March 11, 2004

Dear Small Business Research Community,

I know that many of you are working hard to prepare an application for the upcoming April 1 submission date, so I thought I would pass along some guidance and advice to help you get through the next few weeks. Specifically, I wanted to focus on what I believe to be the essential ingredient to a successful application: **Communication.**

(One of those essential ingredients in life-but we'll stick to SBIR/STTR applications!)

Communication Before Submission

It is very important to communicate with the NIH Program staff in the relevant awarding component (Institute/Center, or IC) *prior* to submitting an application for the following reasons:

- To determine whether your proposed application topic would fit into the awarding component's programmatic area - or possibly fit more than one IC
- To learn about programmatic areas of interest to the IC or other non-NIH agencies
- To find out about research grant mechanisms
- To find out about requesting assignment to an IC or Scientific Review Group (SRG)
- To receive advice on preparing an application (e.g., format, structure)
- To discuss whether you should respond to an RFA

Contacts in the awarding components (ICs) can be found in Part II of the SBIR/STTR Grant Solicitation http://grants1.nih.gov/grants/funding/sbirsttr1/2004-2_SBIR-STTR-topics.doc. A list of the various ICs is also provided at the end of this email.

Communication Through Your Application: Grantsmanship

As you write your application, think about your audience in terms of "who, what, where and how". Know your audience-this is the "who". Know what to communicate, where to say it, and how to say it.

WHO are your reviewers?

Let's start with a clarification: NIH Institute/Center (IC) staff are NOT the reviewers-in fact, the Program staff in the ICs are not able to affect the outcome of your review. You (and about 2000 other applicants) will be communicating your idea to an EXTERNAL peer review group. This is not unlike my son who is going through the college application process-It is essential that you know how to communicate well to capture their attention and make them want to read your application. The **reviewers** of your grant application are composed primarily of non-Federal scientists, physicians, and engineers (from academia and industry) selected for their expertise and stature in particular scientific fields. You may even request in a **cover letter** that a particular area of **expertise** be represented on your review panel. Don't list names of reviewers, just the area of expertise.

WHAT to communicate and WHERE to say it?

The real "meat" of your application in terms of what to communicate to reviewers and where to say it will be in the Research Plan. The Research Plan consists of the following sections: Specific Aims, Significance and Related R&D; Preliminary Studies (not required for Phase I, but may be

included if you have convincing data)/Phase I Final Report (for Phase II applications); Experimental/Research Design and Methods; Human Subjects; Vertebrate Animals; Literature Cited; Consortium/Contractual Arrangements; Consultants; and Commercialization Plan (Phase II and Fast-Track).

Organize *Items a-d* to answer these questions: (1) What do you intend to do? (2) What are the anticipated commercial products, processes, services and societal benefits? Why is the work important? (3) What has already been done? (4) How are you going to do the work?

Reviewers assess the scientific and technical merit of each application using 5 major review criteria (Significance, Approach, Innovation, Investigators, and Environment). Unlike in contracts, these criteria are not "weighted." But don't stop with there. Carefully read the questions under each of the criteria (see below and the Solicitation), and prepare your Research Plan in such a way that you communicate the answers to the questions.

1. Significance

    a. Does the proposed project have commercial potential to lead to a marketable product or process? Does this study address an important problem?

    b. What may be the anticipated commercial and societal benefits that may be derived from the proposed research?

    c. If the aims of the application are achieved, how will scientific knowledge be advanced?

    d. Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries?

    e. Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs?

2. Approach

    a. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?

    b. Is the proposed plan a sound approach for establishing technical and commercial feasibility?

    c. Does the applicant acknowledge potential problem areas and consider alternative strategies?

    d. Are the milestones and evaluation procedures appropriate?

3. Innovation

    a. Does the project challenge existing paradigms or employ novel technologies, approaches or methodologies?

    b. Are the aims original and innovative?

4. Investigators

    a. Is the principal investigator capable of coordinating and managing the proposed SBIR/STTR?

b. Is the work proposed appropriate to the experience level of the principal investigator and other researchers, including consultants and subcontractors (if any)?

c. Are the relationships of the key personnel to the small business and to other institutions appropriate for the work proposed?

5. Environment

a. Is there sufficient access to resources (e.g., equipment, facilities)?

b. Does the scientific and technological environment in which the work will be done contribute to the probability of success?

c. Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

Human Subjects. In conducting peer review for scientific and technical merit, SRGs will also evaluate the involvement of human subjects and proposed protections from research risk relating to their participation in the proposed non-exempt Research Plan according to the following four review criteria: (1) risk to subjects, (2) adequacy of protection against risks, (3) potential benefits of the proposed research to the subjects and others, and (4) importance of the knowledge to be gained.

Vertebrate Animals. The proposed involvement of vertebrate animals will be evaluated by SRGs as part of the scientific assessment of Approach and Environment criteria and according to the following five points: (1) detailed description of the proposed use of the animals; (2) justification for the use of animals and for the appropriateness of the species and numbers proposed; (3) adequacy of proposed veterinary care; (4) procedures for limiting pain and distress to that which is unavoidable; and (5) methods of euthanasia.

HOW to communicate?

The best way to answer this question is to turn it around and list the most common reasons cited by reviewers for an application's failure to gain their enthusiasm. Review this list and make sure none of these items apply to your idea.

- Unconvincing case for commercial potential or societal impact.
- Poorly defined test of feasibility (Phase I).
- Methods unsuited to the objective.
- Problem more complex than investigator appears to realize.
- Not significant to health-related research.
- Too little detail in the research plan to convince reviewers the investigator knows what he or she is doing, i.e., no recognition of potential problems and pitfalls.
- Over-ambitious research plan with an unrealistically large amount of work.
- Direction or sense of priority not clearly defined, i.e., experiments do not follow from one another and lack a clear starting or finishing point.
- Lack of focus in hypotheses, aims, and or research plan.
- Lack of innovation.
- Investigator too inexperienced with the proposed techniques (and failed to enlist collaborators with complementary expertise).
- Proposal driven by technology, i.e., a method in search of a problem.
- Rationale for experiments not provided, i.e., why they are important or how they are relevant to the objective?
- Lack of alternative methods in case the primary approach does not work out.
- Proposed model system not appropriate to address the proposed questions.

- Relevant controls not included.
- Insufficient consideration of statistical needs.
- Not clear which data were obtained by the investigator and which reported by others.

Communication After Peer Review

Feedback to applicants is very important. Once the principal investigator receives the Summary Statement, contact the appropriate awarding component program official (noted on the Summary Statement) for the following reasons:

- To discuss the review outcome of the application and obtain guidance
- To get feedback and answers to any questions about the Summary Statement
- To find out the meaning of a numerical designation pertaining to human subjects or vertebrate animals on the Summary Statement
- To find out the funding status of an application

If at First You Don't Succeed.... Try, Try Again

Some of you will not be successful in getting funded on your first submission. The SBIR/STTR Program is very competitive, and many will need to revise and resubmit. NIH allows the submission of 2 amended applications. Even if your application is unscored (as designated by a "**"), you should discuss the strengths and weaknesses of the application with your Program Director and revise/resubmit if it is believed that the weaknesses can be improved.

- If you are submitting a revised application, be sure to read the summary statement carefully and respond to the reviewers' comments.

- It is also a good idea to contact your Institute/Center Program Official (listed in the upper left hand corner of your summary statement) as s/he can offer some real valuable guidance/advice.

Fast-Track or Standard Phase I Submission?

Fast-Track is the submission of a Phase I and Phase II simultaneously for concurrent review. It takes an incredible amount of work to prepare a Fast-Track application, and the competition is very tough for these applications (fewer than 1 in 5 are funded). If you are contemplating the submission of a Phase I/Phase II Fast Track, you are strongly encouraged to contact the Institute/Center Program staff listed in the Solicitation (Part II below) to discuss the appropriateness of this mechanism for your project.

Questions About Eligibility?

The SBA sets the definition of a small business concern and the eligibility criteria to participate in the SBIR/STTR Programs These eligibility criteria to receive an SBIR or STTR award are described in the PHS 2004-2 Grant Solicitation. If you have questions beyond what is described in the Solicitation, please contact Size Specialist in the SBA's Office of Government Contracting. Addresses and telephone numbers for the six Area offices are available at the following url: http://www.sba.gov/size/indexcontacts.html. E-mail: sizestandards@sba.gov

FAQs: Rest Assured, Someone Else Has Likely Asked Your Question!

If you have not done so already, please take a few minutes to read the following FAQs (and answers!) that are posted to our website. See http://grants1.nih.gov/grants/funding/sbirsttr_faqs__2003.doc

Be sure that you are following the PHS 2004-2 Omnibus Solicitation for SBIR/STTR Grant Application instructions. See Chapter IV of "Part I" below.

- **Phase I** NIH, CDC, and FDA Omnibus Solicitation for SBIR/STTR Grant Applications (PHS 2004-2):

  - Part I - Program Information, Grant Application Instructions and Preparation Requirements (PDF or MS Word)
    - Part II - NIH, CDC and FDA Program Descriptions and Research Topics (PDF or MS Word)

    (**Submission Dates: Apr 1, Aug 1, Dec 1**)

  - **Phase II** NIH, CDC, FDA SBIR/STTR Grant Application Instructions (PDF or MS Word)

    Note: If you experience problems opening any of the PDF files on this page, please update your Acrobat Reader to the most current version, which is available for free at http://www.adobe.com/products/acrobat/readstep2.html.

Preparing the Budget....

Not all types of biomedical and behavioral research can be completed within the statutory award amounts for Phase I ($100,000) or Phase II ($750,000) and statutory project periods (six months for Phase I; two years for Phase II).

- Prepare your budget after you have written your research plan and have a good idea of what the costs of your project will be.

- Contact NIH program staff to discuss all aspects of the application, particularly issues related to the budget.

- Allow enough time to review the instructions (modular vs. non-modular) and to create a budget that reflects your understanding of the work to be performed.

- If you are unable to conduct the project within the statutory award amounts and project periods, propose a reasonable and appropriate budget and project period necessary to complete the tasks in the Phase I or Phase II research project.

- Include a thorough **justification** in the application to explain the need to deviate from the statutory guidelines. Note: CDC and FDA do not make awards above the statutory guidelines.

- Refer to the instructions in the Solicitation for requesting F&A/Indirect costs - these go on the Checklist Page

- Questions about budget preparation? A Grants Management contact for each awarding component is provided in the PHS 2004-2 Grant Solicitation and in the following table (PDF or MS Word).

- Questions about F&A: Visit the Division of Financial Advisory Services (DFAS) websites:

    Main DFAS website, http://ocm.od.nih.gov/dfas/dfas.htm

    FAQS, http://ocm.od.nih.gov/dfas/faqindirectcosts.htm

    Listing of unallowable and unallocable costs and the related FAR citation for each, http://ocm.od.nih.gov/dfas/ unallowables.htm

Delivery Instructions

All applications sent via the **United States Postal Service for Express or regular mail** should use the following address:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive MSC 7710
Bethesda, MD 20892-7710

All applications sent via a **courier delivery service (non-USPS)** should use this address:

Center for Scientific Review
National Institutes of Health
Suite 1040
6701 Rockledge Drive
Bethesda, MD 20817

Applications may not be delivered by individuals to the Center for Scientific Review but must be sent via a courier delivery service or the USPS.

Best wishes for a successful application.

Sincerely,

Jo Anne Goodnight
NIH SBIR/STTR Program Coordinator