

NIH SCIENTIFIC REVIEW ADMINISTRATOR'S ADVICE TO APPLICANTS

Scientific review administrators (SRA) of the study sections are involved in the review process for large numbers of grant applications. Because of this involvement, they are in an excellent position to advise applicants on how to handle a variety of things that might come up during the NIH review process. In this document, we have attempted to compile wisdom provided by SRAs on a number of issues faced by applicants. We have generalized this advice below so that it should represent good advice to ALL NIH applicants, recognizing that the specific practices of some study sections may vary somewhat. For this reason, we suggest that you check with the SRA of the specific study section reviewing your grant, if you have any questions about whether that study section may handle issues differently.

ADMINISTRATIVE REVIEW BY SRA: In general, the administrative review by an SRA entails looking for IACUC approval, answers to the questions covered in Sections E and F (human and animal welfare). These latter items are at the end of 30b and 37 in fellowship applications. Also included in this review is a search for letters from consultants and consortia, biographical sketches from all personnel listed on page 2 with advanced degrees, and modular grant information.

CHILDREN IN RESEARCH: All new applicants to the NIH who utilize human subjects in their research (EVEN those exempt from IRB approval because they meet one of the specific criteria for exemption from 45CFR46) are required to address this point in their application. The following web site provides policy and background information, a decision tree, and questions and answers regarding this issue: <<http://grants.nih.gov/grants/funding/children/children.htm>>.

In brief, if you are using human subjects, you will need to consider whether or not there are valid scientific or ethical reasons for you to exclude all children (under 21 years old) or certain age ranges of children. If there are no reasons for their exclusion, they should be included in your study.

If you discover that you should be including children but had not included them in your protocol, you will need to do two things. First, send the SRA of the study section to which your proposal is assigned a letter describing your plans so that he can pass them on to the study section members who are obligated to include information about inclusion of children as research subjects in their scientific evaluation of your proposal. Second, you will need to obtain IRB approval for the change. Ideally, IRB approval should be obtained BEFORE the study section meeting, however, review will NOT be held up because IRB approval has not yet been obtained. It MUST be obtained before any award can be made, however.

If you decide that you do not need to include children (or, for example, you will exclude children below 18 years old), you will need to send the SRA documentation of your reasoning for this exclusion, if those arguments were not already in the proposal. This will also be distributed to the reviewers.

Send a complete original and 5 collated copies (including cover letter, if used) of any material sent to the SRA. **ALWAYS INCLUDE THE FULL NIH GRANT NUMBER (e.g., 1-RO1-HL12345-01-A1) FOR YOUR PROPOSAL ON ALL CORRESPONDENCE.**

WOMEN AND MINORITIES: When a SRA does his administrative review of assigned proposals, one of the most common items found that has not been fully addressed in a proposal is appropriate information on the inclusion of women and minorities in the proposed study population, INCLUDING ESTIMATES ON PERCENTAGES. The SRA looks for this information either in Section E of the proposal, or in a separate section which some applicants include just before Section E. The goals for inclusion of women and minorities should be available for reviews to evaluate, but even if they are not available at the time of review, they MUST be supplied to the funding institute prior to funding. Best advice is to make them part of the proposal.

If you send the goals late, send six complete collated copies (including cover letter).

IRB APPROVAL: NIH no longer requires that IRB approvals be obtained prior to conducting the review of your proposal. However, if your approval is obtained prior to the meeting date of the study section, you should feel free to send a copy of the approval letter to the SRA. He should pass the memo on to the funding institute and thereby speed the potential funding of the proposal.

IACUC APPROVAL: This is the only administrative item which, by its absence, could prevent your proposal from being reviewed. If you plan to use animals, and you list IACUC approval as "pending" on the proposal face page, and you fail to get a copy of the approval letter to the SRA PRIOR to the meeting date of the study section, your proposal will NOT be reviewed. It will be deferred to the next cycle. If you need to send your approval letter to your SRA, do NOT send a copy of your entire IACUC application, JUST SEND THE APPROVAL LETTER. There is no need to use overnight couriers to send the approval letter(s) unless you are "coming down to the wire," and even then, a FAX copy generally will suffice. If you send a FAX copy to your SRA, follow that up by sending the original to your Program Representative when you are notified of the identity of that individual. Your Program Representative will be named on the Summary Statement you receive after study section review. IACUC approval letters generally are NOT sent to the reviewers; they are provided to them in their "last minute" folders at the time of the meeting.

Send six complete collated copies (including cover letter).

RECALIBRATION: Several years ago all CSR (Center for Scientific Review - formerly, Division of Research Grants) study sections underwent a "recalibration" in order to establish 300 as the median score for proposals being reviewed. Since the scoring range available is 100 (best) to 500 (worst), this makes sense. Spreading scores in this fashion allows funding institutes to more easily discriminate between proposals close to the eventual "payline."

Note that percentiling of priority scores is applied to R01 proposals ONLY (Not to R15, R21, or F32 applications).

WEB-BASED REVIEW: Some CSR study sections have started using "Electronic (web) Reviews". In brief, the concept is that reviewers post their reviews to a secure web site during the month prior to the study section meeting. During most of that period they will have access only to their assigned applications, i.e., those for which they are assigned as primary or secondary reviewers or readers. During the final week before the meeting, the posting phase will conclude, and the web site will open for all reviewers who will be at the study section meeting to view all reviews for that cycle (except any with which they have a conflict). This allows reviewers and discussants assigned to your application to see what strengths and weaknesses have been identified by others, with time enough for reflection and revision of their own draft reviews. This should provide more focused discussion at the meeting, and no one will be caught off guard by an argument that may not have occurred to them. At the end of the meeting, the reviewers will post revised critiques to the web site reflecting, potentially, both changes that they made based on the pre-meeting viewing, as well as changes that they may wish to make based on meeting discussions.

For the most part, this change in study section procedure will have no apparent impact on the Summary Statement received by applicants, although it may provide higher quality Summary Statements. One potential change is that applicants might now find a greater similarity in the arguments, since both reviewers will have an opportunity to modify their critiques to incorporate points raised by their counterparts. This could happen even for "streamlined proposals" (Triaged proposals), which are not actually discussed at the meeting (see below). Another potential way Summary Statements might be improved is by inclusion of points which are actually discussed at the meeting. In the past, reviewers had to complete their written reviews prior to arrival at the meeting and had little, if any, opportunity to change them to reflect "changes of heart" brought about by hearing the views of others.

STREAMLINED REVIEW PROCESS: A complete description of the Streamlined Review Process may be found at the CSR web site at the following URL: <<http://www.csr.nih.gov/review/streamln.htm>>. Streamlining is applied to ALL research proposals, those for which the "mechanism" portion of the NIH grant number begins with "R" (e.g. R01, R15, or R21).

To provide a better view of how this process actually works, the reviewer instructions regarding streamlined review are summarized below:

- 1) By a predetermined date prior to the study section meeting, assigned reviewers/readers are asked to identify to the SRA any of their assigned applications that they believe do NOT fall within the upper half. This process is called "triaging."
- 2) A few days prior to the study section meeting, all study section members receive a list from the SRA of those applications proposed by at least two assigned reviewers/readers to be excluded from the upper half, i.e., triaged. [NOTE: Although the term "triage" is not used officially by NIH, it is widely used by reviewers and applicants to describe those applications in the lower half, and thus are not discussed or scored by the study sections to which they are assigned.] This list of proposed triaged proposals is considered final, pending confirmation at the beginning of the study section meeting.
- 3) At the beginning of the meeting, the list is read aloud by the SRA or study section Chair for final concurrence by the entire study section. Non-concurrence by only ONE member (whether regular or ad hoc) is sufficient to bring an application to full review at the meeting. Occasionally, it may also happen that study section members will unanimously agree, either at the outset of the meeting or later, during discussion of applications, to designate additional proposals as not requiring full discussion and scoring.

For applications NOT in the upper half, only reviewers' critiques, essentially unaltered, are incorporated into the Summary Statement and provided to the investigator, along with an introductory paragraph briefly describing the review process and the resultant summary statement. These proposals DO NOT receive a priority score.

- 4) For those applications that are considered to be in the upper half, and therefore discussed at the study section meeting, and scored, reviewers are expected to modify their critiques appropriately during or after the meeting, removing, for example, criticisms that are negated through discussion during the meeting. Otherwise, the reviewers' critiques will be included in the Summary Statement, essentially unaltered by the SRA. Additionally, for these applications, the introductory paragraph describing the streamlined review process is replaced by a "Resume and Summary of Discussion" section. This section should convey the highlights, i.e., major strengths and weaknesses, identified during the meeting discussion.
- 5) The full range of priority scores from 100 to 500 is NOT used for the applications in the upper half. Logically, if precisely half of the applications are unscored, when scoring an application, study section members should assign a score of approximately 300 for an application of "average" quality," and distribute scores for higher quality applications in the upper half across the range from 100 to 300. However, if significantly more than 50% of the applications are designated in the "upper half," scores over 300 may be assigned. In addition, reviewers are urged to "vote their conscience" on any proposal. That is, if a reviewer maintains that an application is not in the upper half, despite discussion and general consensus of other reviewers, he/she may still provide whatever priority score he/she believes appropriate.

One additional comment regarding the Streamlined Review Process:

ALL competing R01 proposals reviewed by a study section, whether scored or not, are considered in the base for calculating percentiles (R15 and R21 proposals will be excluded). Thus, there is no mathematical advantage to scored applications if the upper half of proposals constitutes more than 50% of the total in a given review cycle.

HOW CAN YOU TELL WHERE YOU ARE IN THE "NON-COMPETITIVE" CONTINUUM?

There really is no way for you to know that if your proposal is triaged, other than by carefully interpreting the language in the Summary Statement. Careful reading of the Summary Statement should give you a good idea of whether a revised proposal is being "invited" or not.

SHOULD I SEND SUPPLEMENTAL INFORMATION? Check with the SRA of the study section to which your application is assigned before sending any supplemental material. The advice provided below is good general advice, but individual study sections may have specific requirements and/or limitations on supplemental material. Supplemental information generally falls into one of three categories:

- 1) **New Preliminary Data:** Please limit submissions of new data to **THREE PAGES**, including figures and tables, and limit it to only one submission per application between the time of original submission of the proposal and the study section meeting date. If you send Preliminary Data, send six complete collated copies (including cover letter). Please report only on significant findings (e.g., demonstration of a new technique); don't risk aggravating reviewers by reporting on 5 new data points which confirm the 20 already in the proposal.
- 2) **Updates on the Status of Publications:** If you are concerned that productivity is (or was, if your proposal is an a revision) an issue, you may send a brief update to let the reviewers know which pieces of the work have progressed from "in preparation" to "submitted," etc. If productivity is not an issue, do not waste your time or the reviewers' with an update. **DO NOT** send reprints to replace draft manuscripts submitted in the proposal appendix. **DO NOT** send new appendix material if you have already reached the limit of 10 appendix items. Send six complete collated copies (including cover letter) of anything you send.
- 3) **Responses to Administrative Review:** Send these items to the SRA as promptly as possible.

DEADLINES: The initial mailing of proposals from the SRA to reviewers takes place 4-6 weeks prior to the date of the study section meeting. Supplemental material sent to the SRA prior to about 3 weeks before the study section meeting will be forwarded to the reviewers. After that, material will be placed in reviewers' "last minute" folders and delivered to the hotel for them to consider when they arrive. While a tentative decision on designating an application as being "triated," i.e., in the lower half, will have been made during the week before the meeting, that decision can be reversed on the first day of the meeting when the "triage list" is read aloud to the convened reviewers. Thus, any information you send can be considered before any proposal is irrevocably placed in the lower half. The best advice during this "last minute" time period, however, is to keep your message **VERY** brief and **VERY** focused, since there are no guarantees that the reviewers will have time to read and absorb material this late in the game. There are also no guarantees that there will be a reference to the late information in the final Summary Statement. Again, whatever information you send, send six complete collated copies (including cover letter).

WHEN WILL SCORES BE AVAILABLE? Scores generally are released into the CSR computer system by the SRA within three working days of the meeting. This will, within another day or two, result in a mailer being sent to you. **PLEASE DO NOT CALL THE SRA FOR YOUR SCORE.** It is NIH

policy that he/she cannot give it to you. In addition, answering such calls slows him/her progress in getting Summary Statements out. Once the review process is concluded your NIH contact for issues regarding your proposal should be your Program Representative.

WHEN WILL REVIEWS BE AVAILABLE? While the card with your priority score will indicate that you should allow 6-8 weeks for Summary Statements to be completed, many SRAs have them ready prior to that time. When each Summary Statement is completed, it is "released" by the SRA into the NIH computer system for the funding institute (e.g., NHLBI) to access, review for errors, and mail out. If you have not received your Summary Statement within 8 weeks of the study section meeting, call your PROGRAM REPRESENTATIVE, NOT the SRA, to see if it has been mailed. Once the study section has met, it is the responsibility of the Program Representative to work with you on any concerns you may have. They will contact the SRA regarding clarification of any ambiguous wording that a reviewer might have used in his/her review. The name and phone number of your Program Representative will be listed on the card notifying you of your priority score.

CONFIDENTIALITY OF THE REVIEW PROCESS: It is entirely inappropriate for you, your mentor, or anyone else to make any contact with a study section member regarding the review of your proposal. Reviewers are instructed not to discuss anything about the review with you for a variety of reasons. First, it puts study section members in an extremely awkward position. Second, while you may think you know who reviewed your proposal, you may well be wrong. Third, frequently when any information is passed on by reviewers it is distorted, often inaccurate or incomplete, and may be useless or misleading. Fourth, no reviewer will know your final priority score, i.e., the average of all reviewers' scores assigned to your proposal. Final priority scores are computed after reviewers return home. Further, reviewers will not know final percentiles and institute paylines. Reviewers work very hard to keep the system operating for very little reward; badgering them will only make it more difficult for NIH to recruit top quality reviewers willing to make the sacrifices involved in making the peer review system work as well as it does.