



UNIVERSITY OF MARYLAND
SCHOOL OF PHARMACY

Funding Success at Biomedical research

Tips for Better Grantsmanship

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“Grantsmanship is the art of acquiring peer-reviewed research funding”
It is a learning experience

Young Investigator Award of the IRP, NIDA, NIH (1993-1994)

Intramural Funding (1995-1998)

PhRMA Faculty Development Award (1996-1998)

NIH R29 First Award (1998-2003)

NIH RO1 Award (2004-2010)

NIH KO2 Award (2005-2010)

NIH R21 Award (2012-2014)

NIH DP1 Award (2011-2016)

Stanley Foundation (2015-2018)

NIH UO1 (in submission)

Reviewer, Contract review committee

NIDA/NIH 1997-2009

Member of the training and career development review committee,

NIDA/NIH, 2002-2006

Ad hoc member of CSR/NIH, ZRG1 F03B-D (20) study section,

2008-2010

Member of CSR/NIH, MNPS study section,

2009-2012

Member of CSR/NIH, SAT study section,

2013-2019



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NIH grant review policy

Scored Review Criteria:

1. Significance
2. Investigator(s)
3. Innovation
4. Approach
5. Environment
6. Overall Impact

Additional Review Criteria:

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Resubmission
- Renewal
- Revision



Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of items, but will not give scores for these items and should not consider providing an overall impact score.

- Applications from Foreign Organizations
- Select Agent
- Resource Sharing Plans
- Authentication of Key Biological and/or Chemical Resources
- Budget and Period Support



A research strategy

- Not just about experiments, but how you think about solving the problems raised.
- Must provide a clear picture of your research and its impact, how you will overcome challenges and what you hope to accomplish.
- Importance of clarity in the specific aims and matching them to your approach section.
- How to impress the reader regarding innovation and your credentials.
- Level of detail needed in approach.
- Importance of focusing on strategy rather than INDIVIDUAL experiments.
- Must show the reader that you can interpret your own data.



A useful plan is to break the proposal into the following headings:

- **Hypothesis and long term objectives**--testable hypotheses
- **Specific aims**--logical and sequential
- **Background and significances**--known, not known, and why to find out
- **Progress/preliminary studies**--relevant previous work, unique qualifications and skills, and actual data .
- **Research design and methods**--Be focused and clear (Number the research designs and methods to correspond to the numbers of the Specific Aims); Reference, but do not describe well-known or standard procedures. For new methods, explain why they are better than existing methods; Discuss relevant control experiments (This is often lacking); Explain the processes for data collection, analysis and interpretation; Discuss potential difficulties and limitations of the proposed procedures and give alternative procedures to achieve the aims; Document all proposed collaborative arrangements.
- **Timetable**



Rigor and Transparency in Research

To support the **highest quality science, public accountability, and social responsibility in the conduct of science**, NIH's Rigor and Transparency efforts are intended to clarify expectations and highlight attention to four areas that may need more explicit attention by applicants and reviewers:

- Scientific premise
- Scientific rigor
- Consideration of relevant biological variables, such as sex
- Authentication of key biological and/or chemical resources



Scientific Premise: Guidance for Reviewers

GOAL: Ensure that the underlying **scientific foundation** of the project—concepts, previous work, and data (when relevant)—is sound.

- Pertains to the **underlying evidence/data** for the project
- Addition to the review criteria: “Is there a strong scientific premise?”
- Specifically, has the applicant:
 - Provided sufficient justification for the proposed work?
 - Cited appropriate work and/or preliminary data?
 - Appropriately identified strengths and weaknesses in prior work in the field?
 - Proposed to fill a significant gap in the field?
 - OR has the applicant explained why this is not possible?



Scientific Rigor: Guidance for Reviewers

GOAL: Ensure a strict application of scientific method that supports robust and unbiased design, analysis, interpretation, and reporting of results, and sufficient information for the study to be assessed and reproduced. Give careful consideration to the methods and issues that matter in your field.

Pertains to the **proposed research**

Addition to review criteria: Are there “strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”

Possible considerations, if appropriate for the scientific field and research question, include plans for:

- determining group sizes
- analyzing anticipated results
- reducing bias
- ensuring independent and blinded measurements
- improving precision and reducing variability
- including or excluding research subjects
- managing missing data



Relevant Biological Variables: Guidance for Reviewers

GOAL: Ensure that the research accounts for sex and other relevant biological variables in developing research questions and study designs. The ways in which sex and other biological variables need to be accounted for will differ across research questions and fields of study.

Pertains to the **proposed research**

Applies to studies in vertebrate animals and/or human subjects

Addition to review criteria: Are there “adequate plans to address relevant biological variables for studies in vertebrate animals or human subjects?”

Consideration of sex is required in all studies involving human subjects or vertebrate animals (see next slide).

Specific considerations to assess include:

- Applies broadly to all biological variables relevant to the research such as sex, age, source, weight, or genetic strain.)
- Has the applicant considered biological variables, such as sex, that are relevant to the experimental design?
- Will relevant biological variables be controlled or factored into the study design appropriately?



Sex as a Biological Variable: Guidance for Reviewers

Consideration of sex, included under the umbrella of “Relevant Biological Variables”, is required in all studies involving human subjects or vertebrate animals.

NIH expectations for applicants:

If little is known about sex differences, the application should include both sexes.

- Sufficient numbers should be provided to inform the presence or absence of sex differences. Statistically powered comparisons between sexes may not be warranted.
- Specific hypotheses about sex differences may not be possible.
- Findings should be reported separately by sex in progress reports and publications.

If sex differences are known not to exist, a strong justification should be provided if the application proposes to study one sex.

If sex differences are known, experiments should be designed with appropriate group sizes to detect sex differences.

NIH expectations for reviewers:

As part of the Consideration of Relevant Biological Variables, assess whether the plans to address sex as a biological variable are adequate (for studies in vertebrate animals or human subjects).

If the study involves only one sex, is this justified scientifically?

Assess within the context of the research question and current scientific knowledge.



Plan for Resource Authentication: Guidance for Reviewers

GOAL: Ensure processes are in place to identify and regularly validate key resources used in their research and avoid unreliable research as a result of misidentified or contaminated resources.

- Researchers are expected to authenticate key biological and/or chemical resources used in their research, to ensure that the resources are genuine.
- New Additional Review Consideration
 - Authentication of Key Biological and/or Chemical Resources: For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.
- Rate as acceptable/unacceptable (provide brief explanation if unacceptable)
- Does not affect criterion scores or overall impact score



	Applies to which applications?	Where will I find it in the application?	Where do I include it in my critique?	Addition to review criteria	Affect overall impact score?
Scientific Premise	All	Research Strategy (Significance)	Significance	Is there a strong scientific premise for the project?	Yes
Scientific Rigor	All	Research Strategy (Approach)	Approach	Are there strategies to ensure a robust and unbiased approach?	Yes
Consideration of Relevant Biological Variables, Such as Sex	Projects with vertebrate animals and/or human subjects	Research Strategy (Approach)	Approach	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?	Yes
Authentication of Key Biological and/or Chemical Resources	Project involving key biological and/or chemical resources	New Attachment	Additional review considerations	Comment on plans for identifying and ensuring validity of resources.	No



Mentored Career Development Applications

	Applies to which applications?	Where will I find it in the application?	Where do I include it in my critique?	What should I consider?	Affect overall impact score?
Scientific Premise	All	Research Strategy	Research Plan	Is there a strong scientific premise for the project?	Yes
Scientific Rigor	All	Research Strategy	Research Plan	Are there strategies to ensure a robust and unbiased approach?	Yes
Consideration of Relevant Biological Variables, Such as Sex	Projects with vertebrate animals and/or human subjects	Research Strategy	Research Plan	Are adequate plans to address relevant biological variables, such as sex, included for studies in vertebrate animals or human subjects?	Yes
Authentication of Key Biological and/or Chemical Resources	Projects involving key biological and/or chemical resources	New Attachment	Additional review considerations	Comment on plans for identifying and ensuring validity of resources.	No



Budget

- Make sure the budget is well documented, realistic, appropriate and justified. Do not inflate, or under budget.
- Give sufficient details for each item to make it difficult and unreasonable for the reviewers to arbitrarily suggest major cuts.
- For equipment, document convincingly why the piece is essential (not just "nice to have" or "faster and better"), and why the specified model is required.
- For personnel: Make sure they are allowed. Specify the unique and essential role that each will play, and state how their qualifications are matched with the role.
- Avoid "to be named" if possible.
- For travel, specify who will travel and whether they will be presenting a paper. Justify a request for more than one meeting per year for any one person.
- Be honest and complete for other grants received and/or pending
- Be careful if stating "no overlap". It may be more accurate to state "There are certain similarities in the systems and/or methods but there is no overlap in specific aims or objectives".



Appended Documents

- Make sure that all that are required are included. If allowed, include material that is supportive but not integral to the contents of the application. But the application, without appendices, must stand on its own.
- Do not include documents if they are not required:

Publications

- Unfortunately many reviewers tend to "weigh" or "count" publications, rather than assess the quality, significance and contribution of the applicant.
- Aim for a good number of first authored publications in first-order peer-reviewed journals.
- A high ratio of abstracts / full-length papers is not well received
- Other kinds of publications (books, chapters, reviews, non-peer reviewed articles) may not impress the reviewers.



COMMON ERRORS MADE

New Applicants

- unrealistically ambitious. There are no clearly defined priorities and the timetable (if present) is unrealistic, with no sense of what can realistically be accomplished during the term of the grant.
- literature and background reviews are uncritical. They read like an undergraduate review.
- no results of pilot studies or other preliminary data.
- time listed to be spent on research should be at least 50%, and preferably over 75%. Anything less than 50% may be unacceptable (a smaller percent effort is usually acceptable for established investigators).
- The budget is unrealistic.

Established Investigators

- The application is fragmented and disjointed. Different parts were obviously written by different junior colleagues and then hastily assembled by the applicant.
- "I don't have to go into detail. Trust me and examine my track record. Rely on my reputation". This no longer works.
- The proposals tend to be too cautious and do not venture into new and unexplored areas. They tend to be "more of the same".



Ten Simple Rules for Getting Grants

Rule 1: Be Novel, but Not Too Novel

Rule 2: Include the Appropriate Background and Preliminary Data as Required

Rule 3: Find the Appropriate Funding Mechanism, Read the Associated Request for Applications Very Carefully, and Respond Specifically to the Request

Rule 4: Follow the Guidelines for Submission Very Carefully and Comply

Rule 5: Obey the Three Cs—Concise, Clear, and Complete

Rule 6: Remember, Reviewers Are People, Too

Rule 7: Timing and Internal Review Are Important

Rule 8: Know Your Grant Administrator at the Institution Funding Your Grant

Rule 9: Become a Grant Reviewer Early in Your Career

Rule 10: Accept Rejection and Deal with It Appropriately

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ACKNOWLEDGEMENTS

"Stealing from one source is plagiarism, while stealing from many is research"

This presentation is incorporated ideas from the following sources:

- “Art of Grantsmanship” by Jacob Kraicer, University of Toronto, Canada
(<http://www.hfsp.org/funding/art-grantsmanship>)
- Rigor and Reproducibility in grant applications (OER site):
<http://grants.nih.gov/reproducibility/index.htm>
- NIH presentation of background and goals of Rigor and Transparency (video)
https://grants.nih.gov/reproducibility/module_1/presentation.html
- Reviewer Guidance on Rigor and Transparency:
http://grants.nih.gov/grants/peer/guidelines_general/Reviewer_Guidance_on_Rigor_and_Transparency.pdf
- Consideration of Sex as a Biological Variable in NIH-funded Research
http://orwh.od.nih.gov/sexinscience/overview/pdf/NOT-OD-15-102_Guidance.pdf