

Writing a Phase I NIH SBIR/STTR Grant Proposal

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The Well-Tempered Word, LLC

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Overview

- **Why SBIR?**
- Registrations
- Plan your proposal
- Write your proposal
- Post-submission tasks
 - Not funded: Resubmit?
 - Funded: Next steps
- The application package – the rest of the submission

Value of SBIR/STTR funding

- Non-dilutive investment; increase equity
- Vetted by federal agency
- Increases business credibility, visibility, recognition
- Supports R&D for new products; stimulates economy
- Helps bootstrap start-up company – attract investors
- Encourages academic-industrial partnerships

Funding is tight

- ~17% funded
- Consider submitting to more than one agency
 - It's more work, though!
- ***Funding is not “free” – pay attention to requirements!***

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Registrations

- Set up company (EIN)
- DUNS (Data Universal Numbering System) number
 - “Universal identifier for applicants for Federal grants or cooperative agreements”
- Central Contractor Registry (CCR)
- Grants.gov
- eRA Commons; FastLane; DoD
- ***Help desks***

Registrations – Timing

- Set up company: days to months
- DUNS number: ≤ 1 week
- CCR: ≤ 1 week
- Grants.gov: < 1 week
- FastLane: < 1 week
- eRA Commons: ≤ 2 weeks
- DoD: ≤ 1 week
- ***Track information!***

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Plan your proposal

The 8 Ps: Prior planning and proper preparation and processes prevent poor performance.

- **Phase I proposals: 200–450 h**
- Unmet need; fits your technology
- Commercializable
- Patentable
 - IP protected
- Business model
- ***Then, get started!***

SBIR/STTR *not* R01

- Solve a problem, an unmet need
- Commercializable idea
- Shorter grant periods
- Protect your IP – proprietary language
- Ad hoc, not standing, review committees – *not* specialists
- Compelling/Interesting proposal

Preliminary steps

*You might not need a business plan, but you **do** need a plan for your business.*

- Read instructions ***carefully***
 - Note institute's/center's mission
 - Note program officer's contact information
 - Note (and abide by) requirements
 - Note (and abide by) deadlines

Contact program officer

- Contact program officer *early*
- Before contact, assemble information on
 - Your company
 - Overall project
 - Specific aims
 - Team (internal and external)
 - Budget
 - Phase II
 - Commercialization
- Attend national or regional SBIR/STTR conferences and workshops
- ***Subscribe to notices!***

Basic planning

- Determine scope of project
- Look on NIH Reporter for similar topics (<http://projectreporter.nih.gov/reporter.cfm>)
- Confirm team and consultants
- Assign tasks
- Determine budget
- Literature search (bibliography)
- Market research
- Graphics/Data

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Write your proposal

- *More time than expected!*
- Focused proposal
- Assign tasks to team
- Literature search
- Assemble preliminary data/graphics
- Market research/Competitive landscape
- Experimental design
- Think ahead to Phases II and III

General writing tips

- *Scientific American* style
- Avoid calculus and jargon
- Use subheadings
- Summarize key points
- Break up text with graphics and tables
- Use color (when permitted)

More writing tips

- Be critical of your technology
 - Think like competitors and customers
- Copy key points from instructions into proposal outline while drafting
- Mark proprietary language
- Re-read draft after each revision
 - Requirements met?
 - Still on target?

Common-sense tips

- Spell check
- Define acronyms when first used (repeat, if appropriate)
- Note and abide by formatting guidelines (page limits, font size, etc.)
- Have ***at least*** one outsider read your proposal

Phase I proposal structure

- Specific aims
- Research strategy
 - Significance
 - Innovation
 - Approach
 - Preliminary studies
 - Experimental design

Order of writing differs from structure

Specific aims

- Write *first* – Informs entire project
- ≤1 page
- Brief introduction
 - Problem/Need
 - Your solution
 - Overall goal
- 1–5 aims/objectives
 - Sub-aims OK
- Concrete milestones/expected outcomes
 - Achievable *and* innovative
- Think ahead to Phase II and Phase III
 - Long-term objectives

Platelets_R_Us

Aim 1. Development of a better platelet storage system.

TrüBlüd

Aim 1. Develop a method to maintain platelet competence after refrigeration. A method to maintain platelet functionality must be inexpensive, reliable, and easy to implement. We will use our existing “dipstick” assay to confirm functionality of the platelet samples. Our preliminary studies (**Fig. 3**) indicate that adding ammonium sulfate to the platelets shortly after collection maintains their viability during refrigeration.

TrüBlüd

We will test the effects of two factors on platelet viability: **(1)** varying the concentration of ammonium sulfate and **(2)** varying the temperature at which the treated platelet samples are stored. **Milestone:** Optimized ammonium sulfate concentration and refrigeration temperature that yields safe, functional platelets.

Approach: Experimental design

- Write after specific aims section
- Summary table of project
- Well-developed/Well thought-out plan
 - Not just **what**, but **how**
- Potential commercial applications
- Milestones
- Potential pitfalls/Alternative approaches
- Timeline for project

Approach: Project overview

The entire Research Plan contains proprietary/privileged information that [name of company] requests not be released to persons outside the Government, except for purposes of review and evaluation.

3.C.2. Proposed Research

Expected results could also be milestones.

Table XX. Overview of project.

Aim	Experiment	Method	Expected results
1 ■ Restate aim here	1 Name/purpose of experiment (very brief).	Briefly describe method or approach that will be used	State expected result and how result will affect subsequent experiments.
2 ● Restate aim here	2 Name/purpose of experiment (very brief)..	Briefly describe method or approach that will be used	State expected result and how result will affect subsequent experiments.
	3 Name/purpose of experiment (very brief).	Briefly describe method or approach that will be used	State expected result and how result will affect subsequent experiments.
3 ▲ Restate aim here	4 Name/purpose of experiment (very brief).	Briefly describe method or approach that will be used	State expected result and how result will affect subsequent experiments.
4 ◆ Restate aim here	5 Name/purpose of experiment (very brief).	Briefly describe method or approach that will be used	State expected result and how result will affect project.

■ **Aim 1.** nima ximusci pitatemque consequi blaudi omniminis necture dolorro eatia nonsequ.
Milestone: nima ximusci pitatemque consequi blaudi omniminis necture dolorro eatia nonsequ idipsapienet quae volore sum nobit, conecto mi, sam aliquatur simi, simi, tempor solorem volendere as resendi gendandae.

Experiment 1: Esto min cullam fugia nobitas derferumquis aspe nescias pidunt et re nes re reribus ellabor

Approach: Preliminary studies

- *“Not required”*
- Write after experimental section
- ~1.5 pages
- Establish credibility/skill
- Choose data/graphics wisely
- Summarize results
- Experiments
 - Purpose
 - Approach used
 - Importance of results
- Potential commercial applications

Significance

- Write after approach section
- ~1.5 pages
- Current situation/Lit review
 - History (knowledge of field)
 - Limitations (need for better solution)
 - What your company has accomplished
- Your solution
 - Concept diagram
 - Focus on problem/need, **not** your technology
- Current market
 - Knowledge of competitive landscape
 - Commercial potential

Innovation

- Put the I in SBIR
- Write after approach section
- ~0.5 page
- Distinguish your method/technology from others
 - Advantages
 - Characteristics of ideal
- Demonstrate novelty or uniqueness
 - Know your competition
 - Disruptive technology

Abstract/Project summary

- Write last
- Reviewers *will* read
- Complete, concise, and compelling overview of project
- **No** proprietary information
- 30 lines; third person

Final steps

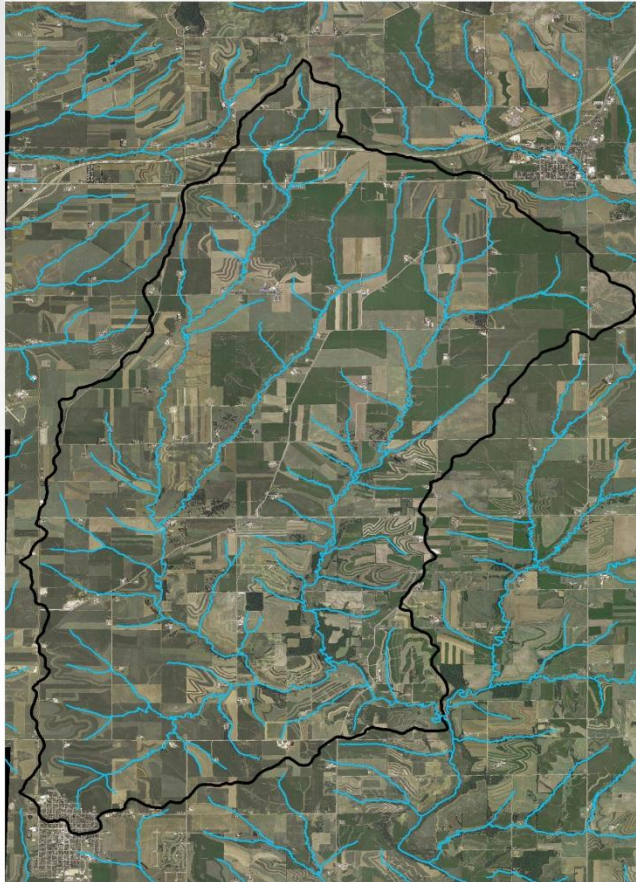
- At least one other set of eyes –
well in advance
 - Someone outside company,
preferably outside field
 - Program officers will sometimes help
- Eye-opening reality check

Graphics and design *do matter*

- Use wisely
- Complement, strengthen text
- White space
- Clear labels
- Clear captions



Graphics and design *do* *matter*



Presentation *does* matter

Specific Aims

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We propose the following specific aims for this Phase I study:

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Specific Aim 2: Nostio. Et autasincte nullabor rehenia dolor reariae venis quo corro occus doluptate nam alitate ndelestem sum aut omnistet fugita ditistius. Essimini volupti denihiligent dolupta turissedi ilit dolorem quam cullatem repudicimpos porem ut apistrum nobita voloremquos sit minvendis di culloriatum rehenecte cum quantis et officimus non por sit harumet volupta tectis. Milestone: Modigni vitincipsus aditaqui omnissitaqui qui am, si dolorerum audis eium quo voluptam isitat vitio. Luptati officitis quo ipistem quodistempor a nis eum quatiunt quaerum ut volor aut et la quo bea velibus aci alitat.

Presentation *truly* matters

The entire Research Plan contains proprietary/privileged information that [name of company] requests not be released to persons outside the Government, except for purposes of review and evaluation.

2. Specific Aims

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■ **Specific Aim 1:** Nostio. Et autasincte nullabor rehenia dolor reriae venis quo corro occus dolup-tate nam alitate ndelestem sum aut omnistet fugita ditistius. Essimini volupti denihiligent dolupta turissedi ilit dolorem quam cullatem repudicimpos porem ut apistrum nobita voloremquos sit minvendis di culloriatum rehenecte cum quuntis et officimus non por sit harumet volupta tectis. **Milestone: Modigni vitincipsus adita-qui omnissitaqui qui am, si dolorerum audis eium quo voluptam isitat vitio. Luptati officitis quo ipistem quodistempor a nis eum quatiunt quaerum ut volor aut et la quo bea velibus aci alitat.**

● **Specific Aim 2:** Ulles maximagnis inullore nobit ratiae. Nequi bla doloruptae. Mo vent que volo-dus mi, venimusa corum aut veliqui bustiatur rero expla consequi sit as velenimus nisim. Auta pe sust-cii squidit, qui invelitam quatia qui autate experfe rnatquas maionsequae is denti odi nonsequibus, consed ulpa quis derum eosam. **Milestone: Asperia aligation cum aut intibearum ea que il et.**

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Post-submission tasks

- Monitor status on eRA Commons
 - Supplemental materials rarely permitted
- Be prepared: ~17% funded
- Read summary statement carefully

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Not funded: Resubmit?

- Read summary statement carefully
- Reflect
- Briefly summarize issues
- Contact program officer
- ***Substantially*** revise and resubmit

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Funded – Next steps

Business risk management strategies

- Intellectual property (IP)
- Patents, trademarks, copyrights (PTO)
- Quality management system (QA/QC)
- Regulatory affairs
 - FDA (medical)
 - OSHA (safety)
 - EPA (chemical-intensive)
 - USDA (agriculture)

Funded – More steps

- Manufacturing and distribution
- Human resources (HR)
- Information technology (IT)
- Reporting requirements
- Financial (bookkeeping, accounting, letter of credit)
 - ***Misuse of Federal funds is a felony***

Summary

- ~\$700M/year for NIH SBIR/STTR
- Unmet need fits your technology
- IP covered
- Business started
- Business and PIs registered
- Strong team
- Communicate with program officer
- Excellent proposal submitted
- ***Adhere to post-award rules***

Post-workshop information

- Tip sheet for registrations
- Company data sheet (to track registrations)
- Information about NIH institutes, centers, study sections

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Application package

- Application package (≥ 40 –60 hours)
 - ***Not trivial – don't wait to start!***
 - Read instructions; make checklist
 - Many attachments (infrastructure documents) can be finished well in advance
 - ***Request and assemble them ASAP***

Application >> proposal

Final_Ph_II_Application.pdf - Adobe Acrobat Pro

File Edit View Document Comments Forms Tools Advanced Window Help

Create Combine Collaborate Secure Sign Forms Multimedia Comment Sticky Note Text Edits Show

1 / 301 198%

OMB Number: 4040-0001
Expiration Date: 06/30/2011

**APPLICATION FOR FEDERAL ASSISTANCE
SF 424 (R&R)**

1. * TYPE OF SUBMISSION <input type="checkbox"/> Pre-application <input checked="" type="checkbox"/> Application <input type="checkbox"/> Changed/Corrected Application		3. DATE RECEIVED BY STATE []	State Application Identifier []
2. DATE SUBMITTED 04/05/2011	Applicant Identifier []	4. a. Federal Identifier []	
		b. Agency Routing Identifier []	

- NIH Ph. II
 - Proposal – 13 pages
 - Application – **301 pages**

Needed details

- Zip+4 for each project site
- DUNS number – project sites and sub-awardees
- Congressional district number – company and project sites

Required NIH attachments

- Abstract
- Bibliography
- Biosketches
- Budget and justification
- Cover and Assurance letters
- Facilities and equipment
- Letter(s) of support – from consultants
- Letter(s) of support – from potential customers, collaborators, investors
- Narrative
- Research plan (the proposal itself)

More NIH attachments

- Commercialization history
- Consortium arrangements
- Data/Resource sharing plan
- Human subjects – 4 sections
- Justification for foreign business
- Leadership plan
- Letter(s) of intent and consortium
- Select agents
- Sub-award budget(s) and justification(s)
- Vertebrate animals