

SBIR: Grantsmanship
or
How to swim with the sharks and
survive!

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NIH/DHHS

Don't be afraid of the water- jump in!

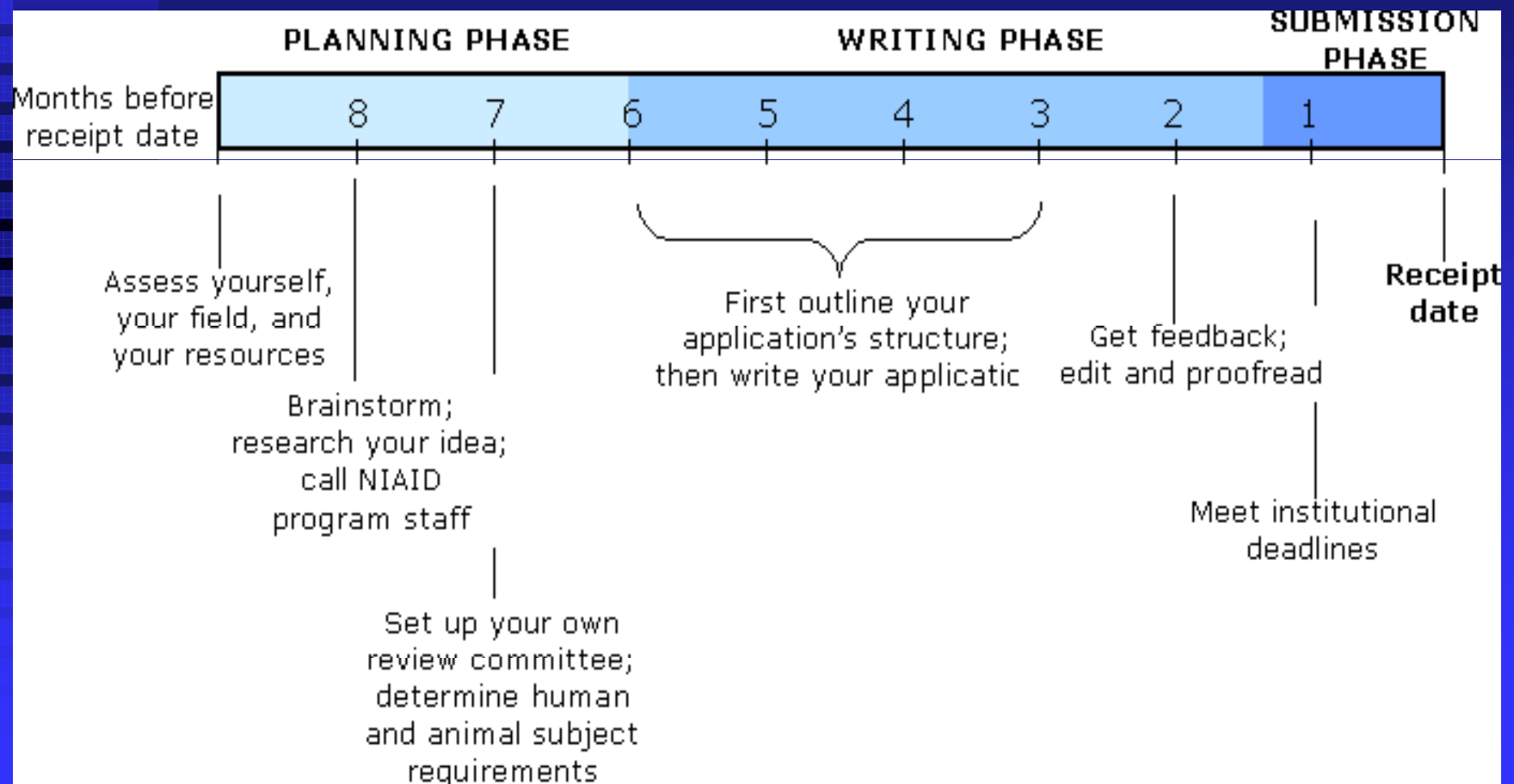
- Government is looking—ideas and products
- There is money!!!!
- There is help and guidance
 - ◆ SBTDC
 - ◆ Agency Program Director
- Procedure is simple.
- High expectation of success.

I. NIH SBIR Overall Process and Review

- Timeline from idea to funding
- Understanding the process

Start Planning Early!!!!

Planning Schedule.....



NIH GRANT PROCESS



Applications Submitted to NIH Center for Scientific Review



APPLICATION, REVIEW, and AWARD



APPLICATION TO AWARD TIMELINE

2-tiered review process



SBIR/STTR
Receipt Dates

Apr 1

Aug 1

Dec 1

Scientific/Technical
Peer Review

June/July

Oct/Nov

Feb/March

Adv Council
Board Review

Sept/Oct

Jan/Feb

May/June

Est. Award
Date

Nov

Mar

July

90-Day pre-award costs are allowable:

At your own risk.....

So.... When will I get the money?

- Minimum of 9 months after submission

- ◆ Holdups

- ◆ **Bars to funding:** human subjects, children, minorities, animal welfare, biohazard
 - ◆ Indirect costs, final budget, EIN, review issues resolved

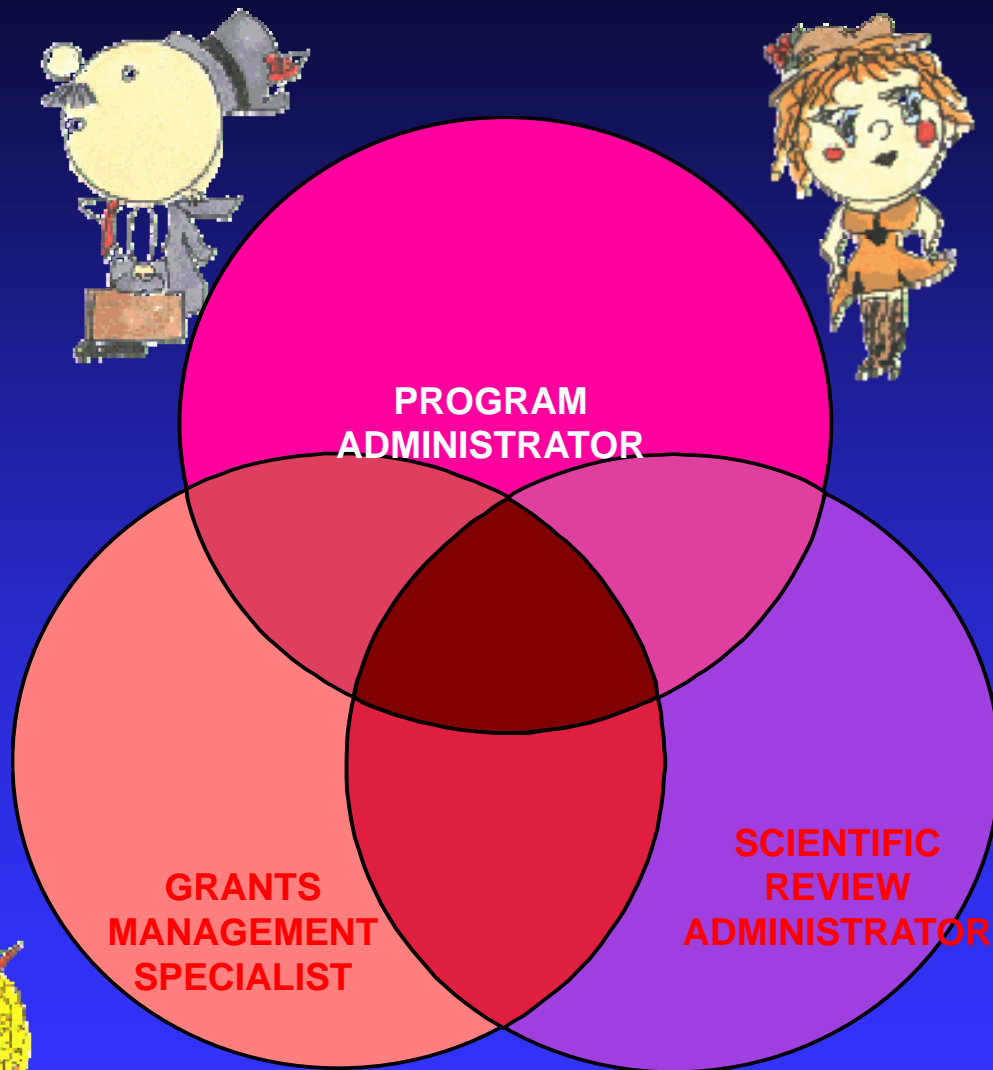


- Holdups minimized by interaction with agency representatives at all phases.

II. Who to talk to, When and About What!

- Start talking to agency representative before start writing.
- Be sure agency is interested in idea.
- Check out possible review panels.
- Get grantsmanship training.
- Information on budgets and financial matters.
- Information on patent rights.....

THE NIEHS EXTRAMURAL TEAM !





Scientific Program Administrator

- Develop program initiatives
- **Provide guidance and assistance to applicants**
- Attend Scientific review group (SRG) meetings as program resource person(s)
- Communicate results of review to applicants
- Make funding recommendations
- Monitor progress during the award period



Scientific Review Administrator

Review administrators **setup and conduct scientific and technical reviews** of grant applications to identify those of highest scientific and technical merit in their respective discipline and disease areas.



Grants Management Specialist

Grants Management Officials ensure that **business management actions** for NIH programs and awards are performed correctly, efficiently, and in accordance with pertinent grant policies and good business practices, including responsibility for maintaining official grant files.

When to Interact with Various Staff Members

Scientific Program Administrator:

- ❏ Prior to submission
- ❏ After the review is complete
- ❏ Prior to the award
- ❏ During the progress of the research



Grants Management Official:

- ❏ Fiscal or Administrative questions prior to submission or award and throughout award



Scientific Review Administrator:

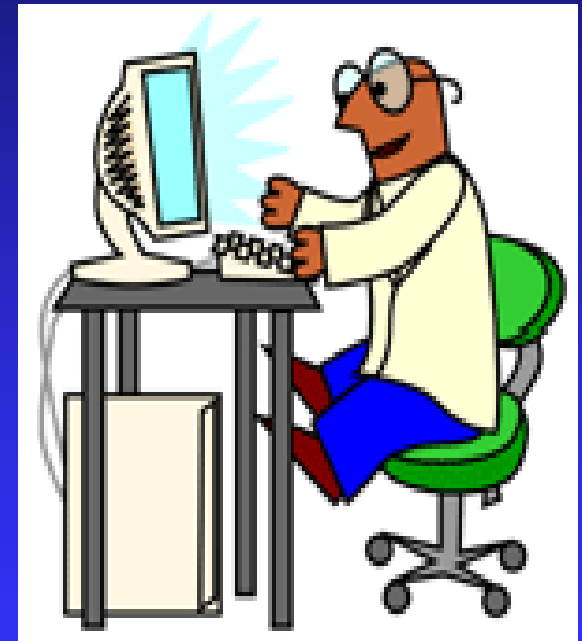
- ❏ After Submission
- ❏ Prior to Summary Statement



III. Principles of Grantsmanship

Preparing an SBIR Application

- Title
- Abstract (200 words)
- Research Plan
 - ◆ Specific Aims (1 page)
 - ◆ Significance (2-3 pages)
- Experimental Methods/Approach



General NIH Guidelines

■ Phase I

- ◆ Research Plan 15 pages
- ◆ Total of 25 pages
- ◆ No appendices
- ◆ Biographical sketches 4 pages each

■ Phase II

- ◆ Research Plan 25 pages
- ◆ Product development plan 10 pages
- ◆ Appendices permitted
- ◆ No limit on total pages
- ◆ Biographical sketches 4 pages each

It is not the will to win that's important. Everyone wants to win! It is the will to *prepare* to win that makes the difference.

Bobby Knight

Important Points to Remember

- SBIR applications now use the NIH 398 forms.
 - ◆ TIP: USE STYLE OF RESEARCH GRANTS

- There is an art to writing applications!
 - ◆ TIP: MELD SCIENCE,
SALESMANSHIP
AND COMMUNICATION SKILLS



Grantsmanship : General Preparation

- Assess the field....know state of field and opportunities
- Check out the competition
- Brainstorm ideas....match them to NIH
 - ◆ Novel, innovative, impact
- Check with NIH program directors
- Give yourself plenty of time....3-6 mo!
- Write clearly, consisely and with grantsmanship in mind!

Grantsmanship: Know your Audience!

■ The Reviewers

- ◆ Accomplished, dedicated, fair
- ◆ Overly committed, tired, inherently skeptical, overly critical
- ◆ General understanding only
- ◆ **Assume reviewers are uninformed but intelligent!**
- ◆ Used to reviewing R01 applications



SBIR Review at NIH

- Special review panels for SBIR
- Review criteria
- Score 100-500
- Summary statement

Scoring Grant Applications Is Like
Judging Different Breeds of Dogs
at a Dog Show



They are judged
against an ideal
breed standard,
not against
each other.

The key to success in grant writing is to engender **enthusiasm** in the reviewer--- who then becomes an **advocate** for the proposal!

The more energy and time a reviewer has to devote to figuring out your application, the less energy a reviewer has to **review** your application!

Grantsmanship: Know your Audience

.....SBIR Scientific Review Criteria

■ **Significance**

- ◆ Important problem; commercial potential

■ **Approach**

- ◆ Conceptual framework, design, methods, analyses well developed; potential problems identified and addressed; time frame; sound approach for achieving technical and commercial feasibility

■ **Innovation**

- ◆ **Novel** concepts, approaches or methods; **challenge existing paradigms** or develop new or **innovative technologies**

SBIR Scientific Review Criteria

■ Investigator

- ◆ Experience, technical and managerial capability of principal investigator; consultants or collaborators expertise;

■ Environment

- ◆ Sufficient scientific and technical resources (space and equipment); useful collaborative arrangements

■ Additional issues

- ◆ Human subjects, gender and minority plans; animal welfare; reasonableness of budget; biohazards

SBIR Scientific Review Criteria

■ Phase II

- ◆ Progress in phase I: Demonstration of feasibility
- ◆ Product development plan

■ Fast Track

- ◆ Measurable goals in phase I
- ◆ Product Development Plan
- ◆ Commercialization

Importance of Communication Skills

- One reason some branches of government have trouble operating jointly is that they don't speak the same language.
- Goal: "Secure a Building"
 - ◆ Navy
 - ◆ Army
 - ◆ Marines
 - ◆ Air Force

Grantsmanship: Sell yourself and your ideas!

- What are you selling?
- Why is it important?
- Impact (who will benefit)
- How will you do it?
- Advantages/strengths/limitations
- Track record (can you do it?)



And put it in the proper form !

Principle of Successful Selling

- Make people like you...develop rapport
- Find out what they need or want
- Get the other person point of view
- Know your product
- Show advantages of your product
- Develop a desire for your product
- Get people saying YES

ABSTRACT: Stated Guidelines

- State the application's broad, long term objectives and specific aims.
- Make reference to the health-relatedness of the project.
- Describe concisely the research design and methods for achieving goals.
- Discuss potential for innovation.
- Avoid summaries of past accomplishments and the use of first person.
- Do not exceed 200 words.

Grantsmanship: ABSTRACT

- IDENTIFY PROBLEM:
 - ◆ What is the problem addressed? (Must be public health problem!!)
 - ◆ Who cares
- SOLUTION:
 - ◆ Hypothesis/goal/product
- PLAN:
 - ◆ Approach
 - ◆ Specific aims/milestones
 - ◆ Techniques/methodologies used
- BENEFITS:
 - ◆ Expected results
 - ◆ Application/benefit

Grantsmanship: Specific Aims Section (One Page)

■ Introductory Paragraph

- ◆ Statement of long term health-related goal (1 sentence)
- ◆ Background/significance of problem (1-2 sentences)
- ◆ Preliminary data/state of the art (2-3 sentences)
- ◆ Data gaps/controversy (1-2 sentences)
- ◆ Clearly defined hypothesis/specific goal
(1-2 sentences)

Specific Aims (Cont'd)

■ Specific Aims/Milestones

- ◆ 2-5 aims (One sentence each)
- ◆ Specifically focused to prove hypothesis/develop product
- ◆ Logical order with no dead ends

■ Summary Statement

- ◆ Emphasize novel product and innovative approach and impact on field (2-3 sentences)

Experimental Methods/Research Plan

For Each Aim/Milestone:

- Rationale for approach
- Experimental Design in detail including data analysis and interpretation
- Potential Difficulties/Limitations
- Alternative approaches

Justify everything including timetable and that you have experience and expertise needed

Background and Significance

- Logical development of background information that forms basis of proposal
- Logical flow from more global to specific
- Critical evaluation of current knowledge
- Identification of data gaps, conflicts, needs, what's new and novel and innovative
- Importance of research and how it will fill need
- Public health benefit

Time and Budget

■ Phase I:

- ◆ Suggest one year!
- ◆ Justify budget needed—don't limit to \$100,000
- ◆ Discuss with SBIR program director at agency before submission



Phase II: Specifics

- Phase I final report
- Describe development of working prototype
- Describe Product Development Plan
- Add letters of commitment for commercialization

Time and Budget

Phase II

- Suggest time as appropriate, can be more than 2 years
- Suggest budget as appropriate, can be more than \$750,000
- Discuss time and budget with agency program director

Product Development Plan

- **Company information:** size, specialization areas, prior successes, regulatory experience,
- **Value of Project:** key technology objectives, current competition, advantages of proposed product
- **Commercialization Plans:** milestones, target dates, market analysis, estimated market share (1st year and after 5 yrs)
- **Patent Status** or other protection of project intellectual property

Grantsmanship: From the Test Tube to the Medicine Cabinet

- **Small BUSINESS Innovation Research**
- **Think very early about your commercialization pathway**
 - HOW will you commercialize? WHO will buy it?*
- **Research... Research.... Research**
 - Market will willingly accept your idea... NO*
- **Business Planning is CRITICAL to the Company's Commercialization Plan**

Future Directions at NIH to Assist Companies in Commercialization

- Competing Continuation Phase II application

<http://grants.nih.gov/grants/guide/pa-files/PA-02-173.html>

Purpose

- To take existing, promising compounds developed under a Phase II through the next step of drug discovery and development.
- Additional research support to address clinical issues, and other issues relevant to regulatory approval
(e.g., FDA, ICCVAM)

Fast Track Option

- Preliminary data and clear milestones in phase I that increase confidence in success.
- Submit separate Phase I and Phase II proposals at same time.
- Phase II must have Product Development Plan.
- Reviewed at same time and given separate scores.
- Results can be either Fast Track accepted or only Phase I accepted or neither accepted based on review.

Applications Submitted to NIH Center for Scientific Review

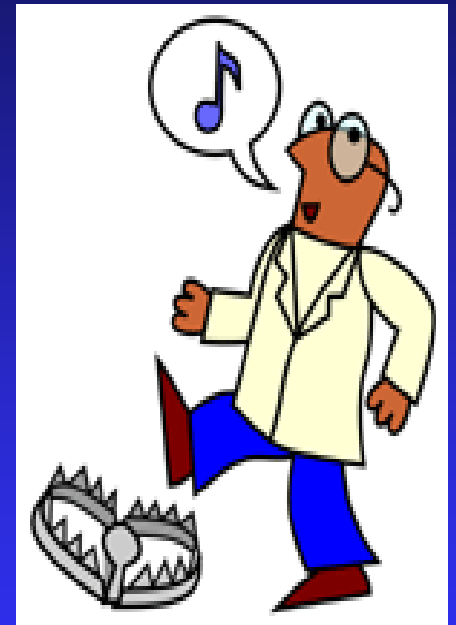


Cover Letter: A Valuable Tool

- Suggest potential awarding component(s)
- Discuss areas of expertise appropriate for the application's review
- Indicate individual(s) or organization(s) in conflict

Common Problems with Applications

- Lack of innovation
- Unconvincing case for commercial potential
- Lack of experience with methods
- Questionable reasoning in approach
- Lack of experimental detail
- Overly ambitious
- Unfocused research plan that does not test feasibility



Summary

- Government is looking—ideas and products
- There is money!!!!
- There is help and guidance
 - ◆ SBTDC
 - ◆ Agency Program Director
- Procedure is simple.
- Grantsmanship/salesmanship
- High expectation of success.

Grantsmanship Guidance at NIH

- <http://www.niaid.nih.gov/ncn/grants/default.htm>
- http://grants1.nih.gov/grants/funding/sbir_policy.htm
- <http://grants1.nih.gov/grants/funding/sbirgrantsmanship.pdf>
- <http://niaid.nih.gov/ncn/sbir/advice/advice.pdf>