“Introductions are Everything!”

NIH Resubmission DOs & DON’Ts

Alexis Nagel, Ph.D.
MUSC Office of Research Development

Faculty Panel
Judy Dubno, Ph.D., College of Medicine
Steven Kautz, Ph.D., College of Health Professions
Teresa Kelechi, Ph.D., College of Nursing
Who: MUSC Research Community
What: Informational seminar + Specific Aims Workshop
When: Annually (possibility of biannual offering)
Why: To provide additional NIH grant writing resources & training

Link to 2017 “Nail Those Aims!” seminar
Link to PEERS Specific Aims Workshop information
Resubmission Objective

Convince the reviewers to enhance your application’s score by demonstrating that you have improved the scientific content, not just the written clarity, of your proposal
Outline

1) To Resubmit or Not to Resubmit?
   a) NIH Merit Review and Scoring
   b) Evaluating Your Score and Summary Statement
   c) NIH Policy on Resubmissions

2) Introduction to the Resubmission
   a) Resubmission Requirements
   b) More Do’s and Don’ts
   c) NIH Policy on Marking Changes
NIH Application Review Process
NIH Application Review Process

- SRG meeting (preliminary scores are prepared 6 weeks prior)
- Discussed applications are assigned a final impact score
- Scores (< 3 days after) and summary statement (< 30 days after) are posted
• I/C Advisory Council meets to review meritorious applications

• Center Director makes final award decisions

• Interim activities:
  A) Evaluating your score
  B) Speaking with Program Officer
  C) Resubmitting your application
To Resubmit or Not to Resubmit?

Question #1: What was my review outcome?

Question #2: What does my score mean? Can I satisfactorily address reviewer concerns?

Question #3: Will my resubmission application be compliant?
To Resubmit or Not to Resubmit?

Question #1: What was my review outcome?

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NIH Merit Review and Scoring

- Preliminary Scoring
- SRG Meeting (Final Scoring)
- Discussed Applications
- Not Discussed Applications
Final overall scores are privately submitted by each reviewer, averaged, and $\times 10$

Summary statement will include a “Resume and Summary of Discussion”
• Receive criterion but not a numerical impact score

• Summary statement will **NOT** include “Resume and Summary of Discussion”
To Resubmit or Not to Resubmit?

Question #1: What was my review outcome?

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Question #3: Will my resubmission application be compliant?
<table>
<thead>
<tr>
<th>Score</th>
<th>Descriptor</th>
<th>Strength(s)</th>
<th>Weakness(es)</th>
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<td>Exceptional</td>
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<td>none</td>
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<td>8</td>
<td>Marginal</td>
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<td>few major</td>
</tr>
<tr>
<td>9</td>
<td>Poor</td>
<td>very few</td>
<td>many major</td>
</tr>
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</table>
SCENARIO #1: My application WAS discussed and received an overall impact score

• Evaluate the “Resume & Summary of Discussion” for score-driving themes

• Talk to your Program Officer

• Talk to your mentor or other colleagues

• Determine whether you will be able to implement necessary changes
SCENARIO #2:
My application was NOT discussed and did NOT receive an overall impact score

• Try to ascertain the reviewers’ “enthusiasm” for the proposal – can this be improved?

• For identification of themes, note strengths/weaknesses brought up by more than one reviewer

• Talk to your mentor or other colleagues
### A0 Application Summary Statement  
**Handout**

#### Applicant Organization:
MEDICAL UNIVERSITY OF SOUTH CAROLINA

**Review Group:**
IPTA  
Interventions to Prevent and Treat Addictions Study Section

**Meeting Date:** 10/06/2016  
**Council:** JAN 2017  
**Requested Start:** 04/01/2017

**Project Title:** [Redacted]

**SRG Action:** Impact Score: 43  
Percentile: 32

**Next Steps:** Visit [http://grants.nih.gov/grants/next_steps.htm](http://grants.nih.gov/grants/next_steps.htm)

**Human Subjects:** 30-Human subjects involved - Certified, no SRG concerns

**Animal Subjects:** 10-No live vertebrate animals involved for competing appl.

**Gender:** 1A-Both genders, scientifically acceptable

**Minority:** 1A-Minorities and non-minorities, scientifically acceptable

**Children:** 3A-No children included, scientifically acceptable

**Clinical Research - not NIH-defined Phase III Trial**

#### CRITIQUE 1
- **Significance:** 2
- **Investigator(s):** 2
- **Innovation:** 3
- **Approach:** 7
- **Environment:** 1

#### CRITIQUE 2
- **Significance:** 4
- **Investigator(s):** 2
- **Innovation:** 2
- **Approach:** 5
- **Environment:** 2

#### CRITIQUE 3
- **Significance:** 1
- **Investigator(s):** 1
- **Innovation:** 2
- **Approach:** 6
- **Environment:** 1
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Review Group: IPTA
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RFA/PA: PA16-072
PCC: CC/WMA

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Significance: 4
Investigator(s): 2
Innovation: 2
Approach: 5
Environment: 2

CRITIQUE 3
Significance: 1
Investigator(s): 1
Innovation: 2
Approach: 6
Environment: 1
Quick stats

MUSC (2015-2017): All type 1 proposals with award decisions

• Award rate for NEW (n=659) proposals = 18%
• Award rate for RESUBMISSION (n=243) proposals = 42%
Quick stats

NIH (2012-2016): Unsolicited, type 1 R01 applications (n=69,714)

• Award rate for A0 applications (approximate):
  • scoring 10-30 = 62%
  • scoring 30-40 = 10%

• Overall award rate (A0 or A1) for applications where the A0 (approx):
  • Scored 10-30 = 80%
  • Scored 30-40 = 40%

https://nexus.od.nih.gov/all/2017/02/17/resubmissions-revisited-funded-resubmission-applications-and-their-initial-peer-review-scores/
To Resubmit or Not to Resubmit?

Question #1: What was my review outcome?

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Question #3: Will my resubmission application be compliant?
To Resubmit or Not to Resubmit?

You may RESUBMIT (A1) your application IF:

• Your FOA allows resubmissions
• You are eligible
• You are resubmitting w/in 37 months of your A0
• You have received your A0 summary statement
To Resubmit or Not to Resubmit?

You **must** submit a NEW (A0) application IF:

- Your A0 and A1 were both rejected for funding
DO’s and DON’Ts (to be continued…)

✓ DO: evaluate your review outcome for score-driving themes

✓ DO: talk to your Program Officer and seek feedback

✗ DON’T: (re)submit a non-compliant application
Introduction to the Resubmission

• Required for resubmission of your A1, factored into the score

• One page, and must include:

  1. Summary of substantial additions, deletions, & other changes

  2. Responses to issues/criticisms from the summary statement

https://grants.nih.gov/grants/policy/amendedapps.htm
Introduction to the Resubmission

- Thank the reviewers
- Point out major themes you will address
- Address them!

- Summarize minor comments
- No room? Mention they are addressed within the application
INTRODUCTION: We are grateful for the reviews of our RO1 application, which we believe have helped us craft a substantially enhanced resubmission. Specifically, five important changes have been made: 1) high-impact publication of preliminary data that addresses several reviewer concerns, 2) reduced sample size, 3) addressed concerns about sample age range and smoking history variation, 4) modified fMRI methods are fully justified, and 5) fully addressing the inconsistencies in the literature. These changes are detailed below.
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DO: make it easy for reviewers to comprehend

• Use formatting to your advantage (listed format, bolding, underline…) 

• Use the same language/phrasing as the reviewer 

• You may choose to annotate responses to reviewers (e.g. R1, R2, R3…) or delineate where changes occurred (e.g. Section 2.1.c)
Introduction to Resubmission (Handout)

Third, there were inter-related concerns about potential inflated variability due to (a) broad sample age range (18-65), (b) smoking exposure inclusion criterion of 10+ CPD for ≥ 3 years, and (c) lack of quantifying lifetime tobacco use. It is important to note that neither participant age nor years of smoking modified the published treatment effects. Nonetheless, since the age range of the R21 sample was 22-64 yrs. and only 3 individuals (3% of the sample) were under the age of 25, we have elected to narrow the proposed age range to 25-65. This change may seem minor but it mitigates concerns about confounding effects of brain development within younger participants (who are now excluded). **Our primary goal is to ensure the generalizability of the findings to the vast majority of adult regular smokers.** Additionally, the Approach clearly states that we will thoroughly assess smoking history in the interest of being able to derive measures of lifetime tobacco use for inclusion in data analytic models. In the R21, we used the FTND score (proxy for tobacco exposure) as a stratification variable and it, together with randomization, resulted in the groups being equivalent with respect to years smoking (measure of lifetime exposure). Consequently, we believe that the combination of randomization and stratification on FTND score will serve as a suitable means to equate the groups on lifetime tobacco exposure. Lastly, the smoking exposure inclusion criterion (10+ CPD for ≥ 3yrs) is retained in the interest of ensuring the sample is homogeneous with respect to recent tobacco exposure.
RESUME AND SUMMARY OF DISCUSSION: This application proposes a three-group randomized controlled trial to test the acute and long-term effects of retrieval-extinction (R-E) training on cigarette smoking; functional magnetic resonance imaging (fMRI) is included to assess the associated brain activity. Novel, theoretically-grounded non-pharmacological treatment strategies are needed to address the significant public health problem of cigarette smoking. In discussion, reviewers were enthusiastic about the innovative and mechanistic application of the retrieval-extinction paradigm and the well-qualified investigators. The scientific premise is strong and supported by very promising pilot data from the investigators with R-E training in cigarette smokers, although there was concern that the pilot data have not been published and that the wide individual variability in response to the training in previous studies is not addressed. Reviewers’ concerns centered primarily around the approach, including that the significant variability in responses introduced by the very wide age range weakens the scientific rigor, the rationale for the timing of the second fMRI scan is unclear, the use of a mock scan as a control condition is not well justified and the design is complex. Some reviewers also had significant concern that the large sample size (which necessitates a long recruitment period) is not well justified, although other reviewers found the sample size appropriate to the design. Overall, the strengths of this innovative application are somewhat offset by the weaknesses and the project has the potential for moderate impact.
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The “Resume” is Your Roadmap!

Reviewer #1: Approach (Weaknesses) – Page 5

- The scientific rigor of the approach is weakened by the fact that the proposed age range of 18-65 is extremely broad and this alone will introduce significant variability in responses. The team will need to stratify based on age and as a result the power will be reduced.

- This same weakness applies to the lack of quantifying prior lifetime use of tobacco (i.e., such as pack years), which will increase variability.

- The inclusion criterion of needing to smoke 10+ cigarettes for three or more years is a fundamental weakness in the approach. An 18-year-old subject will have to have started smoking at age 15 while older participants could easily have started at a much later age. The fact that early onset smoking has a significant impact on brain development will add an entirely new dimension to the variable responding to the R-E approach. Furthermore, individuals who have had 50 years of smoking (the 65 year olds who started at age 15) will have had 5 decades of reinforced cues that does not equate to the much younger individuals who will be included together in the analyses. Compared to a 20-year-old, there is a lot of basic neurobiology that differs between them and thus will add considerable confounds to the data and its interpretation.

Make sure you examine all written critiques for interrelated concerns!
Introduction to Resubmission (Handout)

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Introduction to Resubmission (Handout)

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A number of less worrisome issues are also addressed. One of these pertained to the use of a mock fMRI session. Originally, we thought that participants who were not going through the fMRI should have some type of parallel procedural experience, thereby equating all participants on variables such as experimenter contact time, etc. However, reviewers indicated there is no evidence that mock scanning serves as a control for active scanning. We concur this is the case and have eliminated this manipulation from the study procedures.

Reviewers also questioned our biochemical assessment of smoking. In the case of CO, it was noted that the overnight abstinence criterion of ≤ 8 ppm may be high given that our inclusion CO criterion was ≥ 10 ppm. Accordingly, we have adopted a more stringent overnight abstinence criterion of ≤ 5 ppm. In the case of salivary cotinine, it was noted that we did not state an abstinence cutoff. Although we intend to use cotinine only as a continuous measure of smoking level, we have now included an abstinence cutoff of ≤ 15 ng/ml.

Finally, the application has been updated (recent literature) and numerous other modifications have been made to enhance clarity of exposition (substantive changes indicated by “[ ]” bracketing).
NIH Modification to Guidance on Marking Changes in Resubmission Applications (NOT-OD-15-030)

• NIH has removed the requirement to identify 'substantial scientific changes' in the text of a Resubmission application…

• …it is sufficient to outline the changes made to the Resubmission application in the Introduction attachment
More DO’s and DON’Ts

- DO: thank the reviewers and be gracious in your responses
- DO: make it easy for reviewers to comprehend
- DO: provide detailed responses to major concerns
- DON’T: be defensive or argue with a reviewer
CRITIQUE 1
Significance: 2
Investigator(s): 1
Innovation: 1
Approach: 3
Environment: 1

CRITIQUE 2
Significance: 1
Investigator(s): 1
Innovation: 1
Approach: 2
Environment: 1

CRITIQUE 3
Significance: 2
Investigator(s): 1
Innovation: 2
Approach: 2
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NIH Resources

1. NIH Resubmission Applications (Introduction Requirements) [link]
2. NIH NOT-OD-18-197 NIH/AHRQ Application Submission/Resubmission Policy [link]
3. NIH Center for Scientific Review (Study Sections & CSR Assisted Referral Tool) [link]
4. NIH Timelines for Assignment, Review & Funding [link]
5. NIH Peer Review [link]
6. NIH Scoring System and Procedure [link]
7. NIH Extramural Nexus Open Mike: Resubmissions Revisited (Funded Resubmission Applications and Their Initial Peer Review Scores) [link]
8. NIH Research Project Grant (RPG) Critique Criteria & Considerations [link]
9. NIH Career Development (K) Critique Criteria & Considerations [link]
10. NIH Rigor & Reproducibility in Grant Applications [link]
Resources for Today’s Presentation

Crafting a Winning Grant Resubmission – John S. Adams, M.D. (UCLA CTSI)
https://www.ctsi.ucla.edu/education/files/view/training/docs/study-sections-adams.pdf

Writing Dissertation and Grant Proposals (Chapter 20: Resubmission of the Grant Proposal) – Lisa Chasan-Taber (CRC Press, 2014)
https://www.crcpress.com/rsc/downloads/KZN23_K14871_TP, SER AD TOC and Ch1.pdf

MUSC ORD Proposal Library (Example Applications and Summary Statements)
https://academicdepartments.musc.edu/research/ord/proposal-library/access.html

NIAID Sample Applications & More
https://www.niaid.nih.gov/grants-contracts/sample-applications
Acknowledgements

Faculty Panel
Judy Dubno, Ph.D., Professor of Otolaryngology – Head and Neck Surgery
Steve Kautz, Ph.D., Professor of Health Sciences and Research
Teresa Kelechi, Ph.D., Professor of Nursing

Office of Research Development
Carla Stipe M.B.A, Director
Wanda Hutto, C.R.A, Assistant Director
Kimberly Cannady Ph.D., Lead Advisor, Research Training & Outreach Initiatives
Danielle Hutchison, M.A., Program Coordinator
Lynn Veatch, Ph.D., Director, SmartState Centers of Economic Excellence