

INFORMATION FOR NIH GRANT APPLICANTS

Basics

Types of grant programs (“funding mechanisms”) – details at http://grants.nih.gov/grants/funding/funding_program.htm

Research Project Grants

R01 - primary mechanism for investigator-initiated projects; up to 5 years + renewable; no specific funding cap

R21 – investigator-initiated exploratory/developmental projects; ≤\$275k / 2 years; nonrenewable; prep for R01

R03 – investigator-initiated SMALL grants: \$50k/yr for 2 years; not renewable

U01 – cooperative agreement research projects – NIH staff have “substantial involvement” in research effort

Career Development Awards (K’s): K01, K02, K05 (NCI only), K07, K08, K22, K23, K24, K25, K99/R00

K99/R00 – Pathway to Independence award (post-doc...tenure-track)

Training and Fellowship Awards (T’s and F’s): T32 (institutions); F30, F31, F32, F33 (individual pre- and post-doc)

Program Project/Center Grants (P’s): P01, P20, P30, P50, P60

SBIR/STTR – R41, R42, R43, R44; small business awards for development and commercialization

R13 – conference grants; **R15** - small research projects for institutions that have never been funded by NIH

Roles

Grantee – generally the university or other institution that legally receives the grant and employs the principal investigator

Principal Investigator(s) (PI or MPIs) – researcher(s) responsible for proposing, managing, and carrying out the project

Co-investigators, subcontractors, consultants – members of the research project team engaged by the PI(s)

Institutes and Centers (ICs) – the 27 components of NIH with grant-making authority. Each has its own budget.

Program officer (PO) – NIH staff member responsible for scientific oversight of your project; advises & serves as agent

Grants specialist (GS) – NIH staff member responsible for administrative and financial oversight of your project

Scientific review officer (SRO) - NIH staff member responsible for administering peer review of applications

IRG / study section / review committee – group of extramural researchers who review (all) and score (the top 40-50% of) grant applications. May be organized at the NIH level under the Center for Scientific Review or by the IC

National Advisory Council – conducts second-level review of applications and advises ICs. Each IC has one.

IC Director – makes final funding decisions

Process – much more info at http://grants.nih.gov/grants/grants_process.htm and linked pages

Application submission deadlines: 3x/year (specific dates vary by grant mechanism). Most require electronic submission.

Each grant mechanism has its own rules and requirements in terms of time limits, funding limits, page limits.

Each grant application must identify the “Funding Opportunity Announcement” (FOA) to which it responds – there are generic (“parent”) FOAs for each funding mechanism as well as FOAs with specific programmatic focus.

- FOA types: **Program Announcements (PAs)** describe areas of interest for which applications are encouraged, but no specific funds are dedicated. (PARs are PAs with special review considerations. PASs are PAs with designated funding set-asides.) **Requests for Applications (RFAs)** describe project areas for which specified funds have been set aside; each RFA generally has only a single receipt date and a designated review committee.

Accepted applications receive assignments to a primary IC, a PO, a GS, and a review group with SRO.

Criteria for review: *Significance*; Investigator(s); Innovation; Approach; Environment. Some FOAs have modified or additional review criteria. Other considerations include Human Subjects protections, inclusions for gender/minority/children. Budget issues are always considered separately from scientific merit.

Applications referred to IRG/study section. All applications receive written critique by 2-4 reviewers that include these reviewers’ scores for the individual review criteria. Approximately half (or more) of applications are Not Discussed (aka “streamlined” or “triaged”); these do not receive an Impact/Priority score and are not eligible for funding.

Impact/Priority Score – the final score assigned by the IRG/study section. Not an average or any other specific function of the criterion scores; reflects votes of all IRG members, generally within the range of scores set by the primary, secondary, and tertiary reviewers. Impact/Priority scores range from 10 (best) - 90 (worst). R01s also receive **percentile scores** (1-99) that adjust for variation in scoring across study sections.

Scored applications (most mechanisms) are presented to Council for concurrence or non-concurrence with the IRG.

Funding decisions are made by ICs; procedures vary. Review score, program relevance, budget are key considerations.

Unfunded applications (including Not Discussed) can be resubmitted with a response to the previous critique or revised and submitted as a new application, even if the new application proposes essentially the same idea.

General advice

Identify an *important research question* that you have the skills and knowledge to answer. Take stock of the resources that you will need to thoroughly investigate and address the question, including time, funds, access to data or subject populations, expert consultants and collaborators, computing resources, training. Explore availability of all critical elements and assess feasibility of project success with the resources you will have (may entail preliminary analyses).

Seek the advice of a PO in one of the ICs that might be interested in funding your project. Send email with a one-page summary of your proposed project, including a statement of Specific Aims. Set up a conversation with the PO to discuss:

- Would the IC be interested in funding a project in this area? • Are there other ICs that might be interested?
- What is the appropriate funding mechanism for this project? • When are applications due?
- What FOA is most appropriate for the project? • Which study section is most suitable to review this?

Developing an Application

Consult the FOA for application requirements for the funding mechanism you will use. Read the FOA carefully! Pay close attention to dates and any special instructions, guidance, review considerations, etc. that apply to that FOA. Consult the Application Guide linked near the beginning of the FOA. Applications must be submitted electronically. Use current versions of all forms. Adhere to page limits. Strict limitations apply to allowable Appendix materials; violations will cause applications to be withdrawn without review. Work with your Office of Sponsored Programs beginning well in advance. Remember that NIH seeks to fund top-quality science. This means that your project should address the full range of technical and scientific issues that need to be confronted to answer the scientific question you pose. It also means that you should enlist expert collaborators or consultants to guide any aspects of the project for which you are not the expert. Application page limits are quite constraining – be direct in providing reviewers with the information that they need to assess how well your application meets the review criteria (Significance; Approach; Innovation; Investigator; Environment). The key objective is to convince reviewers that your proposal represents an important scientific project that *needs to be done*, that *your approach will accomplish the Aims*, and that *you and your research team* are well-prepared to succeed. Provide details that reviewers need in each section of the application. Begin with a clear statement of

Specific Aims – identify the main research question with a concise explanation of why it is important. Provide ~2-4 *specific* questions that you will answer for this project and identify the main elements of the approach that you will use to answer them. There is an art to this – be specific, but not too narrow and not too broad. The Specific Aims are the central defining element of the *scope* of your project. Once awarded, the scope can only be changed by NIH approval of a formal request submitted by your institution. Avoid jargon and highly discipline-specific details of the approach in the Specific Aims – focus on the research questions to be answered and the general strategy for answering them.

Background & significance – Make a strong, clear case for the scientific and public health importance of the project – don't leave it for reviewers to infer significance. Describe the *scientific premise* for your project, considering the strengths and weaknesses of published research or preliminary data that support your application. Describe how your project extends the extant scientific literature, potentially including literature from outside of your discipline.

Preliminary studies – Describe work that you and members of your team have done that supports the research you propose for this project. Include preliminary analyses, studies involving the same or similar data, similar methods, similar health areas, whatever shows you already have done work that provides the foundation to carry out this project successfully. Note that R03s, R15s, and R21s do not *require* preliminary studies, but they are nonetheless helpful, and reviewers may be skeptical of proposals that do not include them. For New/Early Stage Investigator R01s, reviewers are instructed to place reduced emphasis on preliminary studies in scoring.

Research plan – Provide a clear, logical exposition of the specific methods you will use to accomplish the Specific Aims and explain how they will achieve robust and unbiased results. Avoid excessive jargon; realize that some reviewers will be from other disciplines. Use section headings to help reviewers understand your plan clearly. Describe data to be employed and consider any data quality concerns. If the project involves original data collection, describe sampling and recruitment plans, interview/questionnaire procedures, and expected response rates. Describe specific analyses or experiments to be conducted, explaining why the selected approach is the superior choice to provide meaningful answers to the questions posed in the Aims. Describe how results will be interpreted. Identify threats to validity and significant limitations of the approach and describe strategies you will use (e.g., alternate analyses, secondary hypothesis tests, etc.) to mitigate. For statistical analyses, *include a power analysis* to demonstrate that the data and approach you propose will be able to discern plausible, meaningful effect sizes with statistical significance. Include a *dissemination plan* that describes how your work will be communicated to key audiences; including a brief accounting of how many published articles you expect will result from your project – aim for at least one each year.

Submitting Your Application – *much more info at <http://grants.nih.gov/grants/submitapplication.htm> and linked pages*

Prepare for electronic submission: Both the institution and the PI must register (separately) with the NIH eRA Commons.

Institutions also must register with Grants.gov. Registration can take 8 weeks or more – start early!!

Use correct forms – All grant mechanisms now require electronic submission. NIH posts the appropriate application forms with each funding opportunity announcement.

Include signed letters of commitment from all collaborators and consultants stating agreement to take on a specific role.

Plan ahead for on-time submission. Be aware of the receipt date for your application long in advance. Work with your Office of Sponsored Programs to address the range of issues involved in finalizing your submission.

Request assignment to a specific IC, a specific review group, or simply outline the areas of expertise needed to provide competent review of your application using the form that is now included in the application forms.

Submit on time – Late applications generally are not accepted. For standard receipt dates, electronic submissions must be successfully submitted to Grants.gov by 5 pm local time on the due date.

Track submission status with tools provided through the eRA Commons.

After Submission – Several weeks (or more) after you submit your application, you will see information in the eRA

Commons about when your application will be reviewed and by which review group. Once you have submitted, the primary contact is the SRO, but there usually is no need to contact the SRO. Check the roster for your review meeting. Contact the SRO if you believe that the committee lacks the appropriate scientific expertise to review your application. A few days after the review meeting, you will see the result of the review in the form of either an Impact/Priority score or notification that your application was Not Discussed. Several weeks after that, you will receive the summary statement. Only after you receive the summary statement should you contact your PO to discuss the results of the review.

Resubmission – Discuss prospects for resubmission with your PO and with members of your research team. NIH now allows one resubmission that responds to review critiques or submission of a new application even if it proposes essentially the same idea. In either case, consider reviewers' concerns and criticisms objectively and think about changes you could make to strengthen the project. Consider fairly whether you can address the main concerns to a level that will satisfy reviewers. For resubmission applications, respond to ALL of the concerns raised by the reviewers in the summary statement, and summarize how you have responded to the critiques in the 1-page Introduction. Resubmit as soon as you can while providing thoughtful and thorough responses to critiques. Recognize that some reviewers of your resubmission may be different from the reviewers of your initial application. Resubmitting soon can help to minimize reviewer turnover. If submitting a “new” application, do not make specific reference to the previous application or critiques, but incorporate ideas from critiques to make your new submission as strong as possible.

After you receive your award – Get to work! Pursue the project as you proposed it. You can make modest changes in approach, budget, personnel, etc. to accomplish the aims of your project without seeking NIH permission. Know the rules (see the NIH Grants Policy Statement section on “Changes in Project and Budget”.) Do not modify the scope or specific aims of your project! Keep your PO informed of significant developments, obstacles, findings, and publications. Submit progress reports (noncompeting renewal applications) on time. Stay as close to on-schedule as possible in both progress and budget terms. (Approval of a 1-year no-cost extension is automatic, but additional extensions may not be approved.) Comply with the NIH Public Access Policy and anti-lobbying provisions. Publish. Plan for your next project.

FAQs

Which type of grant (funding mechanism) should I apply for? This depends on the nature of your proposed project and the time and resources it will require. Read the parent FOAs for the main categories of investigator-initiated research project grants (R01, R21, R03) to understand requirements; talk with experienced colleagues and a PO for more specific advice.

Which FOA should I apply to? Talk with a PO about which FOA to cite in your application. You do not need to apply under an FOA that corresponds to your specific project – the majority of NIH applications are submitted in response to “Parent Announcements”. However, responding to an FOA that calls for research in your specific area can strengthen your case for the significance and programmatic relevance of your project. To find FOAs that may be focused on your area of interest, search the NIH Guide for Grants and Contracts and the web sites of ICs that may be interested in your research topic, and/or contact a program official from a likely IC. *Read FOAs carefully* for participating ICs, eligibility criteria, time and funding limits, application instructions, review criteria, other requirements.

How do I find a PO to contact about my project? Look in the “Scientific Contacts” section of the FOA that you are interested in (including the “parent” FOAs for the various funding mechanisms). Check IC web sites. Don't worry too much about getting exactly the right PO on the first try – we will help refer you to someone who is knowledgeable in your area.

Which IRG/study section should I request? Use the “Matchmaker” tab in RePORTER or the “LikeThis” feature in the eRA Commons to find where projects similar to yours were reviewed. Read about areas of responsibility and rosters for standing study sections on the Center for Scientific Review (CSR) web page. If applying to a Request for Applications (RFA) or a Program Announcement with Review Considerations (PAR), your application will be assigned to the review group designated for that FOA (often a Special Emphasis Panel). Discuss these issues with your PO.

Can I find out who reviewed my application? **NO** – reviewer anonymity is vigorously protected. Do not attempt to contact any reviewers from the study section.

My application was Not Discussed – now what? First, recognize that many worthy projects are Not Discussed. Discuss the outcome of the review with your co-investigators and with the PO. Carefully consider the reviewers' comments and decide whether you realistically can improve the application enough to assuage the major concerns. If not, think about a different (possibly related) project that you could propose that would have better prospects. If so, decide whether to resubmit or submit as a new application. Work with your collaborators to strengthen the application. For resubmissions, address ALL of the identified concerns, making actual changes to your research strategy where appropriate.

Is this a good score? What does it mean? **Discuss with your PO.** Paylines and procedures for making funding decisions vary across ICs and over time. New/Early Stage Investigators may face slightly less stringent paylines.

I got a good score – when will my project be funded? Regardless of scores, no one can promise that your project will be funded until all the steps in the process are complete and you receive the official Notice of Grant Award (NGA). Applications are subject to a second round of review by the National Advisory Council associated with the IC. Final funding decisions are the responsibility of the IC Director. The entire process, from receipt date to award, takes a *minimum* of about 10 months, often longer. Unfunded applications remain eligible for funding consideration for a year.

Notes

In general, your application should fit with the programmatic interests of an IC at NIH. Read the IC's mission statement and strategic plan to assess fit with your application and discuss your ideas with a relevant PO. Ensure that your project is one that the IC would be interested in funding should you get a good priority score in review. For projects funded by the NIH Common Fund (<http://commonfund.nih.gov/>), the proposed projects are required to go beyond the mission of one IC. IC assignment is where your application is assigned for funding purposes. IC assignment is made by the Receipt and Referral Office at CSR, and this process happens simultaneously with review assignment. You may state your preferences for IC assignment on the optional form included in your application. Your application can be assigned to more than one IC, but only one will be designated as “primary assignment”. Multiple ICs can be designated as “secondary” or “dual” assignment. The IC with primary assignment is allowed the first opportunity to fund your application

(before other ICs can fund it). If your application gets a good priority score but does not make the payline at the IC with primary assignment, it is possible that an IC with secondary assignment will want to fund it. The peer review process is designed to provide independent evaluation of an application's scientific merit without interference from funding considerations. To preserve the integrity of this process, you are asked not to contact your PO during the review period, which begins once you have submitted your application and ends once you receive your summary statement. During this review period you may contact the SRO with any questions or concerns. Paylines provide program staff with strong guidance about funding decisions, but paylines and priority scores do not dictate all funding decisions. Programmatic balance and priorities are important considerations, and there may be applications outside the payline that do get funded as well as applications that fall within the payline that are "skipped" or not funded. Your application can only be under consideration for funding at one place at a time. You cannot "hedge your bets" and submit the same application under two different FOAs simultaneously. If you find an FOA under which you would prefer to submit, you must withdraw your application to the first FOA before submitting under the second FOA. You cannot be paid twice for the same work. If your grant from NSF (or CDC or NIH or any other funder) is paying you to purchase a particular piece of equipment, to clean your data, or to perform any other specific task, you cannot ask NIH to fund you to do the same task or purchase the same piece of equipment. Volunteer to be a reviewer – Serving on a review committee has much to recommend it: 1) you are participating in the system that makes peer review work – without peers who do the reviewing the system of review breaks down. 2) You will learn a lot about the review process by witnessing it firsthand. 3) You will observe other reviewers in action and learn what pitfalls to avoid in your own submissions. 4) You will be exposed to cutting edge research which may stimulate your thinking about your own research. 5) You will learn to identify strengths and weaknesses in other applications. To nominate yourself as a potential reviewer, submit your CV and request to serve on a review panel to any NIH SRO.

Resources

The NIH **Office of Extramural Research** provides links to most key resources at <http://grants.nih.gov/grants/oer.htm>:

ABOUT GRANTS - http://grants.nih.gov/grants/about_grants.htm

Grant Application Basics - http://grants.nih.gov/grants/grant_basics.htm

Grants Process Overview - http://grants.nih.gov/grants/grants_process.htm

Types of Grant Programs - http://grants.nih.gov/grants/funding/funding_program.htm

How to Apply - <http://grants.nih.gov/grants/how-to-apply-application-guide.htm>

Electronic Research Administration (eRA) - <http://era.nih.gov/>

eRA Commons - <https://commons.era.nih.gov/commons/>

Request IC and/or Study Section Assignment (included in application forms) - <http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.600-phs-assignment-request-form.htm>

GRANTS POLICY

Grants Policy & Guidance - <http://grants.nih.gov/policy/index.htm>

Research Involving Human Subjects - <https://humansubjects.nih.gov/>

Peer Review Policies & Practices - <http://grants.nih.gov/policy/peer/index.htm>

Rigor, Transparency, and Reproducibility - <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html> and <http://grants.nih.gov/reproducibility/index.htm>

NIH Public Access Policy - <http://publicaccess.nih.gov/>

New and Early Stage Investigators - http://grants.nih.gov/policy/new_investigators/index.htm

Multiple Principal Investigators - http://grants.nih.gov/grants/multi_pi/

FORMS & DEADLINES

Due Dates & Submission Policies - <http://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/standard-due-dates.htm>

Forms Library - <http://grants.nih.gov/grants/forms.htm>

FUNDING OPPORTUNITIES, REVIEW, & SPECIAL PROGRAMS

Funding Opportunities & Notices (NIH Guide for Grants and Contracts) <http://grants.nih.gov/funding/index.htm>

"Parent" Announcements - http://grants.nih.gov/grants/guide/parent_announcements.htm

Center for Scientific Review (peer review) - <http://public.csr.nih.gov/>

Study section rosters and descriptions - http://www.csr.nih.gov/Roster_proto/section1.asp

Scoring System - http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

Reviewer Resources - <http://public.csr.nih.gov/ReviewerResources/>

OppNet (Basic Behavioral and Social Science Opportunity Network) - <http://oppnet.nih.gov/>

NIH Common Fund - <http://commonfund.nih.gov/>

Other Useful NIH Resources

Glossary & Acronyms - <http://grants.nih.gov/grants/glossary.htm>

OER's Collection of Frequently Used Links - <http://grants.nih.gov/grants/documentindex.htm>

NIH Institutes, Centers, and Offices - <https://www.nih.gov/institutes-nih>

Research Portfolio Online Reporting Tools (RePORT) - <https://report.nih.gov/>

RePORTER - search the database of NIH funded research - <https://projectreporter.nih.gov/reporter.cfm>

Institute and Center Strategic Plans - <https://report.nih.gov/strategicplans/index.aspx>