10 Dos and Don'ts for Your Phase I NIH Proposal

If you're planning to submit for the April 5 NIH SBIR/STTR deadline, now is the time to start laying out the steps you'll need to take to get your polished, compelling Phase I proposal submitted before the deadline. Over the years, BBCetc consultants have reviewed a great many NIH proposals and accumulated a long list dos and don'ts that we repeat each cycle in our workshops and with our clients. As you plan your proposal, here are our top 10 dos and don'ts for Phase I proposals. (Watch for Phase II's top 10 next month).

1. Proposal Objectives
DON'T: Write an R01. SBIR/STTR does not fund basic science projects. The two mechanisms are definitely NOT the same. SBIR/STTR projects are based on high-risk technological innovation with a *marketable product* as the end result.
DO: Plan for and **Tell** the *entire* story….even in a Phase I. *(Yes, you DO need to include commercialization information …)* The goal of SBIR/STTR is commercialization. Phase I doesn't stand alone. The rationale for Phase I is supported both by what has been done to date (preliminary data), what will be done next (Phase II) and ultimately commercialization. Your Phase I proposal must provide this context so that it can be assessed appropriately.

2. Specific Aims
DON'T: Get the following critique: *"It is unclear how the applicant will know when they've achieved their aims."* The Specific Aims is the most important page of your proposal. It should state measureable, desired end points and show that you have a sensible work plan including steps to be carried out that will yield results/data.
DO: Write milestone-driven Specific Aims with clear success criteria.

3. Phase I Goal
DON'T: Write Phase I without putting it in the context of the overall project timeline:
Preliminary data – Phase I – Phase II – (ongoing work) - Phase III
DO: Focus Phase I on feasibility. Feasibility of what?? Whatever you intend to do in Phase II. This is when you prove that your project warrants further development (in Phase II) toward a marketable product (Phase III).

4. Significance
DON'T: Get the following critique: "*Applicant is clearly unfamiliar with the relevant literature in this field.*"
DO: Complete a thorough analysis of the literature and market to demonstrate your knowledge of "state of the art" and "state of the market." Show that the product of your science is motivated by a significant market need as well as significant commercial opportunity.

5. Impact
DON'T: Write a science fair project. Does your project address an important problem? What will be the effect of these studies on concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? You don't want reviewers saying "so what?"
DO: Analyze the market, know the competition and present a credible plan for how you'll actually achieve commercialization. In a Phase I it will be brief but don't make the mistake of underestimating its importance.

6. People
DON'T: Focus only on the PI in your discussion of key personnel.
DO: Build a team. SBIR/STTR projects typically bring together many scientific/technical/clinical disciplines to enable technological innovations to be reduced to practice in products that function in the clinic/market. Your proposal must first demonstrate that you have ALL of the necessary expertise

to achieve the aims. Beyond that you want to show reviewers that you have access to the skills and input necessary to move forward into Phase II and beyond. Make sure to use consultants, subcontractors and other significant contributors (e.g., advisors) strategically to strengthen the probably of success.

7. Company Resources
DON'T: Look like a "virtual company" - or worse, BE a virtual company.
DO: Describe *all* of the company's relevant resources: your company's research facility(s), subcontractors' research facilities, other resources such as a Scientific Advisory Board, and all commercialization resources (management, strategic partners, funding, regulatory…) Remember: SBIR and STTR awardees MUST have and utilize company controlled R&D facilities suitable to do the work proposed!

8. Budget
DON'T: Over promise and under deliver because *if you over promise you might not have the opportunity to deliver…*
DO: Propose a project that can be completed within the budget (time and duration) *and make sure to clearly justify every line item.* Our advice:
- KEEP IT REAL - Veteran reviewers can smoke out an inappropriate budget.
- KEEP IT ACCURATE - Budget items can raise questions that cause reviewers to take a second look at the proposed work for compliance.
- KEEP IT HONEST - Don't pad the budget, and potentially offend the intelligence of the reviewers.

9. Reviewers
DON'T: Ever say "Trust Me!"
DO: Validate/support all of the claims made in the proposal. In order to support the rationale for this project your proposal must demonstrate a comprehensive "state of the science" and "state of the market" analysis. Claims that other technological approaches are not feasible should be supported by evidence in the literature. Data about the market size, assessments of customer needs, and claims about future fundraising plans should be validated by references in the market literature and letters of validation from customers, strategic partners and/or potential investors.

10. The Hardest Easy Part
DON'T: Ignore all of the lessons learned
DO: Follow every cliché you've ever heard about proposal success and avoid these…

Common Mistakes:
- Assuming you know how to do this because you've written NIH grants before
  - **Utilize all of the resources available through NIH: E.g., SBIR/STTR website, RePorter, SBIR/STTR & Institute program staff**
- Ignoring the requirements for company controlled R&D space
  - **Identify space in the proposal; utilize space if funded**
- Assuming you can get the registrations done faster than
  - **6-8 week minimum (more if your company is just formed or just got an EIN number)** See our online grid (link) of what NIH requires.
- Writing your proposal in 2 weeks (like you do at the university)
  - **Develop the proposal over a minimum of 2-3 months**
- Skimming (or not reading) the instructions
  - **Read all relevant sections; complete forms PER the instructions, not your intuition**
- Submitting on the day of the deadline
  - **Submit a minimum of 3 days before the deadline**