Introduction to NIH Grant Preparation & Submission Process

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Objectives

• Find and read NIH research Funding Announcement
• Key elements for preparation
• Determine necessary documents
  • 2019 Changes
Finding a Funding Opportunity Announcement (FOA)
Finding a FOA, Resources

- NIH
  - grants.nih.gov
    - FUNDING

https://grants.nih.gov/grants/funding/funding_program.htm
Selecting a FOA

- Research (R) Announcements
  - R01
  - R03
  - R13
  - R21

https://grants.nih.gov/grants/guide/parent_announcements.htm
Viewing the FOA

- Activity Code
- Announcement Type
Viewing the FOA

- FOA Number
- Earliest Submission
- Letter of Intent
- Application Due Date
Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this FOA. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the Research (R) instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

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

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this FOA.

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.

SF424(R&R) Senior/Key Person Profile

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

R&R or Modular Budget

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

R&R Subaward Budget

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

PHS 398 Cover Page Supplement

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

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

PHS Human Subjects and Clinical Trials Information

When involving NEI-defined human subjects research, clinical research, and/or clinical trials (and when applicable, clinical trials research experience) follow all instructions for the NEI Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered “Yes” to the question “Are human subjects involved?” on the R&R Other Project Information form, you must include at least one human subjects study record using the Study Record: PHS Human Subjects and Clinical Trials Information form or Delayed Onset Study record.

Study Record: PHS Human Subjects and Clinical Trials Information

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

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start).
6. Funding Restrictions
All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. Pre-award costs are allowable only as described in the NIH Grant Policy Statement.

7. Other Submission Requirements and Information
Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply – Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:
All PDs/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424 (R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this FOA for information on registration requirements.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization’s profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide. See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review. NIH. Applications that are incomplete or non-compliant will not be reviewed.

Requests of $500,000 or more for direct costs in any year
Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/Research Contact at least 5 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

Post Submission Materials
Applicants are required to follow the instructions for post-submission materials, as described in the policy. Any instructions provided here are in addition to the instructions in the policy.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

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. An application does not need to be strong in all categories to be judged 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 critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their fields? If the project is collaborative...
Intent to submit

Stanford process
Proposal Intake Form (PIF)

• Stanford Electronic Research Administration (SeRA)
  • sera.stanford.edu

• Research Management Group (RMG)

• Research Process Manager (RPM)

https://doresearch.stanford.edu/node/3154937
What to expect next

• Once complete
• Email from SeRA
NIH Application Submission System & Interface for Submission Tracking

- ASSIST
- eRA commons
- Initiate w/ FOA

Management team

• Who will be managing the paperwork?
• Keeping track of documents?
• Reaching out to key personnel, Consultants, etc.
Necessary Documents

Research focused documents
Research/Science focused documents

• Research Strategy (6 pgs or 12 pgs)
  • Instructions under “Significance” and “Approach” added

• Project Summary/Abstract (30 lines)

• Project Narrative (3 sentences)

• Bibliography

Other Documents

Required
• Letters of Support
• Resource Sharing Plan

Not Required/It Depends
• Consortium Contractual Agreement
• Multiple PD/PI Leadership Plan
Letters of Support

• Consortium participants
• Senior/Key Personnel
  • Percent efforts
• Other Significant Contributors
• Consultants
  • Rate of charge
  • Verify facilities
Resource Sharing Plan

• $500,000 ≥ direct costs in any budget period
  • Include Data Sharing paragraph

• FOA may also request Data Management Plan

• READ FOA!!
Consortium/Contractual Arrangements

• Arrangements between Consortium organization and Applicant organization

• Why you? If consortium activities are significant to overall project
Some Definitions

**Stanford**

- Principal Investigator
  - Academic Council and/or Medical Center Line faculty

- Co-Investigator
  - Senior members of Academic Staff-Research/Libraries

**NIH**

- Program Director/Principal Investigator
  - Authority & Responsibility

- Co-Investigators
  - Involved in scientific development or execution of a project


https://grants.nih.gov/grants/glossary.htm
Multiple PD/PI Leadership Plan

• Co-Investigator ≠ Co-PI

• Rationale

• Role of Responsibilities

https://grants.nih.gov/grants/glossary.htm
Other required documents

- Budget AND Budget Justification
  - Collaborate with RPM

- Facilities & Other Resources

- Equipment

- Biosketches (5 pgs)
  - Needed from all senior/key personnel

https://grants.nih.gov/grants/forms/biosketch.htm
What about Human Subjects?
Human Subjects Documents

Required
• Recruitment & Retention
• Protection of Human Subjects
• Inclusion of Women and Minorities
• Inclusion of Children
• Study Timeline
• Targeted/Planned Enrollment Table

Depends
• Single IRB Plan

https://grants.nih.gov/policy/humansubjects.htm
Human Subjects and Clinical Trials Info

- Clinical Trial Questionnaire
  - Typically only yes to 1st question
- Study Population Characteristics
- Protection and Monitoring Plans

Study Population Characteristics
Inclusion of Women and Minorities

• Distribution and rationale of subjects by sex/gender, race, and ethnicity

• Describe proposed outreach programs for recruiting sex/gender, racial, and ethnic group members.

• Provide a reason for limiting inclusion of any group by sex/gender, race, and/or ethnicity.
Inclusion of Children

• Rationale for age limits

• Exclusion of any specific age or age range group should be justified by scientific or ethical rationale

• Why is age distribution meaningful/relevant to the study

https://nexus.od.nih.gov/all/2019/02/06/reminder-to-address-inclusion-of-individuals-across-the-lifespan-in-grant-applications/
Recruitment & Retention

• Describe how you will recruit and retain participants in your study
  • Exactly how you plan to recruit
  • Include incentives for retaining participants

• Recruitment Status
  • Not yet recruiting
  • Recruiting
  • Enrolling by invitation
  • Active, not yet recruiting
  • Completed
# Planned/Actual Enrollment Tables

- Enrollment
  - Planned
  - Actual

## Inclusion Enrollment Report 1
PHS Human Subjects and Clinical Trials Information v1.0

**Planned**

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## Cumulative (Actual)

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Protection and Monitoring Plans
Protection of Human Subjects

• Risks to Human Subjects
  • Human Subjects Involvement, Characteristics, and Design
  • Study Procedures, Materials, and Potential Risks

• Adequacy of Protection Against Risks
  • Informed Consent and Assent
  • Protections Against Risk
  • Vulnerable Subjects (if relevant)

• Potential Benefits of the Proposed Research to Research Participants and Others

• Importance of the Knowledge to be Gained
Institutional Review Board (IRB) Plan

Multi-site study that uses same protocol?

Yes

Single IRB
Plan needed

No
Single/Central IRB Plan

• Comply with the Use of sIRB for Multi-Site Research.

• Provide the name of the IRB (if available)

• Briefly describe how communication between sites and the sIRB will be handled.

• Indicate that all participating sites will sign an authorization/reliance agreement that will clarify the roles and responsibilities

• Indicate which institution or entity will maintain records
Changes in 2019 in Review & Tips

• Read the Funding Announcement thoroughly
• Start the process early
• Decrease redundancy
• New requirements
  • Inclusion of Women & Minorities
  • Inclusion of Children
• Ask for help!
Thank you, Questions?

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