

How to Be a Member of an R01 NIH Study Section

Addendum to

**Making the Right Moves:
A Practical Guide to Scientific Management
for Postdocs and New Faculty**

second edition

**Burroughs Wellcome Fund
Howard Hughes Medical Institute**

Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty, second edition

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“How to Be a Member of an R01 NIH Study Section”: Electronic addendum
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HOW TO BE A MEMBER OF AN R01 NIH STUDY SECTION

Peer review of grant applications is the cornerstone of the U.S. research enterprise. Scientists are routinely asked to serve as peer reviewers for several public and private funding agencies in the United States and abroad. In the United States, the National Institutes of Health (NIH) is by far the largest funder of academic research. That means that sooner or later you will be tapped to be a reviewer for NIH.

Chances are you were not taught how to review grants during your graduate or postdoctoral training. While nothing can replace hands-on experience, advice and suggestions from seasoned reviewers can help prepare you to do a better job, right from the start.

This chapter provides an overview of what to do if you are asked to serve on an NIH study section and what your duties and responsibilities will be. There are many kinds of NIH study sections, which review different types of grants (see page 2 for a list of various types of NIH grants and fellowships). This chapter emphasizes the review of R01 grants, the investigator-initiated research grants that are the bread and butter of NIH funding.

WHAT IS A STUDY SECTION?

The Center for Scientific Review (CSR) evaluates most grant applications submitted to NIH. CSR assigns grant applications to study sections—groups of 20–40 scientists focused on a particular research field who are charged with reviewing applications. Each study section is managed by one of CSR’s Scientific Review Officers (SROs).

The SRO makes the initial contacts with scientists, asking them to become members of a study section. The SRO also assigns grant applications to specific members of a study section and organizes review meetings, where applications are discussed.

CSR runs different kinds of study sections. They include:

- ◆ **Regular standing study sections.** These study sections meet three times a year and are “chartered,” or formally established by the government with slates of permanent members. (As a result, they are often referred to as chartered study sections.) They review most of the investigator-initiated (R awards) applications and career development (K awards) applications, among others. These study sections vary in terms of scientific focus, size, and typical workload. A list of CSR regular standing

NIH Investigator-Initiated Awards

The Research Project Grant (R01) is the original, oldest, and most frequently used grant mechanism. But NIH also provides a number of non-R01 research awards to investigators. Some of the more common ones include:

- ◆ Small Grant (R03)—provides limited funding for a short time to support a variety of types of projects, including pilot or feasibility studies and collection of preliminary data.
- ◆ Exploratory/Development Grant (R21)—encourages new, exploratory, and developmental research projects by providing support for the early stages of project development.
- ◆ Academic Research Enhancement Award (R15)—supports small research projects in the biomedical and behavioral sciences conducted by students and faculty in health professional schools and other academic components that have not been major recipients of NIH research grant funds.

NIH Career Development Awards

- ◆ Mentored Scientist Development Award (K01)—provides support and “protected time” (3–5 years) for an intensive, supervised career development experience in the biomedical, behavioral, or clinical sciences leading to research independence.
- ◆ Independent Scientist Award (K02)—provides support for newly independent scientists who can demonstrate the need for a period of intensive research focus as a means of enhancing their research careers.
- ◆ Mentored Clinical Scientist Development Award (K08)—provides support and “protected time” to individuals with a clinical doctoral degree for an intensive, supervised research career development experience in the fields of biomedical and behavioral research, including translational research.
- ◆ Career Transition Award (K22)—provides support to an individual postdoctoral fellow in transition to a faculty position.
- ◆ Pathway to Independence (PI) Award (K99/R00)—provides up to five years of support consisting of two phases: 1) one to two years of mentored support for postdoctoral research scientists and 2) up to three years of independent support contingent on securing an independent research position.

More information about the different types of grant funding provided by NIH can be found at http://grants.nih.gov/grants/funding/funding_program.htm.

study sections, along with the names of the SRO and the study section members, is available at <http://www.csr.nih.gov/committees/rosterindex.asp>.

- ◆ **Special emphasis panels.** CSR runs a number of special emphasis panel meetings for specific scientific areas and applications. These panels consist of temporary reviewers only. Many special emphasis panels meet only once, while others are reoccurring or “standing” panels. (Though standing special emphasis panels do not have permanent or chartered members, the “temporary” members of these study sections sometimes make commitments to serve for a year or more as if they were chartered members of a regular standing study section.)
- ◆ **Fellowship study sections.** These study sections review individual fellowship grant applications, including F30, F31, F32, and F33 applications.

NIH Fellowship Awards

NIH provides several fellowships to graduate students and postdoctoral fellows. They include:

- ◆ Individual Predoctoral National Research Service Award for M.D./Ph.D. (F30)—provides a fellowship for predoctoral training leading to a combined M.D./Ph.D.
- ◆ Predoctoral Individual National Research Service Award (F30)—supports predoctoral individuals with supervised research training in specified health and health-related areas leading to a Ph.D.
- ◆ Postdoctoral Individual National Research Service Award (F32)—provides postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.
- ◆ National Research Service Awards for Senior Fellows (F33)—provides opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

- ◆ **SBIR/STTR study sections.** These study sections review small business innovation research and small business technology transfer grant applications. They do not have permanent members but rather are assembled on an ad hoc basis. These panels typically include CEOs and presidents of companies, along with basic scientists.

The rest of the chapter focuses on regular standing study sections.

WHO MAKES UP A STUDY SECTION?

A regular standing R01 study section typically consists of 20–40 scientists whose combined expertise covers a broad range of knowledge in a designated area of study. At a given meeting of the study section, the expertise of the group is commonly adjusted by supplementing the permanent membership with ad hoc invitees to ensure adequate coverage of the science represented in the grant applications assigned to this round of study section review.

Permanent versus Temporary Members

Two kinds of reviewers participate in R01 study sections. They include:

- ◆ Permanent or standing members. These individuals typically serve a four-year term and attend three meetings per year. CSR recently released new guidelines to give reviewers more flexibility. Permanent members of a regular or chartered study section can now choose to serve for a six-year term and attend two study section meetings per year.
- ◆ Ad hoc or temporary members. These scientists are selected to participate in one meeting of a study section—for example, to replace a permanent member who is unable to attend or to provide additional expertise at the review. They carry out all the responsibilities of permanent study section members but without the commitment to serve again. Being an ad hoc member can be a stepping stone toward becoming a permanent member.

The SRO is responsible for appointing study section members and temporary reviewers.

How Are Study Section Members Selected?

SROs use a number of sources to identify potential study section members. For example, an SRO might approach

- ◆ Authors of recent publications in the area covered by the study section
- ◆ Speakers at scientific meetings
- ◆ Scientists who have obtained NIH grants in the area of the study section
- ◆ Scientists recommended by present and former study section members
- ◆ Scientists recommended by NIH program staff

Recently, professional societies and university research deans have started to nominate volunteer reviewers whose names are added to a CSR database. CSR now has about 4,000 entries in that database, which is searchable by expertise.

Question. I would like to be an ad hoc member in a study section. How can I identify myself as wishing to be considered?

Answer. Information about each study section, including contact information, can be found at <http://www.csr.nih.gov/committees/rosterindex.asp>. First, identify which study section is most appropriate for your expertise. You can then contact the SRO and send him or her your curriculum vitae (CV), asking to be considered for service. If you meet the minimum qualifications to be a reviewer, the SRO will contact you directly. CSR, however, encourages you to contact your professional society or research dean first, letting them know you are interested in being a reviewer. Ask them to add your name to the CSR list of recommended reviewers.

At a minimum, a scientist considered to be a member of a study section usually has

- ◆ Broad and independent research experience
- ◆ A strong publishing record
- ◆ Major peer-reviewed grants (R01) or the equivalent
- ◆ An understanding of the review process

An SRO will often “try out” a potential reviewer on an ad hoc basis before asking him or her to become a permanent member of a study section. In such cases, the SRO is looking for a reviewer who is committed

to high-quality, fair review; is reliable; has the ability to articulate his or her view succinctly and to engage in productive discussions; and has the propensity to work collegially in a group.

A YEAR IN THE LIFE OF A STUDY SECTION MEMBER

If you have ever wondered what a member of a study section does, what follows is a brief summary. For more detailed information, visit the CSR website at <http://cms.csr.nih.gov>.

Responsibilities of Study Section Members

Permanent members participate in two or three study section meetings each year, which are held in January–March, May–July, and September–November. As many as 60–100 applications may be under review per meeting. At each meeting, members need to be prepared to discuss the several grant applications assigned to them.

Each application is assigned to at least three study section members: the primary and secondary reviewers, and one discussant or reader. Together, these three reviewers lead the discussion of the application at the study section meeting.

Timeline and Process of Review

About 6 weeks before a review meeting, the SRO assigns each member 7–10 grant applications for which he or she will be either primary or secondary reviewer or reader. (At this time, reviewers should communicate any conflicts of interest or other concerns to the SRO so that he or she can make other assignments.) The primary and secondary reviewers write detailed critiques and provide preliminary scores for an application.

The reader provides a preliminary score. The reader does not usually have to give a comprehensive critique of an application before the review meeting but rather provides shorter, written comments.

Confidentiality and Conflicts of Interest

Remember, the grant applications are considered confidential, so you should not discuss them outside the review meeting. When the SRO provides the grant applications and assigns reviewers, you should notify him or her if you think additional expertise is needed to review an application.

You should also notify the SRO if you think there is or may be a conflict of interest; the SRO will then assign the application to another reviewer. Conflicts of interest include:

- ◆ You have a personal, financial, or professional relationship with any investigators listed on the application (for example, a collaborator or former postdoc).
- ◆ You will benefit directly from the decision to fund or not fund the application.

If you aren't sure about a circumstance that potentially could be a conflict of interest or that might be perceived as such, you should discuss your concerns with the SRO. It is better to err on the safe side.

Once the preliminary scores and critiques are in, the SRO posts the written comments and scores on a confidential website for all members of the study section to see. This process usually occurs two to three days before the review meeting. The SRO also compiles a list of applications that initially scored in the lower half and posts them at this time. These applications are not discussed at the meeting. (If a study section member does not agree with this decision, he or she can “rescue” an application, or bring it up for discussion at the review meeting.)

Review meetings can last up to two days, depending on the number of applications being discussed. (As a rule of thumb, if more than 45 applications are being discussed, the meeting will last two days.) One member serves as chair and conducts the meeting with the SRO. Meetings of regular standing study sections are conducted in person, although sometimes members participate by phone.

After discussing each application, all study section members assign a final score to it (see section on how scores are calculated). During or after the meeting, a reviewer has a chance to amend some of his or her comments. Then the SRO prepares a “summary statement” for the grant applicant. The summary statement includes the overall score for the application and portions of the written critiques provided by the primary and secondary reviewers, in the so-called pink sheet.

(To see an example summary statement, go to <http://www.niaid.nih.gov/ncn/grants/app/default.htm#sum>.)

What Happens at the Review Meeting

At the review meeting, all study section members receive a list of applications in the order in which they will be discussed. As each application comes up for discussion, each of its assigned reviewers gives a short presentation including a brief summary of the research proposal, its strengths and weaknesses, and recommendation for funding. Typically, these presentations should last about five minutes.

TIP: Strive to be concise and keep your presentation within the recommended five-minute time frame. Your colleagues will appreciate it!

After the three presentations, all members of the study section discuss the grant application. Most other members will not have read the application (although reviewers often read the abstracts of several other applications and may read nonassigned applications that interest them), but they might provide information about the investigator or the research field. They will also typically ask questions and want clarifications from the three reviewers. A discussion can last from five minutes to half an hour. The chair is responsible for leading the discussion to make sure it is focused and the comments are relevant. The chair is responsible for bringing the discussion to an end.

Once the discussion is over, study section members score the application.

At a Glance—Study Section Timeline

Four to six weeks before the study section meeting: SRO sends all study section members a CD with all the applications or makes them available on a secure website. The SRO includes a list of the applications for which members are to serve as reviewers. (At this time, study section members should identify potential conflicts of interest or other concerns to the SRO.)

One week before the study section meeting: The primary and secondary reviewers and the reader provide written comments and preliminary scores.

Two to three days before the study section meeting: Comments and scores are available for viewing, along with a proposed list of applications with the lower half of scores, which will not be discussed. (Now is the time to tell the SRO that you want to rescue an application and include it for discussion—don't wait until the meeting to do this.)

Study section meeting: Applications are discussed and scored.

Up to two weeks after the study section meeting: Grant critiques are still available for viewing on the review meeting website. Reviewers have an opportunity to change their written comments.

Two weeks after the study section meeting: The website is closed and the SRO starts to prepare summary statements to the grant applicants.

Time Commitment

Most scientists say that it takes about a day to read each grant application assigned to them, research the literature, write a critique, and prepare to discuss it at the review meeting. Study section members spend time reading other reviewers' comments and preparing to defend their views if there are any differences of opinion. Attending a meeting typically requires a couple of days plus travel time.

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A permanent study section member will spend about two solid weeks preparing for each meeting—about six weeks a year. Adding in some ramp up and ramp down work around the study section meeting and travel time—that amounts to an investment of about 7 weeks a year.

—Keith Yamamoto, University of California,
San Francisco

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WHY SERVE ON A STUDY SECTION?

The main reason to serve on a study section is that it's one of your responsibilities as a scientist. But there are many advantages to serving on a study section. By participating in this process, you will

- ◆ Be exposed to the newest research. Many grant applications describe results and ideas that have not been published.
- ◆ Broaden your scientific horizons. You will read about research that is not strictly in your field and hear scientists discuss science from different perspectives.
- ◆ Become more successful at obtaining grants. You will become intimately familiar with the process of evaluating proposals and know exactly what the reviewers are looking for in a competitive application.
- ◆ Advance your career. This type of service looks good on your CV and is a good way to network with other scientists in your field.
- ◆ Become a better mentor. You will be able to tell your students and postdocs what makes a good grant application.

The main disadvantage of serving on a study section is that it is time-consuming. Especially if you are just starting out in your career, the time required to review grants and participate in study section meetings will take valuable time away from your research, which should be your focus at this stage of your career.

I often hear that being a study section member is the best way to learn how to write grants. But the job of a study section is to provide fair and objective assessments of grant applications. It is not to mentor scientists on how to write a grant. That mentoring function is crucial but it is the responsibility of senior scientists within each research institution, not of the NIH peer review system.

—Keith Yamamoto, University of California,
San Francisco

But do think about the offer carefully. If you don't think you have the time to participate in a particular meeting, it is okay to turn down an SRO letting him or her know when you might be available (for example, after you finished teaching a course or once an important site visit is behind you). You could also offer to serve as an ad hoc reviewer.

Question. I have been asked to be a permanent member of a study section, but I have not yet started the process of applying for tenure. Should I agree?

Answer. Most established scientists caution against becoming a permanent member of a study section before obtaining tenure. Until then, your top priority should be establishing your laboratory. Some scientists, however, point out that serving on a study section as an ad hoc reviewer can be helpful to a career because you will become more knowledgeable about how to write successful grant applications and you will have the opportunity to network with other scientists (also see page 8, "Why Serve on a Study Section?").

YOU HAVE BEEN ASKED TO SERVE: NOW WHAT?

When an SRO asks you to become a member of a study section, there are some things you might want to discuss and possibly negotiate.

- ◆ If you are being asked to be a permanent member, find out the size of the study section and how many grant applications each member is asked to review. The answers might help you choose whether you want to be

appointed for a four-year term and attend three meetings per year or for a six-year term and attend two meetings per year.

- ◆ If you accept the invitation to serve, you can sometimes negotiate whether you need to attend all meetings in person. If a particular meeting coincides with a family obligation, you may be able to participate in the meeting by phone. You can also negotiate the start of your term of service.
- ◆ If you are being asked to serve as an ad hoc member, ask how many grants you will have to review for this particular meeting. If the SRO would like you to review 10 grant applications but you don't have the time to do so, you can say, "I have too many other obligations right now but I am happy to review 4." This is not something that can be "officially" negotiated but many people do it.
- ◆ Let the SRO know if there are certain scientific fields covered by the study section that you are not willing to review or feel uncomfortable reviewing because you are not sufficiently knowledgeable. Once the grant applications have been assigned to you, you have a chance to turn certain ones down if you don't feel qualified to review them, but that causes problems for the SRO. It is better to discuss these things upfront.

THE JOB OF A STUDY SECTION MEMBER

What to Cover in Your Critique

After you have read the applications assigned to you, you will have to critique them. If you have never written such a critique, NIH provides some guidelines for what is expected at <http://cms.csr.nih.gov/peerreviewmeetings/reviewerguidelines/>.

For R01 applications, the critique consists of a discussion of the following five criteria:

- ◆ **Significance.** Does this study address an important problem? If the aims of the application are achieved, how will scientific or clinical practice be advanced?
- ◆ **Approach.** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the study? Here you might want to mention preliminary results and how they will be enhanced by further work.
- ◆ **Innovation.** Is the project original and innovative?

- ◆ **Investigators.** Are the investigators appropriately trained and well suited to carry out this work?
- ◆ **Environment.** Does the scientific environment in which the work will be done contribute to the probability of success?

TIP: The summary statement prepared by the SRO will include unedited reviewer comments, so take care not to include personal identifiers.

In addition, if the application is for a renewal grant, the reviewers should include an evaluation of progress over the past project period. For amended applications, the reviewers should address progress, changes, and responses to the critiques in the summary statement from the previous submission.

Writing an Effective Critique

Current and former study section members offer the following advice for writing critiques.

- ◆ **Don't get bogged down.** There is general consensus among scientists that the review process has become overly dependent on detailing routine research methods, at the expense of considering the overall impact of the application to science and health. Ask yourself, “Even if all the issues regarding experimental methods and approaches are addressed, how big a difference will this work make if it goes forward?”
- ◆ **Be clear.** Reviewers are often too subtle when providing negative feedback. If you think there is a fatal flaw in the proposal, say what it is. Without this information the applicant will make only “cosmetic” changes and resubmit the application without addressing the flaw.
- ◆ **Give a balanced assessment.** Don't focus solely on the negatives. In addition to identifying weaknesses in the application, your review should summarize its major strengths.
- ◆ **Don't rewrite the application.** Your job is to assess the application. The applicant should have a clear idea of where the application falls short, but you should not suggest experiments or come up with better references.

TIP: Ask senior colleagues in your department to give you copies of critiques they have received. Reading several of these critiques will give you an idea of the structure, length, and tone you should use.

(Some of these suggestions were adapted from the “Insider Guide to Peer Review for New Reviewers” at <http://cms.csr.nih.gov/PeerReviewMeetings/Advice4Reviewers.htm>.)

Discussing Grant Applications at the Study Section Meeting

It can be intimidating to participate in a study section meeting with established and well-known scientists in your field, especially if it is your first time there. Here are some suggestions on how to conduct yourself:

- ◆ **Stand your ground.** You were chosen to be a reviewer because you are an accomplished scientist. Don't be afraid to voice your opinion on the merits of a proposal if you think another reviewer has missed them. (At the same time, don't be afraid to change your mind if another reviewer points out something you missed.)
- ◆ **Be prepared.** Make sure you are prepared to discuss in detail the grants you are presenting—including issues raised in the online comments—especially if you feel strongly that they should be funded, along with any applications you are rescuing. If you don't present them well, the investigator does not have a chance to get funded. If you are a primary reviewer, prepare your opening statement carefully, so that you can keep your discussion within a five-minute time frame.
- ◆ **Focus your discussion.** There is no need to talk about every aspect of a study. Just focus on the main strengths and weaknesses of the proposal, which will help other study section members arrive at a score.
- ◆ **Be an advocate for the application.** Make clear why you think it will really make a difference.
- ◆ **Avoid repetition.** If you agree with everything the previous reviewer said, just say that you agree and maybe add a couple of points. You don't need to give an identical presentation.
- ◆ **Keep the focus on the application.** You don't need to show others how smart you are! You are there to assess the merits of the applications.
- ◆ **Provide a balanced discussion.** There is no need to rip apart a grant application. Stick to listing its strengths and weaknesses.

When you go to a study section meeting, make an effort to network with everyone. Don't just sit in your hotel room reading grant applications. Make plans to go out for dinner or a drink. Try to make it a collegial occasion and have fun.

—Laura Knoll, University of Wisconsin–Madison

HOW SCORING WORKS

After discussing a grant application at the review meeting, each reviewer assigns a confidential score from 1.0 to 5.0 (with 1.0 being the highest score) to two significant figures (i.e., 2.2). The score reflects consideration of the five review criteria: significance, approach, innovation, investigators, and environment.

It is okay to give a score that is different from your preliminary score. If the discussion changed your mind about a particular application, your score should reflect that.

Once all the scores are in, individual scores are averaged and then multiplied by 100 to yield a single overall priority score for each application (i.e., 253). Priority scores are then converted to percentile rankings. This ranking is based on scores assigned to applications reviewed during the current round of review, plus the past two review rounds, for standing committees.

NIH IS RESTRUCTURING ITS PEER REVIEW SYSTEM

Former NIH director Elias Zerhouni (2002–2008) charged an advisory committee—cochaired by Lawrence Tabak, director of the National Institute of Dental and Craniofacial Research at NIH, and Keith Yamamoto at the University of California, San Francisco—to provide recommendations on how to improve the current system. NIH released its first set of proposed plans on September 12, 2008 (<http://enhancing-peer-review.nih.gov/>), which will be implemented in 2009 and 2010.

NIH is examining ways to improve its system for reviewing R01 grant applications. The “renovation” plans, scheduled for implementation in 2009 and 2010, include shortening grant applications—which are currently 25 pages or more. NIH plans to reduce the description of the experimental approach and methods. The intent is to make grant writers and reviewers focus more on why something is worth doing rather than on the details of how to do it. In addition, shorter grant applications will take less time for reviewers to read, making it possible for more reviewers to be assigned to each grant application.

Other changes include providing integer “grades” to each of the five rating criteria of grant applications to make more transparent the perceived strengths and weaknesses of each application, permitting only one resubmission or “amendment” of an application that is not funded (currently, two amended applications are allowed), providing more incentives and guidance for reviewers, and awarding more grants to early career investigators.

Reviewing grant applications is one of the most important services you will be asked to provide. It goes without saying that you should take this responsibility seriously. Not only are you deciding on the science that is supported and carried forward, but the way you conduct yourself in a study section will affect your reputation and standing among your peers.

RESOURCES

Center for Scientific Review, NIH: <http://cms.csr.nih.gov>.

Office of Extramural Research, NIH, Peer Review Policies and Practices:
<http://grants.nih.gov/grants/peer/peer.htm>.

“Getting Funded” (Chapter 9), *Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty*: www.hhmi.org/labmanagement.

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