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

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National Institute of Environmental Health Sciences
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
Applying for Funding
Start Planning Early!!!!!!

Planning Schedule.....

<table>
<thead>
<tr>
<th>PLANNING PHASE</th>
<th>WRITING PHASE</th>
<th>SUBMISSION PHASE</th>
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<tbody>
<tr>
<td>Months before receipt date</td>
<td>8 7 6 5 4 3 2 1</td>
<td>Receipt date</td>
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- **Assess yourself, your field, and your resources**
  - Brainstorm; research your idea; call NIAID program staff
  - Set up your own review committee; determine human and animal subject requirements

- **First outline your application’s structure; then write your application**

- **Get feedback; edit and proofread**

- **Meet institutional deadlines**
NIH GRANTS

Formula for Grant Success
Elements of Grant Success

- Good Ideas
- Good Timing
- Good Presentations
- Good Reviewers
- Good Luck
- Good Grantsmanship
NIH GRANT PROCESS

Initiates Research Idea and Prepares Application

Conducts Research

Submits Application

Manages Funds

CSR Assigns to IRG and Institute

20 Institutes and Over 100 study sections

Institute Makes funding Decisions and Awards

THE NATIONAL INSTITUTES OF HEALTH

INVESTIGATOR

GRANTEE
Applications Submitted to NIH Center for Scientific Review
APPLYING, REVIEWING, and AWARDS

Small Business Concern

- Submits SBIR/STTR Grant Application

Center for Scientific Review

- Assigns to IC and IRG

Scientific Review Group

- Reviews for Scientific Merit
- Institutes
- Evaluates for Relevance

Advisory Council or Board

- Recommends Action

Institute Director

- Allocates Funds $$
- Conducts Research
- Takes final action for NIH Director

~2-3 months after submission

~2-3 months
External Peer Review

- Experts from academia and industry
- Numerical Score (~100-300) vs. **
- Critiques sent to all applicants
- Confidentiality and non-disclosure statements signed by reviewers
Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

Provides Initial Scientific Merit

**Review** of Grant Applications

Rates Applications and

**Recommends** for Level of Support and Duration of Award

Second Level of Review

Advisory Council

Assesses Quality of SRG Review of Grant Applications

**Makes Recommendation** to Institute Staff on Funding

Evaluates Program Priorities and Relevance
APPLICATION TO AWARD TIMELINE

2-tiered review process

<table>
<thead>
<tr>
<th>SBIR/STTR Receipt Dates</th>
<th>Scientific/Technical Peer Review</th>
<th>Adv Council Board Review</th>
<th>Est. Award Date</th>
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<tr>
<td>Apr 1</td>
<td>June/July</td>
<td>Sept/Oct</td>
<td>Nov</td>
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<tr>
<td>Aug 1</td>
<td>Oct/Nov</td>
<td>Jan/Feb</td>
<td>Mar</td>
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<tr>
<td>Dec 1</td>
<td>Feb/March</td>
<td>May/June</td>
<td>July</td>
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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.....
Offices at NIH
THE NIEHS EXTRAMURAL TEAM!

- Program Administrator
- Grants Management Specialist
- Scientific Review Administrator
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 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
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!
NIH REVIEW CRITERIA
(Phase I)

- Significance (Real Problem/Real People)
- Approach (Research Design, Feasible)
- Innovation (New or Improved?)
- Investigators (PI and team)
- Environment (Facilities/Resources)
  - Protection of Human Subjects
  - Animal Welfare
  - Budget
See Previous Slide
- Demonstrated Feasibility in Phase I
- Commercialization Plan
- High Degree of Commercial Potential based on Commercialization Plan
- Protection of Human Subjects
- Animal Welfare
- Budget
Grantsmanship: Know your Audience
…..SBIR Scientific Review Criteria

- **Significance (real problem/real people)**
  - Important problem; commercial potential

- **Approach (feasible research design)**
  - 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 (PI and team)**
  - Experience, technical and managerial capability of principal investigator; consultants or collaborators expertise;

- **Environment (facilities and resources)**
  - 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/Commercialization potential

- **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
Principles of Grantsmanship
Preparing an SBIR Application

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

- **Company information**: size, specialization areas, prior successes, regulatory experience,

- **Value of Project**: key technology objectives, current competition, advantages of proposed product

- **Commercialization Plans**: production and marketing plans, target dates, market analysis, customer, estimated market share (1st year and after 5 yrs)

- **Patent Status** or other protection of project intellectual property plan
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
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)
NIH SBIR/STTR Program

Gap Funding Options

- Phase I / Phase II Fast Track
  Simultaneous submission / concurrent review

- No-Cost Extension (Ph I or Ph II)
  Extension in time with no additional funds

- Administrative / Competitive Supplements
  Discuss with Program Director

- Phase II Competing Continuation
  Maximum of $1M/yr for 3 years
  Response to IC-specific PA

New!
NIH SBIR “FAST-TRACK”
Best Option For Everyone?

- Convincing preliminary data?
- Clear, measurable, achievable milestones?
- Well-conceived Commercialization Plan?
- Letters of Phase III support/interest?
- Track record for commercializing?
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.
NIH SBIR/STTR FAST-TRACK
Bridging the Funding Gap

Phase I + Phase II
(Simultaneous submission and Concurrent review)
7-9 months

Phase I
6 month award (SBIR)
12 month award (STTR)

Phase II
2-year award

Funding Gap
Reduced/Eliminated

Discuss Fast-Track option with Program Director
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
NIH SBIR/STTR FUNDING RATES
FISCAL YEAR 2002

- SBIR:
  - Phase I: 27%, 880
  - Phase II: 48%, 335
  - Fast-Track: 17%, 44
- STTR:
  - Phase II: 33%, 81
  - Fast-Track: 63%, 29
  - Fast-Track: 0, 25

$499 M
SBIR/STTR

$499 M
SBIR/STTR
Invention Reporting

- Grantees must report inventions
- Interagency Edison

Interagency Edison provides Federal grantee/contractor organizations and participating federal agencies with the technology to electronically manage extramural invention portfolios in compliance with federal reporting requirements.

Interagency Edison was developed by the Office of Policy for Extramural Research Administration, National Institutes of Health, Bethesda, Maryland.

What is Interagency Edison?

Interagency Edison supports a "Common Face" for Invention Reporting to the Government. The system has been designed to facilitate grantee/contractor institutions with the compliance of laws and regulations mandated by the Bayh-Dole Act whose purpose is to ensure transfer of technology from the research laboratory to the commercial/public sector.

What are the steps necessary to become an Interagency Edison user?

To become an efficient and effective Interagency Edison user, follow these steps:

http://www.iedison.gov
Common Problems with Applications

- Inadequately defined test of feasibility
- Diffuse, superficial, or unfocused research plan
  - Lack of sufficient experimental detail
- Questionable reasoning in experimental approach
  - Uncritical approach
  - Failure to consider potential pitfalls and alternatives
- Lack of innovation
- Unconvincing case for commercial potential or societal impact
- Lack of experience with essential methodologies
- Unfamiliar with relevant published work
- Unrealistically large amount of work proposed
Common Problems with Applications

- Lack of innovation
- Unconvincing case for commercial potential
- Lack of experience with methods
- Questionable reasoning in approach
  - Uncritical approach
  - Failure to consider potential pitfalls and alternatives
- 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

How to Write a Grant Application

http://grants1.nih.gov/grants/grant_tips.htm
http://www.niaid.nih.gov/ncn/grants/
http://grants2.nih.gov/grants/grant_tips.htm
http://www.nigms.nih.gov/funding/tips.html
http://www.nigms.nih.gov/funding/moregrant_tips.html
http://deainfo.nci.nih.gov/EXTRA/EXTDOCS/gntapp.htm
http://chroma.med.miami.edu/research/Ellens_how_to.html
http://www.cfda.gov/public/cat-writing.htm
http://cpmcnet.columbia.edu/research/writing.htm