Preparing NIH Grant Proposals
Office of Research, Scholarship, and Sponsored Programs
April 11, 2023
NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce illness and disability.
NIH is made up of 27 institutes and centers (ICs) of which 24 award grants.
In addition to supporting research, NIH provides funding for career development.
NIH Research Training **Resources**

- Research Career Pathway Infographics
- Career Guidance
- NIH Institute/Center Research Training and Career Development Information
- Early-Stage Investigators Policies
- How to Apply - Application Guide
- NIH Forms & Applications
- NIH Grants YouTube Channel
- NIH All About Grants Podcasts
- NIH Grants Conference
- NIH Grants Policy Statement
- General Resources for the Responsible Conduct of Research
- eRA System Resources
- FAQs

Investigators new to applying for NIH funding opportunities can find several resources on the NIH webpages. In addition, NIH hosts a grants conference every year and offers conference session recordings and materials after the conference. We have taken some of this information to present to you today.
NIH Notice of Funding Opportunity (NOFO)

- Program Announcements (PA)
  - Identifies areas of increased priority and/or emphasis on particular funding mechanisms for a specific area of science
  - Usually accepted on standard due dates on an on-going basis
  - Remains active for three years from date of release unless the announcement indicates a specific expiration date, or the NIH Institute/Center (I/C) inactivates sooner

- Special Types
  - PAR: a PA with a special receipt, referral and/or review considerations as described in the PAR announcement
  - PAS: a PA that includes specific set-aside funds as described in the PAS announcement

NIH has recently changed the name of their funding opportunity announcements to notices of funding opportunities to be more consistent with other federal agencies. However, you will see both terms used on the NIH website and in this presentation.

Program announcements are one type of funding announcement that the NIH uses. They are characterized by the use of standard due dates which typically fall in the months of February, June, and October.
NIH Types of Funding Opportunities

- Notice of Special Interest (NOSI)
  - Notices are used to alert the community of potential opportunity for funding in special topics of interest
  - Notices are being used to replace IC-issued program announcements to highlight interest in a research area that does not have set-aside funds or special review criteria and/or review considerations
  - Notices direct applicants to one or more active funding opportunity announcements for submission of applications for the initiative described
NIH Types of Funding Opportunities

- Request for Application (RFA)
  - Identifies a more narrowly defined area for which one or more NIH institutes have set aside funds for awarding grants
  - Usually has a single receipt (received on or before) date specified in the RFA announcement
  - Usually reviewed by a Scientific Review Group convened by the issuing awarding component
NIH Notice of Funding Opportunity (NOFO)

- Parent Announcements
  - Broad funding opportunity announcements allowing applicants to submit investigator-initiated applications for specific activity codes
  - Open for up to 3 years
  - Use standard due dates
### NIH Notice of Funding Opportunity (NOFO)

- **Parent Announcement Activity Codes (Grant Mechanisms)**
  - Research (R) – R01, R03, R13, and R21
  - Research Training (T) – T32 and T35
  - Career Development (K) – K01, K02, K08, K23, K24, K25, and K99/R00
  - Fellowships (F) – F30, F31, F32, and F33
  - Administrative Supplements

Today we’ll look at three of the more common parent announcement activity codes: R01, R03, and R21. All these parent announcements were set to expire in May 2023, but in March their expiration dates were extended to May 2024.
# NIH Research Grant Mechanisms

<table>
<thead>
<tr>
<th>Code</th>
<th>Parent FOA No.</th>
<th>Purpose</th>
<th>Budget and Project Period</th>
<th>Standard Due Dates (New)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>PA-20-185</td>
<td>Supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his or her specific interest and competencies.</td>
<td>Not limited but special requirements for total budgets over $500,000 for max of 5 years</td>
<td>February 5, June 5, October 5</td>
</tr>
<tr>
<td></td>
<td>PA-20-184</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>PA-20-183</td>
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</tbody>
</table>

R01 is the activity code for the NIH Research Project Grant program that supports a discrete project that is related to the programmatic interests of one or more of the participating NIH institutes and centers based on their scientific missions. There are three parent announcements for the R01 activity code.

- PA-20-185 (clinical trial not allowed)
- PA-20-183 (clinical trial required)
- PA-20-184 (basic experimental studies with humans required)
R03 is NIH’s Small Research Grant Program that supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, sell-contained research projects; development of research methodology; and development of new research technology. The parent announcement for R03 projects is PA-20-200. It does not support applications proposing clinical trials.

The R21 program is intended to encourage new exploratory and developmental research projects. Examples include projects that assess the feasibility of a novel area of investigation or a new experimental system that has the potential to enhance health-related research. Another example could include the unique and innovative use of an existing methodology to explore a new scientific area. The R21 mechanism is not intended to support long-term projects, or projects designed to increase knowledge in a well-established area.

There are three parent announcements for the R21 activity code. PA-20-195 (clinical trial not allowed); PA-20-194 (clinical trial required); and PA-20-196 (basic experimental studies with humans required).
NIH Research Enhancement Award (R15)

The goals of the R15 are to:
• Support meritorious research,
• Expose students to research, and
• Strengthen the research environment of the institution.

Two types of R15 awards:
• Academic Research Enhancement Award (AREA) for Undergraduate-Focused Institutions
• Research Enhancement Award Program (REAP) for Health Professional Schools and Graduate Schools

Supports small-scale research projects at educational institutions that provide baccalaureate or advanced degrees for a significant number of the Nation’s research scientists but that have not been major recipients of NIH support.

Faculty/staff employed by the main campus can apply for R15 awards, but faculty/staff employed by the HSC campus cannot apply for R15 awards.

Faculty and staff in the School of Nursing, School of Pharmacy, Department of Kinesiology, and Department of Psychology and Counseling can apply for REAP awards. Faculty and staff employed by the main campus in biology, chemistry, engineering, physics and similar departments can apply for AREA awards. As long as they are not the PI of an active NIH research grant at the time of a R15 award.
### NIH Research Grant Mechanisms:
#### Academic Research Enhancement Award (AREA)

<table>
<thead>
<tr>
<th>Code</th>
<th>Parent FOA No.</th>
<th>Eligibility</th>
<th>Budget and Project Period</th>
<th>Standard Due Dates (New)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R15</td>
<td>NIH no longer posts Parent Announcements for the R15 program. PAR-21-155</td>
<td>The application must be submitted by the eligible undergraduate-focused organization that grants baccalaureate degrees in biomedical sciences. At the time of application submission, all the non-health professional components of the institution together have not received support from the NIH totaling more than $6 million per year (in both direct and F&amp;A/indirect costs) in 4 of the last 7 fiscal years. Direct costs are limited to $300,000 for max of 3 years</td>
<td>February 25</td>
<td>June 25</td>
</tr>
</tbody>
</table>
On April 10, 2023, there were 26 active NOSIs for which PAR-21-155 can be used for submission of applications.
### NIH Research Grant Mechanisms: Research Enhancement Award Program (REAP)

<table>
<thead>
<tr>
<th>Code</th>
<th>Parent FOA No.</th>
<th>Eligibility</th>
<th>Budget and Project Period</th>
<th>Standard Due Dates (New)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R15</td>
<td></td>
<td>The application must be submitted by the eligible health professional or graduate school that grants baccalaureate or advanced degrees in health professions or advanced degrees in biomedical and behavioral sciences. At the time of application submission, the applicant institution may not have received support from the NIH totaling more than $6 million per year (in both direct and F&amp;A/indirect costs) in 4 of the last 7 fiscal years.</td>
<td>Direct costs are limited to $300,000 for max of 3 years</td>
<td>February 25 June 25 October 25</td>
</tr>
<tr>
<td></td>
<td>NIH no longer posts Parent Announcements for the R15 program. PAR-22-060 PAR-21-357</td>
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</table>

NIH Research Grant Mechanisms: Research Enhancement Award Program (REAP)
On April 10, 2023, there were 28 active NOSIs for which PAR-22-060 can be used for submission of applications.

### Active NOSIs

<table>
<thead>
<tr>
<th>Title</th>
<th>Notice Number</th>
<th>Organization</th>
<th>Release Date</th>
<th>Expiration Date</th>
<th>Activity Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice of Special Interest (NOSI): Promoting Language and Communication in Minimally Verbal/Non-Speaking Individuals with Autism</td>
<td>NOT-DC-23-009</td>
<td>NIDCD</td>
<td>Apr 3, 2023</td>
<td>Jun 6, 2025</td>
<td>R13, R15, R01, U01, R21, R43/R44, R41/R42, R03</td>
</tr>
</tbody>
</table>
On April 10, 2023, there were 15 active NOSIs for which PAR-21-357 can be used for submission of applications.

<table>
<thead>
<tr>
<th>Active NOSIs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
</tr>
<tr>
<td>Notice of Special Interest (NOS): Promoting Language and Communication in Minimally Verbal/Non-Speaking Individuals with Autism</td>
</tr>
</tbody>
</table>
### NIH Research Grant Mechanisms: Support for Research Excellence (SuRE) Program

<table>
<thead>
<tr>
<th>Code</th>
<th>Parent FOA No.</th>
<th>Eligibility</th>
<th>Budget and Project Period</th>
<th>Standard Due Dates (New)</th>
</tr>
</thead>
<tbody>
<tr>
<td>R16</td>
<td>Components</td>
<td>Supports research capacity building at eligible institutions that award degrees in biomedical sciences, have enrolled at least 25% of undergraduate students supported by Pell grants in each of the most recent two years, and have received no more than $6 million dollars per year (total costs) through NIH Research Project Grants (RPGs) in each of the preceding two fiscal years at the time of application submission; or be accredited medical/health professional schools that were founded to educate students from populations underrepresented in the U.S. (NOT-OD-20-031).</td>
<td>Direct costs are limited to $300,000 for max of 3 years</td>
<td>February 25 June 25 October 25</td>
</tr>
</tbody>
</table>

R16 mechanisms are used for the Support for Research Excellence (SuRE) Program. Investigators on the main campus may be eligible for R16 awards.
PAR-21-169 SuRE research awards provide research grant support for faculty investigators who are not currently funded by any NIH Research Project Grants.

### Active NOSIs

<table>
<thead>
<tr>
<th>Title</th>
<th>Notice Number</th>
<th>Organization</th>
<th>Release Date</th>
<th>Expiration Date</th>
<th>Activity Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice of Special Interest (NOSI): Optimization of Data Storage and Utilization for the Sequencing Read Archive (SRAC)</td>
<td>NOT-DR-23-015</td>
<td>NIDCR</td>
<td>Jul 19, 2022</td>
<td>Sep 8, 2023</td>
<td>R15, R51, R16, R22</td>
</tr>
</tbody>
</table>
PAR-21-173 (SuRE-First) awards provide research grant support for faculty investigators who have not had prior independent external research grants.

<table>
<thead>
<tr>
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<th>Expiration Date</th>
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</thead>
</table>
How do you know if your human subjects research study meets the NIH definition of clinical trial?

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
How do you know if your human subjects research study meets the NIH definition of clinical trial?

Answer the following four questions:
1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

How do you know if your human subjects research study meets the NIH definition of clinical trial?

Your study is considered to meet the NIH definition of a clinical trial even if:

• Your study uses healthy participants, or does not include a comparison group (e.g., placebo or control)
• Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
• Your study utilizes a behavioral intervention
• Your study uses an intervention for the purposes of understanding fundamental aspects of a phenomenon
Once you have determined if your planned research will be considered a clinical trial or not, you’re ready to search for funding opportunities. UT Tyler has a subscription to Pivot, an online database of global funding opportunities. We present a workshop on using Pivot every fall semester. If you know you want to submit a proposal to one of the Health and Human Services agencies, you can use NIH’s Find Grant Funding webpage: https://grants.nih.gov/funding/searchguide/index.html#/
Before deciding if a funding opportunity is the right one for your proposed research, be sure to check the components of participating organizations to see if the institute or center that you wish to review your research proposal is included. This information is at the top of the first page of NIH’s notice of funding opportunities.
How to Apply – Application Guide

Application Form Instructions

- SF424 (R&R) Form Version H General Instructions (effective on January 25, 2023)
- Research Instructions for research only activity codes (R)
- Career Development Instructions for career development only (K)
- Training Instructions – for training only (T) and some (D and K activity codes)
- Fellowship Instructions – guidance for fellowship only (F)

How to Apply – Human Subjects and Clinical Trials Information G.500

- Form is used to collect information on human subjects research, clinical research, and/or clinical trials

If your proposal includes research on human subjects, you will need to complete the Human Subjects and Clinical Trials Information. This process begins by first entering some basic answers to questions regarding your use of human subjects in G.220 – Other Project Information Form. Information from that form auto fills some of the information needed in G.500. I recommend completing the G.500 form before writing the research strategy since the process of completing the form may inform the research strategy. Avoid repeating information in the research strategy that is included in G.500 – reference it instead. The Office of Research, Scholarship, and Sponsored Programs has templates to help you fill out the required documents attached to the G.500 form.
2023 NIH Data Management and Sharing Policy

- Issued effective January 25, 2023, to promote sharing of scientific data
- Under the DMS policy, investigators will:
  - Prospectively plan for the managing and sharing of scientific data
  - Submit a DMS plan
  - Comply with the approved plan
- Usually, it is not provided to reviewers unless stated in the NOFO


Beginning January 25, 2023, most NIH proposals must include a Data Management and Sharing Plan. This plan replaces the former data sharing plan that was only required for investigators seeking $500,000 or more in direct costs and only required a brief 1-paragraph description.

Under the new data management and sharing policy, investigators must plan and budget for managing and sharing of scientific data, submit the plan with their proposal, and comply with the plan when awarded funds. The data management and sharing plan is not sent to reviewers in most cases, unless the data management and sharing plan is an integral part of the project as stated in the NOFO. If a proposal is awarded, the DMP becomes a term and condition of the grant award.
When is the DMS Policy Applicable?

- The DMS Policy applies to all research that generates scientific data, including:
  - Research Projects
  - Some Career Development Awards (Ks)
  - Small Business SBIR/STTR
  - Research Centers

- The DMS Policy does not apply to research and other activities that do not generate scientific data, including:
  - Training (T)
  - Fellowships (Fas)
  - Construction (C06)
  - Conference Grants (R13)
  - Resource (Gs)
  - Research-Related Infrastructure Programs (e.g., S06)
What Scientific Data Need to Be Shared

- Scientific data are defined as the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.
- Scientific data do not include
  - Laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers
  - Plans for future research, peer reviews, communications with colleagues or physical objects (lab specimens)

Scientific data are those data that can be used to validate and replicate your findings, regardless of whether they were used to support your publications.
Examples of Data Types to Be Shared

- “Omics” Data
  - Genomics and epigenetics (e.g., WGS, WES, EPIC arrays, targeted panels)
  - Transcriptomics e.g., RNA-seq
  - Microbiomics (e.g., bacteria, virus)
  - Proteomics (e.g., mass spec, RPPA)
  - Metabolomics (e.g., mass spec)

- Imaging Data
  - Medical imaging (e.g., ultrasound, MRI, CT)
  - Non-medical imaging (e.g., fluorescence microscopy)
  - Other (e.g., histopathology)
Examples of Data Types to Be Shared

- Biological Data
  - Electrophysiology (e.g., sensor data, ECG)
  - Biochemical (e.g., X-ray, NMR, AMF, FRET)
  - Pre-clinical (e.g., PDX growth curve)
- Imaging Data

- Phenotype Data
  - Non-human (e.g., phenotypic features of animal models)
  - Human traits (e.g., blood type)
  - Demographics
  - Clinical data (including specimen information)
Examples of Data Types to Be Shared

- Additional Data
  - Clinical trial results
  - Associated metadata
  - Epidemiology/surveillance
  - Administrative
  - Algorithm/Simulation
  - Social/Behavioral
  - Survey/questionnaire
When Should Data Be Shared

• No later than the time of an associated publication or
• End of the award (for unpublished data), whichever comes first

Expectation of when data should be shared is no later than the time of an associated publication or at the end of the award if data is not published, whichever comes first.
Planning and Budgeting for DMS

• DMS Plans are recommended to be two pages or less in length
• NIH offers an optional DMS Plan format page that aligns with the recommended elements of a DMS Plan
• Important: Do not include hypertexts (hyperlinks and URLs)
• NIH offers several sample DMS plans for the various types of research NIH supports
• NIH recommends budgeting for data management and sharing


NIH now offers many resources to help investigators meet the data management and sharing policy including a template in Word format and several samples of DMS plans. NIH recommends budgeting for data management including salary, fringe, repository fees etc. These costs are expected to go into the Other category, although creates some issues with calculating indirect costs. Budget justification is expected to include a line item for DMS costs or an explanation as to why there are no costs budgeted for DMS.
Elements of a Data Management & Sharing Plan

1. Data Type
2. Related Tools, Software and/or Code
3. Standards
4. Data Preservation, Access, and Associated Timelines
5. Access, Distribution, or Reuse Considerations
6. Oversight of Data Management and Sharing
Office of Research, Scholarship, and Sponsored Programs

https://www.uttyler.edu/research/

Health Science Center Campus
- grants@uthct.edu
- 903-877-7392

Main Campus
- research@uttyler.edu
- 903-565-5858

Resources that ORSSP offers to support grant proposals
- Proposal checklists for R01, R03, R15, and R21 grant mechanisms
- Templates and/or boiler plate text for many of the proposal documents
- Grant proposal review and editing
- Workshops
- Research Design and Data Analysis Lab
Office of Research, Scholarship, and Sponsored Programs

Health Science Center Campus
  • Legal name: The University of Texas Health Science Center at Tyler
  • Office of Research, Scholarship, and Sponsored Programs
    • grants@uthct.edu
    • 903-877-7392

Main Campus
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<table>
<thead>
<tr>
<th>Pre-Award Staff</th>
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<tbody>
<tr>
<td><strong>Health Science Center Campus</strong></td>
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</tr>
<tr>
<td>Matthew Lee</td>
<td>Grants &amp; Contracts Lead</td>
</tr>
<tr>
<td>Audrey Gray</td>
<td>Grants &amp; Contracts Specialist II</td>
</tr>
<tr>
<td>Angela Fazarro</td>
<td>Grants &amp; Contracts Specialist II</td>
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