

Optimize Your Grant Application: News You Can Use From NIH

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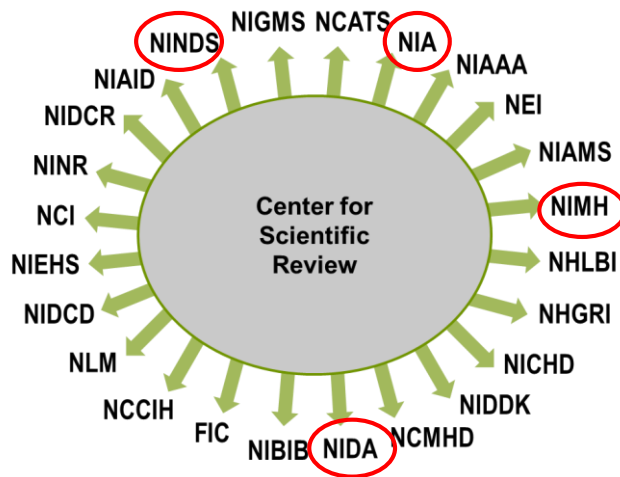
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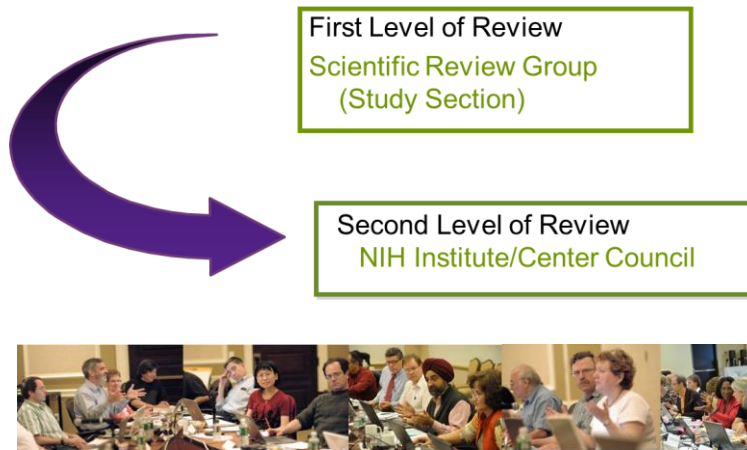
- No disclosures
- Photographs permitted
- Slides available from

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24 NIH Institutes and Centers Fund Grants



NIH Peer Review System for Grant Applications



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 1: Overview Information

All the relevant key dates related to the FOA are found in Part 1: Overview Information.

Section V: Application Review Information

Section V of a FOA details all the review criteria including any special criteria specific to the announcement. The 2nd half of this section identifies the reviewing organization.

Section VII: Agency Contacts

Contact information or instructions on how to locate this information for NIH staff associated with the application can be found in this section

Part 1: Overview Information
This section contains information about the FOA, including the key dates, the review process, and the award process. It also includes information about the funding opportunity, such as the amount of funding, the type of award, and the review process.

Section V: Application Review Information
This section contains information about the review process, including the review criteria, the review process, and the review process. It also includes information about the funding opportunity, such as the amount of funding, the type of award, and the review process.

Section VII: Agency Contacts
This section contains information about the agency contacts, including the name, title, and contact information for the agency staff associated with the application. It also includes information about the funding opportunity, such as the amount of funding, the type of award, and the review process.

Criteria for Judging Research Applications

5 Domains

- **Significance***
- **Investigator(s)**
- **Innovation**
- **Approach***
- **Environment**

Each scored from 1-9

Overall Impact

Assessment of the likelihood for the project to *exert a sustained, powerful influence on the research field(s) involved*

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

NIH Center for Scientific Review

Assisted Referral Tool (ART) Help | Disclaimer

ART Home >> SEP >> Report

Title: RECONSTITUTED HIGH DENSITY LIPOPROTEIN PARTICLES AS SIRNA CARRIERS

multiple diseases, including cancer. However, significant barriers still exist on the road to clinical applications of siRNA drugs, including poor cellular uptake, instability under physiological conditions, off-target effects and possible immunogenicity. The successful application of siRNA for cancer therapy requires the development of clinically suitable, safe and effective drug delivery systems. We are developing a novel therapeutic strategy for this cancer by harnessing the power of the body's natural lipoproteins to deliver siRNA specifically to cancer cells that inhibits tumor growth. These siRNA interfere with processes critical to tumorigenesis and metastasis, and offer the potential to reverse poor survival outcomes. Further, inhibition of this gene results in increased tumor apoptosis, which results in the cessation of metastasis to other tissues. Mice that received siRNA delivered by lipoprotein particles showed significantly reduced tumor growth. These results will be reported by frequency of appearance in the list above. The process is automated and confidential. ART does not track or store submitted text. (Character limit: 1000)

Currently the following SRGs are not yet available in ART: CHSA, CHSB, ARM, and IPTA. Please consider these study sections if your application is in their respective areas.

Rank	IRG	Membership (Click SEP link to see roster)	Name
1	OTC	OTC-B(1), OTC-A(10), OTC-H(3), OTC-A(14), OTC-R(1), OTC-T(9), OTC-T(12), OTC-Y(9)	Oncology 2 - Translational Clinical IRG
2	IMST	IMST(10), IMST(12), IMST(14), IMST(15)	Interdisciplinary Molecular Sciences and Training IRG
3	BST	BST(10)	Bioengineering Sciences and Technologies IRG

<https://art.csr.nih.gov>

Details on all CSR study sections are on the web



Integrated Review Groups

Review activities of the Center for Scientific Review (CSR) are organized into Integrated Review Groups (IRGs). Each IRG represents a cluster of study sections around a general scientific area. Applications generally are assigned first to an IRG, and then to specific study section within that IRG for evaluation of scientific merit.

Chartered Study Sections

Review most investigator-initiated research applications (R01, R01, R13, and K0). Chartered study sections are those with both regular and temporary members.

Small Business Innovation Research and Technology Transfer Research Study Sections

Review special emphasis panels (SEP) review Small Business Innovation Research (SBIR) and Technology Transfer Research applications (TTG). They include only temporary members, recruited based on expertise needed for each meeting.

Fellowship Study Sections

Reviewing special emphasis panels (SEP) review individual fellowship grant applications (F01, F02, F03, F04). Temporary members are recruited based on expertise needed for each meeting.

All Other CSR Study Sections (Special Emphasis Panel)

Other one-time or recurring Special Emphasis Panels (SEP) are held to review applications on special topics and members conduct applications. They include only temporary members, recruited based on expertise needed for each meeting.

<https://public.csr.nih.gov/StudySections>

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.

Use the Assignment Request Form (ARF)

PHS Assignment Request Form (OMB Number: 0925-0047; Expires: 03/31/2016)

Funding Opportunity Number: [Redacted]
Funding Opportunity Title: [Redacted]

Assigning Component: [Redacted] | [Redacted] | [Redacted]

Identify Conflicts: [Redacted] | [Redacted] | [Redacted]

Suggest Expertise: [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted]

<https://public.csr.nih.gov/ForApplicants/SubmissionAndAssignment/RequestScientificReviewGroup>

NIH Center for Scientific Review

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

<https://grants.nih.gov/ct-decision/index.htm>

- ✓ Talk to your program officer



NIH wants to be helpful. It's a complex process. Give yourself time. NIH offers substantial resources to help.

<https://grants.nih.gov/policy/clinical-trials.htm>

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/>

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.nimh.nih.gov/funding/opportunities-announcements/clinical-trials-foas/index.shtml>

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

<https://www.ninds.nih.gov/Current-Research/Research-Funded-NINDS/Clinical-Research>

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

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

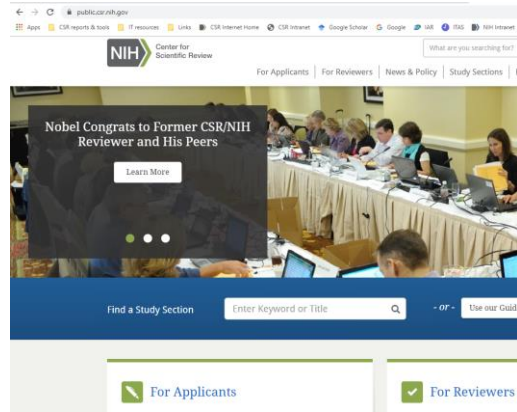


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[Review Matters](#)

<https://public.csr.nih.gov>



Questions?