RUG: RESPONDING TO NIH CRITIQUES

Melody Montgomery
TODAY’S SESSION

• Successful Resubmissions and Perseverance
• Processing the Critiques and the Original Score
• Common Problems Cited by Reviewers
• Response in Resubmission: Addressing Critiques Individually and Objectively
“Learn from yesterday, live for today, hope for tomorrow. The important thing is not to stop questioning.”

~ ALBERT EINSTEIN

“Insanity: doing the same thing over and over again and expecting different results.”

~ ALBERT EINSTEIN
EXAMPLES OF SCIENTISTS WHO HAVE MET WITH OPPOSITION:

Galileo Galilei (Roman Inquisition)

Isaac Newton (Robert Hooke)

Nikola Tesla

Charles Darwin

Edward Jenner (Smallpox vaccine)
CHANGING THEORIES

Origin of house flies

Dinosaur fossils

The moon

The Earth and Universe

Tomatoes are poisonous
FIVE TRAITS THAT SUCCESSFUL PEOPLE POSSESS

Goal Clarity

Drive

Emotional Intelligence

Social Savvy

Curiosity

http://www.matthewferrara.com/rssfeed/five_traits/
GOAL CLARITY

• clear, measurable, and written goals

• Every aspect: personal, physical, spiritual, and professional

• work on entire self, every day

• Professional success is just one element of a much bigger momentum

http://www.matthewferrara.com/rssfeed/five_traits/
DRIVE

• High performers are driven.

• Having clear goals releases inner drive.

• When you see the goals, which you believe in, your energy sparks to achieve them.

• The reverse is true; without goals in mind, you can not give your all.

http://www.matthewferrara.com/rssfeed/five_traits/
EMOTIONAL INTELLIGENCE.

- Ability to manage how emotions affect performance.
- Successful people are aware of their feelings’ impact upon their performance.
- Manage emotions so they don’t interfere with achieving the best outcomes.

http://www.matthewferrara.com/rssfeed/five_traits/
SOCIAL SAVVY

• Adjusting personal behavior to different people and situations.

• Adjusting communications and interpersonal behavior styles to best reach each individual.

• Interacting with others in a way that permits a mutual exchange of value.

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CURIOSITY

- Curiosity throughout life.
- Trends, new ways of creating value, interesting ideas and emerging technologies.
- Willing to listen and explore opportunities.
- “A healthy sense of curiosity protects them from accepting defeats and drives them to seek pathways around obstacles.”

http://www.matthewferrara.com/rssfeed/five_traits/
EXAMPLE OF A SUCCESSFUL RESUBMISSION

FIRST SUBMISSION:

Score: 43

Percentile: 44%

SECOND SUBMISSION:

Score: 18

Percentile: 6% *(Funded $1.7-$1.4 Million)*
SUCCESSFUL RESUBMISSION

“I replied to ALL of the comments, reached for perfection, did not leave a stone unturned, and asked for your help (which made a BIG difference). Also I must have had good karma (which is often referred to as good luck.)”

Mohammad Siahpush, PhD

Professor
PLAN FOR RESUBMISSIONS.

Have multiple applications in place for each cycle. Actively work on resubmissions and gathering data. Ex. 5-6 pending and multiple active grants.

TRIAGED PROPOSALS

What can you do when your proposal is “triaged”? i.e., not scored or discussed.

Work with a Scientific Mentor:  http://www.unmc.edu/vcr/
Processing the Critiques and Original Score
Consider feedback an opportunity.

Using our emotional intelligence, we can determine that a critique is not personal, but instead an opportunity to improve our work.
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Other Designations for Final Outcome

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LOOK AT YOUR SCORE FIRST

• Brace yourself for the comments. Allow some time to pass before reading the comments again. Try to consider the critiques objectively. They are not personal. Can you see the reviewer’s point after stepping away. Did you fail to communicate ideas? Can you see room for improvement?
ALLOW YOURSELF TIME TO PROCESS THE LOSS

(FIVE STAGES OF GRIEF)

1) Denial and Isolation
2) Anger
3) Bargaining
4) Depression
5) Acceptance
Lessons Learned…

Forget.

Borrow.

Learn.
Most-Common Reasons Cited by Reviewers for Application Failure
### Significance

**Investigator**

**Innovation**

**Approach**

**Environment**

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Significance
PROBLEM NOT IMPORTANT ENOUGH

Not significant to health-related research. Mechanistic approach.

• Address and convey significance.

STUDY NOT LIKELY TO PRODUCE USEFUL INFORMATION

• Provide examples and strengthen your rationale (why).
PROPOSAL DRIVEN BY TECHNOLOGY, I.E., A METHOD IN SEARCH OF A PROBLEM.

- **Technology** is to help answer your questions not to generate unfocused data

- What positive and new information will the technology provide?
Approach
STUDIES BASED ON A SHAKY HYPOTHESIS OR DATA.

- Strengthen preliminary data and perform additional experiments.
- Reformulate central hypothesis. Evaluate hypothesis overall.
- Why is it important? What important findings will it reveal? What is the next step/translational value?
STUDIES BASED ON A SHAKY HYPOTHESIS OR DATA (continued)

• Hypotheses are not to be “proven”; they are to be tested.

• Consider the directions of a “yes” answer and a “no” answer. Does the “no” answer create a dead end?

• Have studies in place for both directions.
INSUFFICIENT CONSIDERATION OF STATISTICAL NEEDS

• Work with statistician.
• Utilize CCORDA.
• Broaden scope.
• Budget considerations.
RATIONALE FOR EXPERIMENTS NOT PROVIDED, I.E.,
WHY THEY ARE IMPORTANT OR HOW THEY ARE
RELEVANT TO THE HYPOTHESIS.

- Explain why you are performing assays.
- What will the expected information reveal?
EXPERIMENTS TOO DEPENDENT ON SUCCESS OF AN INITIAL PROPOSED EXPERIMENT. LACK OF ALTERNATIVE METHODS.

• If one experiment fails, others cannot take place. Relatively independent aims are important.

• Consider several alternative approaches.
PROPOSAL LACKING ENOUGH PRELIMINARY DATA, OR PRELIMINARY DATA DO NOT SUPPORT PROJECT'S FEASIBILITY

• The latter could be a communication issue.

• Gather additional data, and highlight it in the response and summary.
PROPOSED MODEL/SYSTEM NOT APPROPRIATE TO ADDRESS THE PROPOSED QUESTIONS

- Consider suggestions provided.
- Develop alternatives.

RELEVANT CONTROLS NOT INCLUDED

- Incorporate accordingly.
PROBLEM MORE COMPLEX THAN INVESTIGATOR APPEARS TO REALIZE

• Do not eliminate complexity but explain and reinforce feasibility; review past studies for feasibility.

• Consider conflicting results in past studies.

  • What could be causing these incongruencies?
OVER-AMBITIOUS RESEARCH PLAN WITH AN UNREALISTICALLY LARGE AMOUNT OF WORK

- Refine approach.
- Consider removing a specific aim.
ALTERNATIVE HYPOTHESES NOT CONSIDERED.

METHODS UNSUITED TO THE OBJECTIVE.

• Reevaluate approach. Are the proposed experiments capable of reaching your targeted and clear objective?

• Where are possible pitfalls in your approach?
DIRECTION OR SENSE OF PRIORITY NOT CLEARLY DEFINED, i.e., experiments do not follow one another and lack a clear starting or finishing point.

- **Reorganize.** Map out experiments.
- **Use** transition words.
- **Consider** alternative approaches for each experiment.
- **Note** possible modifications that might be necessary.
LACK OF FOCUS IN HYPOTHESIS, SPECIFIC AIMS, OR RESEARCH PLAN

- **Discuss** your hypothesis(es) with peer(s).
- **Consider** your direct, overall goal and rephrase for clarity, eliminating noun stacks.
- **Develop** secondary/sub-hypotheses.
INVESTIGATOR TOO INEXPERIENCED WITH THE PROPOSED TECHNIQUES

- Refine techniques.
- Bring in an expert.
- Reiterate strengths and experience.
- Highlight your experience and environment.
  
  *Recall, your application is the only interface between you and the reviewer*
TOO LITTLE DETAIL IN THE RESEARCH PLAN TO CONVINCE REVIEWERS THE INVESTIGATOR KNOWS WHAT HE OR SHE IS DOING.

• e.g., no recognition of potential problems and pitfalls.

(Note: Too much detail is not good either)
NOT CLEAR WHICH DATA WERE OBTAINED BY THE INVESTIGATOR AND WHICH WERE REPORTED BY OTHERS

• Reference experiments by others.

• Clearly state “our data” -- unlike a manuscript, first person use is more common in grant proposals.
Innovation
LACK OF ORIGINAL OR NEW IDEAS.

- **Communicate** what is novel in your study.
- **What** is innovative and has not been studied?

PROPOSED PROJECT A “FISHING EXPEDITION” i.e., no basic scientific question being addressed.

- **Study** is to look at a specific problem or issue through careful examination with an overall concept in place.
Response in Resubmission.
INTRODUCTION

We are thankful to the DT Study Section for its thoughtful and encouraging review of this application originally reviewed in Month Year.

HIGHLIGHT YOUR STUDY’S STRENGTHS.

All reviewers were enthusiastic about …
SUMMARIZE KEY AND POSITIVE REMARKS MADE BY REVIEWERS.

_Reviewer 1_ found the … design “elegant and innovative.”

_Reviewer 2_ predicted that … would be “extremely beneficial to researchers and clinicians.” _Reviewer 3_ found the use … in our … “novel and unique in terms of delivery.” Still, weaknesses were identified.
We have studied the critiques thoroughly and have taken time to collect additional data to address concerns regarding the feasibility of some of the studies. As a result, we have completely *overhauled* our preliminary studies section to improve …, solve the problem of …, and demonstrate combined activity of ABC with XYZ in 123. This extensively revised resubmission retains the major strengths and strengthens and enhances the weaker areas critiqued. Vertical lines indicate changes to the proposal.
Addressing Critiques

Individually and Objectively
**REVIEWER 1** found our ABC approach and capacity of … to be a major strength and, if feasible, a major advancement for experimental therapeutics, but had the following critiques addressed in this resubmission:

- *Concerns about the selectivity* .... We agree this is an important issue. In turn, we have conducted additional *in vitro* and *in vivo* studies that confirm that (i) … (Fig. 3B), and (ii) we have obtained indirect evidence that … (Fig. 6).
**REVIEWER 2** found our ABC approach and capacity of … to be a major strength and … but had the following critiques addressed in this resubmission:

- *Factors impacting particle production...additional data could increase the significance.*” We have added data showing feasibility of … (Fig. 1, 2). These new data confirm the following …

- “*Goals are very ambitious.*” On reflection, we agree. To address this concern, we conducted additional studies to “de-risk” the primary aspects of the project. Also, to reduce the extent and complexity of *in vivo* experiments, we focus on only *one* … model, and … are eliminated from ...
• **Clearance of the particles not addressed during toxicology studies.** We agree that this is an important issue in a project focused on…

• **No rationale for using ....** We have corrected this omission…

• **Concerns about effective removal of ...** We have added data to show faster release of the drug in a reducing environment (Fig. 2). This issue is also addressed by … studies.
REVIEWER 3 continued…

Step-by-step assembly...to cause dumping. We have taken time to address this crucial issue. As the newly included data show, .... We have resolved the issue of ... taking advantage of the...
Conclusion: End on a positive note.
MELODY MONTGOMERY, EDITORIAL GRANTS SPECIALIST

As part of the Office of the Vice Chancellor for Research, Melody assists UNMC faculty members with proposal development and editing. Support services include copy editing for grammar, style, consistency, and word choice, formatting to agency guidelines, and commentary on the content and flow of the proposal. Grant writing and grant editing services are partially subsidized through the Office of the Vice Chancellor of Research. Manuscript editing services are also offered, but are not subsidized. Email Melody Montgomery at m.montgomery@unmc.edu to check the current availability and to schedule time for editing and more details. Depending on the content and notice provided, a two-week timeframe for edits is considered standard, and edits take place on a first-come first-serve basis. Please send your electronic documents and the completed request form to m.montgomery@unmc.edu.

Upcoming Events
For information on upcoming sessions and additional resources for UNMC researchers, please visit the Researchers Users Group (RUG) website.

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Phone: 402.559.4132
http://www.unmc.edu/vcr/research_editorial.htm