

After Your NIH Grant Review: Next Steps

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Goals of Today's Talk

- You have worked hard to write and submit your NIH grant application. Congratulations! That is an amazing achievement given the complexity and difficulty of drafting and submitting an NIH grant application. Reflect on that accomplishment for a moment.
- What comes next?
- The purpose of today's presentation is dual-fold:
 - To help demystify what comes next.
 - To offer one possible set of steps that will hopefully be useful to you as you navigate the winding road to eventual funding.

The NIH Review: Preliminary Scoring

- Three reviewers will be assigned to read and score your application prior to the study section meeting (*assigned reviewers*).
- R grant applications will receive *preliminary* scores in five areas:
 - Significance
 - Innovation
 - Investigators
 - Approach
 - Environment
- K grant applications will receive *preliminary* scores in these areas:
 - Candidate
 - Career Development Plan/Career Goals & Objectives
 - Research Plan
 - Mentors/Co-Mentor(s), Consultant(s), Collaborator(s)
 - Environment and Institutional Commitment to the Candidate

Additional Review Criteria

- While not officially part of the scoring process, reviewers are asked to comment on other features of the application, such as:
 - Study Timeline
 - Protections for Human Subjects
 - Plans for Including Participants with Representation based on Sex/Gender, Race/Ethnicity, and Age
 - Vertebrate Animals
 - Biohazards
 - Training in the Responsible Conduct of Research (K and other training grants)
 - Resource Sharing Plans
 - Budget and Period of Support

Preliminary Impact Score

- Area scores will inform (not be averaged to yield) an *overall impact score*.
- The overall impact score from each reviewer is on a 1-9 scale.
 - 1 is the best: outstanding with no weaknesses.
 - 9 is the worst.
- Reviewers are encouraged to use the full scale range.
- The three scores are averaged and multiplied by 10 to obtain an overall *preliminary* impact score ranging from 10 to 90.
- Applications' *preliminary* impact scores are rank-ordered. The top 50% considered by that study section move on to be discussed.
- The *preliminary* impact scores for not discussed applications are usually posted on ERA Commons from one to several days after the review.

Application Not Discussed

- If your application happens to be in the lower 50% of the preliminary scores distribution, it will most likely be *not discussed (triaged)*.
 - At the beginning of the study section review meeting, reviewers are asked if there are any specific applications in the lower 50% of preliminary scores which they wish to discuss. While this can happen, in my experience it is rare.
- If your application is not discussed (triaged), do not despair – many strong applications are not discussed initially.
- If your application is not discussed, you will receive the reviewers' comments and the preliminary scores for the five areas in a PDF document known as a *summary statement*.
- If the application was triaged, you must decide whether to submit an improved resubmission application. Sometimes such resubmissions have been scored and funded. Others get scored, but not in a fundable range, positioning the application for another submission.

Discussed Application

- The review group will contain the three reviewers who read and scored your application with detailed comments to be placed in the summary statement plus other reviewers who are supposed to have read the application.
- If your application is discussed, the first reviewer will present/summarize it for the members of the review group and then give their preliminary score. The primary reviewer's summary sets the stage for the discussion.
- The other two reviewers add comments on topics unaddressed by the first reviewer and give their own preliminary scores.
- The committee discusses the application further as a group. This usually takes just a few minutes (e.g., 5-10 minutes per application).
- The three reviewers then state their final scores. Those could change based on the discussion that just took place.
- The chair of the review asks if any remaining study section members plan to vote outside the range of scores set by the three reviewers who read the application. Then all study section members record their final scores confidentially.
- Any non-scoring area concerns are discussed (e.g., budget, human subjects)

Discussed Application: Final Impact Score

- Check ERA Commons after submitting the application to learn to which NIH review group (study section) it is assigned for review.
- The assignment information in Commons will also tell you when it will be reviewed.
- Final impact scores from the study section members are averaged and multiplied by 10 to yield a final impact score that ranges from (10) best/perfect to 90 (worst possible).
- See: <https://www.niaid.nih.gov/grants-contracts/scoring-summary-statements#A4> for a table mapping the scores onto plain language descriptors such as “outstanding”, “fair”, and “poor.”
- Since the worst applications are triaged prior to the review, scored applications usually receive scores in the range of 10-50.
- Scores can be difficult to interpret without the summary statement.

Discussed Application: Receiving Your Score

- Scores are usually posted by NIH to ERA Commons within 1-2 days following the review session.
- Depending on the grant mechanism (e.g., R01) and NIH institute, some institutes will also supply a percentile ranking of the score.
 - While not all institutes adhere to a percentile-based pay line, for those that do the percentile ranking can give you an initial intuition of your application's chances for eventual funding.
- Scores and even percentile rankings are difficult to interpret without context; summary statements supply that context.
- Summary statements take longer to issue, usually 2-6 weeks. This is because they contain written comments in bullet lists, one each per review criterion, in addition to the final area scores.
- **Once you get your summary statement, what should you do next?**

Digesting the Summary Statement

- Just opening a summary statement can be stressful; when I get a summary statement, I like to read through it quickly the first time.
- Take pride and satisfaction in the strengths.
- Glance at and try to understand the weaknesses in a general way.
- Don't overlook the non-scoring criteria (which, despite instructions for reviewers to the contrary, may have affected your score).
- Set it aside once you are done reading it. Go do something else, preferably something fun and distracting. Don't look at the statement again for at least 48-72 hours (preferred) or 24 hours (minimum), including at least one night's worth of sleep.
- Receiving a summary statement can be very jarring, even shocking psychologically. Giving the unconscious mind to adapt to the shock will help you view the statement in a new light later on.

Analyzing the Summary Statement

- Whether your application was discussed or triaged, return to the summary statement later to do a more in-depth reading of it.
- Create two matrices to summarize its contents:
 - Numeric matrix of the scores by reviewer and area with averages across the rows and columns, possibly with red/yellow/green traffic highlighting.
 - Text table with the following columns:
 - Theme/Issue
 - Reviewer 1 comments
 - Reviewer 2 comments
 - Reviewer 3 comments
 - Ideas for response: This can contain a bullet list of ideas for possible responses, names of collaborators to help you with a given response, etc.
 - Don't forget to include comments in the overall impact paragraphs offered by each reviewer if they aren't listed in one of the 5 key impact areas.
 - Also don't forget to include the non-scoring topics comments/concerns (e.g., budget, timeline, and most especially human subjects protections comments)

Example of Numeric Scores Matrix

| <u>Area</u> | <u>Reviewer 1</u> | <u>Reviewer 2</u> | <u>Reviewer 3</u> | <u>Area Avg.</u> |
|---------------|-------------------|-------------------|-------------------|------------------|
| Significance | 3 | 6 | 1 | 3.33 |
| Investigator | 4 | 3 | 3 | 3.33 |
| Innovation | 4 | 4 | 1 | 3 |
| Approach | 7 | 5 | 6 | 6 |
| Environment | 2 | 4 | 1 | 2.333 |
| Reviewer Avg. | 4 | 4.4 | 2.4 | |

Reviewer Comments Table Example

| Issue | Reviewer 1 | Reviewer 2 | Reviewer 3 | Ideas for Response |
|--|--|--|---|---|
| Definition of mentoring | "lack of foundation of what mentoring is and its linkages to social support (we know a great deal about social support and HIV care engagement)" | "Definition of informal mentors as put forth in the interview guide is vague." | | <ul style="list-style-type: none"> Clarify definition of mentoring Summarize social support literature and how mentoring is a distinct construct |
| Rigor of qualitative methods | "lack of qualitative rigor (limited/none theme developed methods provided, interview guide that focuses on yes/no responses)" | "Research methods are standard" "Not specified if the dyads will be out-of-care or in-care." | <p>"there is little innovation in the proposed qualitative methods and data analysis." "The methods are not particularly innovative, nor is the analysis plan." "Interview guides should be provided or at least a brief table of topics and more sample questions." "Data analysis procedures for Aim 2 are under-described. What are the principles of dyadic qualitative data analysis?"</p> | <ul style="list-style-type: none"> Changed approach to mixed methods such that qualitative participants selected based on whether they are in engaged in care and level of support from informal mentors The interview guide has been revised to only include open-ended questions Description of data analysis plan has been expanded |
| Limited involvement of experienced investigators | "The PI does not have experience in intervention research, and have limited local support to successfully conduct this work." | "Dr. Arnold will devote 0.6 calendar months to the project, while the other investigators will be consultants with limited commitment to the project." "Co-investigators don't appear to have adequate support to contribute to the project, while 2.0 FTE for coordinators/assistants appears excessive given the limited scope of the project." | "Investigative team is a little thin with Co-I Arnold at only 5% time and the consultants only offering between 5 and 8 hours per year." | <ul style="list-style-type: none"> The time devoted to the project for Dr. Arnold has been increased to 7.5%, Dr. Brewer has been added as a Co-Investigator for 5% in Year 1 and 2.5% Year 2, and Dr. Johnson's consultation has been increased to 2.5% in Year 2 |

Contact Your Program Officer

- After receiving, digesting, and analyzing your summary statement, **contact your NIH program officer (PO)** for a real-time conversation.
 - Sometimes POs attend NIH reviews and can share their impressions of what caused reviewers the most concern and drove the scoring.
 - Even if they did not attend the review, POs will still often have helpful insights for next steps.
- If an application was scored, you need to know whether the score is good enough for your application to be considered for funding by NIH vs. needing to be resubmitted. The PO can give you that information.
- Unless your score is so strong that it is a “slam dunk” for funding, you will likely need to resubmit a revised application.

What if I Need to Resubmit?

- If the PO tells you that you will need to resubmit a revised version of the application, you will need to revise the application
- Revised applications include a 1-page introduction responding to the reviews.
- There are various options for how to structure it.
- One suggested format:
 - A brief opening paragraph containing thanks to the reviewers plus a few of their more laudatory quotes.
 - 3-6 paragraphs summarizing your changes made in response to the biggest issues identified in your summary statement analysis.
 - Penultimate “other issues” paragraph with a brief numbered list in paragraph form touching on the smaller points raised by reviewers.
 - Closing paragraph restating high significance (referencing relevant NIH priorities if applicable) and leaving reviewers on a high note.

Intro Page – Further Thoughts

- Some NIH-funded investigators contend that the intro page is the most important part of a revised grant application and that reviewers will read it most carefully.
- As such, it pays to get drafts of this page reviewed and possibly re-reviewed by experienced colleagues and mentors. This is a document where you definitely want to put your best foot forward.
- Before starting to revise the application or draft the response letter, you should give some thought to your process. Do you prefer to make changes in the application and then work on the 1-page intro (bottom up) or draft the 1-page intro first (top down)? It's up to you to choose which approach works best for you. Having a plan (vs. switching back and forth a lot between the main application and the intro without a plan) can be less stressful and limit confusion and discouragement.

Application in Line for Funding

- What if you are told by your NIH Program Officer that NIH is considering advancing the application for funding?
- Congratulations! This is fantastic news. Take a deep breath and pat yourself on the back for getting the application this far in the process. Then respond promptly to any NIH paperwork requests (e.g., Just-in-Time [JIT] requests).
- First, **confirm with the PO whether they advise you to resubmit a revised application vs. not resubmit.** This is because some applications that are at the agency's pay line or uncertain to receive funding may be recommended to be resubmitted, even if it turns out later that NIH can fund the initial submission.
- Next, **ask the PO what they need from you as a response.** Often POs will ask for a letter from you to the PO laying out the reviewers' concerns and your responses to them.

In Line for Funding: Letter to PO

- Keep in mind that the audience for your PO letter has shifted from NIH reviewers to NIH itself. You are writing this letter to the PO so that the PO can make the strongest possible case to their colleagues at NIH and to members of the NIH budget council to fund the application.
- Ask the PO what format and content of the letter would be most helpful to them. POs may tell you which issues they would like you to address as being most important in their view as well as whether other issues raised by the NIH reviewers are of less concern to the PO.
- Sometimes, the format of the response letter will resemble a journal manuscript revise-and-resubmit letter to the editor.
- The PO letter is often limited to 1-3 pages in length, but format and length preferences may vary widely among POs. Check with them.

Letter to PO - More

- As with a 1-page intro to resubmission document, share it with your mentors and colleagues for feedback.
- Also, ask the PO whether they can give feedback, too, if you are able to get an initial draft of the letter to them early enough for them to comment on it and send it back to you to revise.
- Note that when the PO needs your final version of the letter will likely be driven by NIH internal deadlines such as when budget councils meet.
- The PO will take the letter to the budget council and be prepared to address any questions raised by the council about your application.
- Once the council proposes to move your application forward for funding and the PO alerts you about that, “get the champagne ready, but don’t pop the cork” until you get the official notice of grant award from NIH.

Notice of Grant Award (NOA)

- Funding for the project is official when you receive the *notice of grant award (NOA)* from NIH. The NOA will stipulate the award amounts per project year as well as any FOA- or agency-specific restrictions on how the funds may be used.
- First, take a moment to celebrate the amazing accomplishment of not only applying for but receiving NIH funding!
- Work closely with your post-award budget team as the award gets set up in your institution's financial system.
- Launch your study and keep in regular contact with your finance team to ensure your study activities comply with all applicable federal and home institution guidelines.
- Alert your PO ASAP to any significant study-related issues you encounter that might threaten your ability to complete study aims.
- Prepare to draft and submit annual progress reports to NIH (RPPRs).

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