

Advice on NIH SBIR & STTR Grant Applications
Writing for Reviewers



Gregory Milman
National Institute of Allergy
and Infectious Diseases
gmilman@niaid.nih.gov
July 2009

1

Hello, I am Gregory Milman. In these presentations I provide advice on the NIH SBIR and STTR programs. This module is titled Writing for Reviewers. It was updated in July 2009. Send your comments, suggestions, and criticisms to gmilman@niaid.nih.gov.

Agenda Writing for Reviewers



- Before you write your application
- Focus on a product not your technology
- Review criteria
- SF424 Application Components
 - Application Title
 - Biographical Sketches
 - Specific Aims
 - Background and Significance
 - Preliminary Studies
 - Research Design and Methods
- Research and Related Project Information
 - Project Summary/Abstract
 - Bibliography
 - Facilities and Resources

2

Agenda – Writing for Reviewers

This module provides my advice on how to write a strong application. Conduct market research on your product before you begin writing. Winning applications focus on a product and not on technology. In this module I interpret each of the five criteria used by reviewers to score your application and suggest how to write each component of your application.

Focus On A Product, Not On Your Technology



- Core technology builds a business.
- A single use of core technology builds an SBIR/STTR application.
- Advantages of focus on single use.
 - Meets needs of specific problem.
 - Targets committed reviewers.
 - Demonstrates business acuity.
 - Allows additional applications using same core technology.
 - Direct different uses of your technology to different ICs and different review groups!
- Describe the public health and financial significance of your product.

3

Focus on a product, not on your technology

Developing core technology that can be used to create many different products is outstanding business strategy but a flawed approach for an SBIR/STTR application. I believe a better grant writing strategy is to focus on a single product for a single health problem. For example, imagine that your technology enables inexpensive rapid genetic tests for susceptibility to cancer, heart disease, infectious diseases or other health problems. Your application would probably be assigned to the National Human Genome Research Institute based on this technology but would Genome program staff be supportive? Would scientific reviewers be supportive? How would business reviewers evaluate the product when it is not clear what the product will be?

Consider instead an application focused on applying your genetic testing technology to breast cancer. The application would be assigned to the National Cancer Institute. Cancer reviewers are likely to be enthusiastic about an innovative product that impacts their area. Business reviewers are likely to be enthusiastic about sales of a new innovative product.

Because you focused on a single use, you could submit additional SBIR/STTR applications for other uses based on the same core technology. I strongly suggest you direct your applications to different review groups and different ICs. For example, an application on cardiac screening could be directed to the National Heart, Lung, and Blood Institute and one on asthma to NIAID. In each application, it is critical to focus on the public health significance of the product in that area, and the financial impact of the product in the market and to your company.

Application Review Criteria



- Five Core Review Criteria (My Interpretations):
 - Significance, *How important is the problem?*
 - Investigators, *How qualified are the investigators?*
 - Innovation, *How important is the product?*
 - Approach, *How well designed is the research?*
 - Environment, *How critical are the collaborators and the facilities?*
- Overall Impact: The overall impact of proposed research is not an average of the five Core Review Criteria.
- Significance and innovation are the most important criteria!

4

Application review criteria

Reviewers judge all NIH grant applications using five core review criteria: Significance, Innovation, Approach, Investigators, and Environment. Here is how I think each review criterion is applied to small business applications

Significance is the importance of the public health problem. You must convince reviewers why they should care about the problem your product addresses.

Investigators is the qualifications of the PI and collaborators.

Innovation is the ability of your product to significantly affect the unmet public health need you have identified.

Approach is your research design.

Environment is your resources and those of your collaborators.

Reviewers assign an overall impact priority score to an application. The priority score is a gestalt measure of the impact of the proposed research and not an average of the five review criteria. I believe that significance and innovation are the most important of the five criteria!

Application Components Relating to Review Criteria

APPLICATION COMPONENT	REVIEW CRITERIA
SF424 R&R Descriptive Title of Project	Significance, Innovation
Biographical Sketches	Investigators, Environment
PHS398 Research Plan (15 page limit)	
Section	
2. Specific Aims	Approach
3. Background and Significance	Significance, Innovation
4. Preliminary Studies – Progress Report	Approach, Investigators
5. Research Design and Methods	Approach, Innovation
Research and Related Project Information	
Project Summary/Abstract	All Criteria
Bibliography and References Cited	Investigators
Facilities, Resources, Equipment	Environment

5

Application components relating to review criteria

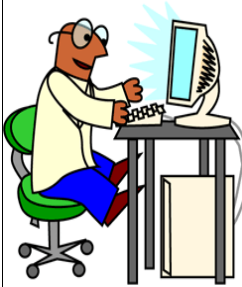
There is not a one-to-one correlation between the review criteria and the components of your application. NIH may change the organization of applications in the future.

The current components of your grant application and the review criteria each is likely to impact are shown in this slide. The significance and innovation criteria should be prominent in your title, background and significance, and abstract.

Some components of your application will reiterate what you say in other components, sometimes in more detail. Only a few reviewers are assigned to read your entire application. Most reviewers read only some sections of your application, but all reviewer votes count equally. Repeating information and including clear figures, charts and tables communicates to those reviewers who skim your application.

In the following slides, I suggest how to write each application component. The slide titles indicate the review criteria in parentheses. Please pause my presentation now to consider how you would write each component before I discuss them. Continue my presentation when you are ready.

Title – One Product and One Problem in 81 Characters
(Significance, Innovation)



- What is the public health problem?
 - How large is the problem?
 - What are current solutions and their drawbacks?
 - What progress is being made?
- What is your product?
 - Why is it better than what is available?
 - What are the requirements to sell it?
 - What are the milestones necessary to bring your product to the point of sales?
 - What are estimated time and cost to reach each milestone?
 - What is your exit strategy along the development pathway?

6

Before you write your application

Theoretically, one would identify an unmet public health need or problem and then develop a product that significantly impacts the problem. In the real world, companies develop a technology and then search for a problem where their technology can create a product. Young companies often have difficulty deciding on which problem to focus. A grant application that does not focus on a narrow unmet public health need is unlikely to fare well in review.

You need a clear vision of the product you will make with your technology before you begin writing a grant application. It is probably not good business strategy to let NIH Funding Opportunity Announcements (FOA) influence your choice of problem or product. Instead, deciding on your product and its development pathway requires both market research and strategic planning.

You need to know the size of the public health problem, current solutions and their drawbacks, and ongoing research efforts and progress.

For your product or technology, you need to know its market advantages and be able to list the milestones necessary to develop the product for sale, the estimated time and costs for each milestone, and your exit strategy along the development pathway.

Examples of Actual Phase I SBIR Applications Titles (Product, Problem)

1. Development of Antimicrobial Peptides
2. Antigen Detection Assay for the Diagnosis of Visceral Leishmaniasis
3. Enteric-coated Vector Microparticles for Oral Vaccination
4. Coupled Enzyme Reporter Assay for Proteases
5. An Immunoadhesin Therapy for Gastrointestinal Anthrax
6. Proteolytic Antibodies for Treatment of Psoriasis
7. A Dynamic Web-based Geospatial Data Visualization and Distribution System
8. Virus-like Particle (VLP) Vaccine for RSV
9. Molecular Screen for Antiviral Agents
10. Multi-antigen Peptide Assay for the Serodiagnosis of Lyme Disease
11. Rapid, Low Cost, Point-of-Care Diagnostic Device for Group B Streptococcus
12. Potential Benefits of Personalized Interferons

7

Examples of Actual Phase I SBIR Applications Titles (Product, Problem)

A title should concisely convey two pieces of information: the product and problem it addresses within the title's 81 character limit. This slide shows titles of real Phase I SBIR applications. Please pause my presentation to consider which of these titles gives information on both the product and the problem. Continue when you are ready for my opinions.

1. "Development of Antimicrobial Peptides" does not identify a pathogen or public health problem.
2. "Antigen Detection Assay for the Diagnosis of Visceral Leishmaniasis" states both the product and problem.
3. "Enteric-coated Vector Microparticles for Oral Vaccination" describes technology but not a problem.
4. "Coupled Enzyme Reporter Assay for Proteases" does not identify a pathogen or public health problem
5. and 6. Both these titles identify a product and a problem.
7. I do not understand this title, do you?
8. "Virus-like Particle (VLP) Vaccine for RSV" identifies a product and a problem.
9. "Molecular Screen for Antiviral Agents" describes technology but not a specific disease.
10. and 11. Both these titles identify a product and a problem.
12. "Potential Benefits of Personalized Interferons" does not identify a problem.

Biographical Sketches (Investigators, Environment)



- Follow instructions to include biographical sketches for all PIs, Key Personnel, and other Significant Contributors.
- Reviewers use biography information to evaluate both the investigator and the environment.
- The lists of ongoing and completed research support demonstrate research management experience.

8


Biographical Sketches (Investigators, Environment)

Follow the application instructions to include biographical sketches for all PIs, Key Personnel, and other Significant Contributors.

Reviewers will use biography information to evaluate both investigators and the environment.

The lists of ongoing and completed research support should demonstrate your research management experience. Be careful you do not indicate that you are requesting funds for work already supported by the government.

Specific Aims (Approach)



- Paragraph 1
 - Problem and its significance
 - Current solutions, gaps, roadblocks
- Paragraph 2
 - Your product
 - Why it is an innovative solution to problem
- Specific Aims (bullets for each)
 - No more than necessary to justify Phase II
 - Easily assessed by a review committee
 - Timeline
 - End point for each as opposed to a best effort
 - A best effort Specific Aim is "to evaluate a number of potential drug candidates."
 - An end point Specific Aim is "to select the best drug candidate for Phase II study."

9

Specific Aims (Approach)

Begin your Specific Aims section with a paragraph briefly describing the problem and why it is significant. Then, briefly describe the current status of solutions and unmet public health needs. Check the IC's WebPages for background information that may help you.

Describe your product in the next paragraph. Hypothesize why your product is an innovative solution to the problem.

Present your Specific Aims in bullet format. Describe two to four measurable Specific Aims for Phase I research and for each, the criteria by which success will be judged. Make your Specific Aims "end points" as opposed to a "best effort." Your Specific Aims may be milestones, or if appropriate, each of your Specific Aims may be subdivided into milestones.

A review committee should easily be able to determine if your Specific Aims have been achieved and agree that successfully accomplishing them justifies Phase II funding. Propose a timeline for achieving your Specific Aims in table or graphic format. Do not propose more work than reviewers would think reasonable to achieve in Phase I. Estimate the additional time and funding necessary to bring your product to market after the completion of Phase I.

Background and Significance (Significance, Innovation)



- Describe the Public Health Problem (**Significance**)
 - Single disease is best because the application will be assigned to a reviewer who knows and cares about that disease.
 - What are the number and composition of the population affected?
 - What discoveries are needed?
- Product (**Innovation**)
 - Why is your product innovative (better, faster, at lower cost, etc.)?
 - What are the public health implications?
 - What are the product's financial projections?
 - After Phase II, what additional steps will be necessary before your company can realize a profit?

10

Background and Significance (Significance, Innovation)

For "background," describe the significance of the public health problem. My advice is to appeal to reviewers by focusing on a single disease even if your technology has multiple applications. Describe the number and composition of the population affected. Give references to supporting statistical data. Provide background on the current solutions to the problem, their limitations, and the discoveries needed. Show reviewers you know the field by the breadth of your knowledge of both published and unpublished work by others, some of whom could be your reviewers.

For "significance," describe why your product is innovative. Does it work better, faster, or at lower cost than what is currently available? What are its public health implications? Estimate your product's potential financial projections. How are you protecting your intellectual property? Explain why the Phase I milestones outlined in Specific Aims will justify a Phase II award. Describe milestones projected for Phase II and the progress necessary for your company to either sell the product or license the further development to another organization.

Spend considerable effort on this section because it greatly affects your score.

Preliminary Studies – Progress Report (Approach, Investigators)



- Phase I applications – Preliminary studies
 - Omnibus Solicitation states “Preliminary data are not required.”
 - But, most applications present preliminary data.
 - Reviewers want to see preliminary data.
 - Preliminary data should support your proposal and the feasibility of Phase I and Phase II.
 - Preliminary data may consist of publications by you and your collaborators and your unpublished data.
 - Interpret preliminary data critically and evaluate alternative meanings.
- Phase II applications – Phase I progress report
 - Milestones proposed
 - Milestones achieved

11

Preliminary Studies (Approach, Investigators)

Although the SBIR/STTR solicitation states that “Preliminary data are not required,” most applications include preliminary data. Review committees are likely to have greater enthusiasm for proposals with good preliminary data. Poorly presented or poorly interpreted preliminary data can hurt your score.

Include preliminary studies that support the feasibility of your project. They may consist of your own publications and those of others, as well as unpublished data from your laboratory. Emphasize work you have accomplished that indicates you can direct the proposed research and achieve your Specific Aims. Interpret results critically and evaluate alternative meanings but do not over interpret. You can be assured that critical members of the review committee will look for explanations other than the ones you propose.

The preliminary studies section of your Research Plan should convince reviewers that your approach could work. Reviewers may also use your work described in this section to assess the investigator criterion.

Be aware that the Phase I progress report in your Phase II application will list the milestones proposed and achieved in Phase I.

Research Design and Methods (Approach, Innovation)



- Describe your research design and methods in parallel to your Specific Aims and include a timeline in table or diagram format.
- Include for each set of experiments:
 - Expected results, limitations, potential difficulties, and planned statistical analysis if relevant
 - Criteria for evaluating success, failure, or other possible interpretations
 - Hazards anticipated, precautions proposed
 - Reagents, animals, human subjects, equipment, etc. Follow NIH guidelines.
 - Purpose of collaborators, if any, and letters of agreement

12

Research Design and Methods (Approach, Innovation)

The Research Design and Methods section of your Research Plan should spell out in detail what you are going to do, how you are going to do it, and your criteria for success. Reviewers will use this section to evaluate your approach.

Make it easy for reviewers by organizing this section by Specific Aims and include a timeline in table or diagram format to quickly convey your entire project to reviewers.

Give a rationale for each set of experiments. Convince reviewers that your methods are appropriate to your Specific Aims. If your methods are innovative, show how you have changed existing or proven methods while avoiding technical problems. Provide supporting data and references.

Describe the kinds of results you expect and how they will support continuation of your project. Present other possible outcomes and contingency plans.

Define the criteria for evaluating the success or failure of each set of experiments. If possible, include statistical analysis as reviewers are impressed by statistics.

Describe hazards anticipated and precautions you propose. Spell out your sources of important reagents and equipment, and details of any use of animals or human subjects. Be sure to follow NIH guidelines.

Explain how credible collaborators will participate in your proposed research. You should include letters that describe collaborators agreements with you, including their role on the project and hours to be committed.

Project Summary/Abstract (All Criteria)



- All reviewers read your abstract.
- Compose after you complete rest of application.
- Concisely summarize application.
- Include no proprietary information.
- Write a few sentences on each:
 - Public health problem
 - Issues with current solutions
 - How your product addresses unmet needs
 - Summary of approach
 - Collaborators and unique resources and capabilities
 - Phase I Specific Aims
 - How anticipated results justify Phase II and further product development
- Your Project Narrative is three sentences or less on the relevance of your project to public health.

13

Project Summary/Abstract (All Criteria)

Your title and project summary/abstract are very important components of your application because all reviewers read them and they contain information relating to all five review criteria. Compose your abstract last because your plans may change as you write other components. Hone your abstract to summarize everything in your application in the 30 lines allowed. Include no proprietary information because your abstract will become public if you receive an award.

Write a few sentences each on the public health problem, issues with current solutions, how your product would address unmet needs, a summary of your approach, collaborators and unique resources, Phase I Specific Aims, and how anticipated results will justify Phase II and further product development. Conclude with the additional time and funding necessary to bring your product to market after the completion of Phase I.

The required Project Narrative is a description in three sentences or less of the relevance of your project to public health.

Bibliography & References Cited (Investigators)



- Follow instructions for the "Bibliography and References Cited" component.
- Reviewers may examine your references to see:
 - Are they current?
 - Are they sufficiently inclusive?

14

Bibliography & References Cited (Investigators)

Follow the instructions for the Bibliography and References Cited component of your application including required citations. Your bibliography will not improve your investigator evaluation but could hurt if your references are not current or not sufficiently inclusive. Use the bibliography only for references and not for footnotes to annotate information in other sections!

Facilities, Resources, Equipment (Environment)



- Company's current or tentatively leased research facilities
- Company's research resources necessary for project
- Unique company capabilities
- Not a virtual company
- Research resources of collaborating laboratories and institutions
- Subcontractor R&D Resources

15

Facilities and Resources (Environment)

Reviewers will use your Facilities and Resources component to evaluate the environment.

If you do not have research facilities at the time of application, you should have a lease agreement on facilities conditional on your receiving an award.

Describe your facilities and any unique company capabilities for the project. Include enough information to assure reviewers that you are not a virtual company. Describe collaborators' resources that will be used for the project. If you propose subcontracts, describe what resources and capabilities the subcontractors bring to the project.

Other Items in PHS 398 Research Plan – View Tips and Tricks Presentation



- Human Subjects
 - Protection of Human Subjects
 - Inclusion of Women and Minorities
 - Targeted/Planned Enrollment
 - Inclusion of Children
- Other Research Plan Sections
 - Vertebrate Animals
 - Select Agent Research
 - Multiple PI Leadership Plan
 - Consortium/Contractual Agreements
 - Letters of Support
 - Resource Sharing Plan

16

Other Items in PHS 398 Research Plan - View Tips and Tricks Presentation

This slide lists a number of other components in your application that can delay or derail funding. Carefully read the application instructions for each. My Tips and Tricks module contains suggestions on these and other issues.

More Presentations



TOPICS

- Basic Information
- Managing the NIH Timeline
- Writing for Reviewers
- FY2008 Data
- Tips and Tricks
- More than SBIR/STTR Funds
- Small Business Funds for Academic Investigators

17

Thank you for watching this module. Close this window to select another topic.