NIH R15 Awards: Application Submission Requirements

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Goals of R15 mechanism

• Support small scale research projects
• Expose students to research
  ■ Undergraduate (preferably) and/or graduate
  ■ Not high school / Not postdoc/residents/clinical fellows
• Strengthen the research environment of educational institutions that have not been major recipients of NIH research grant funds
Key features

• Project period is limited to 3 years
• Direct cost limited to $300,000 over combined 3 years
• Multiple PIs are allowed, if all eligible
• Research Strategy limited to 12 pages
• Grants are renewable
• Preliminary data not required but can be provided
Differences between R15 & other Rs

• Eligibility
  ■ Institution
  ■ PI

• Unique review criteria

• Unique application requirements
Application logistics

• Receipt dates
  ■ Standard application deadlines: February 25, June 25, and October 25
  ■ AIDS-related research deadlines: May 7, September 7, and January 7

• Most NIH Institutes/Centers (ICs) participate

• ASSIST (new!) or downloadable forms
Read Funding Opportunity Announcements (FOAs) Carefully

- Funding Opportunity Announcements outline everything about the application requirements and grant awards, such as:
  - Participating Organizations (the IC that can accept applications)
  - Receipt date
  - Award Limits
  - Is a Clinical Trial allowed?
  - Eligibility – Institution and PI
  - Locus of Review
  - Review Criteria
Currently (8/22/2018), there are 11 R15 Funding Opportunity Announcements at NIH.

NIMH participates in two FOAs:

- **PA-18-504 (Clinical trial not allowed)** -- typically referred to as the “parent” announcement
- **PA-18-343 (Clinical trial required)** – 8 ICs participate

These FOAs will be available for one more receipt date – October 25, 2018.

New FOAs will be issued later this year.

For February 2019 receipt dates and beyond:

- Search the NIH Guide: [https://grants.nih.gov/funding/searchguide/index.html](https://grants.nih.gov/funding/searchguide/index.html)
- Contact an NIH Program Officer.
Where to find participating ICs

### Department of Health and Human Services

#### Part 1. Overview Information

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
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<tr>
<td>National Institutes of Health (NIH)</td>
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#### Components of Participating Organization

- 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 of Diabetes and Digestive and Kidney Diseases (NIDDK)
- National Institute on Drug Abuse (NIDA)
- National Institute of Mental Health Sciences (NIMH)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute of Nursing Research (NINR)
- National Library of Medicine (NLM)
- National Center for Complementary and Integrative Health (NCCIH)
- National Institute of General Medical Sciences (NIGMS) (No longer participating as of May 8, 2018)

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 interests.

#### Funding Opportunity Title

Academic Research Enhancement Award (Parent R15 Clinical Trial Not Allowed)

#### Activity Code

R15 Academic Research Enhancement Award (AREA)

#### Announcement Type

Reissue of PA-16-500 for due dates on or after January 25, 2018

#### Related Notices
- March 15, 2018 - Changes In NIGMS Support of Academic Research Enhancement Award (R15) Grants in the Basic Biomedical Sciences. See Notice NOT-GM-18-001

#### Funding Opportunity Announcement (FOA) Number

PA-18-504
Another example
Where to find eligibility in the PA

R15-specific eligibility criteria are in Part 2, Section III, Part 1

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions
- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISI)

The following types of Higher Education Institutions are always encouraged to Education:

In addition, all organizations must meet the following two criteria:

- The applicant organization must offer baccalaureate or advanced degrees in a
  subject area related to the proposed project.
- The applicant organization may not receive research support from the NIH to
costs in each of 4 of the last 7 years.

Note that the following activity codes are excluded: C06, S10, and all activity

Institutions with Multiple Schools or Colleges

For institutions composed of multiple schools or colleges, the criterion of financial
inclusion (university or college) as a whole, but by the individual school/college or
section where the PD(s)/PI(s) has a primary appointment (e.g., School of Medicine,
Eligibility

- Eligibility = applicant institution and PI only
- Eligibility ≠ collaborators
Institution eligibility

- US institutions only
- Baccalaureate or advanced degree in biomedical or behavioral science
- Degree granting & accredited
- Public or private non-profit
- Receives less than $6 million per year in NIH support in 4 out of last 7 years
  - Everything except C06, S10, G series

- NIH’s public list of Ineligible Institutions may not be available in future FOAs. Institutions are required to verify eligibility during submission.
PI eligibility

- Primary appointment at eligible institution
- Multiple PI OK if all eligible
- R15 supports small scale projects
  - Eligible:
    - Also serve as consultant (e.g., Key Personnel) on another grant
  - Not Eligible:
    - Also serve as PI of other NIH research grants at time of award
    - Also serve as Multiple PI on another NIH research grant at time of award
    - Research is broadly defined
Can I have an ineligible collaborator?

- Eligibility answer: Yes
- Merit answer: *But*
  - Majority of research should be directed by PI at grantee institution
  - Student profile & student inclusion are for applicant/eligible component
  - Consider the unique goals and criteria of the R15
    - No one can predict what level of involvement will be seen as counter to the R15 goals
    - Pre-PA-12-006, unique attributes not included in review criteria
Review criteria map to application instructions

Application instructions are in Part 2, Section IV, Part 2

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   Section VI. Award Administration Information
   Section VII. Agency Contacts
   Section VIII. Other Information

Section IV. Application and Submission Information

1. Requesting an Application Package
Applicants must download the SF424 (R&R) application package as instructed with this funding opportunity using the "Apply for Grant" Electronically

2. Content and Form of Application Submission
It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity or in the Application Guide. In case of a discrepancy, use the Application Guide.

For information on Application Submission and Receipt, visit Frequently Asked Questions - Application Guide, Electronic Submission.

Page Limitations
All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

Required and Optional Components

The forms package associated with this FOA includes all applicable components, required and optional. Please note that some submission of applications for this FOA. Follow all instructions in the SF424 (R&R) Application Guide to ensure you complete the

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for pl

SF424(R&R) Cover
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations
All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information
All instructions in the SF424 (R&R) Application Guide must be followed.

Facilities and Other Resources: Include the following information:

- A profile of the students of the applicant institution/academic component and any information or estimate of the number of professional doctoral degree in the health-related sciences during the last 5 years.
- A description of the institutional/academic component that make it appropriate for an AREA mentorship research. Strengthen the research environment of schools that have not been major recipients of NIH grants in such environments to research. Include a description of the likely impact of an AREA grant on the PD(s)/PI(s) and the
- Although it is expected that the majority of the research will be directed by the applicant investigator and conducted at the institution is permitted. For any proposed research sites other than the applicant institution, provide a brief description
- If relevant, a statement of institutional support for the proposed research project (e.g., equipment, laboratory space, re
Where to find review criteria

Review criteria are in Part 2, Section V, Part 1

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission, all applications submitted for the review process are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

The objectives of the R15 program are to (1) provide support for meritorious research, (2) strengthen the research environment of the available undergraduate and graduate students in such environments to meritorious research. Preliminary data are not required for a

Overall Impact

Reviewer will provide an overall impact score to reflect their assessment of the likelihood for the project to make an important scientific opportunity to students and to strengthen the research environment of the institution, in consideration of the following review criteria:

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. A likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a barrier to progress in the field? If the aims of the project are achieved, how will successful completion of the aims change the concepts, methods, technologies, treatments, services, or products that have a substantial effect on the scientific field in terms of strengthening the research environment and exposing a

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators are involved, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have achieve the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational expertise in supervising students in research?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches, or methodologies, instrumentation, or interventions novel to one field of research or novel in a broader context? Are the concepts, approaches, or methodologies, instrumentation, or interventions proposed well-designed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Is the project success in the early stages of development, will the strategy establish feasibility and will particularly in evidence that the project can enable the interests of students so that they consider a career in the biomedical or behavioral sciences?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address -1) the protection of human individuals on the basis of sex/gender, race, and ethnicity; as well as the inclusion (or exclusion) of children justified in terms of the

Environment
Some review criteria are unique

- PA-12-006 & PA-13-313
- Significance
  - Strengthen research environment
  - Expose students to research
- Investigator
  - Experience supervising students in research?
- Approach
  - Can project stimulate students’ interest so they consider biomedical/behavioral science career?
- Environment
  - Adequate institutional support & resources?
  - Well qualified students available?
  - Have or likely will students pursue biomedical/behavioral science careers?
During Submission Process – View Your Assembled Application

- Once an error-free application is received, NIH holds that application for two days (Monday-Friday, excluding Federal holidays) to allow PIs to view the final assembled application in eRA Commons.

- This is your opportunity to see the application just as a reviewer will see it
  - Take advantage of it!

- If time allows, you can correct any errors by withdrawing and resubmitting prior to the deadline.
  - This is important because errors cannot be corrected after the receipt date.
Assignments for R15

• Institute/Center:
  - The participating organization responsible for funding consideration
  - Identified in application number
    - 1 R15 **MH** 123456 01

• Scientific Review Group
  - Standing committee/”standing study section”
    - e.g. AIP, VMD
  - Special Emphasis Panel/SEP
    - e.g. ZRG1 OTC-N 80, ZRG1 SBIB-D 57
After Submitting an Application

- Use the eRA Commons to follow your application
- Find details about:
  - Review Assignment / Roster
  - Date of Review
  - Scientific Review Officer
  - Program Assignment
- All rosters available on the web: [https://public.era.nih.gov/pubroster/](https://public.era.nih.gov/pubroster/)
• [https://area.nih.gov/](https://area.nih.gov/) -- a good resource for general questions about the R15 mechanism

• It is always a good idea to reach out to program contacts prior to submission – see: [https://grants.nih.gov/grants/guide/contacts/parent_R15.html](https://grants.nih.gov/grants/guide/contacts/parent_R15.html)
Strategies for success

• What can the institution do?
• What can the investigator do?
Build a healthy research environment

• Understand the NIH extramural research program
  ■ Know guidelines, deadlines, submission & correction process, and review criteria
  ■ Create an environment in which the grants office can succeed
    ▪ Get training; Pass along training
    ▪ Get to know the investigators (and create opportunities for investigators to get to know the grants office – before it’s time to submit)
    ▪ Communicate clearly about expectations and deadlines

• Establish an environment where research can succeed
  ■ Start up packages
  ■ Pilot grants, student research grants
  ■ Stimulate new collaborations
Build a healthy research environment

- Reinforce the importance of collaborative research
- Do not rush investigators to apply
  - Balance “quality over quantity” and persistence
  - Don’t submit just to “Get some feedback from the reviewers”
- “Facilities and Other Resources” section of application
  - Should be personalized/relevant for the application
  - Profile of student body
  - Description of the institution and research environment
  - Letter of institutional commitment to research project
Strategies of successful PIs

- Identify the “gaps” in your team; Include a collaborator or consultant if you don’t have the necessary expertise or resources
- Understand the review criteria and the review criteria questions (i.e., read the entire funding announcement)
  - Each question should be addressed in the application
- In resubmissions, respond thoroughly and diplomatically to all of the reviewer comments
- AREA grant is a research award, not a training award
  - Focus on hands-on research not coursework
  - Describe PI’s role in research & supervision
Strategies of successful PIs

- Address the AREA-specific programmatic goals in the application; these are reflected in review criteria
  - Support meritorious research
    - Research should contribute to the field
    - Results should be publishable
  - Expose students to research
    - Profile of available and former students at the institution
    - Experience of the investigator in working with students
    - How students will be incorporated into the research project
    - How students will benefit from this research experience
  - Strengthen the research environment
    - The suitability of the institution for an award
    - The impact the AREA grant will have on the institution (and the larger community?)
Strategies of successful PIs

- Research Strategy should address feasibility
- Try to involve students at different phases of their training
- Ask students to make a multi-semester commitment
- Consider in-depth research experience at a major research institution (e.g., summer externship)
- Assess what students will need to participate successfully
- Help students plan workload realistically
- Involve students in training new students
- Consider partnering with community-based organizations
There is no “winning formula”

• No one – not even an NIH program officer - can give specifics of what will score well

• Use NIH Reporter Query tool to view abstracts of funded grants

• Use NIH Reporter Matchmaker tool to view similar grants (and their NIH institutes, program officers, and review committees)
NIMH-specific considerations

- Experimental therapeutics
  - Does the treatment engage the target?
  - Does engaging the target affect the clinical outcome?
- Efficacy trial *versus* mechanistic trial
  - NOT-MH-18-004: NIMH Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements
- NIMH clinical trials information:
NIMH-specific considerations

- Research Domain Criteria www.nimh.nih.gov/rdoc
Resources

• AREA Program website: https://area.nih.gov
• AREA Program FAQs: http://grants.nih.gov/grants/funding/area_faq.htm
• Institute/Center contacts: http://grants.nih.gov/grants/guide/contacts/parent_R15.html
• Strategic plans: http://report.nih.gov/strategicplans/
• NIH Reporter: https://projectreporter.nih.gov/reporter.cfm
Thoughts?
Questions?
Suggestions?
Thank You

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• Gamsahabnida
• Gratias Ago Vos
• Dankon
• Xièxiè Nín
• Danke
• Dan

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• Merci
• Dankie dat U
• Terima Kasih

• Thank you
• Grazie
• Thaks
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• Thank you
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• Obrigado
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