Top Ten Most Common Grant Writing Mistakes

Brett T. Phillips, MD, MBA Howard Levinson, MD



Most Common Mistakes

- Proposal lacks significance
- 2. Approach doesn't include a testable hypothesis
- 3. Weak or absent preliminary data
- 4. Overambitious aims
- 5. Aims that hinge on the success of previous aims
- 6. Untested or overly complex methodology
- 7. Absent statistical justification
- 8. Lacks Innovation
- 9. Investigator lacks experience or collaboration
- 10. Didn't follow the guidelines



Rejection Rates

PSF grants >70%
NIH grants >90%

Learn to critically evaluate your own project!



Common Problem Areas

Significance

Addresses an important problem or critical barrier to progress in which success will yield improved scientific knowledge and/or clinical practice.

Innovation

Innovation is a new idea that is likely to change or impact the field, more effective device, or process.

Approach

Approach includes the methodology in which an investigation progresses.

Investigator

This includes the expertise of the principal investigator, their laboratory and collaborators.

Proposal Lacks Significance

PROBLEM: Why should the reviewer care? It's critically important to get the reviewer excited about your work. Disinterest is the single most significant reason for a low score.

SOLUTION: Clearly state the affected target population and how this project will improve knowledge and/or clinical outcomes.

- Provide quantification and reference all numbers.
- Examples of quantifiable outcomes may include:
 - Prevalence
 - Cost
 - Quality of life



BAD: "Abdominal wall hernias are a major problem in our society with high recurrence rates and increased morbidity."

GOOD: "Two million laparotomies are performed annually in the U.S., with ventral hernia being a frequent complication in 10-30% of patients.¹⁻⁵ The average cost/patient for each hernia operation in the U.S. in 2006 was ~ \$15,899, which amounts to ~ \$3-9 billion annually.⁶ The ten-year ventral hernia recurrence rate ranges from 32-63%.⁷ With significant increases in the morbidly obese population, hernia formation is expected to significantly increase as well.⁸ "

Lack of Testable Hypothesis

PROBLEM: The Approach lacks a testable hypothesis.

SOLUTION: The hypothesis should be testable by each specific aim. Include a supposition or proposed explanation made on the basis of background evidence and preliminary data as a starting point for further investigation.



BAD: "Needle trauma and suture material result in scar formation. Reducing manipulation of injured nerve ends with light activated sealing and cross linked amnion wraps is a solution to this problem."

GOOD: "In recent years, light-activated sealing of nerve repair sites with amnion nerve wraps has emerged as an alternative to standard suture, resulting in superior functional and histologic outcomes.^{26–29} NHS and EDC has been used to improve biomechanical strength and resistance to degradation of several collagen-based biomaterials, including amnion.^{36–40} Recent ex vivo work has confirmed that EDC/ NHS treated amnion is stronger and more resistant to proteolytic degradation (manuscript in preparation).⁴¹

Weak or Absent Preliminary Data

PROBLEM: Proposal is missing preliminary data.

SOLUTION: Preliminary data should demonstrate the ability to complete the methods, measure outcomes, overcome technical hurdles, and diminish risk in the project.

- It should support the creation of the hypothesis.
- It should demonstrate the selection of correct models to test the hypothesis.



Overambitious Aims

PROBLEM: Approach includes overly ambitious aims.

SOLUTION: Limit Specific Aims to what you can <u>realistically</u> accomplish during the grant period. Make sure you know how long the grant period is and do not submit proposals that clearly will take longer than that time period. Aims should concisely state how you will test your hypothesis.



Domino Aims

PROBLEM: Specific Aims where each aim hinges on the success of the previous aims.

SOLUTION: Sequential Aims are appropriate in engineering grants but the preliminary data should show feasibility for each Aim.

 Identify aims that are independent, yet jointly supportive of your overall hypothesis.



BAD:

The overall goal of this proposal is to develop and use a novel implantable optical oxygen monitor to detect flap viability.

This proposal has the following specific aims:

Aim 1: To further develop a novel implantable optical oxygen sensor using a hydrogel scaffold.

Aim 2: To evaluate the ability of the optical oxygen sensing system to detect differences in tissue oxygenation in a rodent model.

Aim 3: Correlation of tissue oxygenation monitor with viability of flaps.

Aim 4: To determine the length of time that the sensors are functional after implantation and are reabsorbed by surrounding tissue.

GOOD:

The overall goal of this proposal is to use and validate a novel implantable optical oxygen monitor to detect flap viability.

This proposal has the following specific aims:

Aim 1: To evaluate the ability of our previously developed optical oxygen sensing system to detect differences in tissue oxygenation in a rodent model.

Aim 2: Correlation of tissue oxygenation monitor with viability of flaps.

Comment [1]: Innovative technology to assist in assessment of flap perfusion. Development of a device along with evaluation of its functionality and longevity is overambitious in terms of a 1 year grant proposal.

Comment [2]: Novel approach to detection of tissue oxygenation. Aims 2-4 are all based on the success of developing an implantable oxygen sensor. Failure of Aim 1 will prevent the completion of these aims.

Comment [1]: Innovative approach in detection of flap perfusion with a previously developed implantable tissue oxygenation sensor.

Comment [2]: Although results of Aim 1 will impact the validity of Aim 2, correlation between the sensor and clinical viability will provide additional information to confirm its usefulness.

Comment [3]: The aims of this proposal will likely be completed during the 1 year grant period and seem appropriate as the next step in evaluation of these devices.

BAD:

In light of the proposed benefits of light-activated sealing and nerve wrap cross-linking, this study aims to:

Aim 1: Develop methods of amnion crosslinking with nontoxic agents to reduce its enzymatic degradation.

Aim 2: Evaluate role of amniotic cross-linked nerve wraps in nerve repair.

Aim 3: Prove that light activated sealing of amnion-wrapped nerve graft <u>coaptation</u> sites are advantageous over conventional, gold standard suture.

Bartlomiej No..., 28/10/2015 20:17

Comment [1]: Development of methods of amnion crosslinking is ambitious even for a separate study and non-realistic with its simultaneous evaluation.

Bartlomiej No..., 28/10/2015 20:23

Comment [2]: Aims 2 and 3 are based on the success of degradation – resistant amnion crosslinking.

GOOD:

In light of the proposed benefits of light-activated sealing and nerve wrap cross-linking, this study aims to: **Aim 1:** Disprove the null hypothesis that light activated sealing of nerve graft coaptation sites with cross-linked nerve wraps offers no advantage over conventional, gold standard suture.

Bartlomiej No..., 28/10/2015 20:52

Comment [3]: A null hypothesis will be disproved when crosslinked amnion wraps will prove more effective than nerve suture. Light activated tissue sealing and amnion crosslinking are recently described methods of nerve repair. They should be effectively applied and compared with suturing.

Untested/Complex Methodology

PROBLEM: Untested or overly complex methodology within Approach.

SOLUTION: It is necessary to use approaches that you have already performed or have published from your laboratory. Innovative or newer approaches require inclusion of appropriate expertise/collaborators.



Absent Statistical Justification

PROBLEM: Absent statistical justification or interpretation of data within Approach.

SOLUTION:

- The best way to improve your statistics section is to include a biostatistician in your proposal.
- Include sample size calculation and specific methods for data analysis and interpretation.
- Power analysis is critical for animal and human studies.



Research Lacks Innovation

PROBLEM: Research proposal lacks innovation. Avoid insignificant incremental advancements

SOLUTION:

- Innovation is challenging and seeks to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- It may include concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense.
- It may include refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed.
- State the leading edge of the field and how the grant will advance the field.



Investigator Lacks Experience

PROBLEM: Investigator lacks experience or have poor collaboration.

SOLUTION:

- Grant proposals should be framed around the expertise of the principal investigator, their laboratory and collaborators.
- Letters of Support should describe in detail your Co-Investigators
 & Collaborators' <u>credibility</u>, <u>intended contribution and role</u>, as well as stating their support.
- % of Effort for key personnel should be clearly noted within proposalCENTRAL to provide an accurate picture of how the proposed work will be accomplished.

Reviewer Comments on a Bad Example:

• "Investigator: PI is a general surgery resident with several clinical publications but lacks basic science background relevant to angiogenesis or gene therapy. It is unclear how well supported this basic science study will be. The team could benefit from formal collaboration with other basic scientists that are experts in angiogenesis and gene therapy."

Reviewer Comments on a Good Example:

• "Investigator: The investigator is a PGY3 general surgery resident with a 2 year dedicated research fellowship who has been provided adequate support to complete this clinical study."

Not Following Guidelines

PROBLEM: Investigator did not read and strictly adhere to published guidelines.

- Institutional signatures not obtained in time
- Budget does not add up or follow guidelines
- Missing required documents
- Spelling & grammatical errors
- Letters are not on letter head or signed
- Roles for Key Personnel are unclear or conflicting
- Human/Animal Subject Protection lacks detail regarding minorities, women, children, prisoners, veterans, etc or animals.

SOLUTION: Administrative review or scientific reviewers can triage a grant if the grant does not follow the correct format. Reviewers want a well-written, grammatically correct, succinct proposal.

Professionalism demonstrates aptitude.

Remember To...

- Get the reviewers excited about your work!
- 2. Have your hypothesis testable by each specific aim.
- 3. Include strong preliminary data.
- 4. Be realistic in what you can accomplish.
- 5. Identify <u>independent</u> yet supportive aims.
- 6. Include a clear and plausible approach.
- 7. Improve your statistics with power analysis.
- 8. State how your research will advance the field.
- Cleary show the experience your team brings.
- 10. Follow the guidelines and proof your work!



References

- http://www.nimh.nih.gov/funding/grant-writing-andapplication-process/common-mistakes-in-writingapplications.shtml
- http://www.ninds.nih.gov/funding/ grantwriting_mistakes.htm
- https://principalinvestigators.org/pdf/ 5_Common_Mistakes.pdf
- http://www.niaid.nih.gov/researchfunding/grant/strategy/ pages/2designproj.aspx#d1