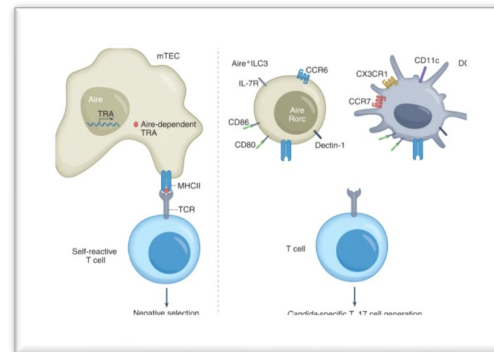
Preparing an application

Facilitate the Review

- Have clear organization and headers

- Make it visually appealing and readable

- Figures, tables, diagrams, flow-charts of adequate resolution

- Cross-reference, label, number everything

- Watch out for typographical errors

- Tips and tricks at **Center for Scientific Review (CSR)**

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Preparing an application

Study Sections:

- **most applications reviewed at CSR**
- **applications assigned based on area of science**
- **RFAs are generally reviewed by sponsoring institute**
- **Tools to find a study section**
- **Use PHS assignment request form**

CSR
- PTHE
- IHD
- III
- AIRT
- GVE

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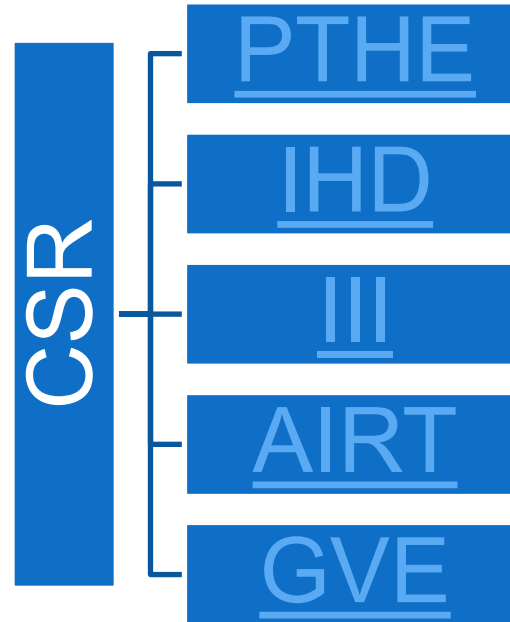
Frequent reviewer comments

What are some common obstacles encountered in study section?

Understand the review process

Overall Impact and the [Five Review Criteria](#)

- **Assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved**
- *Likelihood* **(i.e., probability) is primarily derived from the** <u>**investigator(s)**</u>**,** <u>**approach**</u> **and** <u>**environment**</u> **criteria**
- *Sustained powerful influence* **is primarily derived from the** <u>**significance**</u> **and** <u>**innovation**</u> **criteria**

For due dates on/after Jan 2025 [Simplified Peer Review Framework](#)

- **3 factors will be considered, 2 will be scored and will include approach, significance, innovation**

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Understand the NIH fiscal year

Activity Codes	Program Description	Cycle I Due Date	Cycle II Due Date	Cycle III Due Date
R01 *new*	Research Grants	February 5	June 5	October 5
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
R01 *renewal, resubmission, revision*	Research Grants	March 5	July 5	November 5
R03, R21, R33, R21/R33, R34, R36, U34, UH2, UH3, UH2/UH3 *renewal, resubmission, revision*	Other Research Grants and Cooperative Agreements	March 16	July 16	November 16

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Understand the NIH fiscal year

Submission to funding timeline

Review cycle	NIAID Council	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
													Fiscal Year									
cycle I	September	Due dates					Review				possible payment											
cycle II	January					Due dates					Review			possible payment								
cycle III	June									Due dates			Review			possible payment						

- Maximum time ~1.5 years
- Minimum time ~6 months
- Multiple submissions are usually required
- Some Institutes post paylines

NIAID Timeline and due dates

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Communicating with program officers

Do program officers welcome communications from applicants?

YES!

❑ determine if research fits the Institute's mission

❑ find out about possible funding opportunities

❑ inquire about <u>end of year opportunities</u>

❑ discuss review and decode summary statement

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Communicating with program officers

Summary statements and the 7 stages of grief

❑ be open to constructive criticism

❑ be prepared to go through summary statement point by point

Shock*	• Initial paralysis at hearing the bad news.
Denial	• Trying to avoid the inevitable.
Anger	• Frustrated outpouring of bottled-up emotion.
Bargaining	• Seeking in vain for a way out.
Depression	• Final realization of the inevitable.
Testing*	• Seeking realistic solutions.
Acceptance	• Finally finding the way forward.

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Additional support for researchers

www.niaid.nih.gov/research/resources

www.niaid.nih.gov/research/therapeutic-development-services

Resources for Researchers

Synthesis & Manufacturing

- Medicinal chemistry synthesis
- Small molecule manufacturing
- Vaccine manufacturing
- Biopharmaceutical manufacturing (for products containing monoclonal antibodies, recombinant proteins, peptides, and nucleic acids)
- Diagnostics reagent production or procurement

Non-clinical Studies

- *In vitro* ADMET profiling
- Screening pharmacokinetics (mouse, rat, hamster)
- Bioanalytical method development and qualification
- Non-GLP and GLP pharmacokinetics
- Non-GLP and GLP safety and toxicology
- Assay development for non-clinical and clinical samples
- Immunogenicity
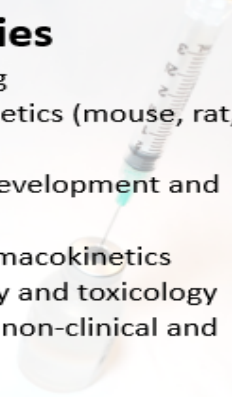
Efficacy Studies

- *In vitro* MIC
- Hollow fiber infection models
- Validated animal infection models
- Developing new animal infection models
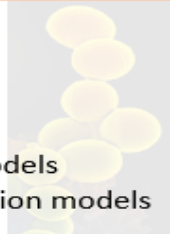
Documentation and planning support

- Product development plan production
- Support for regulatory activities and documentation

Interested in PCS? *Email: erin.zeituni@nih.gov, erica.raterman@nih.gov* *Interested in more information on PCS and contacts?* *See: https://www.niaid.nih.gov/about/dmid-preclinical-clinical-services-contacts*

Additional support for researchers

Thank You

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