

Responding to a Grant Review

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This talk presumes:

- You got a “close but no cigar” review
 - If discussed, the priority score is likely below 40 and the percentile is likely below 30
- You plan to submit a revised version of the first application, rather than submit a new application
- Nothing about whether the first application was actually discussed

If you are on the fence about resubmission vs. new submission

- NIH is now quite vigilant about detecting “new” submissions that smell a lot like prior submissions
- NIH will examine all parts of the application, “particularly the Specific Aims and Research Strategy sections using text comparison software....”
- A handy website:

<http://cms.csr.nih.gov/ResourcesforApplicants/OverlapEvaluation.htm>

**“Significant and substantial change
in content and scope”**

**Examples of Changes that could be
“Substantial”**

- Using significantly different model systems
- Changing the disease model
- Using a similar methodological approach for a substantially different question
- Asking a significantly different question
- Using a very different methodological approach to address a similar issue

Examples of Changes that Are Not Substantial

- Rewording large sections of the application while retaining the scientific goals and objectives
- Adding one or more new collaborator(s)
- Changing the Principal Investigator
- Making changes to sections such as the Significance or Innovation but not changing the intent of the application
- Including additional preliminary data
- Changing the application in response to the previous reviewers' critiques
- Making substantial additions to the pre-existing Approach when the majority of the old design persists in the "new" application
- Deleting parts of the Approach such that the subsequent application is merely a subset of the old one or a concurrent submission
- Requesting assignment to a different NIH Institute/Center or review by a different Scientific Review Group
- Submitting the application to a different program announcement (PA, PAS or PAR)

Now, back to the task at hand...

*Resubmission: a 15 step manual for
survival and success*

1. Dealing with the initial shock

- Do an initial lookover of the “pink sheets” (which are not really pink) and then **PUT THEM AWAY FOR A WEEK.**
- Have whatever emotional reaction you are going to have over the next week (after all, they did just call your baby “ugly!”)

Remember the five stages of grief

- Denial: “there was nothing wrong with my grant proposal.”
- Anger: “the reviewers are a bunch of idiots.”
- Bargaining: “Maybe if I respond to a few of the concerns, it won’t be too difficult to resubmit.”
- Depression: “OMG I actually do have to go through this process again!”
- Acceptance: “I have got to deal with it, so I might as well start preparing for it.”

2. The second look

- Read the pink sheets again, and try not to take the criticism personally.
- Remember, this is about the “best science” from the perspective of a committee that may or may not know you or your specific content area.
- It's NOT about you!!!

3. Gather more information

- Talk to the Program Officer assigned to your grant (NOT the Scientific Review Administrator – it's out of his/her hands now).
- If the grant was discussed, find out what the “feeling” in the room was as well as the principal concern in the discussion of the grant.

Your Program Officer

- Talking with your PO will help you consider the following:
 - The **meaning** of the score – in addition to considering the percentile rank, was there enthusiasm for revising and resubmitting? Are you close, or is a major overhaul indicated? Or should you consider another career (plumbers make a good living!)
 - If a revision is in order (which is most of the time), what should you **emphasize** or make sure to address in EXTENSIVE detail in your response?

4. Make a list

- Make an ITEMIZED and UNCENSORED list of criticisms from each reviewer
- Check the list for accuracy
- Make sure that it is comprehensive – that all concerns are included

5. Re-read the grant

- With the list of concerns in hand, re-read the grant.
- Start by identifying those areas that are **LOW EFFORT**, for example, clarifications that can be done by:
 - simply revising text,
 - adding a consultant or additional expertise,
 - revising the list of measures, or
 - doing the statistical analysis plan and power calculation

Minor versus major changes

- Identify those areas that will require MAJOR changes, for example:
 - Entirely revising the study question,
 - Redesigning the study,
 - Need for additional pilot data
 - Figuring out how to address what might be a “fatal flaw”

6. Sorting the comments

- Group the comments into themes
- Similar concerns may be voiced by different reviewers
- Some concerns may be overlapping and addressed by a common remedy

7. Talk

- Talk to mentors/experts/colleagues
- Senior mentors and colleagues have seen many, many reviews, including unfavorable ones
- They have also acted as reviewers
- They can be helpful in considering the gravity of the critiques and if there is a message “between the lines.”

8. To change or not to change

- Consider altering aspects of the design
- Is there something more elegant, rigorous, generalizable, etc?
- Is it feasible to make these design changes?

9. If it ain't broke...

- Changing something that was NOT identified as a problem is usually a **MISTAKE**
- Unless it is truly a weakness that you missed the first time and absolutely need to fix it.
- Otherwise, making a change in study design risks opening up a new opportunity for the reviewer to find a flaw that was not in the initial submission

10. Pilot data

- Do you need additional pilot data?
- How will you get it?
- If possible it is always good practice to continue collecting pilot data while the grant is being reviewed, allowing for additional data to be provided in the revision.
- This strategy is usually applauded by reviewers (intangible brownie points!!!)

11. Writing your reply

- Start early!
- It will help you organize your time.
- It will force you to see the work that you need to do.
- Keep in mind that it is highly likely that most of the reviewers will still be on the study section and will be assigned to review your grant again!!!

No matter what you really think...

- The reviewer is ALWAYS right!
- Reviewers should be acknowledged, thanked, and yes, praised!
- In writing the response, keep in mind that the reviewer has generally spent hours reading and thinking about your grant and is essentially donating time to advance the quality of science in the field

Thanks...

- Thank the reviewer for the detailed review and constructive comments
- Mention any and all ways that the critique will result in improving the study.
- **REMEMBER**, if the reviewer simply **DID NOT UNDERSTAND** what you were trying to say, it is **YOUR** problem... not the reviewer's

12. Taking issue with a review

- Select your battles VERY carefully.
- In general, it is wise to use the review as a “blue print” for revision.
- If you do not agree with the critique and want to argue for NOT making a requested revision, make sure that you have EXTENSIVE justification.
- Check with senior researchers and colleagues to make sure that you want to take this on.

13. The format of your response

- Respond in detail, point by point to the itemized list of concerns
- You used to have three pages, now it's just one
- This is your opportunity to show the reviewers how thoughtful, careful and responsive you are

Format part 2

- Respond in detail to ALL critiques
- Then, make it easy for the reviewer to find your revision in the grant. This should be done in one of several ways:
 - by identifying the page number in your detailed response,
 - by changing text font (e.g., **BOLDING** or *italics*),
 - by providing a vertical line in the margin that identifies those lines that have been revised

Example: W.S., P.I.

I wanted to thank the reviewers for their helpful comments.

I agree that the second line, “Summers are so rotten in Avon” may have been too harsh. I have replace this line with *Thou art more lovely and more temperate*.

Please see change on page 2.

The reviewer is correct that the original ending was much ado about nothing. The last six stanzas have been rewritten.

Example: Sonnet #18

Shall I compare thee to a Summer's day? *Thou art more lovely and more temperate*: Rough winds do shake the darling buds of May, And Summer's lease hath all too short a date: Sometime too hot the eye of heaven shines, And oft' is his gold complexion dimm'd; And every fair from fair sometime declines, By chance or nature's changing course untrimm'd:

But thy eternal Summer shall not fade Nor lose possession of that fair thou owest; Nor shall Death brag thou wanderest in his shade, When in eternal lines to time thou growest: So long as men can breathe, or eyes can see, So long lives this, and this gives life to thee.

14. Before resubmitting...

- When you have written and re-written the response and revised the grant, read the reviews one more time.
- Make sure that you have responded to the spirit, intent, and specifics of the critique
- If time allows, send the revised grant and your response to one or two advisors who are familiar with the grant to date.

15. And finally...

- UPLOAD IT
- TAKE A BREAK
- GET A LIFE
- LOOK FOR THE “JUST IN TIME” REQUEST