Optimize Your Grant Application: News You Can Use From NIH

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SfN

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• Slides available from

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24 NIH Institutes and Centers Fund Grants
The score given by the study section is far and away the strongest determinant of funding. BUT Institutes can and do take into account their own scientific priorities, high and low. If your application does poorly in review, Institute priorities won’t help.
Your Application Goes to the NIH Center for Scientific Review (CSR)

Focal Point for Merit Review at NIH

- Receives all NIH applications
- Refers them to NIH Institutes/Centers and to scientific review groups
- Reviews majority of grant applications for scientific merit

CSR review 60,000+ applications per year. CSR reviews most R01s, R21’s, F’s, SBIR plus some K and special mechanisms. The Division of Neuroscience, Development and Aging (DNDA) reviews ~12,000 applications per year. Most, but not all AD research, most NIA applications, most NINDS applications, most NIMH applications.
Steps to Success

1. Talk to program officers at the Institute that would fund your grant

2. Read the Funding Opportunity Announcement

3. Understand how your application will be reviewed and write your grant accordingly
Read the FOA

- FOA = Funding Opportunity Announcement
- Applications must be submitted to a particular FOA
- FOAs contain information you should know
  - The science of interest
  - Due dates
  - Review criteria
  - Which Institutes will consider funding the application
  - Who to contact

- Types of FOA
  - General "parent" vs. special interest
    - PAR Program Announcement with special Receipt, Review, or Referral considerations
    - RFA Request for Application
    - NOSI Notice of Special Interest

FOAs: a) show IC interest in a topic; b) explain the rules. Talk to program while developing your grant application idea.
Funding Opportunity Announcement Overview

Table of Contents
- Part 1: Overview Information
- Part 2: Full Text of the 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

Funding Opportunity Announcement Sections

Part I: Overview Information
All the relevant key dates related to the FOA are found in Part I: Overview Information.

Section II: Award Information
Contact information or instructions on how to locate the information for NIH staff associated with the application can be found in this section.

Section III: Eligibility Information
Section V of the FOA details all the review criteria including an special criteria specific to the announcement. The 2nd half of this section identifies the reviewing organization.
Criteria for Judging Research Applications

<table>
<thead>
<tr>
<th>5 Domains</th>
<th>Overall Impact</th>
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<tbody>
<tr>
<td>Significance*</td>
<td>Assessment of the likelihood for the project to <em>exert a sustained, powerful influence on the research field(s) involved</em></td>
</tr>
<tr>
<td>Investigator(s)</td>
<td></td>
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<tr>
<td>Innovation</td>
<td></td>
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<tr>
<td>Approach*</td>
<td></td>
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<tr>
<td>Environment</td>
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</tbody>
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Each scored from 1-9   Scored from 1-9

Significance - how important is the proposed science? Does it address critical problems or gaps, will it change our understanding?? Overall Impact is the one that counts. It is NOT an average of criterion scores. In red are the core criteria that usually drive overall impact. * = areas where there have been significant changes.
Write your application with the review criteria in mind.

**Significance**
- Show the significance of the science, not the importance of the problem.
- Address rigor of the prior research—the empirical foundation of your proposal

**Investigator(s)**
- Productivity
- Expertise in the topic
- Experience with the methods

**Innovation**
- What is new?

**Approach**
- Strong design, methods cutting edge, analysis and interpretation solid
- Address rigor and reproducibility
- Address sex as a biological variable

**Environment**
- Demonstrate capability

Comment on each
Rigor of the prior research

- NIH expects applicants to describe the general strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. It is expected that this consideration includes attention to the rigor of the previous experimental designs, ….

- Address this in your Significance section

Does your proposal rest on a solid empirical foundation?
Scientific Rigor: Guidance for Reviewers

• Are there “strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”

• Possible considerations:
  ▫ Are sample sizes well justified
  ▫ Is a high-quality statistical analytic plan in place
  ▫ Have steps been taken to reduce bias
  ▫ Are measurements independent and blinded
  ▫ Are steps taken to improve precision and reduce variability
  ▫ Are inclusion/exclusion criteria clear and appropriate
  ▫ How are missing data handled
Sex as a Biological Variable:
Guidance for Reviewers

Consideration of sex, included under the umbrella of “Relevant Biological Variables”, is required in all studies involving human subjects or vertebrate animals.

NIH expectations for reviewers:
• As part of the Consideration of Relevant Biological Variables, assess whether the plans to address sex as a biological variable are adequate
• If the study involves only one sex, is this justified scientifically?
• Assess within the context of the research question and current scientific knowledge.
Review Criteria for Fellowships

The NRSA Fellowship is a training award and not a research award. Overall Impact Score reflects the likelihood that this fellowship experience will enhance the candidate’s potential for, and commitment to, a productive independent scientific research career in a health-related field.

1. Fellowship Applicant
2. Sponsor, Collaborators, and Consultants
3. Research Training Plan
   1. Sponsor provided
   2. Applicant generated (Scientific Approach)
4. Training Potential
5. Institutional Environment and Commitment to Training

All criteria bear on Training Potential and can drive overall impact score. Note, quality of the science is not a criterion.
Strategies for finding the right study section

1. Ask your colleague which study section gave his or her last grant a good score — Bad idea
2. Do nothing — Not a bad idea
3. Use the tools CSR provides — Good idea

http://www.csr.nih.gov/

1. Applications on the same general topic but with different Aims, Methods, or Models may be in different study sections. Study sections evolve.
2. CSR devotes tremendous attention to getting applications to the right study section. Multiple people, expert in our study sections, look at each application. Expertise is the #1 consideration for CSR.
Assisted Referral Tool (Art)

Enter application text and get a list of relevant study sections

https://art.csr.nih.gov
Details on all CSR study sections are on the web

Alternatively, if you’d prefer to browse the CSR website, you can browse the clusters of study sections (called IRGs or integrated review groups) and you can look at the individual study sections in the clusters and get more information about them.

https://public.csr.nih.gov/StudySections
Suggested expertise is valuable. CSR always considers PI requests. It does not always agree and may assign elsewhere. Conflicts? Someone asked ‘how to avoid being reviewed by someone with strong biases against our lab or our ideas?’ ARF is the best way to communicate this to CSR.
General Grant Writing Tips

• Convince the reviewer
• Make it easy for the reviewer
• Don’t annoy the reviewer
• Vet your ideas and application. Get friendly but fierce criticism.
• Address your weaknesses
  - in methods and approach
  - as a PI/fellowship applicant
• Respond fully to the summary statement

It’s not just a description, it’s your chance to make your case. Reviewers ask- What is the significance of this? Where is the innovation? Etc. Tell them!
Identifying Whether NIH Considers Your Study to be a Clinical Trial is Crucial

For ALL HUMAN SUBJECTS applications

✓ Mismatched applications will be withdrawn.

✓ Clinical trials applications require additional information.
  ❑ New human subjects and clinical trials information form

✓ Additional review criteria pertain to clinical trials applications.
Writing an application that uses human subjects?

✓ Visit this website
https://grants.nih.gov/policy/clinical-trials.htm

✓ Use this tool

✓ Talk to your program officer

NIH wants to be helpful. It's a complex process. Give yourself time. NIH offers substantial resources to help.
NIH Might Define Your Research to be a Clinical Trial

Does your study...

✓ Involve one or more **human subjects**?
✓ **Prospectively assign** human subject(s) to intervention(s)?
✓ Evaluate the effect of intervention(s) on the human subject(s)?
✓ Have a **health-related biomedical or behavioral outcome**?

If “yes” to ALL of these questions, your study is considered a clinical trial.

We have a tool that can help!

https://grants.nih.gov/ct-decision/

[NIH Center for Scientific Review]
What type of clinical trial are you proposing?

**FOAs may restrict the type of clinical trial allowed**

**BESH**: Basic Experimental Science involving Humans

Mechanistic: Mechanistic studies are designed to understand a biological or behavioral process, the pathophysiology of a disease, or the mechanism of action of an intervention

Other: Safety and efficacy studies, studies of pharmacokinetics or pharmacodynamics, or clinical trial feasibility, early phase, dosing, clinical management, clinical implementation

**Talk to the Institute. Look at their resources**


https://www.nia.nih.gov/research/grants-funding/nia-guidance-clinical-trials

How Does the Human Subjects & Clinical Trials Information Form Impact Applicants?

**New form collects information previously included in the Research Strategy**

Applicants will now be instructed to:

- ✔ Use the PHS Human Subjects and Clinical Trials Information form to capture detailed study information
- ✔ Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of proposed research, but *do not duplicate* information collected in the PHS Human Subjects and Clinical Trials Information form

**Tip:** Applicants should familiarize themselves with the new Human Subjects and Clinical Trial Information form to ensure information is captured appropriately in the application

**National Institutes of Health**
New Review Criteria for Clinical Trials

**FOAs that accept clinical trials will include new review criteria**

**Scored Review Criteria**
- ✓ Significance
- ✓ Investigator
- ✓ Innovation
- ✓ Approach
- ✓ Environment

**Additional Review Criteria**
- ✓ Study Timeline & Milestones

Tip: Read the FOA carefully and be sure your application addresses the review criteria appropriately.

“ Appropriately” is the key. Science, not mechanism, is primary.
How NOT to Submit a Late Application

Start Early!

- Application must be accepted **TWICE**: Grants.gov and NIH

**Check eRA Commons for your submitted application**
(e-mails are sent but can be caught in SPAM filters)

- High volume at deadlines slows processing/validation time
- On time application = submitted error-free by 5 PM local time on due date
- **Errors** cause rejection – **Warnings** are error-free and accepted
- **No error correction window that extends deadline**

One very important policy is NIH’s late application policy. Submitting to the NIH is not like buying a book from a major on-line retailer where 30 seconds after you click on the “buy” button, the book is successfully downloaded to your e-reader. NIH applications must be accepted twice, first by Grants.gov and then by the NIH. Grants.gov serves as a general portal for electronic applications submitted to various federal agencies. When you receive a tracking number starting with the capital letters GRANT (and a 9 digit numeral) this just means it has been accepted by Grants.gov. At that point, NIH retrieves your application and performs numerous validations, all of which must be successfully passed in order for your application to be accepted by the NIH. E-mails are sent at various points during this process but e-mails are not 100% reliable, so you should always be checking the status of your application in eRA Commons. High volumes around submission deadlines can slow validation/processing times to an hour or more. If your application does not pass the validations, it will be rejected with an “error”. You need time to fix that error and start the submission process all over again. To be on time, your error-free application must be submitted by 5 PM LOCAL TIME on the due date. There is no error correction window that extends the deadline. Applications submitted after the deadline, including those to correct errors, are late and will not be sent forward to review.
Summary

• Talk to the program officer when planning your project
• Know whether your application is a clinical trial or not
• Read the Funding Opportunity Announcement
• Write your application so as to convince the reviewer
• Address every criterion
• Vet your ideas and application. Get friendly criticism.
• Address your weaknesses as a PI/fellowship applicant
Keep in touch

@CSRpeerreview

Review Matters

https://public.csr.nih.gov
Questions?