Phase I/II Proposal Development: Beyond The Basics

University of San Diego, MRH Warren Auditorium
May 1, 2019; San Diego, California

Disrupting Old Habits

Martin Kleckner III PhD MBA
2nd of a Four-Part Series

April 18: SBIR STTR – The Basics

May 1: SBIR/STTR Phase II – Beyond the Basics

May 23: Funding Your Innovation: SBIR Phase I & II Grants, SBIR III Support, Business Alliances, Private Equity

June 13: Business Model Discovery & Validation for Capitalization; the I-Corps Way
SBIR “Deal Killer” (Avoidance) Program

1) Registration for SBIR/STTR Applications

2) Preparing a Fundable Study Approach
   ▪ Research Design/Protocol
   ▪ Writing Hypotheses and Aims

3) Writing Your Phase II Commercialization Plan

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Date: 6/3/2019 - 8/30/2019
Time: 8:00 AM - 12:00 PM (PDT)
Status: Open - 15 places remaining
Registration Deadline: TBD
Fee: $350.00

Program Format: Multi-session Course
1) A facilitated peer-learning work group – Target: the NIH
   September 5, deadline
2) In each session, instructors and peers work in concert on the
   same topics
3) Not a guarantee that you will receive a SBIR; we will not write
   or submit an application for you

SBIR Writer's Work Group
- Curt Becker, Brink SBDC Advisor
Industry Specific: (e. g. Life Sciences)

Commercialization (Navigation Roadmap)

- Coding, Coverage; Joint FDA/CMS Parallel Review
- Analytical Validity, Clinical Validity; Clinical Utility
- Economics (Cost/Benefit Impact)
- Health Technology Assessment (HTA)
- FDA Regulatory Affairs
- Licensing Best Practices, Optimal Alliance/Partnership Structuring
- Enterprise Economic Value Management; Strategic Accounts

FDA, CMS, AMA, BS/BC (Evidence Street), Evicore, Hayes, ECRI, Aetna, Precision Medicine, New Ventures Funds, Quest, American Healthcare Research & Quality (AHRQ), U S. Preventive Services Task Force, Palmetto GBA; CLSA
## Future: BRINK I-Corps Site/Accelerator

**Fixed Term: 7 – 8 Weeks**

1. Business Models & Customer Development
2. Value Proposition
3. Customer Segments
4. Distribution Channels
5. Customer Relationships
6. Revenue Streams
7. Partnerships/Alliances
8. Resources, Activities, & Costs

**Seed Fund/Equity Stake**

1. Investor Presentations, Documents
2. Terms Sheets, Deal Terms, other Related Funding issues
3. Types of Funding Vehicles
4. Sales & Marketing Strategies
5. Management Policies/Procedures
6. Hiring & Staffing Issues -- Including cash and stock compensation for Other Team Members
7. Board of Directors Acquisition/Compensation
8. Advisory Board Creation, Utilization & Compensation
9. Board Governance Issues
10. Strategic & Tactical Planning

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Where I’m Coming From . . .

1) National Science Foundation I-Corps Adjunct Faculty
2) Six Launches; Two Exits
   - RegeneMed
   - InSilicoMed
   - SpyFinder (Sold)
   - Sal-Flex (Sold)
   - + RefluxMD
3) Also: Not-For-Profit 501 (c) 3 – Venture Philanthropy
4) SBIR/STTR: NSF, NIH, DoD, DOE, Commerce, Trans., Coulter, Drexel; Univ. of Calif (San Diego, Merced, Irvine, Riverside, Los Angeles); USC
5) Times Mirror, AmHS, General Electric, Roche, Toshiba America (La Costa Group LLC)
6) $55.8 MM in Capital & Grants 2016 – Q2 2018
What is Your Odyssey?
Agenda

For Our Discussion

1. Reiterations (Phase I)
2. Phase II Award Criteria
3. Designing and Defending a Fundable Study Approach

Addendum
Budgeting, Accounting & Government Audits
Essential Rules

1. Ask Questions
2. Jump-In
3. "Your Take"
4. Discuss
The Phase II “Sniff Test”

1) You Meet **Eligibility Requirements**
   - Size, United States Based; For Profit

2) You have the **Facilities**

3) You have the right Research & Commercialization **Team**

4) **Awarded Phase I** or have in-house equivalent data for a Direct-to-Phase II

5) **Phase I Aims Achieved** (or will be)

6) **Fast Track**
This workshop pertains to both Phase I & II
PART I:

REITERATIONS
(from April 18)
They’re still here

- Eleven (11) Agencies Have an SBIR Program
- Five (5) Have an STTR Program (✓)
- High Risk – Innovative – Transformative
- Strong Chance For Commercial Success
  - Credible Commercialization Plan w/ Evidence
    - (I-Corps Programs “Linked to” SBIR)
    - Partnerships for Innovation (NSF)
- Well-Designed Study, Strong Team
Characteristics (again)

**PHASE I (Proof of Concept):** Merit, Feasibility, Commercial Potential
- ALSO: Your Quality & Performance w/ a small amount of money
- Amounts Vary; 6 – 12 Months: $75,000 - $225,000 + + (inflation)
- There may be a Hard Cap Waiver

**PHASE II: Complete R & D; Efficacy, Potential, Merit**
- Amounts Vary; 24 Months: $750,000 - $2.25 MM + +
- Phase IIB (NIH; DOE: Sequential) or Special/Supplemental (e.g. DOE, NSF)
- Commercial Potential: Past Record; Funding + “Commitments” (P II & III)

**PHASE III: Commercialization**
- Unfunded (except for the DoD); Non-Cash; In-Kind Support
To Be Eligible (SBIR) . . .

1. Organized For-Profit; based in the U. S.
2. No more than 500 Employees (incl. Affiliates, PT & Temp.)
3. ≥ 50.1% directly-owned or controlled by 1 or more Permanent Citizens or Resident Aliens ("Green Card"/"Substantial Presence" Test)
   ▪ Other small businesses meeting the above criteria
4. A Joint Venture wherein each entity meets the above
5. 1/3 of Funded Work May Be Sub-Contracted
6. Principal Investigator Must Be > 50% Employed By You
Eligibility (STTR) . . .

1. Organized For-Profit; based in the U. S.; ≤ 500 employees
2. ≥ 51% directly-owned or controlled by 1 + permanent citizens or resident aliens; Other small businesses meeting the above criteria
3. Research Institution Partner:
   ▪ Located in the US; Nonprofit college or university; Domestic Nonprofit Research Organization; Federally Funded R&D Center (FFRDC)
4. Must Have an IP Agreement: Allocation, Research, Commercialization
5. Company Performs 40% - 70%; NFP Partner Does 30% - 60%
6. Principal Investigator - No Need To Be Primarily SBC Employed
Cross Program Awards
  - Agency Discretion: Can Allow STTR Phase I Awardee to receive SBIR Phase II Award/Other Way as Well

Cross Agency Awards
  - Phase I Awardee May Receive Phase II Award From Another Agency

Direct to Phase II (It’s Back!)

All Phase I Awardees Must be Allowed To Apply For Phase II

Second Sequential Phase II May Be Awarded
SBIR: 6% by 2028 (S 2812)  
4.5% by 2022 (HR 4783)  

STTR: 0.6% by 2022 in the House bill  
1% in the Senate bill  

Latest Action:  
(There are related bills introduced & pending.)
SBIR: 6% by 2028 (S 2812)
4.5% by 2022 (HR 4783)

STTR: 0.6% by 2022 in the House bill
1% in the Senate bill

SBIR & STTR reauthorized; SBIR stays at 3.2%; STTR: 0.45%

The government was initially funded through a series of five temporary continuing resolutions. The final funding package was passed as an omnibus spending bill, the Consolidated Appropriations Act, 2018, enacted on March 23.
Base Program Remains . . .

. . . “pilot” Programs Return
Re-instated (NIH):

- Direct to Phase II
- ‘Phase 0’ Proof of Concept Partnership
  - NIH Centers for Accelerated Innovations (3)
  - Research Evaluation and Commercialization Hubs (3)
DoD Commercialization Readiness Program stays in force through 09/30/2022

DoD Rapid Innovation Fund
$250 MM in Phase III funds now permanent
Supplemental Funds

Phase II Match Funding (NSF “Phase IIB”) - 50% of 3rd Party Investment Funds Up To $500,000

Commercial/Strategic Partnerships - 20% of the Phase II award, up to $150,000

Commercialization Assistance - $10,000 per Phase II award (one per active Phase II grant)
## FY 2019 SBIR & STTR Budget (est.)

<table>
<thead>
<tr>
<th>Agency</th>
<th>SBIR</th>
<th>STTR</th>
<th>Total</th>
<th>Chg</th>
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</thead>
<tbody>
<tr>
<td>Defense (DoD)</td>
<td>$1,535</td>
<td>$215</td>
<td>$1,750</td>
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<tr>
<td>HHS/NIH</td>
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<td>131</td>
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<tr>
<td>Energy (DOE)</td>
<td>256</td>
<td>36</td>
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<td>+58</td>
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<td><strong>TOTAL</strong></td>
<td><strong>$3.2B</strong></td>
<td><strong>$430M</strong></td>
<td><strong>$3.6B</strong></td>
<td><strong>$756</strong></td>
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</table>
1) Can a VC (HF, PEF) owned company apply for a SBIR grant?
   - VC, HF, PEF can hold minority shares
   - Affiliation Rule: majority VC-owned companies (Total ≤ 500 employees)

2) Can a Single VCOC (HF, PEF) hold a majority share - > 50%?
   - NO. They can hold a Minority Share + Not Have CONTROL.
   - No single VC, hedge fund or private equity firm may own more than 50%
   - EXCEPT: VCs owned/controlled by 1 + US Citizens, perm. resident aliens

3) NDAA authorizes NIH, CDC, & DOE (Advanced Research Projects Agency) to award SBIR Funds to VC Majority-owned
   - BUT ONLY IF no one VC/HF/PEF owns more than 50%
VC, Hedge Fund, Private Equity

1) **What about STTR?** Companies that are more than 50% owned by multiple VCs, hedge funds, or private equity firms or any combination are **NOT eligible to apply**

2) **Joint Venture?** Still ‘No’ (& each party must meet ownership requirements)

3) Each VC must have a **U.S. place of business** AND be created or organized in the U. S.; operate under U. S. laws
PART II: Reviewer Decision Criteria

PROPOSAL PLANNING & DEVELOPMENT
CONTENT: WHAT’S IMPORTANT
Reviewer Criteria Synopsis

Study Approach
Ability/Credentials
Impact

Significance
Innovation
Approach
Investigators
Environment
Impact

Relevance
Objectives
Scientific Excellence
Impact
Qualifications
Facilities
Budget
Commercialization

Intellectual Merit
Impact/Benefit
Advance Knowledge
Creative, Original,
Transformative
Well-Reasoned
Qualifications
Resources
Phase I/II Preparations

- ‘Scientific’ Literature & Market Research
- Commercialization Plan (I-Corps, Validation)
- Phase 0/I Findings/Data Analysis
  - Have Confirmed/Demonstrated Feasibility?
- Phase I/II Study Approach; Research Design
- Facilities & Other Resources
- Accounting/Management System (Phase II)
- Convene Your Phase I (& II) Team

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Questions

- What are you going to do?
- Why is it worth doing?
- Who is going to do the work?
- Where are you going to do the work?
- How much will it cost?
- How are you getting it to market?
What Question* Do You Want to Answer?

- **What is Known already** - literature review: relevant findings
- **Where is there missing information** (“unknowns“)?
- **Your Aims** – what do you want to find out; how will you achieve the answer (Study Approach)?
- **Impact** – how this project will substantially add to science or technology, change practice, save money, save lives or improve quality of life in substantial numbers of people. Include an **Economic Impact (Quantify)** if possible.

* Problem that you want to solve
Reviewers Should Understand:

1. What is your Research Question,
2. Is it Original and Relevant,
3. How will it help Fill the Gap (in research, our lives, un-met needs, value. . .?)
Important for Phase II . . .

4. How did you Manage Phase I?
   ▪ Aims
   ▪ Communications
   ▪ Relationships with Program Managers

5. Can you handle a Larger Budget, tougher Objectives, and . . .

6. Execute an “evidence-based” Commercialization Plan
When Are Phase II Award Decisions Made?

Phase I Kick-Off Meeting

Status Meeting

Status Meeting

Starts around here
Part III: Study Approach
What are you going to do? Why, How?

- Specific Aims
- Project Description; Research Strategy
- Team, Expressly Relevant to the Study
- Commercialization Plan
Key Criteria

1. Significance
2. Investigators
3. Innovation
4. Approach
5. Environment
6. Overall Impact

NIH Reviewer
“Marching Orders”

- Title
- Abstract
- Problem
- Solution
- Specific Aims
- Research Strategy
- Facilities
- Biographies

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Phase II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
- Research Strategy (12 Pgs.)
  - Significance
  - Innovation
  - Approach
- Inclusion Enrollment Report
- Progress Report/Publication List
- Protection of Human Subjects
- Inclusion of Women & Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Appendix
- Bibliography & References Cited
- Project Summary/Abstract (30 Lines)
- Public Health Relevance Statement
- Senior/Key Person Profiles
- Biographical Sketches (4 Pgs. Each)
- Facilities & Other Resources
- Equipment
- Project Budget
- Cover Letter
- Commercialization Plan (12 Pgs.)
- Forms
Phase II

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- **Specific Aims (1 Pg.)**
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Statement of Aims

- Very Important Page
- Establishes Objectives/Value
- What Question are . . .

. . . you answering?

AIMS – APPROACH - IMPACT
Anatomy of an Aims Page

The most vital part of any (NIH) grant application . . . central to our proposal.

Difficult to write - gain reviewer trust and confidence - simultaneously convince them that our work is important to fund & we are the right ones for the job.

Category: Scientific Grant Writing
Opening Paragraph

1) First Sentence – The Hook (Importance/Urgency)
2) Introduce your Research Topic – Why is it Critical
3) Significant Knowledge Gap Relative to the Critical Need

Necessary Details Only: Be Concise & Focused

Hook | What is Known | Knowledge Gap | Critical Need
Second Paragraph

Your Solution

1) WHAT are you going to do
2) WHY are you doing it
3) HOW you will do it – Simple, Relevant, to the Point
4) Long-Term GOAL – Hypothesis & Proposal Objectives – Rationale – Your Qualifications
3rd Paragraph: Your Aims

1) What aims will you use to test your hypothesis (2 – 4 Aims)
2) Describe your experimental approach
3) What are your anticipated outcomes from this test?
4) How will this answer your hypothesis, develop a new tool, or establish a new technique?

<table>
<thead>
<tr>
<th>Aim</th>
<th>Experimental Strategy</th>
<th>Outcome or Impact</th>
</tr>
</thead>
</table>
Example Aims

▪ **Establish** an innovative mouse model for HTLV-1 Tax tumorigenesis
▪ **Create** a novel, scalable energy storage and power boost system for 100 kW and larger solar PV arrays.
▪ **Develop and evaluate** an opioid use disorder chatbot that administers a patient version of MINI
▪ **Verify** the feasibility of an innovative, computer-based program to improve cognitive skills in mTBI subjects.
▪ **Increase** the use of the five major components of a brief tobacco cessation intervention
**Aim 1:** Develop algorithms for C. elegans viability assays to identify modulators of pathogen infection. **Challenge:** To identify individual worms in thousands of two-dimensional brightfield images of worm populations infected by Microsporidia, and measure viability based on worm body shape (live worms are curvy whereas dead worms are straight).

**Approach:** We will develop algorithms that use a probabilistic shape model of C. elegans learned from examples, enabling segmentation and body shape measurements even when worms touch or cross. **Impact:** These algorithms will quantify a wide range of phenotypic descriptors detectable in individual worms, including body morphology as well as subtle variations in reporter signal levels.
Closing Paragraph

1) Innovation: What is innovative/transformative?
2) Expected Outcomes: What do you expect to see?
3) Impact: How will this be beneficial?
Objective (Aim) & Endpoints  (Example)

**Objective** (Aim) may be to assess the accuracy (effectiveness, impact) of (a Proposed Solution) in determining the foods to be eliminated from your diet that measurably lower symptom severity of your IBS.

**Endpoints (or Outcomes)** are the Quantitative Measurements that tell you that you have attained your Objectives. For example, what measurements of change in IBS symptom severity would you use to evaluate a favorable result?
"Deal Killers" for Some

- Research Question
  - [Literature, Pertinent Work to Date, . . .]
- Purpose or Hypothesis
  - [Predictions, Variable Relationships, Cause & Effect, Possible Explanation(s) . . .]
- Specific Aims
  - [What is Measured, How, Controls, How Data Interpreted]
- Study Approach

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Why 65% of SBIRs are Partnerships

**Study Design**
e.g. Single/Double Blind
Study Population
Sample Size/Power Anal.
Outcomes/Endpoints

**Study Procedure**
e.g. Sampling Plan, Criteria
Recruitment Procedure
Screening
Randomization (if applicable)
Study Intervention
Assessments & Activities

**Analysis Plan**
Statistical Methods
Background
## Phase I & II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
  - Research Strategy (Pages vary)
    - Significance
    - Innovation
    - Approach
- Inclusion Enrollment Report
- Progress Report/Publication List
- Protection of Human Subjects
- Inclusion of Women & Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Appendix
- Bibliography & References Cited
- Project Summary/Abstract (30 Lines)
- Public Health Relevance Statement
- Senior/Key Person Profiles
- Biographical Sketches (4 Pgs. Each)
- Facilities & Other Resources
- Equipment
- Project Budget
- Cover Letter
- Commercialization Plan (12 Pgs. +/-)
- Forms
- Forms
Research Strategy

Significance

Innovation

Approach
Significance

1) Product/Technology
2) Science/Technological Innovation
3) Market Need
4) Commercial Opportunity

Use References, Citations

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Significance

- Problem to be Solved
- Effects/Impact/Ramifications if not Addressed
- Solution Needed; Product/Technology Planned
  - Impact of Proposed Product
  - Effect of Innovation on Science/Technology
- Solution Value/Value Proposition
- Commercial Potential (Summary)
  - Market Analysis; Competition; Commercialization Plan
- Other Applications/Indications
Innovation

- **Description**
- **It’s Relevance to Current Science/Our Understanding**
  - *Why* is it Innovative? Transformative?
  - How does it Move the Field Forward?
  - What future **Advancement** will this Innovation Enable?
- **It’s Value** to Targeted Customers/Stakeholders
Approach

- Phase I (or in-house) Progress Report
  - Beginning and Ending Dates of Phase 0/I
  - Summarize/Reiterate Phase 0/I Aims
  - Findings, Results & Conclusions/Aims Achieved
  - Any changes to Aims/New Directions?
  - Appraisal of Findings
    - Demonstration of Feasibility (Proof of Concept or Principle)
    - How do/will the outcomes **Support Transition to Phase II**?
    - Technology Developed, Intended Use, Product Development Status
Approach (continued)

Experimental **Design & Methods** (in Detail)

- **Study Population**, Characteristics, Source(s), Criteria
- Detail Discussion of **Experiments to be Performed** to complete Aim
- **Study Procedure/Methods** to be employed in each Experiment
- **Is there a shift** in how things will be/have been studied?
  - Data Collection, Analysis & Interpretation, Management, Safety
  - Potential Pitfalls/Alternative Approaches
    - What could go wrong; how will that be dealt with?
  - Expected Outcomes
  - Statistical Analysis; Finance/Resource Use (Direct v. Indirect Costs)
Review of the Literature . . .

. . . Relevant Research, Methods, Findings

1) Some of us ignore this part, or overdo it, which could be a “death sentence”.

2) Some of us overplay “Disruption” and ignore “advancement” of quality work.

“We’re turning the industry upside down”
Summary

▪ Specific Aims
  — What are they?
  — Why (Significance, Innovation, Phase I Feasibility)
▪ How will Research Strategy be Performed?
▪ Who, When & Where (Summary)
  — Gantt Chart
    • Detailed Timeline
    • Who will be responsible for each Aim’s Completion?
    • Where will the work be done (Company, Contractor, etc.)
## What, Who, When, Where

### Specific Aims

<table>
<thead>
<tr>
<th>Specific Aim 1</th>
<th>Experiment 1</th>
<th>Researcher, Facility</th>
<th>Experiment 2</th>
<th>Researcher, Facility</th>
<th>Specific Aim 2</th>
<th>Experiment 1</th>
<th>Researcher, Facility</th>
<th>Specific Aim 3</th>
<th>Experiment 1</th>
<th>Researcher, Facility</th>
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</table>

1  | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 | 11 | 12 | 13 |

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Phase I/II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
- Research Strategy (12 Pgs. +/-)
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- Senior/Key Person Profiles

- **Biographical Sketches (4 Pgs. Each)**

- Facilities & Other Resources
- Equipment
- Project Budget
- Cover Letter
- Commercialization Plan (12 Pgs. +/-)
- Forms
Biosketch Format

- **Use a Personal Statement** to highlight work/performance
- **Describe Five (5) most significant contributions** to science with historical background
- **Central findings of prior work/influence of those findings on the field**
- **Per Description, accompany with a list of up to four (4) relevant peer-reviewed publications** or other non-research publication research
- **You can include a link to a full list of published work in MyBibliography or SciENcv**
A. Personal Statement

I have the expertise, leadership, training, experience, and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuroendocrinological changes associated with addiction. As PI or co-investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research, developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

New Since 2015: Replaces Publications

Don’t forget the small business (SBC) for personnel who will be working there on the project.
Phase I/II

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  - Project Budget
  - Cover Letter
  - Commercialization Plan (12 Pgs.)
  - Forms

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Slide 64
Phase I/II

- Introduction To Application (1 Pg)
- Specific Aims (1 Pg.)
- Research Strategy (12 Pgs. +/-)
  - Significance
  - Innovation
  - Approach
- Inclusion Enrollment Report
- Progress Report/Publication List
- Protection of Human Subjects
- Inclusion of Women & Minorities
- Targeted/Planned Enrollment Table
- Inclusion of Children
- Vertebrate Animals
- Select Agents
- Multiple PD/PI Plan

- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Appendix
- Bibliography & References Cited
- Project Summary/Abstract (30 Lines)
- Public Health Relevance Statement
- Senior/Key Person Profiles
- Facilities & Other Resources
- Equipment
  - **Project Budget**
- Cover Letter
- Commercialization Plan (12 Pgs.)
- Forms

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Slide 65
- Intellectual Merit
- Impact on Society

1. Advance Knowledge and Understanding
2. Benefit Society
3. Creative, Original and Transformative
4. Well-reasoned; well organized; sound rationale; mechanism to assess success
5. Your Qualifications and Resources
NSF Phase II

- Cover Sheet
- Table of Contents
- Project Summary
- Project Description (15 Pgs.)
- Proposal Budget
- References Cited
- Biographical Sketches
- Facilities, Equipment & Other Resources
- Current & Pending Support
- Data Management Plan
- Mentoring Plan

- Other Supplementary Documents
  - Payment Schedule
  - Project Milestone Chart
  - Commercialization Plan*
  - Commercialization History
  - Phase I Technical Report
  - STTR Cooperative Agreement
  - Letters of Support (Max 5)
  - Humans/Vertebrate Animals

*Number of pages may vary per FOA
Project Description

I. Phase 0/I Results, Findings
   ▪ Feasibility Established

II. Phase II Technical Objectives, Approach
   ▪ Objective (1, 2, 3 . . .)
     — Rationale
     — Experimental Methods
     — Data Analysis & interpretation
     — Potential Pitfalls/Alternative Approaches
     — Anticipated Outcomes
     — Project Development Chart

III. Organization Information
   ▪ Income Statement/Staffing profile; Plans/Phase I/II/III Team

IV. Consultant Sub-awards
Who is going to do what work?
Where will the work be done?
How much will it cost?
Strong Team Needed

- PI(s)
- Employees
- Subcontractor(s)
- Consultants
- Other Significant Contributors

(Think Ahead to Commercialization)
NSF Phase II

- Cover Sheet
- Table of Contents
- Project Summary
- Project Description (15 Pgs.)
- Proposal Budget
- References Cited

- **Biographical Sketches**
  - Facilities, Equipment & Other Resources
  - Current & Pending Support
  - Data Management Plan
  - Mentoring Plan

- Other Supplementary Documents
  - Payment Schedule
  - Project Milestone Chart
  - Commercialization Plan
  - Commercialization History
  - Phase I Technical Report
  - STTR Cooperative Agreement
  - Letters of Support (Max 5)
  - Humans/Vertebrate Animals
NSF Phase II

- Cover Sheet
- Table of Contents
- Project Summary
- Project Description (15 Pgs.)
- Proposal Budget
- References Cited
- Biographical Sketches
- Facilities, Equipment & Other Resources
- Current & Pending Support
- Data Management Plan
- Mentoring Plan

Other Supplementary Documents
- Payment Schedule
- Project Milestone Chart
- Commercialization Plan
- Commercialization History
- Phase I Technical Report
- STTR Cooperative Agreement
- Letters of Support (Max 5)
- Humans/Vertebrate Animals
- Your Facilities
- Subcontractor(s’) Facilities
- Other R & D Resources
  (Significant Contributors, e.g. Sci/Eng Adv. Board)
- Commercialization Resources*
  (Management, Strategic Partners, Funding, Regulation, Coding & Reimbursement), Environment, Topic Specialists

* Critical for Phase II
Phase II

- Cover Sheet
- Table of Contents
- Project Summary
- Project Description (15 Pgs.)
- Proposal Budget
- References Cited
- Biographical Sketches
- Facilities, Equipment & Other Resources
- Current & Pending Support
- Data Management Plan
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- Other Supplementary Documents
  - Payment Schedule
  - Project Milestone Chart
  - Commercialization Plan
  - Commercialization History
  - Phase I Technical Report
  - STTR Cooperative Agreement
  - Letters of Support (Max 5)*
  - Humans/Vertebrate Animals

* Excludes those from subcontractors & consultants (included with Budget Justification)
Validate Your Resources & Commercial Opportunity

- Consultants (required) – incl. rate/time
- Subcontractors
- Other Significant Contributors
- Research Resources (Facilities, equipment not on budget or owned by the company)

- Commercialization (Critical)
  - Strategic Partners
  - Investors
  - Key Customers
  - Potential Licensees
  - Key Opinion Leaders

Convincing; well-thought out; why are they buying-in?
Letters of Support AND Commitment

PHASE I

▪ Market Validation by Third Parties
▪ Evidence that you have been communicating with stakeholders

PHASE II

▪ Evidence of Commitment of follow-on resources from investors, partners, licensees, customers, and other stakeholders
▪ Contingent on Technical Success

DON’T FORGET: NSF has Matching Funds
Letters of Commitment – Phase II

- From prospective investors, strategic partners, customers, licensees, et al.
- Commitment of tangible resources (e.g. funding, services, business agreements)
- Estimated dollar/economic value
- Describe achievements necessary to secure the commitment
PART IV: “Crossing The Chasm”

COMMERCIALIZATION
Congress Loses Sense of Humor

Reauthorization Act of 2011

1) More Emphasis on Commercialization
2) Requirements
   - SBC Applicant Registers at SBIR.gov (Commercialization database)
   - Phase II Awardee Commercialization History
   - Phase II – Commercialization Process
   - Phase III Acquisition Preference
3) Added Agency Flexibility
   - VC/HF/PEF – Ownership Stakes
   - Commercialization Assistance programs
   - Option for Non-Agency Commercialization Support
“Can Your Dog Hunt?”

1) Your Past Record
2) Phase II Funding Commitments
3) Phase III Follow-On Commitments
4) Other Indicators
# Commercialization Plans

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Slide 81
Commercialization Plan

1. Company Information
2. Customer & Competition
3. Market
4. Intellectual Property
5. Financing
6. Assistance & Mentoring
Commercialization Support

I. NIH: Phase I “Technology Niche Analysis” (TNA)

II. NIH, NSF: Commercialization Assistance Program (Phase II)

III. All: The I-Corps Program - Innovation & Technology Commercialization Methodology (“Lean Launch Pad”)
  - The Business Model Canvas
  - The Customer Discovery & Validation Process
  - Supplemental (e.g. Matching Funds)

IV. DOE, DOT: Commercialization Assistance Program
CAP for Phase II Awardees (NIH)  
(https://sbir.nih.gov/cap#cap-home)

Managed through a contract with Larta, Inc.  
(www.larta.org) of Los Angeles, CA - individual mentoring and consulting sessions, training workshops, access to domain experts

1) Commercialization Training Track (CTT)
2) Accelerated Commercialization Training Track (ACT)
3) Regulatory Training Track (RTT)
Phase I Awardees

- Kickoff Webinar
- Commercialization Readiness Assessment (CRA)
- Market Research
- Specialty Webinars
- Business Mentoring: Phase II Commercialization Plan

www.dawnbreaker.com
http://science.energy.gov/sbir/commercialization-assistance/
Phase II Match Funding (NSF “Phase IIB”) 

- Aim: Extend R & D Efforts Beyond Current P-II Grant
- Further Accelerate Commercialization
- **50% of 3\(^{rd}\) Party Investment Funds Up To $500,000**
- Must Start Process At least 30 Days Prior to Phase II Award Expiration; 3\(^{rd}\) Investment Minimum of $100K
- (See: https://www.nsf.gov/eng/iip/sbir/Supplement)
Commercial/Strategic Partnerships

- NSF: “Technology Enhancement for Commercial Partnerships” (TECP)
- NSF Funding for additional research that goes beyond the Phase II project’s objectives to meet the technical specifications or additional proof-of-concept requirements. (Submit w/in 18 months of PII award)
- Additional research is anticipated to enhance the commercial potential and lead to partnerships with industrial partners & secure venture/angel investors.

- Max Funding: 20% of the Phase II award, up to $150,000
- Pre-submission Executive Summary + Letter from Commercial Partner

(Reference: www.nsf.gov/eng/iip/sbir/Supplement/instructions.jsp)
Commercialization Assistance

- Funding to **secure the services of a third-party service provider** to assist in commercialization activities.

  - **Max Funding:** $10,000 per Phase II award (one per active Phase II grant)

- **Deadline:** Within 12 months of the effective start date of Phase II award *(recommended)*

Phase 0 POC: NCAI and REACH
Proof-of-Concept Centers (Hubs)*

GOAL: “De-risked technologies with well-designed business cases primed for licensing or startup company formation.

1. Infrastructure
2. Feasibility; Prototype; POC
3. Access to Expertise
4. Skills Development

*Matthew Portnoy PhD
Program Manager
Office of Extramural Research
https://ncai.nhlbi.nih.gov/ncai/aboutncai/mission

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NIH Centers for Accelerated Innovations: Boston Biomedical Innovation Center, Cleveland Clinic Innovation Center, UC BRAID Center for Accelerated Innovation

Research Evaluation and Commercialization Hubs: University of Minnesota, Long Island Biomedical Hub, University of Louisville

National Institutes of Health: NSF, FDA, USPTO, CMS, Kaiser

Source: Matthew Portnoy PhD
I-Corps™ at NIH

Innovation Corps @ Department of Defense (I-Corps @ DoD)
I-Corps Nodes

Bay Area Node
UC Berkeley
UC-San Francisco
Stanford

LANode
U of Southern California
UCLA
California Inst. of Tech.

Southwest Node
U of Texas at Austin
Texas A&M
Rice
Texas Tech.

I-Corps Midwest
U of Michigan
Purdue
U of Illinois at Urbana-Champaign

I-Corps @ Ohio

Upstate NY Node
Cornell
U of Rochester
Rochester Inst. Of Tech.

DMV
U of Maryland-College Park
George Washington U
Virginia Tech
Johns Hopkins

NYCRIN
City U of New York
NYU
Columbia

I-Corps South
Georgia Institute of Tech
U of Alabama at Tuscaloosa
U of Alabama at Birmingham
U of Tennessee at Knoxville
I-Corps Sites
What We Used to Believe

Start With an Business Plan and Financial Model
EVERYONE has a plan until they get PUNCHED IN THE MOUTH.
No battle plan survives first contact with the enemy.
- Helmuth von Moltke¹

No Business Plan survives first contact with customers.
- Steve Blank²

(1) 19th-century head of the Prussian army; (2) Stanford & U C Berkeley (I-Corps)
Five-Year Plans
Venture Capitalists
Soviet Union
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<tr>
<td>Accumulated Depreciation*</td>
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<tr>
<td>Net fixed assets</td>
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<td>Intangible assets*</td>
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<tr>
<td>Other assets*</td>
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<tr>
<td>Total assets</td>
<td>$284.50</td>
<td>$380.05</td>
<td>$464.61</td>
<td>$577.23</td>
<td>$612.00</td>
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</tbody>
</table>

| Liabilities | | | | | |
| Accounts payable* | $31.83 | $63.43 | $83.84 | $94.41 | $80.00 |
| Current debt* | $30.86 | $57.49 | $69.77 | $81.52 | $65.00 |
| Total current liabilities | $62.69 | $121.92 | $153.61 | $176.96 | $145.00 |
| Long-term debt* | $46.92 | $95.43 | $114.75 | $122.26 | $105.00 |
| Other long-term liabilities* | | | | | |
| Total liabilities | $109.69 | $217.37 | $268.36 | $299.22 | $250.00 |

| Shareholders' equity | | | | | |
| Common Stock | | | | | |
| Retained earnings | | | | | |
| Total shareholders' Equity | $284.50 | $380.05 | $464.61 | $577.23 | $612.00 |
Startups Search

Companies Execute

“Execution is a systematic way of exposing reality and acting on it.”
More startups **fail from a lack of customers** than from a failure of product development.
Therefore, Investors, SBIR Reviewers And Our Customers Need Us To DISCOVER & VALIDATE
Seven (7) Week Curriculum (Agency Grant-Funded: $50K)

- Precursor or Regional Competitive Programs
  - IN-LA “Zap” & “Boom” (USC, Caltech, UCLA)
  - UC Riverside (Jay Gilberg; Alexandra Orozco)
  - UC Irvine (Doug Crawford)
  - UC San Diego (Dennis Abremski)
  - SDSU BioTech Focus (Susan Baxter)

- Five + Week Site-Based Programs
Business Model Generation
(Customer Discovery & Validation)

WHAT IS A BUSINESS MODEL?

9 Components...

1. Value Propositions
2. Customer Segments
3. Channels
4. Customer Relationships
5. Revenue Streams
6. Key Resources
7. Key Partners
8. Key Activities
9. Cost Structure

How a company creates value for itself while delivering products or services for customers.

© 2012 Steve Blank (Steve Blank & Bob Dorf, The Startup Owner’s Manual)
THE LOGIC OF HOW WE WILL MAKE MONEY
AKA HOW “THEY” WILL PROFIT
Before Trying to Sell . . .

. . . Customer Development

SEARCH

Pivot

CUSTOMER DISCOVERY → CUSTOMER VALIDATION

CUSTOMER CREATION → COMPANY BUILDING

EXECUTION

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2. CUSTOMER SEGMENTS

Your customers do not exist to buy. You exist for them.

WHO are they?
WHY would they buy?

- GEOGRAPHIC
- SOCIAL
- DEMOGRAPHIC

Customer Archetype...

Oh?

© 2012 Steve Blank
1. Value Propositions

“IT’S NOT ABOUT YOUR IDEA OR PRODUCT!”

“IT’S ABOUT SOLVING A NEED OR PROBLEM.”

“It’s about satisfying a customer need.”

“You hear me?”

“Yay! I’m DELIGHTED!”

“...and WHO are your customers?”

© 2012 Steve Blank
Investors are interested in this after 5, 10, . . . 100 interviews: What’s Your Story?
Confirmation Bias
Where may your first customers come from?
Behind Every Great Product is a Great Story

The Start-Up Curve!
(starring Us)

Source: Paul Graham
Hopefully some of this was helpful

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PART V (Addendum):

BUDGETING, ACCOUNTING, AUDITS

Direct v. Indirect Costs
Eligibility - Allowability
We don’t need no stinking budgets!

“Budgets? We ain’t got no budgets. We don’t need no budgets. I don’t got to show you no stinking budgets!”

Yes, We Do

Alfonso Bedoya (“Gold Hat”), The Treasure of Sierra Madre (1948)
We will need an Approved Accounting System for Phase II

Expectations Change between Phase I & Phase II
Awarding Agencies & Contracting Officers want you to be able to
distinguish Direct and Indirect Costs + also
isolate Unallowable ones
Likely shift from (Firm) Fixed Price (FFP\(^1\)) to Cost Plus Fixed Fee (CPFF\(^2\))

1. FFP = Grant-Established Dollar Amount
2. CPFF = Documented Costs
   (CPFF requires a “smart” accounting system)
DCAA & Pre-Award Surveys*

1) DCAA = Defense Contract Auditing Agency
2) NIH & NSF = External CPA Reviewer

- Assess Our Financial Stability (to complete a 2-Year Phase II project (not to mention Phase IIb)
- Evaluate Our Accounting System

*Audits
Also . . .

3) Evaluate your proposed Indirect Rates
   — Assess how they were calculated
   — Determine if they are suitable for billing

4) Confirm that your Payroll Taxes are current

Memo: Take a look at the “DCAA Guide Information for Contractors”
About that Accounting System . . .

1. Proper segmentation of Direct from Indirect costs
2. Identification & accumulation of Direct Costs by Contract
3. Logical & consistent method for Allocating Indirect Costs
4. Accumulation of costs under General Ledger Control
5. A Timekeeping System
6. Labor Distribution System charging direct & indirect labor correctly
7. Interim Determination of costs charged to contract/grant
8. Exclusion of Unallowable Costs
9. Identification of Cost by Contract Line Item
10. Segregation of Preproduction from Production Costs

Reference: “Standard Form SF 1408"
Seriously, the Timesheet . . .

Need to document/prove where we incur the largest single indirect costs, namely employee time spent running the business, writing proposals, preparing & updating commercialization plans, & similar non-project activities (actual time/not %; do this daily)

*Must be kept by everyone, including the CEO – even if no work performed on grant/contract (see Enclosure 2, Section 4 of that DCAA Guide).
The Phase II Budget

Direct Costs

v.

Indirect Rates
A **Direct Cost** = Incurred when doing work expressly for the project; most common direct cost is labor

An **Indirect Cost** = Not directly accountable to the project; represents general costs of being in business: e.g. rent, employer portion of payroll taxes, phone bill, general operations
Indirect Costs?

- Overhead/Indirect Labor
- Pension Benefit Expenses
- Incentive Compensation
- Rent Expense
- Professional Fees
- Medical Insurance
- Patent Costs
- Payroll Expenses
- Office Supplies & Expenses
- Vacation, Holiday, & Sick (Earned)

- Depreciation
- Computer Supplies
- Trade Shows
- Telephone & Utilities
- Advertising – Recruiting & Hiring
- Postage and Shipping
- Contributions
- Penalties & Interest
- Claimed Expenses
- Travel, Lodging . . .
How should Start-Ups* Budget an Indirect Rate for an SBIR or STTR Proposal?

*No History of Operations
Do the Best You Can*

1. List **ALL realistically expected** cost items – coming year
   - You can amend as you experience actual costs
   - Use a spreadsheet (e.g. MS Excel)
   - Don’t think in terms of Direct v. Indirect yet

2. Estimate **anticipated annual costs** (do the best you can)

3. **Classify line items:** Direct, Indirect, Unallowable, Comments

4. What about **Independent Research & Development**?
   - NIH & NSF will not pay for it (Unallowable)
Eligible Costs

Limits: to help shape SBIR/STTR Direction

- Some agencies: can’t direct-cost equipment
- Others: prohibit travel
- NIH limits Indirect Costs to 40% (% of Direct Costs)
- NSF limits indirect/fringe benefits to 150% of DC
- 7% Fee allowed; some: can’t exceed; “normally”/average
- Unexpected Costs: “Contingency” allowed FFP; not allowed CPFF reimbursement
- Routine furniture and equipment: Nope for direct costs
So, let’s say . . . “Total Plan = $500K”

<table>
<thead>
<tr>
<th>COSTS</th>
<th>TOTAL</th>
<th>DIRECT</th>
<th>INDIRECT</th>
<th>UNALLOWED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labor</td>
<td>$300,000</td>
<td>$175,000</td>
<td>$125,000</td>
<td></td>
</tr>
<tr>
<td>Payroll Taxes</td>
<td>49,050</td>
<td></td>
<td>49,050</td>
<td></td>
</tr>
<tr>
<td>Rent</td>
<td>24,000</td>
<td></td>
<td>24,000</td>
<td></td>
</tr>
<tr>
<td>Office Supplies</td>
<td>6,000</td>
<td></td>
<td>6,000</td>
<td></td>
</tr>
<tr>
<td>Telecommunications</td>
<td>6,000</td>
<td></td>
<td>6,000</td>
<td></td>
</tr>
<tr>
<td>Consultants</td>
<td>15,000</td>
<td>10,000</td>
<td>5,000</td>
<td>1,000</td>
</tr>
<tr>
<td>R &amp; D Subcontractors</td>
<td>45,000</td>
<td>45,000</td>
<td>5,000</td>
<td>10,000</td>
</tr>
<tr>
<td>Travel</td>
<td>12,000</td>
<td>4,000</td>
<td>7,000</td>
<td></td>
</tr>
<tr>
<td>Insurance</td>
<td>950</td>
<td></td>
<td>950</td>
<td></td>
</tr>
<tr>
<td>Independent R &amp; D</td>
<td>10,000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment/Furniture</td>
<td></td>
<td></td>
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<tr>
<td>Depreciation</td>
<td>32,000</td>
<td>10,000</td>
<td>22,000</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>$500,000</td>
<td>$244,000</td>
<td>$245,000</td>
<td>$11,000</td>
</tr>
</tbody>
</table>
So,
Indirect (% of Direct Costs) = 100%
Indirect Rate (% of Direct Labor) = 140%

These rates are deemed equivalent
Use either one; read agency guidance

Actual Costs will, of course, change
## NSF Budget Approach

<table>
<thead>
<tr>
<th>Category</th>
<th>Budget $</th>
<th>$ Remaining</th>
<th>% Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Budget Available</td>
<td>-</td>
<td>$750,000</td>
<td>100%</td>
</tr>
<tr>
<td>Fee (Profit) = ≤ 7%</td>
<td>$52,000</td>
<td>$698,000</td>
<td>6.93%</td>
</tr>
<tr>
<td>Indirect Costs</td>
<td>250,000</td>
<td>448,000</td>
<td>33.3%</td>
</tr>
<tr>
<td>Direct Costs</td>
<td>448,000</td>
<td>-</td>
<td>59.7%</td>
</tr>
</tbody>
</table>

Indirect + Fringe = Maximum of 150% of Only Total Direct Salaries
From Your Forecasted Budget: Indirect Rate % of Direct Costs = 56%

©MKleckner
The Brink
Slide A18
What is a Good Rate (NSF, DOE)?

Allows us to **meet our grant-funded obligations** in our competitive environment while running our business. Government receives Value and Services it purchases – and **We are Sustainable**
A Good (and Reasonable) Rate

- **Fringe**
  - Payroll Taxes = 7.65%
  - Paid Time Off = 8%
  - Other Benefits = 0% - 10%
  - Total = 16% – 25%

- **General & Administrative**
  - 5% - 25%

- 50% Minimum
Can’t be Too High; but don’t make it Too Low.

Agencies like DOE, no Absolute Cap; NSF – 150%

Project Value Prevails
NIH Budget Approach . . .
. . . With a Cap or Restriction

| Budget Cap: $1.5 MM | Direct Costs | $1,000,000 |  
|---|---|---|---|---|---|---|
|   | Indirect Costs* | $1,000,000 X 40% | (\$1.0 MM + \$400,000) X 7% | Direct + Indirect + Fee | $1,498,000 |
|   | Fee | 400,000 | 98,000 |  |
|   | TOTAL | $1,000,000 |  |  |

Maximum NIH Indirect Costs w/o Rate Determination = 40%
*NIH IDC > 40% = Possible Audit
About that 40% Rate

- We Can Propose an Estimated F&A Rate in our application.
- If the requested F&A cost rate is **40 percent of total direct costs or less**, no further justification is required at the time of award.
- If awarded at a rate of 40 percent or less of total direct costs, **we cannot charge actual F&A costs to projects that exceed this rate** unless we negotiate an indirect cost rate(s) with DFAS.
- **Division of Financial Advisory Services (DFAS)** — the office authorized to negotiate indirect cost rates with SBC's receiving NIH SBIR/STTR awards—will negotiate indirect cost rates.
Allowable (Eligible) v. Unallowable

- Allowable – defined in Federal Acquisition Regulation (FAR) 31.205.1-52
  - Generally Allowable (e.g. Manufacturing/Production Engineering, Service & Warranty Costs)
  - Allowable w/ Limitations (Labor, Travel, Rent; Reasonable)
  - Generally Unallowable (Alcohol, Charitable Contributions)

- FAR does not list or discuss all of the costs
Allowable if Reasonable

Salaries and Wages if reasonable number of hours with reasonable compensation

(Use, for example, professional association surveys, Bureau of Labor Statistics, or informal inquiries to companies with similar personnel)
Supplemental Regulations

Department of Defense (DoD) – DFARS
Dept. of Energy (DOE) – DOE Acquisition Regulations
NSF – Proposal and Award Policies & Procedures Guide
NIH – NIH Grants Policy Statement

(There may be additional limits: NIH Independent R & D);
NIH: Max Salary Rate; DOE is OK for Patent up to $15,000)
Need Help?

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