How the NIH Works: Including Tips and Strategies for Having Effective and Valuable Interactions with Program Officers

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Outline

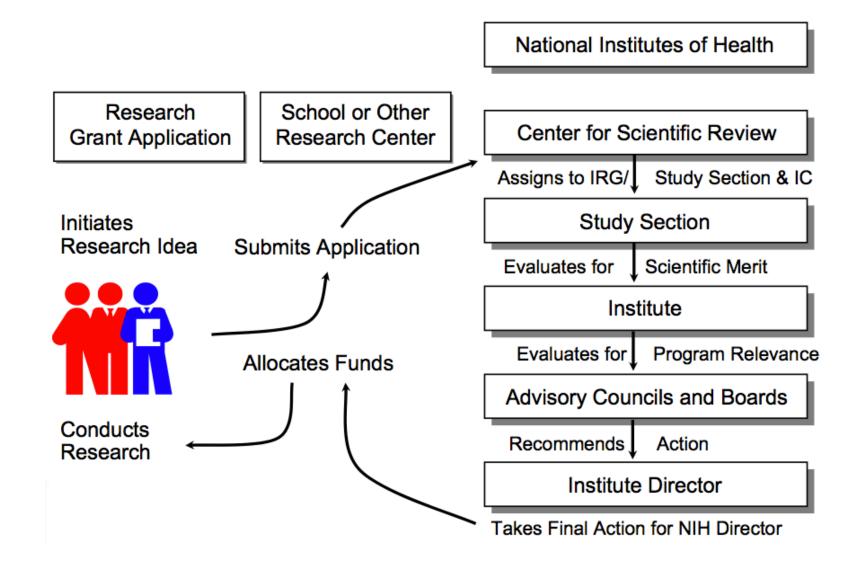
What happens after my application arrives at NIH?

Who is your NIH Extramural Team?

When and why should you contact a Program Officer?

What if I miss the payline...options?

Review Process for an Application



NIH Dual Level Review System

Review System for Grants

Scientific Review Group (SRG)

- Independent outside review managed by NIH
- Evaluate scientific merit, significance, other criteria
- · Provides priority score
- · Recommend length and level of funding

1st level

Output: Impact Score and Summary Statement

3 - 7 months

Advisory Council

- Assess quality of SRG process
- Offers recommendation to Institute/Center Director and staff
- Evaluates program priorities and relevance
- Advises on policy

Output: Funding Recommendations

1 - 3 months

Institute/Center Director

- Makes final decision based on Council input, programmatic priorities
- · Must also pass administrative review

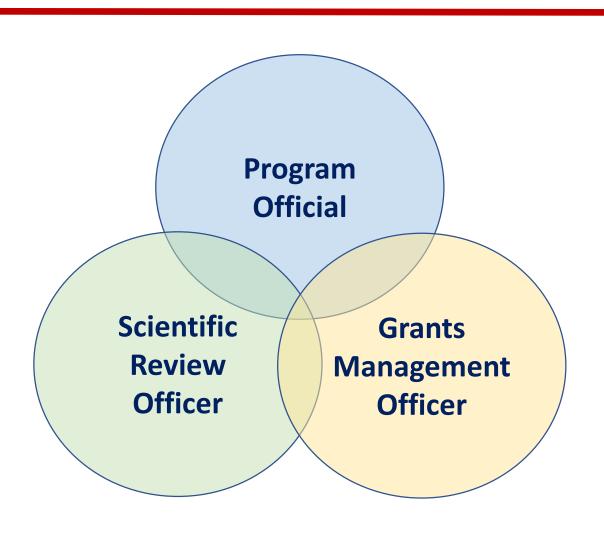
Output: Awards or Resubmission





2nd level

NIH Extramural Team



Program Official

- Responsible for the programmatic, scientific, and/or technical aspects of a grant
- Provides scientific guidance to investigators pre- and postaward
- Develops initiatives
- Provides post-award oversight

Scientific Review Officer

- Responsible for scientific and technical review
 - Ensures fair and unbiased evaluation of scientific and technical merit
 - Provides a summary of the evaluation
 - Reviews applications for completeness and conformance with application requirements
- Point of contact for applicants during the review process

Grants Management Officer

Responsible for completion of business management requirements

- Evaluates applications for administrative content and compliance with policy
- Interprets grants administration policies
- Answer questions about your budget or other support
- Clarify issues related to the terms and conditions of your Notice of Award
- Reviews any action related to NIAID's prior approval

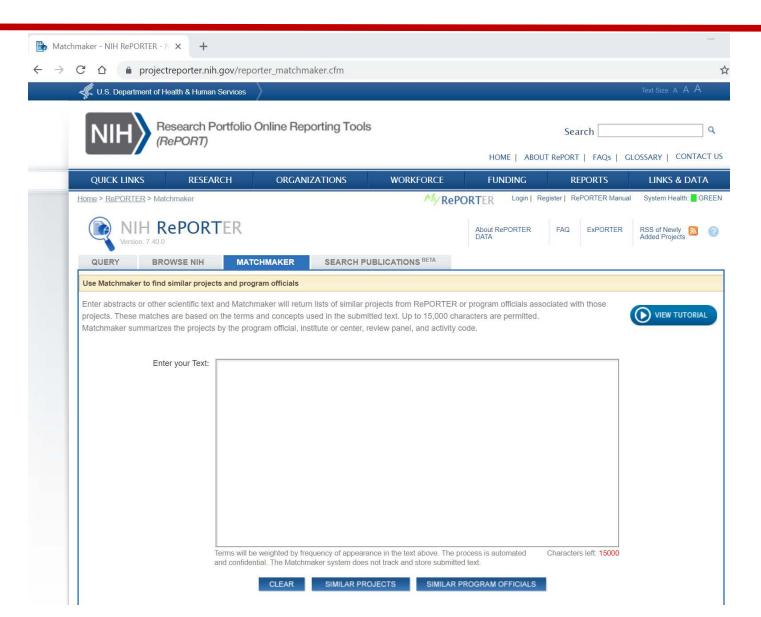
Who to Contact When?

Application in Contact SRO for any review **Contact YOUR GRANTS** related issues such as changing **OFFICE**, or grant.gov, or Pre-Submission IRG, sending in supplements, NIH eRA Help for issues indicating conflicts etc. related to submission. Contact PD/PO for IC scientific mission Peer Review relevance of your research, and advice on Contact PD/PO for grant mechanism, IRG revision and funding. Post-Review selection and/or revision; and GMS for budget related issues. Once funded, contact PD/PO for scientific relevant issues and GMS for process and/or policy issues.

Roles of Program Officers

"To administer NIAID's scientific programs, oversee grant portfolios, set priorities for committing federal funds, and act as an advocate for a scientific area."

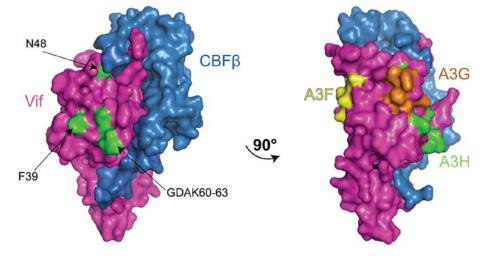
How Do I Find a Program Officer?

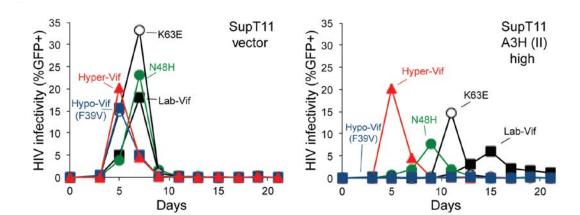


Roles of Program Officers: Scientist

The prime responsibility of the Program Officer is to monitor and understand a particular scientific area

- Provide scientific expertise to NIAID and other NIH components and federal agencies
- Read and review current literature
- Identify knowledge gaps
- Attend scientific meetings
- Interact with the grantee community to assess research needs and opportunities





Roles of Program Officers: *Portfolio Manager*

As a federal official, POs ensure that research supported by federal funds meet scientific program requirements, including compliance with laws and regulations

- Advise on funding opportunities and requirements for applications
- Monitor scientific progress in NIAID-funded grants and cooperative agreements
- Oversee clinical trials and production of scientific resources
- Manage the scientific and technical aspects of NIAID-funded cooperative agreements and contracts
- Provide input on priorities for committing federal funds that support research and resource programs

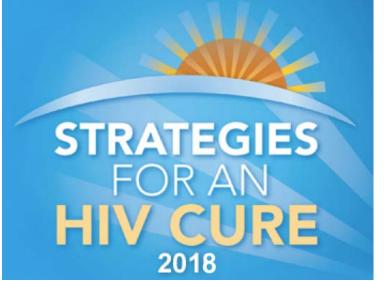


Roles of Program Officers: Advocate

Serve as a resource and advocate for research

- Develop scientific and technical research agendas that address gaps in domestic and foreign public health needs
- Monitor and integrate scientific findings for the government's benefit
- Produce scientific papers and reports
- Move science forward:
 - Organize workshops and symposia
 - Develop research initiatives





"Why should I contact a Program Officer?"



Applications Submitted to the NIH

 Over 80,000 grant applications are submitted each year to the NIH

 Competing grant applications are received for three cycles per year



When to Contact a Program Officer

Pre-submission

- Discuss potential application topics, scientific directions
- Ask about funding opportunity announcements (FOAs)
- Ask about investigator-initiated research
- Strategize application submission timing
- Help you decide which grant type is appropriate for you
- Find out about requesting an assignment to a specific study section or Institute
- Advice on preparing an application



If you are submitting an application requesting \$500K or more in direct costs for any year, you must contact a PO.

When to Contact a Program Officer

Post submission

- Questions about your summary statement:
 - If you see a problematic code on your summary statement
 - To get insights into the discussion of your application at the peer review meeting
- Find out the latest funding status for your application
- Discuss re-submission strategies and alternate options



"OK, So How Can I Get a Grant?"

Where to Start

Researching the best fit for you is critical

Some things to consider:

- To which grants are you eligible to apply?
- What is the potential impact of your research to the field?
- How novel is your idea?
- How much preliminary data do you have?
- Is this something that the NIH is looking to fund (solicited vs. unsolicited)?
- What is the best grant mechanism for your situation?
- Is it best to apply as a principal investigator, co-investigator or collaborator?

Helpful Pointers for Preparing Your Application

- Don't work in a vacuum actively seek out advice from senior faculty
- Allow sufficient time for honest feedback on draft proposal from colleagues/peers
- Seek collaborators/consultants to strengthen your proposal
- Letters of collaboration should clearly state what the collaborators/consultants have to offer
- Follow instructions!
- Be concise and clear clearly label tables, figures
- Reviewers' have zero tolerance for typos and bad grammar

Specific Aims

- The most critical page in the application
- It is a one page summary of the application
 - Why is this problem significant?
 - What is the exciting preliminary data?
 - What are the hypotheses supported by the data?
 - How will this project significantly impact the field?
 - Make sure to emphasize important points that you absolutely want the review to know
 - Make them want to keep reading
- Simple list of your Aims is good
 - Be concise
 - Avoid laundry list of things you are going to do

Common Pitfalls for Young Investigators

- Proposed project is not novel or innovative
- Even if project is successful will have questionable impact to the field
- Failure to convince reviewers of scientific rational for proposed studies
- Research is mainly descriptive or correlative –'looking at' bad, testing good
- Lack of clear, testable hypothesis 'fishing expedition'
- Inadequate preliminary data to support a large investment
- Unfocused research plan
- Lack of experience in the proposed methodology
- Insufficient publication record
- Uncertainty concerning the future directions
- Failure to consider potential pitfalls/alternative approaches
- Unrealistically large amount of work (overambitious)
- Lack of statistical considerations

Other Common Problems with a Weak First Submission

- Significance of problem not obvious or low
- Approach flawed; feasibility unsupported
- Poor writing
- Deficient environment (not independent; lacking institutional support)
- Inappropriate grant mechanism; poor match for FOA

Summary: Hallmarks of an Outstanding Grant Application

- Strong significance to an important problem in public health:
 IMPACT is high
 - High degree of novelty and innovation
- Strong track record by a well qualified applicant and collaborators
- Clear rationale
- Relevant and supportive preliminary data
- Clear and focused approach likely to provide unambiguous results
- Careful attention to details
 - Presentation, readability, clarity of data, graphics, error bars, spelling, etc.

How NIAID Makes Funding Decisions

- Institutes use different policies and paylines to fund grant applications
- NIAID mostly funds by scientific merit as judged by peer reviewers and reflected in the overall impact score, or percentile for investigator-initiated R01s.
- If an application is assigned to a different institute, talk to the PO there to learn what to expect.
- NIAID has two ways of making funding decisions based on opportunity type:
 - Applications for <u>Unsolicited, Investigator-Initiated Research</u> are funded using a percentile or score-based cutoff point, called a payline.
 - Applications for <u>Solicited</u>, <u>NIAID-Requested Research</u> are funded based mostly on overall impact score order based on available set aside funds and depending on the score.

Funding Decisions

Investigator-initiated applications are funded by payline.

- Each major activity code, e.g., R01, has its own payline.
- Paylines are posted online at <u>NIAID Paylines</u>.
- Some applications are funded beyond the payline at the end of the fiscal year and through special funding programs.
- At NIAID, all applications that rank under the payline bar are funded.

RFAs and PAs with set-asides are funded in score order.

- For RFAs and some PAs (called PAS—"S" is for set-aside), applications are funded mostly by overall impact score until we use up the funds—("mostly" because sometimes we may skip to fund others that better meet a priority or need)
- The amount set aside is stated in the initiative's NIH Guide announcement.



Not Funded! Now What?

What if I don't get a grant on the first attempt?

- Carefully read the summary statement.
 - Can you readily fix reviewer's concerns?
 - Can you clarify things that reviewers misunderstood?
 - Did reviewers have conceptual problems that you can address?
- Consult experienced colleagues/mentors.
- Evaluate your options
 - Revise and submit again?
 - Choose a new research direction?

What if I don't get a grant on the first attempt?

- Modify your application based on review (don't rush!).
- Address all major weaknesses, especially those in the summary of discussion and overall impact paragraphs.
- Submit the modified resubmitted (A1) application for review.
- If the A1 application is not considered for funding, the next submission will be considered a new application (A0).
- DO NOT refer to reviewers' critiques in a new (A0) application.

What if I'm not selected for funding?

- Talk to your Program Officer
 - Are there options for special funding?
- Ask the PO about
 - Reviewer support for your idea
 - Additional insight from the review
 - Any issues with the presentation
- Hard to fix problems when to go in a new direction
 - Low-impact research topic
 - Philosophical issues (e.g., reviewers do not think the work is highly significant)
 - Hypothesis is not sound or not supported by the data
 - Work has already been done
 - Methods proposed were not suitable for testing the hypothesis

Don't give up!



- Initial failure is <u>common</u>
- Learn from a failed submission and succeed
 - Keep a positive tone and attitude
 - Introspection is important be willing to critically question your research and future directions

Factors Affecting Grant Award Timing

- Time from application to award can vary by as much as a year.
- Major factors influencing grant award timing:
 - Whether we have a congressional appropriation. If your application goes to September or October Council, it will be funded in the next fiscal year, which may delay funding. You can check the budget status at <u>Paylines and Funding</u>.
 - Whether you are in the funding "gray zone." Many high-quality applications that scored somewhat above the payline are deferred for a funding decision until later in the fiscal year.
 - Whether your application undergoes expedited Council review. About eight weeks before each Council meeting, a subset of members performs an electronic expedited review for qualifying applications. Read more at Second-Level Review: Advisory Council.
 - Whether we need foreign clearance for your application. Contact your program officer for help.
 - Whether the grant type is complex. Contact your grants management specialist for help.

Not Funded Right Away? Take Action

- If you did not get an award right after Council, we will put your application on hold for possible funding at the end of the fiscal year, if it ranks not too far from the payline. We call this the "gray zone."
- If your application is deferred for a funding decision, we strongly advise that you start revising right away. Determine if problems are fixable and see your next steps at Options if Your Application Isn't Funded.
- NIAID typically defers decisions for such applications until June or July, after we know the results of the third review cycle. For more detail on this, see Funding ls Tied to the Fiscal Year.
- Starting in mid to late summer, we fund as many remaining applications as our budget for research project grants allows.

If Funding is Likely

- Resolve concerns
 - Human subjects protections, vertebrate animal protections, inclusion of women, minorities, and children
- Prepare Just-in-Time requirements

What are my options if I miss the NIAID payline?

- If NIAID doesn't fund my application, might another NIH Institute fund it?
 - > Ask your PO to identify another Institute that might be interested in your project.
 - ➤ Paylines vary among NIH ICs, so a percentile that is not fundable in one Institute may be fundable in another.
- If my application misses the payline, can I get funded through selective pay?
 - ➤ Possibly. POs nominate applications that score above the payline for selective pay funding. Our advisory Council then ranks those nominations in priority order.
- If I score outside the payline, should I resubmit or wait?
 - ➤ Advise you not to wait to see if you are funded later in the fiscal year. It's better to get a head start either improving your application based on the feedback from the review or submitting a new application.

Resources

- For NIAID, find a PO listed by extramural program division:
 - Division of Acquired Immunodeficiency Syndrome (DAIDS)
 - Division of Allergy, Immunology, and Transplantation (DAIT)
 - Division of Microbiology and Infectious Diseases (DMID)
- To find program officers across NIH, use NIH's Matchmaker tool.
- If you already have a FOA in mind, contact the Scientific/Research Contact listed.
- After you apply, find your assigned PO in the <u>eRA Commons</u>.
- After award, contact the PO listed on your Notice of Award.

Resources

- https://www.niaid.nih.gov/grants-contracts/apply-grant (All about grants tutorial)
- <u>http://grants.nih.gov/grants/funding/submissionschedule.htm#review</u> (standard receipt dates)
- https://www.niaid.nih.gov/grants-contracts/niaid-paylines
 (Paylines)
- https://www.niaid.nih.gov/grants-contracts/new-investigators
 (Early stage investigators)

Questions?

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