Navigating the NIH Resubmission Process: Strategies for Success

Universidad Central del Caribe

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Workshop Topics

- Overview of the NIH resubmission process
- Resubmission review—NIH’s “enhanced peer review” process
- Strategies that facilitate success
- Analysis of reviewer comments
- Response to reviewer comments
- Development of the Introduction section
- Approaches to strengthen the application
So What is a Resubmission Application?

- Application resubmitted after an investigator whose application was not funded revises it using reviewer feedback.
- To resubmit—you must have a Summary Statement—official document showing review outcome.
- You may resubmit only once!

*NIAID Glossary of Funding and Policy Terms and Acronyms
The Resubmission Dilemma

- My NIH application was not funded…
  - Do I need a new project? Maybe
  - Can I send it (as is) to a different study section? No
  - Is it worth resubmitting? Often

- Right answer = fastest route to funding
NIH Application Identification

- What does the NIH application identification no. tell us?
  - 1R01AG025159-01 (original submission of the application)
  - 1R01AG025159-01A1 (resubmission of the revised original)
A Snapshot of NIH Success Rates

<table>
<thead>
<tr>
<th>FY</th>
<th>New R01 Equivalent Grants by Submission No.</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Original (-01)</td>
<td>12.7%</td>
</tr>
<tr>
<td>2010</td>
<td>First Amendment (-01A1)</td>
<td>39.2%</td>
</tr>
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Still, there’s more to the story…

• At study section review, *original submissions* compete with *resubmissions*, i.e., applications already having the advantage of reviewer input.
Waving the White Flag

- Avoiding resubmission in favor of a new project is not necessarily a success strategy!
- Experienced investigators…
  - Know the resubmission process.
  - Value the resubmission process.
  - Don’t waste valuable time starting over with a new project.

Abandoning a project too soon may make it harder to get funded!
If at First You Don’t Succeed…

- Recognize that you’re in good company—with well-funded investigators everywhere!
- Well-funded investigators…
  - Work the resubmission process through to success.
  - Don’t do anything until they can respond to the critiques calmly.
  - Revise carefully and resubmit.
Key Understandings

- Recognize that resubmission may be the fastest route to funding.
- You, as an investigator, should...
  - Expect *not to be funded* on the original submission.
  - But *develop and write the proposal as conscientiously as possible* (as though you *do* expect to be funded).
  - Avoid a “test” run to get review input.

Cardinal rule of grant-seeking: *Persistence pays!!*
Grant-seeking is most often an *extended process*, not a one-time undertaking.
Study Section “Dialogue”

- It’s easy to fall into the trap of viewing reviewers as your adversaries, so beware!
- Instead, as you read your Summary Statement…
  - View the proposal critique process as scholarly dialogue.
  - Recognize the value of multiple inputs obtained through peer review.
  - Expect to receive constructive input, and be prepared to act on it.
Cultivate Other Sources of Input

- Share the summary statement—solicit other inputs on specific comments.
- **Don’t “go it” alone!**
  - NIH program officer—critically important!
  - Scientific colleagues—invaluable!
  - Your peers with study section experience
  - Established investigators as project personnel *(may be crucial for new investigators)*
  - Other educated readers (lay review)
Email the program official to request a time to call.

In the email, identify…

~ Yourself, your expertise, your institution
~ Your project concept, i.e., send a brief abstract or concept paper
Analyzing Reviewer Feedback

- Using the Summary Statement, *analyze* the...
  - Individual criterion scores...
    - Significance
    - Innovation
    - Investigator
    - Approach
    - Environment
  - Overall Impact score, IF discussed.
  - Reviewer critiques.
- Consider the overall *range* of individual scores.
Analyzing Reviewer Feedback

Consider scores against NIH impact and rating descriptors, relative strengths and weaknesses.

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Impact</td>
<td>1</td>
<td>Exceptional</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
</tr>
<tr>
<td>Moderate Impact</td>
<td>4</td>
<td>Very Good</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
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<tr>
<td>Low Impact</td>
<td>7</td>
<td>Fair</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
</tr>
</tbody>
</table>

- strengths
- weaknesses
Individual Criterion Score Scenarios

Reviewer 1:
- Significance – 8
- Innovation – 6
- Investigator – 2
- Approach – 3
- Environment – 4

Reviewer 1:
- Significance – 2
- Innovation – 3
- Investigator – 4
- Approach – 8
- Environment – 6
Analyzing Reviewer Feedback

- Study the language – is any of the phrasing encouraging? Look for "green light" phrasing…
  - Strong positives/level of enthusiasm
  - Recommendations for specific modifications
  - Indications of significance or strong impact
  - Acceptance of project feasibility
  - Support for the proposed approach
Analyzing Reviewer Feedback

- Identify each and every criticism.
- Look for *specific suggestions* for change (like *gold*)!
- Weigh comments against individual criterion scores.
- Above all, don’t be discouraged by the negatives.
  - Instead, think constructively about how to respond strategically and effectively.
  - Again, consult others!
Resubmit or Not—Deciding Factors

- Analyze the criticisms carefully:
  - Are you **able** to make the changes required to respond to the criticisms?
  - Are you **willing** to make the recommended changes?
  - If not, how **convincing is the case** for your original version?

**Clear-cut indications not to resubmit:**

“The proposed mechanism has already been well established.”

“The study drug has been shown in numerous studies to be **highly toxic** in humans.”
Resubmit or Not—Deciding Factors

- If the answer is yes (able and willing)...
  - Commit to resubmitting.
- If the answer is maybe...
  - Consult your...
    - NIH program officer
    - Your scientific colleagues
    - Your friends with study section experience.
The Streamlined Application

But my application was not discussed!

- NIH’s *enhanced peer review* process…
  - Removes the focus on assessing *whether the original application is improved.*
  - **Resubmission Review Criterion:** …the committee will evaluate the application as *now presented,* taking into consideration the response to comments from the previous scientific review group and changes made to the project.
    (Hint: the one-page introduction reflects decreased emphasis on the original.)

- Recognize that an application that was “not discussed” can succeed at resubmission!
Small Group Analysis

Sample summary statement comments—how would you respond? Would you resubmit?

- “These are nicely designed studies, but it is not clear why the applicant is focusing on.... The rationale for this study focus seems premature.”

- “Aim 3 is dependent on the success of Aim 2. Moreover, the applicant does not include alternate approaches in the event of problems with the experiments in Aim 2.”
Small Group Analysis

- “While these are interesting experiments, they are unlikely to yield any new information on the mechanisms of….”
- “It would be better to use…assays to achieve Aim 3.”
- “It is unclear that the applicant has the expertise to carry out technically very demanding experiments.”
- “The scope of the project is too ambitious, reducing enthusiasm.”
- “It’s not clear whether the sample size is adequate and how the data will be interpreted.”
Common Reviewer Criticisms

- Insufficient or unconvincing preliminary data
- Too ambitious a scope of study for the project period
- Lack of statistical/biostatistical support
- Lack of discussion of data interpretation and analysis
- Missing discussion of potential problems and alternate strategies
- Inadequate environment for the proposed study
Modifying the Application

- Revise thoroughly—throughout the...
  - Specific Aims section,
  - Research Strategy section,
  - In short, wherever the issue arises in the narrative.
- Don’t be selective—address *every* concern raised.
- Comply as fully as possible with reviewer recommendations.
- Correct other flaws.
- Clearly mark changes in the text.
Strengthening the Application (Post-Submission Progress)

- Certain types of revisions are particularly advantageous...
  - Convincing new preliminary data from ongoing studies
  - Recent publications based on the research
  - Addition of valuable collaborators
  - Revisions that result from partial accomplishment of the research.

All of these convey your productivity!
Writing the Introduction

- Introduction—a one-page document that **summarizes** the substantial...
  - Additions
  - Deletions
  - Changes

...in the resubmission application

- Having described a response in the Introduction does not eliminate the **necessity** to include and **mark** the change in the narrative.
Understanding the Introduction

- Introduction to the resubmission application—what it is...
  - A diplomatic tool to “win friends”
  - A set of well thought-out responses in summary form
  - A concise “guide” to each revision in the application
Understanding the Introduction

- Introduction to the revised application—what it isn’t…
  - A rebuttal
    - Arguing is a difficult success strategy!
  - The complete discussion of the changes you’ve made
    - Full details of the change go in the Aims/Research Strategy sections!
- A reiteration of reviewer praise
  - Reviewers will have the original summary statement at hand.
Strategic Use of Reviewer Praise

So when can I use positive reviewer comments? Note the difference between these two iterations of the criticism:

- “…it is troubling that…. ”
- “Despite an impressive set of experiments in Aims 1 and 2, it is troubling that…. ”
Other Content to Omit

- Avoid wasting space by providing...
  - Application number.
  - Application title.
  - Statement that this is a resubmission application.
  - Overall impact score or individual criterion scores on the previous application.
  - Time frame when original was submitted.

- This information is redundant or unnecessary to an effective review.
Preparing the Introduction

- Compose the introduction with utmost care.
  - Tone
    - Professional
    - Diplomatic
    - Not argumentative
    - Not defensive
    - Not gushing
    - Not overly apologetic
  - Approach this section strategically, rather than mechanically.
Setting the Tone and Scope

- Open with *brief* introductory comments.
  - Express appreciation for…
    - “reviewer insights” or
    - “thoughtful review” or
    - “instructive critiques”.
- For major modifications, consider a general summary of the changes.
- Then address each individual criticism as conscientiously as possible.
Language Issues

- To paraphrase or not to paraphrase…
  - Use *direct quotes*, if at all possible.
    - Accuracy and nuance
  - Clarity and ease of review
  - Paraphrase sparingly, *if at all.*

"It is unclear that the applicant has the technical expertise to carry out the proposed experiments."

**Response.** To address this concern, we have added a new collaborator, who has extensive experience with…. She will be responsible for….
Format for Reviewer Concerns

Critique 1: “…plan for data interpretation is poorly described. It is also unclear what Dr. A’s qualifications are ...” We now provide extensive new details on the approach for data analysis and interpretation. Specifically, we will use…. Complete details on specific statistical analyses appear in the Approach section. We also include a biosketch for Dr. A., the biostatistician on the project.
Language Issues

- In describing reviewer concerns, avoid...
  - Your value judgments...
    - Reviewer 1 only had minor concerns...
  - Your subjective labels...
    - Reviewer 2 felt that we proposed an overall strong set of experiments.
- Let the reviewer’s own words speak!
Issues of Selectivity

- A word about picking and choosing what criticisms to address…
  - Don’t take the risk!
  - Do address every concern raised, to the extent possible.
- Avoid a judgment of “non-responsive” to the review.
Responding to Reviewer Concerns

- Say “yes” to the reviewers! (whenever possible)
  - Continue the scholarly dialogue.
  - Note that the resubmission typically goes back to the original reviewers except...
    - In the case of Special Emphasis Panels
    - When reviewers rotate off the study section.
Disagreeing with a Reviewer

- When it’s difficult to say yes, or what if the reviewer is wrong?
  - Seek multiple external inputs.
  - Seek out new data or recent research findings to support your point.
  - Introduce new preliminary data supporting your original point.
- All of these can generate external support for your position.
Disagreeing with a Reviewer

- Recognize the risk.
- Be very, very diplomatic.
  - Open with a positive statement on the context in which the reviewer is or may be correct, i.e., “The reviewer is correct in noting that….”
  - Then discuss with utmost care…
    - Your rationale/context for disagreeing.
    - Your external support for this decision.
Disagreeing with a Reviewer

What if the reviewer *missed* content that I did include—*and* raised the “missing” piece as a criticism?

- You assume responsibility for the oversight.
- Make the content stand out by…
  - Using bold, italics, figure to “signal” the material.
  - Devoting more detail to discussion of the issue.
  - Placing it in a more prominent position.
Closing the Introduction

- Summarize briefly.
- Indicate how you have designated changes in the proposal—bracketing, vertical line in margin, etc.
- Keep in mind that marking changes by...
  - Switching fonts
  - Using bold or italics
    …may confuse reviewers.
  (Hmm…is this emphasis or a change?)
- Aim for a “clean” look.
Issues of Timing

- Resubmit soon—to continue the dialogue.
- But *do* take time to make needed modifications.
- **New** time limit: 37 months after the receipt date of the initial application
  - Effective Jan. 25, 2011
Your Questions...
Resources

Questions and Answers

National Institute of Allergy and Infectious Diseases

All About Grants Tutorials
(including four successful sample R01s!)
http://funding.niaid.nih.gov/researchfunding/grant/pages/aag.aspx

Application Snag: What to Do if You Get Bad News

Not Funded, Reapply