Strategic Approaches to NIH Funding: Grant Writing For Success

Elizabeth M Saltzman – ODU’s Office of Research
esaltzma@odu.edu Request Grant Proposal Support

National Institutes of Health
Office of Extramural Programs
The National Institutes of Health

THE NATION’S STEWARD OF MEDICAL, BEHAVIORAL, & SOCIAL SCIENCES RESEARCH

NIH Mission:
To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.
27 Institutes & Centers (IC) Strategic Plans for each IC

Each with different:

- Mission & priorities
- Budget
- Funding strategy
The PHS Assignment Request form conveys:

- Awarding component assignment requests
- Study section assignment requests
- Individuals who should not review your application and why – talk to SRO first!
- Expertise needed to review the application

Optional form in all NIH application form packages – **highly recommended**

Assignment requests are **NO** longer allowed in the Cover Letter
PHS Assignment Request Form

Funding Opportunity Number:

Funding Opportunity Title:

Awarding Component Assignment Request (optional)
If you have a preference for an Awarding Component (e.g., NIH Institute/Center) assignment, please use the link below to identify the most appropriate assignment then enter the short abbreviation (e.g., NCI for National Cancer Institute) in "Assign to/Do Not Assign To Awarding Component" sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

Information about Awarding Components can be found here: https://grants.nih.gov/grants/phs_assignment_information.html#AwardingComponents

Assign to Awarding Component:  
1
2
3

Do Not Assign to Awarding Component: 

Study Section Assignment Request (optional)
If you have a preference for a study section assignment, please use the link below to identify the most appropriate study section then enter the short abbreviation for that study section in "Assign to/Do not Assign to Study Section" sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

For example, you would enter "CAMP" if you wish to request assignment to the Cancer Molecular Pathobiology study section or enter "ZRG1 HDM-R" if you wish to request assignment to the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.html#StudySection

Assign to Study Section:  
1
2
3

Only 20 characters allowed

Do Not Assign to Study Section: 

Only 20 characters allowed

List Individuals who should not review your application and why (optional)

Only 1000 characters allowed

Identify Scientific areas of expertise needed to review your application (optional)
Note: Please do not provide names of individuals

Expertise:  

Only 40 characters allowed
Locating IC(s) & Study Section(s) that are Best Fit for Reviewing Your Proposal

April 2018 ODU Presentation – Writing to the Right Reviewer

- Center for Scientific Review study sections
  [http://public.csr.nih.gov/StudySections/Pages/default.aspx](http://public.csr.nih.gov/StudySections/Pages/default.aspx)

- Assisted Referral Tool (ART)
  [https://art.csr.nih.gov/ART/selection.jsp](https://art.csr.nih.gov/ART/selection.jsp)

- Rosters are available on NIH websites
  [https://public.era.nih.gov/pubroster/](https://public.era.nih.gov/pubroster/)

- eRA Like (A Thesaurus-based Search Tool)
  [http://era.nih.gov/services_for_applicants/like_this/likethis.cfm](http://era.nih.gov/services_for_applicants/like_this/likethis.cfm)

- Matchmaker on NIH RePORTER
  [https://projectreporter.nih.gov/reporter.cfm](https://projectreporter.nih.gov/reporter.cfm)
Overview

• Start planning early
• Apply for the right opportunities
• Contact appropriate program staff early
• Talk with potential mentors, collaborators, & peers – seek advice from colleagues
• Present your ideas clearly and pay attention to review criteria
• What to do after review
Pre-submission Planning Timeline

- **Assess yourself, field, & resources**
  - Brainstorm; research idea; call NIH staff
- **PLANNING**
  - 8th month:
    - Set up own review committee; determine human & animal subject requirements
  - 7th month:
    - Outline application structure; write your application
- **WRITING**
  - 6th month:
    - Outline application structure; write your application
  - 5th month:
    - Get feedback; edit & proofread
- **SUBMITTING**
  - 4th month:
    - Meet institutional deadlines
  - 3rd month:
    - Meet institutional deadlines
  - 2nd month:
    - Receipt Date

Office of Extramural Programs
Use NIH Resources for Help
https://grants.nih.gov

GRANTS.nih.gov – your home base for info on NIH grant opportunities, policies, processes
Grants Process Overview - top

Get Started

Learn the Basics
Learn how NIH approaches grant funding and how your research fits into our research portfolio. Make sure to explore the different types of grant programs offered at NIH, along with the eligibility requirements.

Plan Your Approach
Find and understand funding opportunities, ensure your research is original, understand your organization's internal procedures, and prepare to write a competitive application.

Apply for Grant Funding

Prepare to Apply
Ensure all registrations are in place, get familiar with requirements, and choose which of the available submission options you will use.

[> 6-8 Weeks Before Submission]

Write Application
Obtain and complete application forms following provided instructions. Find information on developing your budget and formatting attachments.

Submit
Submit your application to NIH. Track and view your application to verify receipt and to confirm that the assembled document correctly reflects your submission.

[Submit early!]
Grants Process Overview - bottom

Application Referral & Review

Receipt & Referral
Applications compliant with NIH policies are assigned to an NIH Institute or Center and to a scientific review group for evaluation of scientific and technical merit.

[Month 1 After Submission]

Peer Review
Applications undergo a rigorous two-stage review. The first level is carried out primarily by non-federal scientists, while the second is performed by Advisory Councils or Boards.

[Months 2-8 After Submission]

Pre-Award & Award Process

Pre-Award & Award Process
Applicants who have scored well submit “just-in-time” information. Final administrative reviews are conducted and Notice of Award documents are sent to successful applicants.

[Months 7-10 After Submission]

Post-Award Monitoring & Reporting
NIH monitors grants carefully. Active monitoring includes reports and correspondence from the grantee, audit reports, site visits, and other information.

[Duration of Award]
Look for the help link on the top of all Grant and Funding pages

- eRA and Grants Info service desks
- Guidance on finding the right NIH staff contacts
- Central mailboxes for topic specific assistance

general.nih.gov
Overview

• Start planning early
• Apply for the right opportunities
• Contact appropriate program staff early
• Talk with potential mentors, collaborators, & peers – seek advice from colleagues
• Present your ideas clearly and pay attention to review criteria
• What to do after review
Funding Opportunities

- Advertised through
  - Grants.gov
  - NIH Guide for Grants and Contracts
  - NIH Listserv
  - NIH Social Media

- GrantForward
  - Funding opportunity search engine provided for ODU investigators by the Office of Research

- Analyze the FOA
  - What is the goal?
  - Which IC(s) support?
  - Which activity codes are being supported?
  - What is the review process?
  - Has this FOA been competed before?
  - Clinical Trial required, not allowed, optional
  - Expiration date, submission dates, research contact, forms…
# Funding Opportunity Announcements

<table>
<thead>
<tr>
<th>Type of FOA</th>
<th>Description</th>
</tr>
</thead>
</table>
| "Parent" Announcements              | • Allow for “investigator-initiated” applications  
• For specific activity codes (R01, R03, etc.)  
• Many ICs participate (cover all NIH interest areas)  
• Usually ongoing; use standard due dates            |
| **Program Announcements (PA, PAR, PAS)** | **PAS Topics (Notices) of Special Interest (TOSI)**  
• Issued by 1 or more ICs to highlight interest in a scientific topic  
• Usually ongoing and use standard due dates  
• For PA with special receipt, referral, and/or review (PAR) review may be in a specific IC or a CSR special emphasis panel (SEP) |
| Requests for Applications (RFA)      | • Issued by 1 or >1 IC to highlight a specific area of scientific interest and achieve program objectives  
• Uses set-aside funds and usually a single due date  
• IC usually convenes review panel                  |
Research Portfolio Online Reporting Tools (RePORT)

In addition to carrying out its scientific mission, the NIH exemplifies and promotes the highest level of public accountability. To that end, the Research Portfolio Online Reporting Tools provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH supported research.

Attention! Review Accuracy Of Your Institution's FY 2018 Grants Award Data before October 5.
Use *RePORTER (Research Portfolio Online Report Tool (Report) Expenditures and Results) to find:

- NIH supported projects in your scientific area
- Which IC(s) support research like yours
- Which Study Sections review research like yours
- Who to talk to at NIH about your area of research – POs & SROs
- Patents, publications, other research outcomes
- Success rates, award trends
- Grantees in your geographic area, in your scientific area
- And more…

*Matchmaker tool
### Administrative Details

**Project Number:** 5R01DA015446-10  
**Title:** THE OPIOID MESOLIMBIC SYNDROME

**Contact PI / Project Leader Information:**
- **Name:** HURD, YASMIN L  
  - Gender: 🌐  
  - Email: Click to view Contact PI / Project Leader email address  
- **Email:** Click to view PO email address  
- **Title:** PROFESSOR

**Program Official Information:**
- **Name:** PILOTTE, NANCY S  
  - Email: Click to view PO email address

**Organization:**
- **Name:** ICahn School of Medicine at Mount Sinai  
- **City:** New York  
- **Country:** United States

**Other Information:**
- **FOA:** PA-07-226  
- **Study Section:** Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section (NPAS)  
- **Fiscal Year:** 2013  
- **Award Notice Date:** 12-FEB-2013

**Administrating Institutes or Centers:**
- National Institute on Drug Abuse

**Project Funding Information for 2013:**
- **Total Funding:** $455,810

<table>
<thead>
<tr>
<th>Year</th>
<th>Funding IC</th>
<th>FY Total Cost by IC</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>NATIONAL INSTITUTE ON DRUG ABUSE</td>
<td>$455,810</td>
</tr>
</tbody>
</table>
Tool to Find Opportunities by Your Career Stage (near bottom of site)

Opportunities for Career Stage
Preliminary Data

- Completely disregard in any NIH FOA: “Preliminary data not required but may be included if available.”
- Establishes your expertise, mastery of the methodology
- Provides evidence to support your hypotheses
- Shows the strength of your track record & resources
- Best if peer reviewed and published
- Are there potential “showstopper” experiments that could be included to wow the reviewer?
- Consider a collaborator if you’re “weak” in an anticipated area or likely to be unknown to the Study Section(s)
Small Grant Program

- **R03**: Provides limited funding for a short period of time to support a variety of types of projects, including:
  - Pilot or feasibility studies
  - Collection of “additional” preliminary data (for an R01)
  - Secondary analysis of existing data
  - Small, self-contained research projects
  - Development of new technology, etc.
- Limited to two years of funding, and grants are not renewable
- Direct costs generally up to $50K per year
- Some IC provide R03 for their K-awardees
- Not all IC fund
Exploratory/Developmental Research Award

- **R21**: Encourages new, exploratory, and developmental research projects by providing support for the early stages of project development
- Sometimes used for pilot and feasibility studies
- ‘High-risk, high-reward’ studies that have the potential to lead to a breakthrough in the field (usually exploratory & novel)
- Paradigm shifting – fundamental change in basic concepts & experimental practices of a scientific discipline
- Limited to up to two years of funding
- Combined budget for direct costs for the two year project period usually may not exceed $275K. No more than $200K in any one year
- Not all IC participate in this program
- NOT A MINI R01
**Academic Research Enhancement Award (AREA)**

**New guidelines coming out soon**

- **R15**: Supports small-scale research projects conducted by faculty and students at educational institutions that have not been recipients of major NIH research grant funds.

- The goals of the program are to: (a) support meritorious research; (b) *expose students to research*; and (c) strengthen the research environment of the institution.

- The project period is limited to 3 years, and grants are renewable.

- Direct costs are limited to $300K over the entire project period.

- Multiple PIs allowed, if all eligible, whereas Collaborators may be from AREA-ineligible schools.

- Clustered for review, different review emphasis.

- 12 page Research Strategy – include involvement of students & their research opportunities and how institutional research will be strengthened.

- Not all IC fund.
Research Project Grant, R01

- Hypothesis- or Discovery-driven research grant
- Individual or multi-Principal Investigator(s) (PI or MPI)
- Up to 5 years in duration
- Target - 3 Specific Aims
- Substantial preliminary data usually expected. (Preliminary data “not required” for ESI – Ignore & provide preliminary data)
- Budget: up to $250K modular; over $250K categorical
- Research Strategy (12 pages)
  - Significance (~1 – 2 pages)
  - Innovation (~0.5 – 1 page)
  - Approach (~9 – 10 pages for R01) - Preliminary studies, Experimental design, Methodology, Schedule, etc.
- ESI proposals clustered separately for review. “At Risk” Investigator???
Next Generation Researchers Initiative

Are You an Early Stage Investigator (ESI)? An “At-Risk” Investigator?

• Pertains to R01 applications only
• **ESI** – never been awarded a R01 and is within 10 years of terminal degree
• Many NIH grants that a PD/PI can hold and still be considered an ESI
• Does it make a difference? **YES!**
  • In a study section, ESI R01 applications are clustered and reviewed together
  • At the IC level, ESI applications have a preferential extended ‘payline’
• **NEW - “At Risk” Investigator:**
  • Involuntary loss if not funded again
  • Prioritize funding for those about to lose NIH funding
  • Prioritize funding of an additional award for promising investigators currently supported by a single ongoing award
  • Advising IC to take into consideration by looking at current investigator support
Human Subjects Research - Inclusion Across the Lifespan Policy

• Revision to Inclusion of Children Policy; effective for applications submitted for due dates on or after January 25, 2019. See NOT-OD-18-116

• Policy purpose – to ensure distribution of study participants by sex/gender, age, race & ethnicity, reflecting the population needed to accomplish scientific goals of the study

  • Requires individuals of all ages be included in NIH human subjects research unless there are scientific or ethical reasons not to do so

  • Requires submission of individual-level data on participant age at enrollment in progress reports
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.

Helpful resources: [https://grants.nih.gov/policy/clinical-trials/definition.htm](https://grants.nih.gov/policy/clinical-trials/definition.htm)
Is Your Study an NIH-defined Clinical Trial?

Does the study involve human participants?

Are the participants prospectively assigned to an intervention?

Is the study designed to evaluate the effect of the intervention of the participants?

Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If YES to all questions, study is a clinical trial

Answers determine:

- Appropriate FOA type
- Application form requirements
- Review criteria for evaluation
- Requirement for GCP training
- Requirement for registration and results reporting. “Ethical obligation to patients. Failure to report is scientific misconduct which impedes progress toward scientific breakthroughs, corrupts the medical literature & wastes research funding.”

Clinical Trial Interactive Decision Tree: https://grants.nih.gov/ct-decision/index.htm
Temporary Leniency Period for Clinical Trials

• Through September 24, 2019 applications submitted to incorrect FOA will not be administratively rejected

• Applications reviewed based on the review criteria of the FOA to which they are submitted


Additionally…for basic science CT reporting

August 2018 - NIH issued a Request for Information (RFI) seeking input on the standards NIH should use in assuring adequate registration and results information reporting for the subset of studies that meet NIH’s definition of a clinical trial and that focus on basic research. They are referring to these studies as “prospective basic science studies involving human participants.”
Resources for Clinical Trails

- Clinical Trials Requirements website: https://grants.nih.gov/policy/clinical-trials.htm
- Clinical Trial FAQs: https://grants.nih.gov/policy/clinical-trials/faq-list.htm
- Video overview of Human Subjects and Clinical Trials form: https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1
Overview

• Start planning early
• Apply for the right opportunities
• Contact appropriate program staff early
• Talk with potential mentors, collaborators, & peers – seek advice from colleagues
• Present your ideas clearly and pay attention to review criteria
• What to do after review
• A scientist & administrator working in a particular IC
• Manages a scientific research portfolio of grants, contracts, and cooperative agreements
• Develops grant initiatives, identifies needs in scientific areas & communicates program priorities
• Provides scientific guidance to investigators pre- and post-award

When to contact: Prior to application submission and after receiving a Summary Statement through award close out
Connecting with a Program Official Before Submission

• If contacting about a specific FOA - only reach out after you have thoroughly read FOA & app instructions numerous times!

• Email to set up a time to discuss/meet. Provide a thumbnail sketch of what you have in mind

• Ask if the PO is willing to read a brief outline of the proposed project - Project Abstract/Summary or draft of Specific Aims

• Ask whether the research idea fits the Institute’s interests & PO’s program

• Discuss the grant mechanisms that can be used and whether there are any IC priorities for those mechanisms

• Ask about appropriate Study Sections

• Remember that this is advice, not a review, and you have no obligation to follow the advice given however, better to get “criticism” here than in a Summary Statement after review
Scientific Review Officer (SRO)

- Typically works in CSR, but may be within IC
- Reviews applications for completeness and conformance w/app requirements
- Ensures fair and unbiased evaluation of scientific and technical merit
- Point of contact for applicants before submission and during the review process
- Provides a summary of the evaluation, if discussed

When to contact: Prior to application submission and after application submission through release of Summary Statement
Grants Management Specialist/Officer (GMS, GMO)

- Responsible for completion of business management requirements
- Works in a particular IC
- Evaluates applications for administrative content and compliance with policy
- Negotiates awards. Interprets grants administration policies

When to contact: After receiving a potentially fundable score through award close out
### Contacting NIH Staff - Summary

<table>
<thead>
<tr>
<th>When to Contact</th>
<th>PO</th>
<th>SRO</th>
<th>GS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Before Application Submission</strong> to discuss:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Research idea (or specific aims) &amp; fit with IC/priorities (PO)</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• Research idea (or specific aims) &amp; fit with SS priorities (SRO)</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• Grant programs and funding opportunities (PO)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Questions about application and review process (PO &amp; SRO)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>After Submission/Before Peer Review</strong> to discuss:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Review assignment or concerns (e.g., panel expertise)</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>• Request to send additional/corrective materials</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td><strong>After Peer Review</strong> to discuss:</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• Summary statement and response to reviewer critiques</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Potential for application resubmission</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>At any point</strong> to discuss:</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>• Budget questions/administrative issues about award</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Interpretation of grants policies</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

PO=Program Officer; SRO=Scientific Review Officer; GS=Grants Specialist
Overview

• Start planning early
• Apply for the right opportunities
• Contact appropriate program staff early
• Talk with potential mentors, collaborators, & peers – seek advice from colleagues
• Present your ideas clearly and pay attention to review criteria
• What to do after review
Find Collaborators for Your Application

• Determine the expertise needed to strengthen your research study team and fill gaps in your own expertise

• Begin to assemble the research study team early and obtain letters of commitment from them

• Determine if collaborative preliminary studies would enhance application

  ✓ Collaborate with others in your department, college, university
  ✓ Network at meetings
  ✓ Stay connected to past colleagues and mentors
  ✓ Cultivate a strong network that understands the funding process
Application “Reviewers”

- Show your Specific Aims, Project Summary, Research Strategy, and/or draft of complete application to:
  - Your collaborators
  - A colleague that does not know what you intend to do
  - Scientists who have been successfully funded
  - Someone who is not your best friend

- Reviewers must understand:
  - What you intend to do
  - Why you believe it is important to do
  - Exactly how you’re going to do it

If they don’t get it, you must revise your application!
Overview

• Start planning early
• Apply for the right opportunities
• Contact appropriate program staff early
• Talk with potential mentors, collaborators, & peers – seek advice from colleagues
• Present your ideas clearly and pay attention to review criteria
• What to do after review
What Reviewers Look for in an Application

A clean, well-written, easy to follow application that responds clearly & explicitly to the FOA, program guidelines, and review criteria

- Significance and potential impact
- A strong persuasive premise leading to exciting ideas
- Clarity of the project’s rationales and goals
- Realistic aims and timelines
- Rigorous experimental approaches
- Discussion of limitations of the study w/ reasonable alternatives

Reviewers continuously scan application for clear answers to:

- What are we going to learn as the result of the proposed project that we don’t know now?
- Why is it worth knowing?
- How will we know the conclusions are valid?
Will You be in Trouble if the Study:

Is discovery-driven (hypothesis generating)? No, but you need to:

• Describe the rationale for the aim and how it will provide the foundation to follow up with more mechanistic questions
• Have a defined plan for prioritizing large amounts of data

Uses a model system? No, but you need to:

• Place the work in context as to how it will propel the field forward
• Emphasize its significance

Not immediately translational? No,

• But if you discuss the potential translatability of a study it becomes fair game for reviewers to disagree
Your Hypothesis is the Basis for a Strong Application

• Make sure that the hypothesis thematically unifies the Abstract, Specific Aims, and the Research Strategy
• Must be solidly based on current information
• Must convey the significance of the project
• Should be clear

• **Not so good:** “We hypothesize that Chronic Kidney Disease causes cardiovascular disease and early mortality”
• **Better:** “We predict that individuals with CKD are more susceptible to the development of atherosclerosis due to uremic solutes directly activating macrophages and promoting inflammation-induced plaque deposition”
Project Narrative (Public Health Relevance Statement)

- Brief statement explaining relevance to human health
- Three sentences
- Should be understandable to a lay audience
- Used by NIH for communication with public, Congress and for portfolio analysis
Project Summary/Abstract
Sell the Big Picture!

• Write this first, last, and along the way – **important**!
• Should be understandable to others beyond your field
• No more than 30 lines of text
• Include
  • Brief background of project
  • Specific aims and hypotheses
  • Innovative aspects of the project
  • Overview of approach
  • Expected results
  • How results will affect other research areas
Specific Aims Page

• Also, write this section first, last, and along the way – important!

• Engage the enthusiasm of the reviewer. This one page should grab the reviewer immediately and entice them to keep reading

• A roadmap for your application

• Use “Action” words - “Determine, Characterize, Identify”

• Begin with an overall section
  • In general – What’s the problem? Why is it important? Give critical details about what is known
  • Include key supporting data
  • State the hypothesis
  • State long-term objectives and expected impact

• Organize the aims in a sequential, numeric format

• Do not spend time/space telling reviewers how you will do the aim, Rather Tell reviewers what the results will mean!
The Anatomy of a Specific Aims Page

Introductory paragraph
• What is the research area?
• What is known?
• What is the gap in knowledge?
• What is the critical need?

Second paragraph
• What is the solution?
• What is the long-term goal and potential impact?

Aims (Make knowledge-focused here, not process-focused)
• What will you do to test the hypothesis?
• What are the expected outcomes?
• Aims absolutely cannot be dependent on each other

Final paragraph
• Return to impact/payoff
### Align Your Application With the Review Criteria

<table>
<thead>
<tr>
<th>Category*</th>
<th>Criteria (Research)</th>
<th>Criterion Scores?</th>
<th>Affect Overall Impact Score?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scored Review Criteria</td>
<td>Significance Investigators Innovation Approach Environment</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Review Criteria</td>
<td>Study Timeline (CT only) Human Subjects** Vertebrate Animals** Inclusion** Biohazards</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Review Considerations</td>
<td>Foreign Institutions Select Agents Resource Sharing Authentication of Key Resources</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

* Found in every Funding Opportunity Announcement  
** If Unacceptable, award cannot be issued until resolved
What is the Overall Impact of an Application?

**Overall Impact for Research Grant Applications** - Assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved

**Likelihood** (i.e., probability) is primarily derived from the investigator(s), approach, and environment criteria

**Sustained, powerful influence** is primarily derived from the significance and innovation criteria

Two questions drive reviewer determination about the likelihood that the proposed studies will have a strong and sustained impact on the scientific field:

- **Should they do it?**
- **Can they do it?**
Significance
Core Review Criterion #1
Should they do it?

• Why is this research important?
• If the aims are achieved, how will scientific knowledge be advanced?
• What will be the effect on concepts or methods that drive this field?
So:
• Show your understanding of the overall field
• Demonstrate that your questions are novel and important and represent a logical next step in research
• Do not write a review article; instead highlight critical gaps that will be addressed by the proposed research: What holes will it fill? What opportunities will it take advantage of? What roadblocks will it overcome?
• Graphics can be very helpful
Significance (cont.)

Scientific premise has been added to the stated review criteria

- **Premise** – defined as ‘the research that is used to form the basis for the proposed research question(s)’
- Consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of the application
- Distinct from hypothesis
- Assessed as part of the Significance criterion
Innovation
Core Review Criterion #3
Should they do it?

• How is what you’re proposing different from what others in the field are doing?

• Have data to support the innovative approach. If preliminary data contains novel or surprising results highlight them here

• Track record – indicate if your research has a past history of being innovative

• Show that proposed research is new and unique

• Either:
  o Show how the proposed research would refine, improve, or propose a new application of an existing concept, method, instrumentation, intervention

  OR

  o Show how the research would challenge/shift a current paradigm

Make a very strong case for challenging the existing paradigm
Preliminary Studies

- If you are applying, include preliminary studies
- Your preliminary studies show availability of key resources, familiarity with the proposed methods, and approach to interpreting results (rigor & reproducibility)
- Tie preliminary data to the big picture – show how this leads your mind to the next step
- If the data are pertinent to only one Aim, include it in this Aim. If the data are generally relevant, include a section at the beginning of Approach before describing individual aims
Approach (cont.)

In General

• Does your plan flow logically from the literature review and prior studies?
• How will each hypothesis be tested?
• Do your measures capture the variables needed to test hypotheses?
• Why did you choose those measures?
• Methods and analyses must match
• Perform critical experiments – convince the reviewer that what you propose is a critical experiment – give reviewer confidence in you
• Consider organizing each aim the same way, including the:
  o Rationale
  o Experimental approach
  o Anticipated results
  o Alternative approaches/pitfalls
Approach (cont.)

Rigor & Transparency Requirement

• Discuss strengths and weaknesses of prior research (including preliminary data) cited to support the **premise**

• Ensure **scientific rigor** with robust and unbiased scientific design and by fully reporting scientific details of experiments so others can reproduce your experiments

• Consider **relevant biological variables**, including sex, age, weight, etc. Sex should be factored into research design unless there is a strong justification for including only one sex

• **Authenticate** key biological and/or chemical **resources** (e.g., cell lines, antibodies, specialty chemicals) – new attachment

• All of above incorporated into **review criteria**

• Details [here](#) and [here](#)
Clinical Studies

• For clinical studies, be explicit and thorough in discussing
  • Intervention or system to be studied
  • Target population
  • Inclusion and exclusion criteria
  • Independent and dependent variables
  • All measures and instruments
  • Power analyses
Investigator

Core Review Criterion #2

Can they do it?

- Are the investigators appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to the experience level of the PI and other researchers?
- Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Tip: use the Biosketch to explain your major contributions or any mitigating circumstances that ‘slowed’ your progress.
Environment
Core Review Criterion #5
Can they do it?

- Does the scientific environment in which the work will be done contribute to the probability of success?
- Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
- Is there evidence of institutional support?
Biosketch

Make it personal

• Only opportunity to tell the reviewers about you, your career, and expertise
• Seek advice and examples from peers and senior colleagues about what a biosketch looks like

Help the reviewers!

• Demonstrate that you are the most qualified investigator to do the work
• Reviewers instructed that publication track record for early career investigators will not match more senior investigators
• Favor clarity over detail and jargon

Opportunity to cite interim research products

Provide a URL to publications via a federal (.gov) website
Hallmarks of an Outstanding Grant Application

- Strong significance for an important problem in public health: IMPACT is high
- High degree of novelty and innovation
- Strong track record of a well qualified applicant with compelling publications
- Clear rationale & focus
- Relevant and supportive preliminary data
- Clear and focused approach that provides unambiguous results
- Careful attention to details
  - Spelling, punctuation, grammar, fonts, clarity of data, error bars, spelling, etc.
Overview

• Start planning early
• Apply for the right opportunities
• Contact appropriate program staff early
• Talk with potential mentors, collaborators, & peers – seek advice from colleagues
• Present your ideas clearly and pay attention to review criteria
• What to do after review
Applications in the bottom half of pre-discussion average scores are not discussed: ND (++)

All discussed applications receive a priority/impact score (PS)

PS = the average of all final scores, multiplied by 10

Most priority/impact scores are ranked by converting them to a percentile
Scoring

Overall Impact:
The likelihood that a project will have a **sustained and powerful** influence on science (and/or clinical practice and/or technological developments?)

<table>
<thead>
<tr>
<th>Overall Impact</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
</tbody>
</table>

- e.g. Applications are addressing a problem of **high** importance in the field. May have some or no technical weaknesses.
- e.g. Applications may be addressing a problem of **high** importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
- e.g. Applications may be addressing a problem of **medium** importance in the field, with some or no technical weaknesses.
- e.g. Applications may be addressing a problem of **low** or **no** importance in the field, with some or no technical weaknesses.

**Evaluating Overall Impact:**
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer’s judgment)

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.
After the Review

• Read the summary statement (don’t take it personally!)
• Reread the summary statement
• Contact your program officer and be prepared to discuss:
  o What the reviewers said about your application (after you have the summary statement)
  o Scores and percentiles
  o The likelihood of funding
  o The prospects of a revised application
• Wait for the AWARD, or
• Listen to advice from Program Officer about options
Revising and Resubmitting

• Write a clear introduction section
• Address all criticisms thoroughly
• Respond constructively
• Don’t be argumentative!
• Don’t be abrasive or sarcastic!
• Don’t start cover page with, “I thank the reviewers for their helpful & insightful comments…”
• Resubmission is an opportunity to improve the entire application
Download Episodes  

So You Wanna...

Prepare a Successful Grant Application?

- Telling Your Story
- Composing Your Cover Letter
- Navigating a Funding Opportunity Announcement
- Deciphering Funding Opportunity Alphabet Soup
- Due Dates, Cycles and Award Dates Oh My!
- Getting Ready to Submit (November

Understand How Your Grant is Reviewed?

- Thinking About Resubmitting
- Summary Statement Basics
- Scoring Your Application
- The Ins and Outs of a Study Section Meeting
Videos on wide range of grants policies, processes and systems
Finding the Right Staff Contacts

• **FOAs** include contact names for program, review and grants management staff.

• **Institute websites** have org charts or contact lists so to help you find a name. [www.nih.gov](http://www.nih.gov)

• **RePORTER** provides the NIH program official’s name for funded projects, funding IC and the FOA. [projectreporter.nih.gov](http://projectreporter.nih.gov)

• Use the **NIH Staff Directory** if you already have a name [ned.nih.gov](http://ned.nih.gov)

• If in doubt, use the help link on grants.nih.gov for guidance.
Additional Resources

- Office of Extramural Research Peer Review Process
  http://grants.nih.gov/grants/peer_review_process.htm

- Peer Review Policies & Practices
  http://grants.nih.gov/grants/peer/peer.htm

- Center for Scientific Review
  http://public.csr.nih.gov/Pages/default.aspx

- NIH Guide to Grants and Contracts
Additional Resources (cont.)

• NIAID Example applications
• NIH Grant Writing Advice and Sample applications
• Scoring System and Procedure
• Critique Template Instructions
• Helpful Discussion: Paylines vs Success Rates
• Extramural Nexus