Making the Right Moves

A Practical Guide to Scientific Management for Postdocs and New Faculty

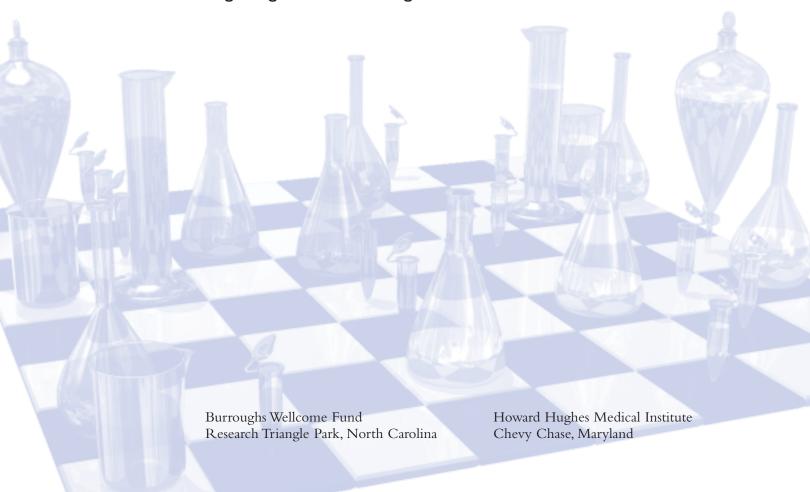


Making the Right Moves

A Practical Guide to Scientific Management for Postdocs and New Faculty

Second Edition

Based on the BWF-HHMI Course in Scientific Management for the Beginning Academic Investigator



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This manual is also available online at http://www.hhmi.org/labmanagement.

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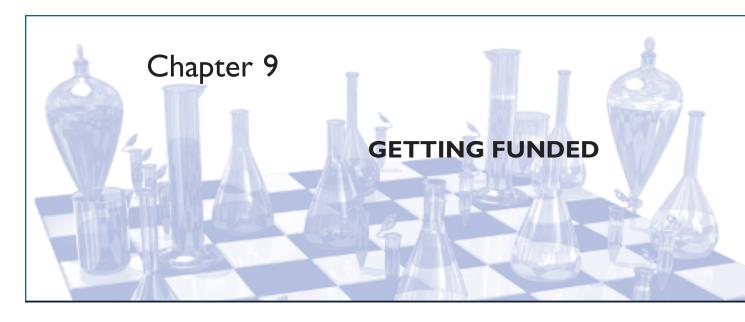
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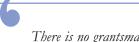
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You've begun your career as an academic scientist. Your lab is up and running, and your research program is under way. But the pressure is on—soon you will have to find financial support for your research from sources other than your institution. It's time to learn the art of getting funded.

Numerous public and private sources support scientific studies, but the National Institutes of Health (NIH), a component of the Public Health Service under the U.S. Department of Health and Human Services, is by far the nation's largest funder of academic research. For that reason, this chapter focuses primarily on NIH and emphasizes the R01 grant, an investigator-initiated research project grant for which most beginning academic investigators will have to apply.

This chapter provides an overview of the NIH funding process and the two-level review system that is used by NIH for most R01 grant applications. It also details the steps involved in preparing a strong R01 grant application, including turning your concept into a solid research plan and making sure that individuals with the appropriate expertise review your application. In addition, the chapter discusses what to do if your application is not funded. The chapter also provides some information about another major funder of basic science research, the National Science Foundation (NSF).



There is no grantsmanship that will turn a bad idea into a good one, but there are many ways to disguise a good one.

-William Raub, former deputy director, NIH

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UNDERSTANDING THE NIH FUNDING PROCESS

NIH Institutes and Centers

An important part of writing a successful grant application is having a good understanding of the mission of the funding organization and the type of projects it supports. At this point in your career, you are probably already familiar with NIH and may have even applied for NIH postdoctoral funding. However, it's still useful to remember that NIH is composed of institutes and centers (I/Cs) whose numbers increase and whose structures are reorganized periodically. (From a grant applicant's perspective, the only relevant distinction between institutes and centers is that an institute can make awards of less than \$50,000 without approval from its national advisory council, but a center cannot.) As of May 2006, NIH had 20 institutes and 7 centers. Each I/C has its own mission and research agenda, and 24 of the current 27 I/Cs have funding programs for extramural awards (research conducted outside their own facilities and staff), including those that fund R01 grants. Although not essential, it will be useful for you to identify an I/C that is likely to be interested in your research (see "Find a Home for Your Application at NIH," page 164).

Question: At what stage in my career should I apply for my first R0I grant?

Answer: After you have accepted a position at a university or medical center, you may be encouraged by your department chair to apply for your first NIH grant, even before you move into your new lab. Some experts warn, however, that it might be better to wait until the second year of your appointment, because it will help your application considerably if you have generated some preliminary data in your new lab. Whenever you decide to apply, remember that you are in that special position of "new NIH investigator" only once; make the most of it.

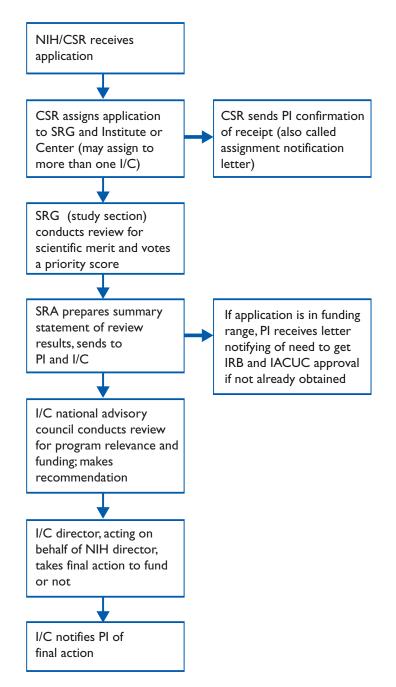
Question: What's the difference between an RFA and a PA?

Answer: An RFA invites grant applications in a well-defined scientific area for which an I/C has determined a specific research need (e.g., to study West Nile virus). This is usually a one-time competition and funds are set aside for a certain number of awards. A PA invites grant applications for a scientific area for which an extramural research program within an I/C has new or expanded interest or continuing interest (e.g., to study drug addiction). These applications are accepted on standard receipt dates on an ongoing basis.

The R01 Review: An Overview

R01 grant applications are usually investigator-initiated. Applications can also be submitted in response to a Request for Applications (RFA) or a Program Announcement (PA), both of which are announced in the NIH Guide for Grants and Contracts (http://grants.nih.gov/ grants/guide/index.html). R01 applications submitted in response to an RFA are generally reviewed by the issuing I/C. R01 applications submitted in response to a PA are reviewed by the Center for Scientific Review (CSR). Regardless, all applications are sent to the CSR and then follow a two-level review process: CSR 1) assigns the application to a Scientific Review Group (SRG) for evaluation of scientific and technical merit and 2) assigns it to one or more I/Cs to review for programmatic relevance and funding recommendations. (Figure 9.1 provides an overview of this two-level review process.) CSR conducts scientific peer review of approximately 70 percent of the applications sent to NIH; I/Cs evaluate the others. Of the more than 68,000 applications received annually by NIH, perhaps only 20 to 25 percent are funded. The funding range can vary from year to year and from one I/C to another.





CSR: Center for Scientific Review

IACUC: Institutional Animal Care and Use Committee

I/C: NIH Institute or Center
 IRB: Institutional Review Board
 PI: Principal Investigator
 SRA: Scientific Review Administr

SRA: Scientific Review Administrator SRG: Scientific Review Group

Common Abbreviations

AREA: Academic Research Enhancement Award

CRISP: Computer Retrieval of Information on

Scientific Projects

CSR: Center for Scientific Review

IACUC: Institutional Animal Care and Use

Committee

I/C: NIH Institute or Center (also written IC)

IRB: Institutional Review Board

IRG: Integrated Review Group

OER: Office of Extramural Research

OHRP: Office for Human Research Protections (formerly OPRR, Office of Protection from Research

Risks)

OLAW: Office of Laboratory Animal Welfare (formerly Division of Animal Welfare within OPRR)

PA: Program Announcement

RFA: Request for Applications

RFP: Request for Proposals SEP: Special Emphasis Panel

SRA: Scientific Review Administrator

SRG: Scientific Review Group

First-Level Review: Scientific Review Group

One type of SRG, the study section, is used by CSR to review R01 grant applications. Study sections are clustered into Integrated Review Groups (IRGs), organized around a general scientific area. Each study section has a specific scientific focus. (For simplicity, the terms study section and SRG are used interchangeably in this chapter.)

R01 applications are usually assigned first to an IRG and then to a study section within that IRG. The study section reviews the grant application for scientific merit, rates it with a numerical priority score from which a percentile ranking is derived, and recommends an appropriate level of support and duration of award.

Scores, ranks, and percentiles. Every member of a study section gives each application a rating, or priority score. Those scores are averaged to create a three-digit number, which is that application's final score in the NIH computer system. A 100 is the best possible score, and a 500 is the worst possible score. Some applications are not dis-

cussed at the review meeting and thus do not receive a score (see "Streamlining and Deferrals," page 158).

Percentiling is a reflection of the rank of a particular score in the pool of all scores given by a study section in its current meeting plus the two previous meetings. For example, an application whose score ranked number 50 out of 100 applications would receive a percentile of 49.5, according to the following formula:

$$P = 100 \times (R - \frac{1}{2}) / N$$

In the formula, P is the percentile, R is the ranking (in this case, 50), and N is the total number of applications.

The percentiling process is specific to each study section and is the way that NIH I/Cs can account for different scoring behavior in the various study sections. Thus, if the 20th percentile is a 150 priority score in Study Section A and a 190 priority score in Study Section B, both applications are considered in the 20th percentile and treated as such when funding decisions are made by the I/Cs.

Behind Closed Doors: Demystifying the Study Section

Chartered study sections

- Are managed by a scientific review administrator (SRA), a professional at the M.D. or Ph.D. level with a scientific background close to the study section's area of expertise.
- Have 12 to 24 members recruited by the SRA, most of whom are from academia—some have long-term appointments and others are temporary members.
- Review as many as 60 to 100 applications per meeting.
- Usually assign three reviewers to each application.
- Are supported by a grants technical assistant, who reports to the SRA.

Under the terms of the Federal Advisory Committee Act, study section meetings are closed. Meetings include

- Orientation (discussion of general business)
- Provisional approval of list of streamlined applications
- Discussion of remaining applications

The discussion of applications includes the following:

- Reviewers with a conflict of interest are excused.
- Assigned reviewers present strengths, weaknesses, and their preliminary scores.
- Other members discuss scientific and technical merit.
- Range of scores is expressed (every member scores every application).
- Codes for gender, minority, and children and human subjects are assigned (NIH has requirements
 for inclusion of women, minorities, and children in clinical research and strict criteria for research
 involving human subjects and animals).
- Recommended budget changes are discussed.

After each meeting, the SRA documents the results in a summary statement, which is forwarded to both the I/C and the principal investigator.

Summary statements may vary somewhat depending on the SRA, but all of them contain

- Overall résumé and summary of review discussion (for applications that were discussed and scored)
- Essentially unedited critiques by the assigned reviewers
- Priority score and percentile ranking
- Budget recommendations
- Administrative notes (e.g., comments on human subjects or animal welfare)

For more information about what happens in a study section, see the CSR Web site (http://www.csr.nih.gov). Also, professional societies, such as the American Society for Cell Biology, often conduct mock study sections at their meetings using already-funded applications.

Poor priority scores. Applications can receive poor priority scores for any number of reasons, including the following:

- Lack of original ideas
- ♦ Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work for the given time frame or funding level
- Uncertainty about future directions

Question: What should I do if an SRA asks me to be a reviewer for a study section?

Answer: Views differ on this question. Service on a study section can provide valuable insights for grant writing and open professional doors in other ways. However, many senior scientists counsel that junior faculty should wait until they have obtained tenure before accepting an invitation to be appointed to a term on a study section, because they should be devoting their energies to their research, which is the primary basis for the tenure decision. However, agreeing to serve as a temporary member might be appropriate at this stage in your career.

Streamlining and deferrals. A study section gives a score to only about half the applications assigned to it every review cycle. Through a process called "streamlining," applications that are deemed by reviewers to be in the lower half of those assigned for review are read by the assigned reviewers and receive written critiques, but they are not scored or discussed at the review meeting. Any member can object to the streamlining of any application, thereby bringing it to full discussion at the meeting. Streamlining was instituted to allow more time for discussion of applications near the fundable range and to shorten the meetings. This more efficient process also helps attract more reviewers.

A study section can also defer an application if, for example, more information is needed before the reviewers can adequately consider the application. Deferred applications require a majority vote by the study section and are rated "DF." Deferrals are rare.

Second-Level Review: I/C National Advisory Council or Board

After an R01 application has undergone study section review, it undergoes a second-level review by the national advisory council or board of an I/C. The advisory council is composed of people outside the I/C. Approximately two-thirds are scientific members who are generally established in their fields, such as deans or department chairs. Others are advocates for specific health issues and patient populations, ethicists, and laypersons. The secretary of Health and Human Services has ultimate authority to make these appointments.

The advisory council assesses the quality of the study section's scientific review, makes recommendations to I/C staff on funding, and evaluates the application's relevance to program priorities. For every scored application, the advisory council will do one of the following:

- Concur with the study section's action.
- Modify the study section's action (but it cannot change the priority score).
- ◆ Defer the study section's action for another review, with no changes allowed (e.g., if the principal investigator has appealed, the council may recommend a re-review because it considers the first review flawed).

The I/C director, acting on behalf of the NIH director, takes final action. Awards are made on the basis of scientific merit, program considerations, and available funds. The director usually (but not always) follows the advisory council's recommendations.

Roughly half of the funding I/Cs post their funding plans on their Web sites. The funding plan is the percentile to which the I/C anticipates being able to fund applications on the basis of its budget, recent funding history, and program priorities. If that information is posted, you can check the Web site after you receive the summary statement that shows your application's percentile. Regardless of whether the I/C to which your application was assigned posts its funding plan, you may want to ask the I/C program official responsible for the administrative management of pending applications/revisions and funded grants about the likelihood of your obtaining funding.

Review and Funding Cycles

The meetings of the national advisory councils form the basis for NIH's three overlapping review and funding cycles (see figure 9.2). However, NIH is trying to expedite the funding process by making some awards before the council meeting. For example, a candidate for expedited funding might be an R01 application that has a high score, is in an area of strong interest, and does not involve human subjects.

Figure 9.2. Typical timeline for a new R01 application

	Cycle I	Cycle 2	Cycle 3
Application Submitted	February	June	October
SRG (Study Section) Review	June	October	February
Advisory Council Review	September	January	May
Earliest Award	December	April	July

Note: This timeline is specific to R01 research grants. Always check with the I/C to verify due dates for specific types of applications. RFA due dates are stated in the solicitations.

Depending on the I/C, approximately 30 percent of funds are allocated at each of the first two meetings; more is spent at the third meeting. Some I/Cs may be a bit more conservative in funding (e.g., to the 25th percentile) in the first two cycles to hold funds in reserve in case strong applications are submitted during the final funding cycle. In addition, every advisory council and I/C staff have "select pay" for which they can nominate applications that have poorer scores but are of high interest for funding.

As much as possible, consider the timing of your application in terms of the career track at your institution. You want to be funded when decisions about tenure are made.

Opportunities for Beginning Investigators

NIH actively seeks to support beginning investigators. When you apply for your first NIH grant, check the box on the form that signals to reviewers that you're a new investigator (meaning you haven't been principal investigator on an NIH research grant before). The reviewers are often more forgiving of applications from novices.

Other, non-R01 research awards available specifically to beginning investigators include

- Mentored Research Scientist Development Award (K01)
- Independent Scientist Award (K02)
- Mentored Clinical Scientist Development Award (K08)
- Small Grant (R03)
- Academic Research Enhancement Award (R15)
- Exploratory/Developmental Grant (R21)
- Career Transition Award (K22)

Many of these programs are announced periodically in the NIH Guide to Grants and Contracts (http://grants.nih.gov/grants/guide/index.html). Each has its own criteria for eligibility and submission of applications. Information on these and other NIH extramural funding opportunities can be found at http://grants.nih.gov/oer.htm.

In addition to NIH, other federal agencies and private sector organizations solicit and fund research grants, and each has its own application and review system (see "Resources," page 173). You can send the same application to multiple funding sources in the public and private sectors, but you must disclose your multiple applications to each potential funder to avoid "double dipping" when awards are made.

PREPARING A STRONG GRANT APPLICATION

Getting Started

Successful grant applications begin with a good idea. Figures 9.3 and 9.4 (pages 162 and 163) show the sequence of steps that can carry you from a good idea through the submission of an application to the final decision about funding.

Once you have a good idea, you can get started in two realms: your own institution and an appropriate NIH I/C. These activities overlap to some extent, but they are presented sequentially below.

Seek input at your own institution. An experienced scientific reviewer and NIH grantee recommends seeking peer review of your research proposal at your own institution according to a plan devised by Keith Yamamoto, University of California–San Francisco. The process, which begins at least two months before the application deadline of your grant, involves the following steps:

- 1. Choose three senior colleagues as your "grant committee." Ideally, these would be successful grantees and would include someone who has experience on a study section.
- 2. Discuss research goals, aims, and ideas with the committee (1.5 hours).

Components of the NIH R01 Grant Application

- Research Plan: Abstract, Specific Aims, Background (like a review article), and Significance
- Progress Report (preliminary results and demonstration of relevant expertise)
- Research Design and Methods
- Resources and Facilities
- Budget
- Budget Justification

Tip: Conclude each section in the research plan with a few sentences stating what you will learn and why that information is important—for example, "These experiments are important because nothing is known about X, and they will enable us to distinguish between two controversial models that are widely discussed in the field."

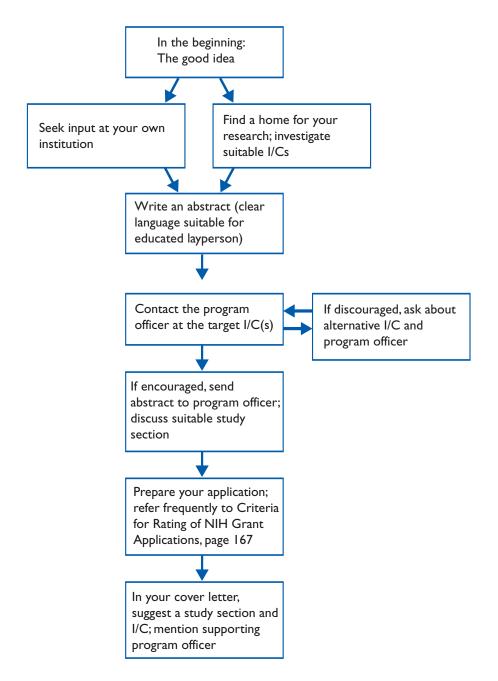
For information about how to prepare a grant application form, visit

http://grants.nih.gov/grants/grant_tips.htm.

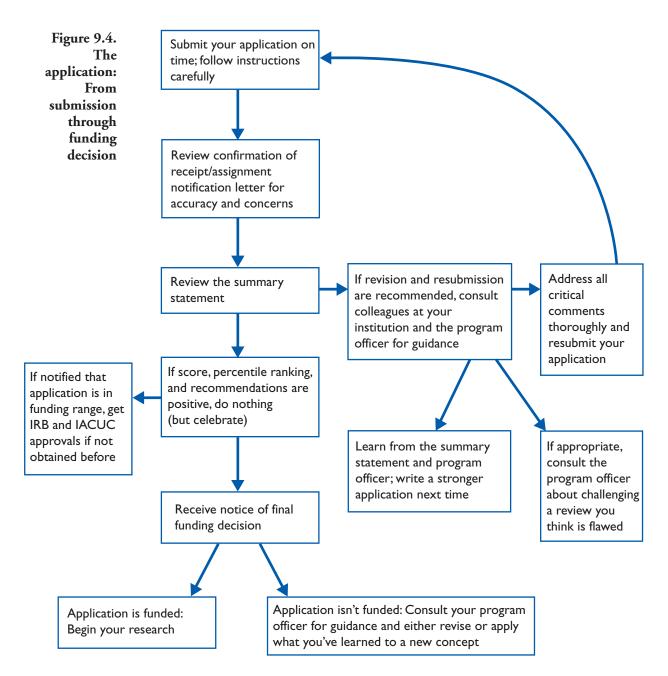
- 3. Draft one page listing three to five specific aims, and explain why each aim is important.
- 4. Discuss your aims and rationales with the committee (1.5 hours).
- 5. Refine your aims according to committee comments.
- 6. Draft the abstract and the research design and methods sections. Then draft the progress report and the background and significance sections. (See box "Components of the NIH R01 Grant Application" and "Preparing Your Application," page 166.)
- 7. Read "Criteria for Rating of NIH Grant Applications" (page 167), and revise your drafts as appropriate.
- 8. Seek feedback on the drafts from your committee.

In addition to seeking advice from other scientists, seek administrative advice from appropriate review bodies, such as your local Institutional Review Board and Institutional Animal Care and Use Committee.

Figure 9.3.
The application:
From concept to submission



I/Cs: NIH Institutes and Centers



IACUC: Institutional Animal Care and Use Committee

IRB: Institutional Review Board



Your NIH R01 history is a form of peer review at the national level and is weighed heavily in decisions about promotion and tenure.

—Suzanne Pfeffer, Stanford University School of Medicine

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Reviewers will look for your track record in the field, so, if necessary, create one by conducting some preliminary work and presenting the results in your grant application.

Find a home for your application at NIH. In many cases the appropriate I/C and program officer for your research might be your mentor's. On the other hand, it may take legwork to find the I/C most likely to be interested in your idea. An experienced NIH program officer suggests that beginning scientists should

- Check the NIH Guide to Grants and Contracts (http://grants.nih.gov/grants/guide/index.html) for relevant and recent PAs and RFAs.
- Check the NIH CRISP (Computer Retrieval of Information on Scientific Projects) database (http://crisp.cit.nih.gov) for projects like yours that have been funded. The two letters in the grant number tell you which I/C funded the project.
- Conduct a literature search to see what has already been done in your area.
 (This can help you address the innovation aspect of evaluation criteria and, if appropriate, revise your study design or methods accordingly.)

Once you've narrowed the list of potential I/Cs, go to the Web site of each I/C to learn what areas they are currently interested in and are funding. (The NIH Web site lists all its I/Cs and offices at http://www.nih.gov/icd.) I/C Web sites commonly describe scientific areas of interest as well as identify the staff members who are responsible for each program area and maintain a portfolio of grants in that area.

The I/C program officer is the best person to help you decide what type of grant to apply for and which study section may be most appropriate. The program officer whose area of responsibility is most appropriate to your research also can be your best advocate and adviser at NIH throughout the application process. The program officer will not evaluate the quality of the research idea or the science. That job is left to your institutional colleagues and the study section.

Before you call this key person, be sure to have an abstract of your research project ready (see box "Tips on Writing an Abstract" on page 165). The program officer will probably ask for a copy; if not, you can offer to send one.

Review by more than one I/C. Remember, you can ask for assignment to a second I/C if you've had encouragement from another program officer or think that your application fits within another I/C's scientific areas of interest. Your application can be funded by only one I/C, but more than one advisory council can

Tips on Writing an Abstract

The abstract should convey the big picture—the general hypothesis and aims, the methodological approach, and the significance of the research. It should also include key words, which the referral officer at NIH will use to assign your application to the right study section, whether or not you request a particular review group. Try to avoid technical jargon, and write the abstract in language an educated layperson can understand.

review it to broaden your chance of funding. In such cases, the application will be assigned a primary and a secondary I/C. The secondary I/C can consider it for funding only if the primary I/C opts to relinquish first right of funding.

Despite your homework on finding the appropriate I/C, the first program officer you contact may not consider your proposal appropriate for funding by that I/C. In such cases, the program officer will likely suggest a more suitable I/C and program officer.

Getting Assigned to the Right Study Section

The most important thing you can do to bolster your chance of funding is to have your application assigned to the right study section. Read the study section descriptions and rosters before finishing and submitting your application. Remember that key words in the title, the abstract, and the specific aims will be used to direct your application to a suitable study section.

If you submit a cover letter, it should contain an informed request for assignment to a specific study section and a brief explanation of why you think it's best suited for your application as you have determined through your own research and your discussion with the program officer. Include the name of the program officer who supports this request. CSR staff members will consider your suggestion for a study section; if your suggestion is logical, it is likely they will honor it. You can also recommend the type of expertise needed to evaluate your application, but you should not provide specific names of potential reviewers.

After you have been notified about the study section to which your application has been assigned, check the roster to make sure the expertise you consider essential to a fair and thorough evaluation of your application is still represented. If someone who you regard as an important interpreter of your research plan has dropped off the roster, you can request that expertise be added. These requests are generally taken seriously and responded to, and appropriate expertise is provided onsite or through an outside review by phone or mail. Similarly, if someone has joined the study section and you think for some reason that this person will not provide a fair review, you can request that this person not review your grant. Be aware, however, that during the study section meeting, the person you are excluding will be informed that you made this request.

Preparing Your Application

First, be sure you're using the most current application form. (The Web site http://grants.nih.gov/grants/forms.htm has the most current version of the PHS 398 Grant Application Kit.) Second, follow a simple mantra: Start early, write, read, rest, re-read, revise.

In your application, you should address the following questions, keeping in mind the information given under "Criteria for Rating of NIH Grant Applications," page 167):

- What do you want to do?
- Why is it important?
- Why do you think you can do it?
- ♦ Has this area been studied before (and if so, what has been done)?
- ♦ What approaches will you use, and why?
- ♦ Why do you think it's feasible?
- What will you do if your initial approach doesn't work as planned?
- ♦ What resources and expertise are available to you from your institution?

You should keep the following suggestions in mind as you prepare your application:

- Read and follow instructions, paying close attention to budget requirements and eligibility criteria (see "A Bit About Budgets," page 168).
- Prepare your application with care, and use spell check. No matter how strong the science, typos and grammatical errors leave a poor impression.
- ◆ Don't try to evade the page limit by using small type or narrow margins. You could delay your application if you disregard NIH's formatting requirements. Don't feel you must write up to the full page limit; you get points for strength, not length.
- Quantify whenever possible.
- ♦ Edit. Try to keep your specific aims to two or three sentences each. Remember that reviewers have dozens of applications to evaluate.
- Use language and formatting to create signposts for overworked reviewers, for example:

The *long-term* objectives of this project are...

The general strategy of the proposed research is to...

The *specific aims* of the present study are to...

Four goals are envisioned: ...

In these experiments, molecular genetic, biochemical, and structural approaches will be used to...

Reviewers Focus on the Four Cs

Clarity. Cross-reference current literature in laying out your premises.

Content. Organize your ideas around associated aims linked to your central hypothesis. (The mission statement of each I/C sets forth its areas of emphasis.)

Coherence of concepts. Present a coherent set of ideas predicated on previous work.

Cutting edge. Be ready to take legitimate risks, preferably based on preliminary data, to move the science forward. NIH rates grant applications on innovation (see "Criteria for Rating of NIH Grant Applications" on this page).

- Don't put anything that is critical for reviewers to read, such as key graphics, in an appendix because reviewers are not required to read appendixes.
- Include clear tables, figures, and diagrams (along with legends) in the text.
- ◆ Conduct a thorough literature search and cite all relevant literature (omissions here are often a source of criticism). Be sure to discuss your work in the context of these published results.
- Provide preliminary data whenever they exist.

Preliminary data. NIH understands that beginning investigators may not have much opportunity to acquire preliminary data. The NIH Guide to Grants and Contracts (http://grants.nih.gov/grants/guide/index.html)

often announces programs (e.g., R03 and R21) that are specifically designed to allow new investigators to obtain preliminary data.

Criteria for rating of NIH grant applications. Here are some questions that reviewers will ask about your proposal:

- Significance: Does it address an important problem? Will it advance scientific knowledge? Will it affect concepts or methods in this field?
- ◆ *Approach:* Are the experimental design and methods appropriate to the aims? Does it acknowledge problem areas and consider alternative tactics (in other words, is there a thoughtful backup plan)?
- ♦ *Innovation:* Does it employ novel concepts, approaches, or methods? Does it challenge existing paradigms or develop new methodologies?

Question: How do I distinguish myself from my mentor if I want to continue in the same research area?

Answer: Get a letter from your mentor explaining that he or she is pleased to know that you will be continuing to work on project X, which he or she will not pursue. Have this discussion with your mentor before you start to write the grant application.

- Investigator: Is the investigator appropriately trained to carry out the proposed work? Is the work appropriate to the experience of the principal investigator and collaborators?
- ♦ *Environment*: Does the institutional environment contribute to the probability of success? Is there evidence of institutional support?

Remember, every yes answer strengthens your application. Every no answer represents an area of potential vulnerability during scientific review. For a detailed description of these criteria, see the PHS 398 application instructions at http://grants.nih.gov/grants/grants_tips.htm. In addition, guidelines for reviewers for grants from new investigators can be found at http://www.csr.nih.gov/guidelines/newinvestigator.htm.

A BIT ABOUT BUDGETS

This section does not discuss how to draw up a budget for your grant application. Most institutions have a central grants office with experienced staff who can devise budgets suitable to the scope of the research proposed and in keeping with your institution's policies. Take advantage of that expertise.

However, this section does provide an overview of six budget-related topics. The first, direct costs versus indirect costs, can be the source of misunderstanding between faculty and administration at academic institutions. The next, modular grants, concerns the initial budget request that is now part of many NIH grant applications. Budget justification, administrative budget supplement, and competing budget supplement are relevant to later requests to supplement the initial award amount. The last topic concerns equipment costs.

Direct Costs Versus Indirect Costs

Direct costs comprise those expenses that are directly related to conducting a research project. They include salaries, employee benefits, equipment and scientific instruments, consumable supplies such as printer paper and pipettes, reagents, laboratory computers, and postage. Indirect costs (informally termed "overhead") comprise the expenses that are paid to your institution by the funding organization to support your research but that can't easily be charged directly to a specific grant. These include administration, utilities, computer infrastructure, building maintenance, security, and custodial services. These costs can be from 10 percent to 80 percent of the total direct costs of a research grant. Generally, an institution's administrators negotiate indirect costs, on behalf of the investigator, with the funding organizations (such as NIH or the National Science Foundation) that allow these costs. The organization then provides funds for indirect costs to the institution, along with funds to cover direct costs charged to the research grants. In general, beginning investigators need not be concerned about indirect costs. However, you should be aware that a significant part of the budget for a large funding agency may include indirect costs; the more paid to institutions for indirect costs, the less available for direct costs for investigators and their research projects.

Modular Grants

To simplify the budgeting process, research budgets are now requested in units, or "modules," of \$25,000. This applies to all investigator-initiated grants (R01, R03, R15, and R21) with direct costs of up to \$250,000 per year over the period of the award. All salary, fringe benefits, and inflation increases must be built into the modular framework. The number of modules can differ from year to year. For example, acquisition of equipment can make first-year costs higher than those for subsequent years. Request what you need, but be sure to justify that amount. Budget cuts are also modular. R01s over \$250,000 per year and P01 grants are nonmodular.

Budget Justification

The budget justification is a categorical description of the proposed costs. Generally, it explains staffing and supply/service consumption patterns, the methods used to estimate/calculate these items, and other details such as lists of items that make up the total costs for a category. The budget justification should address each of the major cost categories, such as

Personnel

Number of positions and level of expertise for each position Percent effort for each position What will each member of the proposed research team be doing?

Equipment

Why do you need this piece of equipment? What equipment did you use to get preliminary data? Why is the above equipment not sufficient to support R01-level effort? (Cost sharing for new equipment is advisable.)

- Supplies Categorize
- Explain large expenses
- ◆ Travel

Describe proposed meetings, travelers, and estimated cost/trip Justify any foreign travel

Other

Detailed description of animal per diem costs Categorize other expenses

Administrative Budget Supplement

This budget request covers unforeseen expenses that arise, generally because initial budget assumptions have changed. Examples are increases in the cost of isotopes or animal care. Administrative supplements are also offered occasionally for special purposes. For example, you may be able to get an administrative supplement to pay for a minority student to work in your lab. These requests are submitted to the I/C program staff rather than to the CSR for peer review. If you have questions about the appropriateness of this type of request, ask your program officer.

Competing Budget Supplement

Competing continuation applications are designed for the principal investigator who wants to modify the scope of approved work (e.g., by adding an aim or following an exciting lead). These requests are subject to the competitive peer-review process, usually through the same study section that reviewed the initial application. If you're considering this mechanism, ask your program officer about the feasibility of getting those funds from the sponsoring I/C.

More advice on laboratory budgets can be found in the resources listed at the end of this chapter.

Equipment: What You Should Know

When planning to buy equipment, keep in mind the following:

- Cost sharing has many benefits. Consider arranging for your department or institution to share equipment costs.
- If you need new equipment to pursue your research, ask for it on your renewal application. Never request major equipment funds in the last year of the grant.

Office of Extramural Research Salary Cap Summary

October 1, 2004, through December 31, 2004: \$175,700

January 1, 2005, through December 31, 2005: \$180,100

January 1, 2006, through December 31, 2006: \$183,500

- ♦ Your institution owns equipment funded by your grant only after the award period ends. If you're the principal investigator and you relocate, the equipment generally goes with you.
- If you're in doubt about anything related to equipment, ask a grants management specialist at your institution.

You may find help with equipment costs through the Shared Instrumentation Grant Program (S10) or the Small Instrumentation Grants Program (S15) run by NIH's National Center for Research Resources. For more information about these programs, visit http://www.ncrr.nih.gov.

SUBMITTING YOUR APPLICATION

Follow instructions for mailing. Applications must be received by or mailed on or before the published receipt date. It's appropriate to send a courtesy copy of your application to the I/C's program officer.

Confirmation Letter

NIH will send you a confirmation of receipt, which is also called an assignment notification letter. Review it carefully to make sure all information is correct and you have no concerns (e.g., about assignment to a study section other than the one you requested). The letter will include the following items:

- ♦ An application number with codes for the type of grant (such as R01), the assigned I/C, and an identifying application ID number. The two letters in the ID number denote the primary I/C to which the application has been assigned.
- The assigned SRG (or study section)
- The name of the SRA and contact information

The letter will also outline the expected timetable for review and funding decisions and explain who to contact if you have questions.

New Data

If new data become available after you have submitted the application, contact the SRA of your assigned study section. You may be allowed to submit this additional information. The SRA can tell you how much to send, what format to use, and when and where to send it.

Interpreting the Summary Statement

After the study section meeting, the SRA will draft a summary statement (see "Behind Closed Doors: Demystifying the Study Section," page 157). Usually, the summary statement is straightforward and will tell you whether your grant is likely to get funded or not, but in some cases, you may need help interpreting it. For example, if your summary statement recommends revision and resubmission, do the reviewers really want to see it again? Or have they politely refrained from stating plainly that they consider your hypothesis untenable, your expectations excessive, or your approach extremely flawed?

The program officer, who usually attends the study section meetings or enlists a colleague to do so, can help you interpret the results of the scientific review. If the program officer wasn't present, he or she can call the SRA for guidance. Your institutional mentor or grant committee can also help you evaluate the summary statement. After the national advisory council meeting, you can discuss the potential for funding or revisions with the program officer.

Occasionally, mistakes are made during the review process. If you believe that the reviewers criticized you for information that they overlooked in your application or think the review was flawed for other reasons, consult the program officer about the possibility of appealing the study section's decision. Although this action is sometimes appropriate, it's usually better to address review comments and resubmit your application. Follow the program officer's guidance on this matter.

If the reviewers thought your starting hypothesis was seriously flawed, don't waste your time revising and resubmitting the application. Instead, learn as much as you can from the summary statement and discussion with the program officer and your colleagues, reconsider your project and approach, and write a stronger application the next time.

Resubmitting Your Application

If your application is not immediately funded, remember that with an NIH funding average of 20 to 25 percent, many applications aren't funded the first time. If the program officer thinks it's worthwhile for you to revise the application, keep the following points in mind:

- Reviewers of amended applications get to see the summary statement from the previous reviews.
- Always treat review comments respectfully.
- Respond to all suggestions and comments, even if you don't agree with them.

- Be explicit about changes: Mark each section of the revised application where you have addressed reviewer critiques.
- Provide any additional data that are now available and update your publication list, if necessary.
- Resubmit the revised application by the due date. Your revised application now begins its journey through the review process all over again, along with the next batch of new submissions from other applicants.

Although your first instinct may be to request that your revised application be assigned to a different study section, you would need a compelling scientific reason for that request to be honored. Further, there's always the possibility that a different study section might find additional reasons to criticize your application.

A revised application supersedes the previous version, erasing the earlier score and pushing you back farther in line in the funding decision-making process. However, as the funding cycles progress and I/C staff have a clearer idea of what remains in their award budget for that fiscal year, they can reactivate the previous version if they find that the score on your initial application looks promising for funding (see "Review and Funding Cycles," page 159). If you submit a revised application and the program officer later tells you to withdraw it because your funding chances now look good, do so.

How many times can, or should, you revise and resubmit the same application? NIH policy is that after a second revision, you must reconsider your project and approach and submit a new application.

THE NATIONAL SCIENCE FOUNDATION

The National Science Foundation (NSF) is an independent federal agency with an annual budget of about \$5.5 billion. It is the funding source for approximately 20 percent of all federally supported basic research conducted by U.S. colleges and universities. It provides funding only for nonmedical biological research: According to NSF, "...Research with disease-related goals, including work on the etiology, diagnosis or treatment of physical or mental disease, abnormality, or malfunction in human beings or animals, is normally not supported. Animal models of such conditions or the development or testing of drugs or other procedures for their treatment also are not eligible for support." Complete information may be found at http://www.nsf.gov/dir/index.jsp?org=BIO.

RESOURCES

Example of a Funded R01

Annotated R01 grant application (NIAID), http://www.niaid.nih.gov/ncn/grants/app/app.pdf.

NIH I/Cs and Offices

General information, http://www.nih.gov/icd.

NIH Peer Review: Process, Forms, Guidelines

CRISP, a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions, http://crisp.cit.nih.gov.

Overview of peer-review process, http://www.csr.nih.gov/review/policy.asp.

Study section rosters, http://www.csr.nih.gov/Committees/rosterindex.asp.

Grant application forms, http://grants.nih.gov/grants/forms.htm.

Preparation instructions, http://grants.nih.gov/grants/funding/phs398/phs398.html.

Office of Laboratory Animal Welfare, http://grants.nih.gov/grants/olaw/olaw.htm.

NIH Funding Opportunities

Grants and funding opportunities, http://grants.nih.gov/grants/index.cfm.

Guide to grants and contracts, http://grants.nih.gov/grants/guide/index.html.

Grants site map, with links to other relevant sites, http://grants.nih.gov/grants/sitemap.htm.

Office of Extramural Research, http://grants.nih.gov/grants/oer.htm.

Other Sources of Funding Information

FedBizOpps, an evolving database of all federal government granting programs of more than \$25,000, http://www.fedbizopps.gov.

GrantsNet, maintained by the American Association for the Advancement of Science, http://www.grantsnet.org.

Laboratory Budgets

Brown, Megan T. "Preparing and Managing Your First Lab Budget: Finance 101 for New Investigators." ScienceCareers.org (October 22, 1999), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/0210/preparing_and_managing_your_first_lab_budget_finance_101_for_new_investigators/(parent)/158.

Making the Right Moves A Practical Guide to Scientific Management

Harmening, Denise M. Laboratory Management: Principles and Processes. Upper Saddle River, NJ: Prentice Hall, 2003.

McClure, Michael. "From Science Fair to Science Fare, Part 2: Establishing a Revenue Stream." ScienceCareers.org (February 28, 2003), http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/2240/from_science_fair_to_science_fare_part_2_establishing_a_revenue_stream/(parent)/158.