Grow
Emerging Companies
551 SW Point Ave.
Depoe Bay, OR 97341
Mark Henry Direct: 303-679-8182
Mark Henry Cell: 303-990-2113
www.growllc.com

WSSI Phase 0 Winner Checklist/Guide for SBIR/STTR Proposals

By Mark Henry, Founder, Grow LLC

This checklist and guide is designed to provide WSSI's Phase 0 winners with fundamental guidance on issues that we believe should be addressed by SBIR/STTR proposal efforts. And the first thing that we believe is that Phase 0 projects should be at least as much about **getting ready to write** the Phase I proposal as they are about actually producing it. *The Guide also provides a checklist for preparing drafts that are required to be submitted for review under the WSSI program 21 days and 7 days out from the SBIR/STTR deadline.*

Producing a competitive proposal is all about getting ready to write it. Some 80% to 90% of the total effort invested in preparing a genuinely competitive proposal (typically between 40 and 200 hours) goes into 1) deciding whether to write it at all, and 2) collecting all of the information and team members you need. It may take you a couple of hours to write about your relevant preliminary data—but it may have taken you months or years to produce it, or to find out about others who have done relevant work that sets up your project. It may take you 15 minutes to write two strong paragraphs about your top-notch collaborator, but it may take you days, or months, or years to find that person and to convince him/her to join your team.

I once worked with the research director at Bend Research (Bend, Oregon) to complete a full Phase I NSF proposal in **12 hours** (3 am to 3 pm).

It won.

This isn't something I would recommend you try at home…but the main point is that he had spent **10 years** compiling the information he needed to write the proposal. His "homework" file was a foot thick, a lot of the key information was already highlighted and organized in the file, and he was working with a world-class team of researchers he could plug into the proposal. [He also had an IQ of about 165 and had earned the highest grade point in the history of Cornell U (4.26 on a 4.0 scale).]

That was one of about 1600 SBIRs and STTRs I have worked on over the past 27 years. (I started doing SBIRs at Bend under the Research Applied to National Needs [RANN] pilot program at NSF in 1980, which was the precursor to the SBIR program.) We won 175 of 350 proposals we produced over the 17 years I was at Bend.

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It's been a long learning curve for me; my goal is to help make it a shorter one for you.

With that in mind, let's look at what I believe are the proposal basics, and the areas where I see companies routinely getting into trouble—often before they even start….

Basic Eligibility Issues

- Is your firm a for-profit entity, or will you be forming a for-profit entity? SBIR/STTR awardees must be for-profit (which is different from profitable).

- Does your firm meet the current ownership requirements and other SBA requirements for "small company" status (500 or fewer employees, including all affiliates; primary ownership by individuals—either in the SBIR firm or in its parent company)? Make sure you read the specific eligibility requirements in the solicitation you are addressing.

- Will all work on your project be carried out in the U.S.? (You can use experts from outside the U.S., as long as they do the work on the project here. For example, if the best person in the field is in Germany, set up the project so that he/she can come to the U.S. for five days of work at a key time. You likely can afford to do that within the budget, and you get that person's resume for the proposal and expertise for the project.)

- **Do you have the R&D personnel, capabilities, and access to facilities needed to credibly carry out at least 2/3 of the Phase I work in-house (for SBIR) or at least 40% of the work in-house (for STTR)?** This is a key issue. You can't get your great idea funded under an SBIR and then "farm out" all of the work (with "work" typically being measured in terms of percent of the budget spent by each participating entity).

- Do you have an "eligible" (see below) Principal Investigator (PI) available during the period of performance of the contract or grant? For SBIR, the PI must be "primarily employed" by the firm during the period of performance (more than 20 hours a week as a W-2 employee for a full-time employee; the majority of employed time for those who may be employed part-time, such as retired professors or part-time post-docs). For an STTR, the PI may be employed by a non-profit research institution for projects with NIH, NASA, DOE, and DOD (not

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NSF). Note that this **is an employment status issue** and not the amount of time the person is assigned to any single SBIR or STTR project. **The PI should have credible R&D and/or project-management credentials,** and that person's credibility can be bolstered by other team members and consultants**.**

Key Logistical Issues

- Most SBIR/STTR agencies now require **electronic submission** of all proposal documents. And, of course, there are several different submission methods. Some—but not all—of the agencies that award GRANTS work through www.grants.gov . If you need to submit through grants.gov, make sure you get registered **early**—especially if you do not already have a corporate bank account, a DUNS number, and CCR (Central Contractor Registry) registration. The National Science Foundation is a grant agency that has its own system, called "Fastlane." Make sure you study the NSF solicitation instructions for Fastlane submissions. NIH uses Grants.gov but adds its own eRA Commons electronic management system on top of it…so for NIH you need to register for BOTH systems—and you need to give yourself WEEKS to do that before the deadline if you are starting from scratch. CONTRACT agencies such as DOD and NASA have their own electronic services that you need to learn about in their solicitations.

- You need to pay attention to the deadline times for electronic (or mail-in) submissions. Some agencies have a deadline based on each time zone. Some base the deadline on Eastern time. DOD has changed its deadline to **6 AM** (!?!) on the day of the deadline to try to keep from having its systems crash with the last-minute overload. Some mail-in solicitations have different ZIP codes for mail and for courier delivery (although paper submissions are rapidly going the way of the Dodo). You need to pay close attention to all of this. Many proposals have gone unaccepted and thus unread because of logistical problems with submissions.

Proposal "Sales" and Credibility Issues

- You need a great RESEARCH idea. Is this project really about research? Are there Phase I **feasibility** issues to address? What research will be done in Phase I? How will Phase I success be measured? What are the critical metrics for success? What outcomes will be pursued? What are the key technical and economic

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questions that will be answered in Phase I? What uncertainties make this work more than just product development? Do you have a realistic work plan sorted out that fits the Phase I scope and budget? Can you do all you need to do with one Phase I, or should you consider splitting your idea into two or more feasibility projects?

- Is your proposal "responsive" in terms of both subject matter and following all of the rules? Does your idea have a clear "fit" at the agency? There are major differences between **grant** and **contract** agencies. Grant agencies tend to have open areas of interest that you address with your own ideas. Contract agencies tend to have specific topics identified that ask you to solve problems that THEY have come up with. If you are submitting a proposal to a contract agency (for example, DOD, NASA), is your idea and project "responsive" to their topic? How do you know? Have you talked with the topic author? Have you taken advantage of any "pre-solicitation" periods they offer (e.g., at DOD) for open communication with topic authors or managers? If you are submitting to a grant agency, do you know that your idea will be considered relevant? Again, <u>how</u> do you know?

- Are your Principal Investigator and the rest of the R&D team likely to be viewed as credible <u>researchers</u> in the eyes of the agency reviewers? (There are lots of differences among reviewers across the agencies. The reviewers tend to look for people who look like themselves, which makes for big differences among NIH (outside academic reviewers), DOD (in-house staff reviews), USDA (external reviewers), etc. What kinds of people need to be added to the team—from anywhere in the country, or even outside the country—to establish the needed credibility? **It is critical to understand that the person who thought of the idea is not necessarily the best candidate for Principal Investigator—although he/she can certainly be involved in the project as a key contributor.**

- What kind of preliminary data has been obtained by you, your team members, or others in the field that indicates the potential for the feasibility of your project? (Even though SBIR law officially states that preliminary data is not required, the reviewers don't spend a lot of time studying the SBIR law….)

- Do you have access to the needed facilities and equipment? Phase I reviewers are not likely to fund projects that ask for $80K in permanent equipment on a $100K project, nor will they be impressed with the amount of research work that can be done with $100K when $65K is needed for "human eyeballs" (I didn't make this

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one up….). Something like $5K to $10K (although there are clearly exceptions) is more reasonable for supplies and equipment—and agencies such as NSF will not pay for ANY "permanent equipment." Beyond the practical matter of the government not wanting to buy you equipment, this is a significant credibility issue: If you don't have the equipment available to do the work you are supposedly experts in, then are you really believable as experts?? There are ways to deal with gaining access to equipment and paying for equipment via rental, leasing, and your indirect costs. Here's an example of a reviewer comment: "Computer $2500, pipette set $2500, and microscope $15,000 should already be there if the principal investigator has been involved in the stem cell research as claimed."

- Do you have a realistic vision of and plan for what has to be done in Phase II and Phase III to prototype/demonstrate and commercialize the idea. (Example: If you are doing a DOD proposal, do you know who the prime contractors are for the military in the broad area your work fits into? Do you have a plan for collaborating with one or more of those potential partners? Do you have contacts or relationships with those firms already?) What is the potential market for your new product or service? **How do you know?** How will the world change if you are wildly successful? What's your vision?

- Does your Phase 0 project recognize any key deficiencies in the above areas, and are you focusing the right amount of your Phase 0 effort on the steps needed to eliminate those weaknesses? Again—this is all about **getting ready to write**.

Method of Selling: Guidance on Proposal Structure and Approach

There are of course many ways to put together successful SBIRs and STTRs. Here are some of the key elements of the process that we use with Grow LLC clients.

- We believe you should "set the stage" and clearly establish the problem/opportunity you are addressing and its significance BEFORE you offer your solution/idea. We believe you need to establish why what's being done now is not good enough; otherwise, there is no reason to do research. We try to tell a compelling and cohesive story with a proposal, and we try to get the reader engaged right from the start (see "bullet points" example below). Some agencies (such as NSF) force you to talk about your idea/solution in the first sentence of sections—but you can still very quickly jump back into telling a compelling story.

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The template we use for telling that story in the abstract and the front section is included below.

- A major problem area in proposals that we encounter the majority of the time is the lack of a DETAILED WORK PLAN. Nearly every solicitation asks for a THOROUGH, DETAILED WORK PLAN—yet we see many drafts in which the work plan is a page or two of bullets about WHAT will be done, and that's it. **Your work plan should be a substantial portion of your proposal—as in a third or more. Provide the level of detail YOU would look for if YOU were being asked to pay for $100K of work by a contractor….** You need to go beyond just writing about WHAT you are going to do. You need to include a detailed narrative that covers WHY you will do it what way, WHO will do the work, WHERE it will be done, HOW LONG it will take, WHAT you expect the results/outcomes to be, WHY you expect those outcomes, WHAT you will do as a contingency plan if you don't succeed, HOW you will measure your results and evaluate your data, and HOW the results being obtained do the following:

    - meet or exceed your Phase I goals/objectives/aims,
    - answer the Phase I technical/economic feasibility questions, and
    - set up the Phase II work.

- For your Aims/Objectives, we believe you should focus on the big-picture goals. What are you going to PROVE in Phase I as a new concept? Try to finish the following statement when you create your list of Aims or Objectives: "In Phase I we will attempt to prove that _____." Then you should list the key technical/economic questions you need to answer to meet your objectives. And finally, you do TASKS in the work plan to answer the questions and to meet your objectives. Note that we don't believe that Objectives/Aims are the same as tasks, even though they are often used interchangeably in proposals. **You can introduce your <u>measurable goals</u> or <u>metrics</u> for success in any of the three areas discussed above.**

Here is the template I told you about earlier:

Set the stage – Identify and Quantify the Problem or Opportunity

A. Get the audience interested at the outset (highlight the national problem or opportunity) with compelling statistics or other information

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B. **Identify *and substantiate* the importance of the problem – the need (if the reviewers don't buy into the need, the proposal is dead, no matter how well it is written)**

C. **Summarize the state of the art and its shortcomings (without shortcomings, there's no need for R&D….) and tell a convincing story about how your technology will overcome the shortcomings without introducing others.**

D. **Discuss why the problem has not yet been solved, if it is so important. Describe the technical challenges to solving the problem and the potential benefits (the TECHNICAL challenges are what the R&D is about--and the reason the problem has not yet been solved)**

State the theme – Your Solution

E. **Describe the concept of your solution, identify the innovation being pursued, and establish the credibility of your team—including your preliminary data. Discuss potential advantages in terms of addressing the disadvantages you identified in the state of the art. *Acknowledge your nearest competition and clearly differentiate your effort from what they are doing.* Anticipate knee-jerk reviewer reactions and other potential criticisms and deal with them immediately.**

F. **Present what you will attempt to prove in Phase I (and indicate how you will know when you are successful—i.e., present measurable goals); list the key technical/economic questions that have to be answered in Phase I**

Create a Vision

G. **Discuss how Phase I success will set up Phase II**

H. **Discuss the overall plan for Phase II. What will the Phase II work involve? What will a prototype look like? How will you get to the point in Phase II where the private sector will be convinced to step in and support Phase III? What do your potential partners/investors need to see at the end of Phase II—and HOW DO YOU KNOW?**

I. **Envision the world with your solution in it ("Phase III"), including how you will finance the commercialization effort—*and evidence that you have team members who know how to commercialize***

Here is an example of the "bullet points" we start with to test our proposal story based on this template:

A. Malaria kills a child every 12 seconds.

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B. Malaria is the world's most deadly tropical parasitic disease (NIAID, 1997). Its burden is felt around the world, with some 300 million to 500 million cases and up to 3 million deaths per year (NIAID, 1997). An effective vaccine could reduce the suffering of millions and could eliminate the threat of renewed outbreaks in temperate regions—*including the United States*.

C. Unfortunately, scientists cannot yet identify drugs that are unique to a stage of growth of a particular microbe (i.e., the microbe's most vulnerable stage)—*which is what is needed to effectively treat malaria.* Even the best currently available methods are too slow and are not sufficiently sensitive.

D. Next-generation technology that has greater sensitivity and higher-throughput capacities is required to identify the needed drugs and vaccines. That technology is not yet available.

E. ADC's experienced electrochemical researchers are teaming with the nation's top malaria expert at the Navy to develop and apply innovative, highly sensitive electrochemical technology for high-throughput screening of vaccine candidates for human malarias. Strong preliminary data with ADC's electrochemical technology combines with excellent foundational work in malaria research to establish a promising starting point for this project.

F. The Phase I goals are to prove the feasibility of 1) developing new sensors/sensor arrays for highly sensitive, quantitative measurement of malarial gene expression in multiple samples (measured by XXXXXXXXXXXXXXXXXXXXXXXXXX); and 2) demonstrating the utility of the sensor arrays for high-throughput screening (ranging from 96-well to 384-well plates).

G. Demonstrating feasibility in Phase I will lay the foundation for a larger Phase II R&D effort designed to produce prototype technology to support initial clinical demonstrations of the technology's effectiveness.

H. Specifically, Phase II will allow us to combine the key components developed in Phase I into a working prototype for ultimate validation and demonstration with malaria samples in studies to be carried out at the nation's leading malaria lab.

I. Phase II success will provide the data needed to attract Phase III corporate partners and financing for human trials of the new malaria vaccine and ultimate commercialization, allowing us to address a multi-million-dollar market and to expand this new drug-discovery technology for use in additional applications that are critical to improving human health around the world.

- **Participating in the WSSI Phase 0 Program and Complying with the Phase 0 Review Requirements**

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WSSI requires that a complete first proposal draft be submitted electronically 21 days before the agency deadline for the proposal you are submitting. Your compliance in preparing and submitting the complete draft will affect the final financial support you receive from the Phase 0 program.

So what do we mean by "complete draft"?

WSSI is looking for a solid attempt at a draft that has all required sections addressed. Each solicitation provides detailed instructions about what must be submitted for a complete and acceptable application. The required material ranges from title pages to **detailed** work plans, from abstracts to budgets, and from cover letters to Related Research sections that include relevant work done by others and by you. Here is an example of the sections that are required in a typical SBIR format:

- Cover page
- Abstract/summary and potential benefits
- Identification and significance of the problem/opportunity
- Technical objectives
- Research plan
- Related work (done both by you and others) state of the art
- Relation to future research or R&D
- Commercialization strategy
- PI/key personnel/subcontractors/consultants
- Facilities/equipment
- Prior, current, or pending awards
- Budget

Note that this is only an example. You need to look at the CURRENT agency solicitation to determine what this year's exact requirements are. (One year, awhile back, NASA changed the requirements for the first paragraph of the "Identification and Significance" section and threw out 40% of the Phase I proposals as "unresponsive" because people didn't pay attention to the change. Handy rapid-screening tool and work-saver for them….)

So—here's what we are looking for in a <u>complete first draft</u>, given format requirements such as this:

- <u>Entire proposal</u>: **Read the solicitation and provide what they ask for in each section as a minimum.**

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- Submit e-mail documentation that you have successfully initiated registration for electronic submission, if required

- **Cover page**—Find and fill out all of the required information. (Some of this is not trivial—such as information about human subjects and related approval numbers or exemptions.)

- **Abstract/summary and potential benefits**—In most applications, the abstract is one of the most important sections—if not THE most important. Some agencies use the abstract to determine if the proposal is "responsive" and therefore worth assigning for review. Others use it to decide WHERE to assign it. And reviewers use it to decide if they want to read any more…. We suggest that you not attempt to draft it until you have a proposal drafted that you can abstract….
  Watch the space limitations and rules. We use our template as a basis for telling a very short version of the whole story in the abstract.

- **Identification and significance of the problem/opportunity**—See **Method of Selling** section above. We believe you should clearly identify the problem/opportunity BEFORE you offer to solve it. We make this section a longer version of the abstract and a short version of the entire proposal "story"—also based on the template.

- **Technical objectives**—see **Method of Selling** section above.

- **Research plan**—see **Method of Selling**, above.

- **Related work (as in R&D done by you and others)**—identify the current state of the art established by others and/or yourselves and make sure it is clear what the current drawbacks are that make it necessary to do the proposed research. Present the state of the art fairly and accurately—as your reviewers may actually BE the current state of the art.

- **Relation to future research or R&D**—present your vision for how Phase I success leads to Phase II and Phase III success (see items at the end of the template).

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- **Commercialization strategy**—more detail about the vision, including how you will FINANCE commercialization, with whom you will partner, etc.

- **PI/key personnel/subcontractors/consultants**—sell the team. Make sure you have a credible R&D team in place**.** Do you need a PhD researcher as Principal Investigator? The government program managers will tell you "no" because they have to say that—and in some cases that's the right answer. Some of it depends on the rest of the team members and the experience level of the non-PhD PI. But you need to be realistic about the agency you are approaching. The grant agencies (e.g., NIH, NSF, USDA) typically have outside academics do the proposal reviews. They call this "peer review." If your PI or others on your team are not their "peers," it is often a problem. Academic reviewers tend to look for people who look like them as PI's. They tend to think they are funding PI's, as that is how academic research is funded. Contract agencies tend to look more at the whole team and the company to see what they have DELIVERED before, as contract (technology "user") agencies are more likely looking for deliverables and performance under contract.

- **Facilities/equipment**—make sure you are credible here. Discuss what key facilities and equipment you have (forget about the fax, the Mr. Coffee, and the phones), and make sure you have a letter verifying your access to any equipment or space/facilities you need to borrow, rent, lease, etc. Don't show that you are going to do scanning electron microscopy in the work plan without showing here that you have access to an SEM….

- **Prior, current, or pending awards**—this is intended to be a punitive section. They want to know if you are double-dipping. Do not use this section to brag about all the similar proposals and awards you have pursued. The best answer is usually "N/A or NONE." If you do have duplicate proposals out to other agencies, you need to report that.

- **Budget**—draft a budget that includes direct and indirect costs. You are also allowed what is typically a 6% to 7% fee or profit. Follow each agency's rules for budget preparation.

WSSI will review the first draft and will provide strategic/content/editing suggestions for preparing the final draft, which is due at WSSI 7 days out from the

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deadline. WSSI will then provide any additional suggestions for improving the submission.

This timeline is of course not one that most small firms would naturally follow. Most SBIRs and STTRs are put together at the last minute. Many actually go in as first drafts. And that is one reason for the approximately 10% hit rate on Phase I's as a national average. Our goal is to achieve a 1 in 2 to 1 in 3 success rate on Phase I's with the applications supported by the WSSI Phase 0 Program. Hence, the requirement for early and complete drafts.

Our goal here is to support your effort in Phase 0 to produce a competitive Phase I proposal. Please call me to discuss any of this.

Mark Henry
Grow LLC
303-679-8182; 303-990-2113 (cell)

