National Institutes of Health

ADVICE AND INFORMATION ON SBIR AND STTR PROGRAMS

AT THE NATIONAL INSTITUTES OF HEALTH

SBIR/STTR Omnibus Solicitation:

http://grants.nih.gov/grants/funding/sbir.htm

Advice and Information:

http://grants.nih.gov/grants/funding/sbirgrantsmanship.pdf

Small Business Innovation Research (SBIR)

Small Business Technology Transfer (STTR)

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INTRODUCTION

Small biotechnology firms represent a unique national resource for economic growth that may be the fastest and most efficient mechanism to create technological innovation to convert cutting edge biomedical research into new technology breakthroughs and competitive new products. The NIH Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant programs provide an opportunity for ALL key players in biomedical research to benefit. SBIR grants provide $850,000 (Phase I and II) or more and STTR grants provide $600,000 (Phase I and II) or more in research dollars to catalyze the commercialization of innovative projects that will benefit public health. Further, these grants offer company scientists an opportunity to pursue innovative projects for which company support may not be available, and they promote and foster partnerships with collaborators, including academic investigators. By serving as a collaborator, consultant, or principal investigator (for STTR), an academic investigator can gain long-term financial and scientific benefits. Collaboration with a company also offers access to company resources and expertise and possibly jobs for graduate students and postdoctoral fellows. In a rapidly changing culture where research institutions are becoming more committed to innovation and entrepreneurship to enhance the economic development of their regions, NIH SBIR and STTR grants can add value to an academic institution's intellectual property. With rapidly expanding biological knowledge, even large corporations can develop only a limited number of promising lead ideas. Large pharmaceutical corporations often look to small biotechnology companies for the initial development of embryonic technology. Thus, the end of a successful project for a small biotechnology company is often the beginning of R&D for a large pharmaceutical corporation. NIH small business grants can help bridge the needs of both by providing early-stage funding for research that adds value to an idea, promoting partnerships that lead to a marketable product.

This ***Advice and Information on NIH SBIR and STTR Programs*** document is intended to provide mentoring and encouragement to those applying for NIH small business grants. The subjective comments are based on the experiences of NIH staff that have knowledge of and experience with the SBIR program. **Nevertheless, you should be aware that the advice and values in this booklet may not be shared by everyone, including those who review applications or decide grant award funding**. In addition, this document in no way obviates the need for an inexperienced applicant to seek further advice from experienced colleagues or from appropriate program personnel at NIH. To distinguish objective information from opinion, the rules and regulations have been formatted in regular type and *advice and commentary in italics.*

The information presented in this booklet is intended to supplement and not replace instructions in the current "Omnibus Solicitation of the National Institutes of Health (NIH) for Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Grant Applications." Any differences between the SBIR or STTR solicitation instructions and the information below are unintentional, as the Solicitations are the official documents for the preparation of SBIR or STTR grant applications.

I. THE INITIAL SBIR AND STTR APPLICATION PROCESS

Be sure to thoroughly read the important changes and reminders in the first few pages of the current SBIR/STTR Omnibus Solicitation, which can be accessed through the NIH "Small Business Funding Opportunities" website posted at http://grants.nih.gov/grants/funding/sbir.htm**.**

SBIR/STTR Phase I Grant Solicitation Availability

The SBIR/STTR Phase I Grant Solicitation and the SBIR/STTR Phase II application is only available via electronic means. Printed copies of these documents are no longer distributed. Applicants are encouraged to check the SBIR/STTR homepage (http://grants.nih.gov/grants/funding/sbir.htm) frequently for updates on the program. Any updates or corrections to the solicitation will be posted there.

General SBIR/STTR Questions

If you have general questions about the SBIR or STTR Programs, please contact:

Ms. Jo Anne Goodnight
NIH SBIR/STTR Program Coordinator
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6705 Rockledge Drive
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or

NIH SBIR/STTR Solicitation Office
Phone: (301) 206-9385 Email: sbirsttr@peacetech.com

Is NIH Interested in My Technology?

To answer this question, it is helpful to understand the mission and culture of NIH. Our mission is to improve human health through biomedical and behavioral research, research training and communications. NIH is an investigator-initiated research institution, and we extend this philosophy to the SBIR/STTR Grant Programs. If you are interested in applying for an NIH grant, the best place to begin is by talking to a program official whose responsibilities lie in the scientific area in which you are interested in doing your research. To find out whom to talk to, try starting with the NIH home page (www.nih.gov/icd) or referring to the Contact Table (http://grants.nih.gov/grants/funding/sbirsttr1/section_2.html) in the SBIR/STTR Solicitation, or calling the NIH GrantsInfo Office at 301- 435-0714). Communication is the essential ingredient to surviving the application, review and award process. Don't be shy about calling NIH staff to get answers to your questions or to obtain guidance.

Announcements of Funding Opportunities

We announce our funding opportunities through a variety of means, including a grant solicitation, a contract solicitation and the NIH Guide for Grants and Contracts. You can stay apprised of funding opportunities by visiting the NIH SBIR/STTR website (http://grants.nih.gov/grants/funding/sbir.htm) and by subscribing to the weekly content notifications in the NIH Guide (http://grants.nih.gov/grants/guide/listserv.htm).

The *Omnibus Solicitation for SBIR/STTR Grant Applications* is issued every January with three receipt dates (April 1, August 1 and December 1). There are 23 NIH awarding components (also referred to as Institutes or Centers, ICs) that define areas of interest, but their list of research topics is not meant to be exhaustive. The topics are generally broad, but more importantly, the last topic for each awarding component is "**Other Areas of Research within the Mission of the Institute or Center**." Therefore, as long as your proposed research falls within the overall mission of NIH, we will accept your grant application for review.

Contracts are different. We issue a Contract Solicitation for SBIR Proposals once a year for a single receipt date. The topics are very specific, and you must be responsive to the particular topic or your proposal will be returned without review. Currently, contract opportunities are not offered through the STTR mechanism. Another important note on contracts is that not all of the awarding components participate in the contract solicitation.

The *NIH Guide for Grants and Contracts* is a weekly publication of additional funding opportunities. These opportunities are issued as "Program Announcements (PAs)" or Requests for Applications (RFAs), and they are used to identify high priority areas of one or more ICs. Be sure to pay attention to the application receipt dates as they may differ from the standard three receipt dates announced in the SBIR/STTR Solicitation. PAs are generally open for three years, are often sponsored by multiple ICs due to overlapping interests, and are reviewed by the Center for Scientific Review. RFAs typically have only one receipt date, are issued by one IC and typically reviewed within that IC, are much more specific than PAs, and have a set-aside of funds. *(So an SBIR/STTR RFA is a set-aside within a set-aside!)*

Forms

All SBIR and STTR applications (Phase I, Phase II, and Phase I/Phase II Fast Track—new *and* revised) **must** be submitted using the Public Health Service Grant Application (PHS 398) in accordance with specific SBIR/STTR-related instructions in Chapter VI of the PHS 398 instructions. It is critical that you read this chapter first as it contains SBIR/STTR-specific instructions. Links to the forms and instructions are noted below.

PHS 398
http://grants.nih.gov/grants/funding/phs398/phs398.html

PHS 398 Chapter VI SBIR/STTR Instructions:
http://grants.nih.gov/grants/funding/phs398/section_6.html

SBIR/STTR Forms as a Full Set: (RTF)
http://grants.nih.gov/grants/funding/sbirsttr1/398_SBIRSTTRforms.rtf.

SBIR/STTR Forms as Individual Form Files:

Form Page 1: Face Page (RTF PDF)

Form Page 2: Description, Performance Sites, and Key Personnel (RTF PDF)

Form Page 3: Research Grant Table of Contents (RTF PDF)

Form Page 4: Detailed Budget for Initial Budget Period (RTF PDF)

Form Page 5: Budget for Entire Proposed Period of Support (RTF PDF)

Modular Budget Format Page (RTF PDF) (For applications of $100,000 total costs or less)

Biographical Sketch Format Page (RTF PDF)

Resources Format Page (RTF PDF)

Checklist Form Page (RTF PDF)

Personal Data Form Page (RTF PDF)

Continuation Page (RTF PDF)

Targeted/Planned Enrollment Format Page (RTF PDF)-- If Human Subjects research is proposed

Enrollment Report Format Page (RTF PDF)--If Human Subjects research is proposed

Mailing Address, RFA and SBIR/STTR Labels (RTF PDF)

STTR Research Institution Budget Form Page (RTF PDF)

Research Institution Certification Format Page (Modular STTR Only) (RTF PDF)

NOTE: There is NO FORM PAGE for the Research Plan.
See http://grants.nih.gov/grants/funding/phs398/section_6.html#9_research_plan for specific instructions.

You may find that the PDF files are easier to use than the RTF files for the "Form" Pages (i.e., Form Page 1, 2, 3, 4, 5, Checklist, and Personal Data Page.) The RTF files may be better for the remaining sections of the application, since you can format the text and add figures or graphics. Please note that the PDF files can be opened and completed using free Acrobat Reader; however, PDF can only be saved if you have obtained full Adobe Acrobat software.

Eligibility Requirements

There are requirements that your small business must meet as the applicant organization to qualify for an SBIR or STTR award. There are also requirements that the principal investigator must satisfy on an SBIR. Refer to the SBIR or STTR Solicitations for a complete description of eligibility and requirements. These eligibility criteria must be satisfied **at the time of award**. For a comparison of the SBIR and STTR programs, see **Table 1**. In addition, you need to be aware of the performance site requirements under the SBIR and STTR program.

SMALL BUSINESS CONCERN ELIGIBILITY CRITERIA

To qualify for an SBIR or STTR grant, the small business concern, which is ALWAYS the applicant/awardee organization must meet the following criteria:

1) have 500 or fewer employees, including affiliates.
2) be independently owned, controlled, and operated for-profit;
3) have its principal place of business in the U.S.;
4) be at least 51% owned, or have at least 51% of its voting stock owned, by U.S. citizens or lawfully admitted permanent resident aliens; and
5) control the research facilities where the research will be conducted.

PRINCIPAL INVESTIGATOR CRITERIA

Give careful consideration to the person you assign as the Principal Investigator (PI) on your application. The PI is the "single individual designated by the grantee in the grant application ... who is responsible for the scientific and technical direction of the project." The primary employment of the PI must be with the small business concern at the time of award and during the conduct of the proposed project. Primary employment means that more than one half of the PI's time is spent in the employ of the small business concern. Primary employment with a small business concern precludes full-time employment at another organization.

When the proposed PI clearly does not have sufficient qualifications to assume this role, the application is not likely to receive a favorable evaluation. *While the PI is not required to be an M.D. or Ph.D., s/he is required to have the expertise to oversee the research project scientifically and technically.*

If your application has the likelihood for funding, the awarding component will require documentation to verify the eligibility of the PI. This will also be necessary when, at the time of submission of the application, the PI is a less-than-full-time employee of the small business concern; is concurrently employed by another organization; or gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position.

If the PI is employed or appears to be employed by an organization other than the applicant organization in a capacity such as Research Fellow, Consultant, Adjunct Professor, Clinical Professor, Clinical Research Professor, or Associate, a letter must be provided by each employing organization confirming that, if an SBIR grant is awarded to the applicant small business concern, the PI is or will become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the PI is employed by a university, such a letter must be provided by the Dean's office or equivalent; for other organizations, the letter must be signed by a corporate official.

PERFORMANCE SITES

Indicate where the work described in the "Research Plan" will be conducted. One of the sites indicated must be that of the applicant small business concern. If there is more than one performance site (such as animal or human subject work), list all the sites on Form Page 2, and provide an explanation on the Resources Format Page of the application. The capability of the company to conduct research at its site should be detailed in the Resources section of the application. If the company site is located in space belonging to another research organization

(a landlord), a letter from the landlord must be included in the application, certifying that the SBIR or STTR-funded company controls its own research space.

For both SBIR/STTR Phase I and Phase II, **the research or R&D project activity must be performed in its entirety in the United States.** In those rare circumstances that necessitate the use of foreign sites (e.g., patient populations) because of the study design, investigators must thoroughly justify the use of these sites in the application. Similarly, in those rare circumstances that necessitate the purchase of materials from other countries, investigators must thoroughly justify the request. These rare situations will be considered on a case-by-case basis. Approval by the funding officer for such specific condition(s) must be in writing. While the SBIR/STTR research or R&D project activity must be performed in its entirety in the United States, other work outside of the United States, which is necessary to the overall completion of the project, could be supported by non-SBIR/STTR funds.

Table 1. SBIR and STTR Comparison

Requirements	SBIR	STTR
Application Forms (Ph I/II)	PHS 398	PHS 398
Application Receipt Dates	Apr 1, Aug 1, Dec 1	Apr 1, Aug 1, Dec 1
Award Period*	**Phase I - normally, 6 mo.** Phase II - normally, 2 years	**Phase I - normally 1 year** Phase II - normally, 2 years
Award Dollar Guidelines*	Phase I - $100,000 **Phase II - $750,000**	Phase I - $100,000 **Phase II - $500,000** (Ph II increasing to $750,000 in FY 2004)
Principal Investigator	**Employed by company more than 50% time during award**	**Minimum of 10% effort. Primary employment with small business not stipulated.**
Performance Site	**Must be entirely in U.S.; part of research must take place in company-controlled research space.**	**Must be entirely in U.S.; part of research must take place in company-controlled research space and part in that of partnering research institution.**
Fast-Track SBIR/STTR	Submit Phase I and Phase II according to specific instructions on each.	Submit Phase I and Phase II according to specific instructions on each.
Product Development Plan	All Phase II and Fast Track applications; 10 pages	All Phase II and Fast Track applications; 10 pages
Administrative Supplement Awards to Phase I/Phase II grants	Allowable under well-justified circumstances; Varies among different Institutes/Centers, so discuss with your Program Director.	Allowable under well-justified circumstances; Varies among different Institutes/Centers, so discuss with your Program Director.
Progress Report (See Phase II for specific information to be included)	Include as part of Phase II application. Otherwise, within 90 days after project end date.	Include as part of Phase II application. Otherwise, within 90 days after project end date.

Requirements	SBIR	STTR
Modular Grant (Phase I only)	**Budget ≤ $100,000 total costs:** **Modular Budget Format Page**: Budget Justification in narrative form, including information for all participating organizations on (1) Personnel, (2) Fixed Fee, (3) Consultant Costs, and (4) Contractual Costs. Budget requests made for total direct costs.	**Budget ≤ $100,000 total costs:** **Modular Budget Format Page**: Budget Justification in narrative form, including information for all participating organizations on (1) Personnel, (2) Fixed Fee, (3) Consultant Costs, and (4) Contractual Costs. Also provide information for Consortium/Contractual Costs associated with the Research Institution's portion of the budget. Label this section as "Research Institution Consortium/Contractual Costs." **STTR Research Institution Certification Page**: A letter from the partnering research institution must be included with the application certifying that the research institution will perform at least 30% of the work on the project. Indicate Research Institution's TOTAL Costs. Budget requests made for total direct costs.
Non-Modular Grant	**Budget >$100,000 total costs:** **Form Page 4**: Budget (Direct Costs) of Applicant (Small Business) Organization with details for Initial Budget Period **Form Page 5**: Budget (Direct Costs) of Applicant (Small Business) Organization (Entire Proposed Project Period) with details and Budget Justification.	**Budget >$100,000 total costs:** **Form Page 4:** Budget (Direct Costs) of Applicant (Small Business) Organization with details for Initial Budget Period **Form Page 5**: Budget (Direct Costs) of Applicant (Small Business) Organization (Entire Proposed Project Period) with details and Budget Justification. **STTR Research Institution Budget Page**: Budget of Research Institution with details

***NOTE: The award period and dollar levels are guidelines and NOT ceilings**. *Certain types of biomedical and behavioral research can be extremely costly. If you know that your proposed research cannot be completed within the prescribed amount of time and dollars, you may propose and justify longer periods of time and greater amounts of funds necessary the research project. Be sure to discuss your budget plans with your IC Program Director.*

II. Preparing Your Grant Application

Type Size

NIH strictly enforces its type setting requirements. Be aware. *There are "font-size" and "page" police who check to see that you have complied with type size and page limitations. Why? Because no applicant should have an unfair advantage of squeezing more text onto a page than other applicants, and because the use of small type makes it difficult for reviewers to read your application.* The PHS 398 Rich Text File (RTF) and Portable Document File (PDF) Form pages as provided are acceptable by NIH. All other sections of the application (e.g., Biographical Sketch, Introduction, if necessary, and the Research Plan) must conform to the following requirements:

- Margins must be at least ½ inch wide.
- The height of the letters must not be smaller than 10 point. *Your application may be better received with 12 point font (Helvetica or Arial)*;
- Type density of letters must not be more than an average of 15 characters per inch *but fewer may be better;*
- No more than 6 lines per vertical inch are allowed, thus *do not squeeze lines together;*
- Figures, charts, tables, figure legends, and footnotes may be smaller in size but MUST be legible.

Page Limitations

SBIR/STTR Phase I applications may not exceed 25 single-spaced standard size (8 ½" x 11") pages, *excluding* the following:

- Cover letter (suggest potential awarding components)
- "Introduction" required when submitting a revised application (limited to 1 page for Phase I and 3 pages for Phase II)
- Biographical Sketch (limited to 4 pages for each key person)
- Sections *e-j* of the Research Plan **Note: Sections a-d of the Phase I Research Plan are limited to 15 pages.**
- Checklist Form Page
- "Personal Data on Principal Investigator" Form Page
- Letters of commitment from collaborators and consultants, and
- Page(s) furnishing information required under "Prior SBIR/STTR Phase II Awards" (Section IV, item F. Prior SBIR Phase II Awards),if applicable.
- Research Institution Certification Format Page (Modular STTR Only)

The 25-page limit includes all other form pages and "continuation" pages.

Remember that unless solicited by the agency, appendices are **not** allowed in Phase I. After the receipt date, you may contact your Scientific Review Administrator of the scientific peer review group to discuss any relevant supplementary material or corrective material pertinent to the review of your grant application.

IMPORTANT!!!

Deviations from the font size specifications and page limitations will be grounds for the PHS to reject and return the entire application without peer review.

Writing Tips

- *Follow all instructions. Don't risk having your application returned because you exceeded the page limits or used an improper font, font size, or margin setting.*
- *Use the active rather than passive voice. For example write, "We will develop a cell line," not "A cell line will be developed."*
- *Keep related ideas and information together.*
- *Edit and proofread your application multiple times.*
- *Maintain a balance between your technical writing and non-technical writing, especially in your specific aims. Why? First, most reviewers will just scan your application, and second, not all of the study section members will be familiar with your field or methods. One way to organize the technical and non-technical information is to keep the parts of the application most reviewers will likely read -- abstract, significance, and specific aims -- simple and non-technical, and get technical and detailed only in the methods section. Your methods section will need to spell all your experiments out in fine detail. Another approach is to include both technical and non-technical information throughout the application. For example, you could begin each paragraph simply and then progress to more complex information, or you could alternate paragraphs that have less and more technical information. To be safe, be sure to include both broader, less technical descriptions as well as more technical information in the most widely read sections of your application.*
- *Address the NIH review criteria:*

  Significance: ability of the project to improve health

  Approach: feasibility of your methods and appropriateness of the budget

  Innovation: a new product or service; or a significant improvement of an existing product or service; or a new application for an existing technology.

  Investigator: training and experience of investigators

  Environment: suitability of facilities and adequacy of support from your institution

- *Know your audience and write TO your audience*

  You are writing to an audience of your "peers." Your application will be assigned to at least two reviewers who are experts in your field, and they will be asked to write critiques prior to the meeting. The Scientific Review Administrator (SRA) will also ask one or more members to serve as readers, who identify strengths and weaknesses of applications. Your objective is to present a cohesive and cogent research plan to the primary and secondary reviewer.

Most likely, other reviewers will read only your abstract, significance, and specific aims, and they will ask the primary reviewer questions about your application. For applications that are scored, each reviewer records a numerical rating that reflects the member's opinion of the merit of the application.

- *Put yourself in the place of a reviewer*

  Reviewers bear an incredible burden, so they appreciate an application that is neat, well organized, and easy to read. Label all sections clearly. Simplify and breakup long, involved sentences and paragraphs. In general, use short simple sentences; they are much easier on the reader. Delete redundant, awkward words and phrases. Start with basic ideas and move progressively to more complex ones. State the key points directly, and write basic concepts as non-technically as possible. A picture is worth a thousand words. Use graphics to help reviewers grasp a lot of information quickly and easily, and break up the monotony of pages of text.

- *Get an "in-house" review before the "outhouse" review. Have someone with good writing skills read your application to make sure your writing is crystal clear and to check for typos and internal inconsistencies in the document.*

- *If you plan to include human subjects in your research, read the PHS 398 instructions carefully and include the requested information on how you will protect subjects from research risks, your plans to include women, children and minorities in your research, your plans for a data and safety monitoring plan, as appropriate. If you fail to include the information specified in the PHS 398, your application will be deemed "incomplete" and it will be grounds for NIH to return your application without peer review. Take this sage advice seriously and ask many questions if you are unclear about what needs to be included in your application.*

Research Plan: What, Why, How?

The purpose of this section in your proposal is to describe the "what" (Specific Aims), the "why" (Background and Significance) and the "how" (Research Design and Methods). *Present your research logically and clearly. Keep the sections of the plan well coordinated and clearly related to a central focus. Suggestions for constructing a research plan follow:*

Label and organize the sections exactly as in the instructions:

A. Specific Aims

B. Background and Significance (include commercial potential)

C. Preliminary Studies (not required for Phase I)/Phase I Progress Report (required for Phase II)

D. Research Design and Methods

E. Human Subjects

F. Vertebrate Animals

G. Literature Cited

H. Consortium/Contractual Arrangements

I. Letters of Support (e.g., Consultants)

J. Product Development Plan (Phase II and Fast-Track only)

K. Prior Phase II Awards (if applicable)

- *State your hypothesis or underlying principles clearly in both the Specific Aims and in the Abstract.*
- *Highlight the importance and innovation of your project.*
- *Be sure your project has a coherent direction.*
- *Demonstrate that the objectives are attainable within the stated time frame.*
- *Explain what gaps in science and/or commercialization your project would fill. If a similar product/service exists, clearly explain why your product/service is better and why it is innovative.*
- *Refer to the literature thoroughly and thoughtfully, but not to excess. Research proposals typically do not fare well when applicants are unaware of relevant published work, products, or services or when the proposed research or study design has already been tried and judged to be inadequate.*
- *Where appropriate, include well-designed and clear tables and figures. Use titles that are accurate and informative. Label the axes and include legends. Reviewers will look for discrepancies between what you show and what you describe in your proposal. Be sure you explain the details, or reviewers may see things differently from you.*
- *Edit and proofread thoroughly for typographical and grammatical mistakes, omitted information, and errors in figures and tables.*
- *Have one or more of your colleagues review the application. They can point out unclear statements and other problems such as typographical errors, omitted figures, absent biographical sketches, missing letters, and confusing budget justifications.*

Preparing the Research Plan

A. SPECIFIC AIMS

The recommended length of this section is one page.

The Specific Aims section should list measurable objectives that you intend to complete by the end of Phase I or Phase II. Do not confuse Specific Aims with your long-term goals for a product. Your specific aims are the objectives of your research project, your project milestones, and the accomplishments by which the success of your project is measured.

Write this section to capture the enthusiasm of the reviewers (particularly the primary and secondary), since they'll all read it. Choose aims reviewers can easily assess. Choose objectives for your Phase I proposal that can be easily and fairly evaluated at the conclusion of this phase. To avoid being overly ambitious, you should probably limit your proposal to three to four specific aims.

Organize and define your aims so you can relate them directly to your research methods. Begin this section by stating the general purpose or objectives of your research. You may want to organize it in outline form: Specific Aim 1, Milestone; Specific Aim 2, Milestone; etc. If you are submitting more than one application, make sure the specific aims differ.

B. SIGNIFICANCE

The recommended length of this section is two to three pages.

This is one of the sections likely to be read by all the reviewers, so write this section in non-technical terms for the broader audience. Tell the reviewers how your work suits the NIH mission to improve health through science. Tie your science to curing, treating, or preventing disease. When reviewing your application, reviewers will judge the likelihood that your research can make an impact on public health.

This section should cover the rationale for the proposed project, the state of existing knowledge (including literature citations and highlights of relevant data) and gaps that the project is intended to fill.

Describe how your research is innovative and how this research could produce a significant commercial product or service. Innovative means new technologies, significant improvement of existing technologies, or development of new applications for existing technologies. Specifically identify the commercial opportunities and societal benefits that the project is intended to address. State concisely the importance of the proposed research by relating its specific aims to the longer-term objectives of Phase II.

Keep it brief! Why is the project or specific research questions important? Write a compelling argument that supports your research to develop a solution to a real problem that affects real people..

Consider including a diagram that illustrates the "big picture" by delineating what you expect to achieve in Phase I (aims and milestones), plans and objectives for Phase II, and what the ultimate commercial endpoint will be in Phase III.

As you prepare this section, consider the following questions:

- *Does the proposed project have commercial potential to lead to a marketable product or process? Does this study address an important problem?*
- *What may be the anticipated commercial and societal benefits of the proposed activity?*
- *If the aims of the application are achieved, how will scientific knowledge be advanced?*
- *Does the proposal lead to enabling technologies (e.g., instrumentation, software) for further discoveries?*
- *Will the technology have a competitive advantage over existing/alternate technologies that can meet the market needs?*

C. PRELIMINARY STUDIES/PHASE I PROGRESS REPORT

NOTE: *Preliminary data are NOT required for Phase I applications. However, some preliminary data can serve to assure reviewers that the proposal has a high probability of success.*

Applications with convincing preliminary data are likely to score better than applications containing only good ideas.

The recommended length of this section is six to eight pages.

By providing preliminary data, you build reviewer confidence you can handle the technologies, understand the methods, and interpret results. Preliminary data can help show you have the expertise to do the job.

Interpret preliminary results critically. Give alternative meanings to the data to show you've thought the problem through and will be able to meet future challenges. If you don't do this, the reviewers will.

D. RESEARCH DESIGN AND METHODS

When reviewers judge your application your Research Design and Methods section has the most "weight" even though the review criteria are not numerically "weighted."

Organize this section in accordance with your specific aims. It's helpful to create a graphical timetable showing how and when you will accomplish your aims, including any overlap of experiments and alternative paths. Use flow charts and decision trees to show paths of experiments and how they progress, including paths that show alternatives -- what you will do if you get negative results.

Anticipate reviewers' questions about the feasibility of what you propose, e.g., how you will gain access to reagents, equipment, or study populations. Describe sources if reagents or equipment are not generally available. If collaborators will provide them, include letters from the sources.

Describe in detail the experimental design and procedures to accomplish your specific aims. While you may assume reviewers are experts in the field and familiar with current methodology, do not assume they will know how you intend to proceed. The reviewers need to be assured that you know what you are doing. It is not sufficient to state "we will grow a variety of viruses in cells using standard in vitro tissue culture techniques." In this example, reviewers would want to know which viruses, cells, and techniques; the rationale for using this particular system; and, exactly how the techniques will be used.

Include a detailed discussion of the way in which results will be collected, analyzed, and interpreted. Remember, you must convince the reviewers that your proposed project is a great idea. You must show through a succinct explication that you understand the science and can do the research.

Make sure the experiments are in a logical sequence, flowing from one another with clear starting and finishing points. Show a timeline for experiments, and take care you are proposing a realistic level of work for the allotted time.

Ask yourself: Are your procedures feasible and within your competence? You'll have to convince reviewers you chose the right methods. If your methods are innovative, state why you chose them and how you will avoid technical problems. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions you will take. If you're working with hazardous materials, your application must state what special facilities are available to protect the environment and staff. Describe the precautions you will take in handling the materials and the training people involved have had in safe practices.

To fill in expertise, rely on consultants. State how collaborators or consultants will fit into the work. List them as key personnel, and provide biographical sketches.

Include a section called "Potential Pitfalls and Alternative Strategies" in which you discuss potential difficulties and limitations of your proposed procedures and propose solutions to them. Since reviewers are experienced researchers, they will be aware of possible problems. Discuss alternative approaches if the initial approach proves not to be feasible or if a result is not what was expected. Tell reviewers what you will do if your results are negative, how this will also advance the field, and what you will do next. Discuss in detail your methods for gathering and interpreting data and making sure your experiment can yield statistically significant results.

IMPORTANT!!!! Include the milestones and criteria by which you will determine that feasibility has been demonstrated.

After you have completed this section, consider whether you have addressed the following questions:

- *Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?*
- *Is the proposed plan a sound approach for establishing technical and commercial feasibility?*
- *Does the applicant acknowledge potential problem areas and consider alternative strategies?*
- *Are the milestones and evaluation procedures appropriate?*

E. RESEARCH INVOLVING HUMAN SUBJECTS

Please give thorough consideration for the need of any human subject involvement in the Phase I feasibility work.

Although no specific page limitation applies to this section of the application, be succinct.

If you are not conducting human subject research, indicate "Not applicable" in this section of the research plan. If you're not studying human subjects but your collaborators are, you need to complete this section and you'll still need to make sure the assurances are in place.

Failure to address the following elements will result in the application being designated as incomplete and it and will be grounds for NIH to return the application without peer review.

If you're studying materials from identifiable people, your work probably qualifies as human subjects research, even if you're not seeing patients. NIH defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations governing the inclusion of human subjects in research extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

If your research comes under the NIH definition, you will need to fulfill a host of application and reporting requirements--even if the human subjects research will be performed by a different organization. Some research using human tissue is exempt, e.g., if the samples are from people who cannot be identified. The following decision trees are extremely useful in helping you to determine whether your research involves human subjects and what is required if it does: http://www.niaid.nih.gov/ncn/tools/decisiontrees/default.htm.

If your project studies human subjects or samples, read the human subjects section of the PHS 398 carefully (http://grants1.nih.gov/grants/funding/phs398/section_1.html#e_humansubs). Be sure to also consult information under "Section III-G, "Assurances and Certifications (http://grants1.nih.gov/grants/funding/phs398/section_3.html#g_assurance)." Follow all instructions to the letter. The PHS 398 expands reporting and inclusion requirements. *Key features you need are listed below, but you should refer to the PHS 398 instructions for a complete description.*

- Description of how you will protect subjects from research risks
- Plans to include:

  -Women

  -Children - include expertise to study children, suitability of your facilities, and how you will recruit enough children

  -Minorities

  -Analyses capable of showing intervention differences between men and women and between minorities and non-minorities for phase III trials
- Data and safety monitoring plans
- Mandated reports
- Benefits to public health

When research involves living persons or samples from living persons, and the research is not exempt, it must be approved by an institutional review board (IRB) prior to funding. If an exemption has been designated in item 4a on the face page, enough detail still must be provided to allow the determination of the appropriateness of the exemption. If no exemption is claimed, the following four items must be addressed in this section:

- Risks To The Subjects;
- Adequacy of Protection Against Risks;
- Potential Benefits of The Proposed Research to the Subjects and Others;
- Importance of the Knowledge to Be Gained.

A full description of these points can be found at: http://grants1.nih.gov/grants/funding/phs398/section_1.html#8_research. Call your Program Director for any questions you may have.

It is also useful to read the instructions (http://grants1.nih.gov/grants/peer/hs_review_inst.pdf) that our peer review committees receive to evaluate research involving human subjects.

Even if the research you propose is exempt from these regulations, you must address the inclusion of women and members of minority groups and their subpopulations, and the inclusion of children in developing the research design. Failure to address these issues will be grounds for NIH to return your application without review.

Before an application is funded, you must file an Assurance of Compliance with the Office for Human Research Protections (OHRP). **IRB approval and an applicable Assurance to comply with 45 CFR 46 (if not already on file with OHRP) is not required at the time of application, but you should start the process early because revisions and final approval can take time.** Read the assurance instructions, and contact OHRP staff at (301) 496-7041 or http://ohrp.osophs.dhhs.gov/phonstf.htm for details and help.

Important information on the preparation of an application for a Federal-wide Assurance (FWA) for the Protection of Human Subjects in Research or other types of Assurances or approval of an Assurance can be found at: http://ohrp.osophs.dhhs.gov/irbasur.htm

F. RESEARCH INVOLVING VERTEBRATE ANIMALS

Although no specific page limitation applies to this section of the application, be succinct.

If you are not conducting vertebrate animal research, indicate "Not applicable" in this section of the research plan.

If the proposed research involves live vertebrate animals, the following items apply:

- Check “Yes” on Item 5, page 1.
- The proposed use of animals must be approved by the Institutional Animal Care and Use Committee (IACUC). **If your company does not have an approved animal welfare assurance on file with OLAW (typically the case for small business concerns), documentation of IACUC approval is not required until just prior to award.** If the applicant organization has an approved animal welfare assurance on file with OLAW, documentation of IACUC approval is needed at the time of application or within 60 days of the application receipt date. Put the date of IACUC approval in the space provided in 5a on page 1, or write “Pending” if submission of IACUC approval date will be delayed.
- If your company has an approved animal welfare assurance on file with OLAW, place the assurance number in 5b. **If you do not have an approved animal welfare assurance on file with OLAW, place “NONE” in 5b. You are not required to obtain an animal welfare assurance until just prior to award.** Instructions will be provided to you when a decision has been made to fund the application.

As with human subjects, you must also provide assurances that research animals are treated properly as well as state the benefits of the research to humanity. When preparing your application, read the Vertebrate Animals section of the PHS 398, **and call OLAW at (301) 496-7163 for additional clarification and assistance.**

In the Research Plan, create a section entitled: “Vertebrate Animals” and address the following five points. When research involving vertebrate animals will take place at collaborating site(s) or

at a site(s) other than your company, provide this information before discussing the five points. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

Failure to address these elements will result in the application being designated as incomplete and it and will be grounds for NIH to return the application without peer review.

Reviewers will also assess the adequacy of proposed protection of animals, to the extent they may be adversely affected by the research.

G. Literature Citations

While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

Citations show reviewers that you have done your homework. Applications do not fare well when applicants fail to reference relevant published research, particularly if it indicates that the proposed approach has already been attempted or the methods were found to be inappropriate for answering the questions you've posed.

List all references. Each reference must include the title, names of all authors (not *et. al.)*, book or journal, volume number, page numbers (first and last page), and year of publication. The reference should be limited to relevant and current literature and need not be exhaustive.

H. Consortium and Contractual Agreements

If you're working closely with an investigator from another institution, you'll need a consortium agreement, an agreement of collaboration between two institutions. Briefly describe any consortium or contractual arrangements, stating the roles of the people or organizations involved. Explain the programmatic and fiscal arrangements made between the your company and the contractor(s).

The consortium investigator and the authorized official at the consortium institution(s) must provide a signed statement or confirming letters that the appropriate programmatic and administrative personnel of each organization involved in the application are aware of the NIH consortium grant policy and are prepared to establish inter-institutional agreements consistent with that policy. See http://grants1.nih.gov/grants/policy/nihgps_2001/part_iib_6.htm#_Toc504812171. Include confirming letters with application. These letters are excluded from Phase I 25 page count.

I. CONSULTANTS

You may not have all of the expertise "in-house" to complete your proposed research. The inclusion of consultants, who are credible and known experts in their field, can strengthen the research team, add credibility to your application and greatly improve its quality.

Attach appropriate letters from each individual confirming his or her willingness to participate as a consultant to your project and what their role will be. Be sure to list your consultants as key personnel and provide biosketches in the application. The Phase I 25-page count of the application excludes letters of commitment (as well as biographical sketches) from collaborators and consultants.

J. PRODUCT DEVELOPMENT PLAN

If you are submitting a Phase II application or Fast-Track application, you must include a succinct commercialization plan, hereafter referenced as a "Product Development Plan (PDP)." **The PDP is limited to ten pages.**

Create a section entitled, "Product Development Plan," and address, *at a minimum*, each of the following areas:

1. Company information: including size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization (see Section III. A for definition of "commercialization".)

2. Value of SBIR/STTR project, including lay description of key technology objectives, current competition, and advantages compared to competing products or services.

3. Commercialization plans, milestones, target dates, market analyses of market size, and estimated market share after first year sales and after five years.

4. Patent status or other protection of project intellectual property.

K. PRIOR SBIR PHASE II AWARDS

If your company has received more than 15 Phase II SBIR awards during the previous five fiscal years, you must include the following information in each application for an award: Name of awarding agency; Award number and date; Amount of award; Title of project; Source, date, and amount of Phase II funding agreement(s); and Commercialization status of each Phase II award. This information is excluded from the Phase I 25-page count of the application.

Completing the Form Pages

Guidance and advice is included in this section for only some (not all) required Forms. You should refer to the PHS 398 instructions to complete all of the forms.

Form Page 1

Item 1. Title of Project

Make your project title as specific and complete as possible, within the 56-space limitation.

Item 2. Response to Specific Request for Application (RFA) or Program Announcement (PA) or Solicitation

Check "Yes."

For Phase I SBIR/STTR applications, insert the solicitation number (e.g., PHS 2002-2) listed on the cover page of the *Omnibus Solicitation of the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration for SBIR and STTR Grant Applications (PDF or RTF)*. Type "Fast-Track," if appropriate. Do not type PHS 398 in this line.

For Phase II SBIR/STTR applications, type "Phase II SBIR" or "Phase II STTR," as appropriate.

If the application is also being submitted in response to an NIH Guide RFA or a PA, check "Yes" and identify the appropriate announcement number and title of the PA or RFA.

Item 3. Principal Investigator/Program Director

Item 3a. Name of Principal Investigator. Name the ONE person responsible to the applicant small business concern for the scientific and technical direction of the project. Under the SBIR Program, routinely the primary employment (more than 50 percent time) of the Principal Investigator must be with the small business concern at the time of award and during the conduct of the proposed project. Under the STTR Program, primary employment with the small business concern is not stipulated.

Primary employment means that more than one half of the Principal Investigator's time is spent in the employ of the small business concern. Primary employment precludes full-time employment with another organization.

Item 6. Dates of Proposed Period of Support

Phase I: Routinely, SBIR Phase I awards do not exceed six (6) months and STTR Phase I awards do not exceed one year.

Phase II: Routinely, SBIR and STTR Phase II awards do not exceed two years.

Under special circumstances, applicants to NIH may propose longer periods of time for completion of the research project (e.g., feasibility demonstration.) Such requests that deviate from the guidelines must be thoroughly justified. You should discuss these issues with the awarding component likely to fund your application.

To select an appropriate beginning date for a new application, consult the review and award schedule. (See "Submitting Your SBIR/STTR Grant Application http://grants.nih.gov/grants/funding/phs398/section_6.html#sbir_receipts.)

Item 7. Costs Requested for Initial Budget Period

Since Phase I SBIR/STTR budget periods normally do not exceed one year, the direct and total costs for the entire" proposed period of support" (Item 8) will generally be the same as the direct and total costs for the "initial budget period" (Item 7).

Item 7a. Direct Costs Requested for Initial Budget Period

Enter the direct costs from Form Page 4 or from the Modular Budget Format Page, as appropriate. (Do not include amount requested for fee, because this is not a direct cost.

Item 7b. Total Costs Requested for Initial Budget Period

Enter the sum of (a) the total direct costs from Form Page 4; (b) the amount requested for fee on Form Page 4, and (c) the indirect costs derived from the Checklist Form Page.

Item 8. Costs Requested for Entire Proposed Period of Support

Item 8a. Direct Costs Requested for Proposed Period of Support

Enter the "total direct costs for entire project period" from Form Page 5 or the "Modular Budget Format Page."

Item 8b. Total Costs Requested for Proposed Period of Support.

Enter the sum of (a) the total direct costs from Form Page 5; (b) the amount requested for "Total fee requested for entire proposed period" on Form Page 5 or the "Modular Budget Format Page;" and (c) the indirect costs derived from the Checklist Form Page.

Item 9. Applicant Organization

Name the one organization (small business concern) that will be legally and financially responsible for the conduct of activities supported by the award. The small business concern is ALWAYS the applicant organization for an SBIR or STTR.

Item 10. Type of Organization

Check the appropriate box under "For-Profit." Check the boxes designating the small business as "woman-owned" or "socially and economically disadvantaged," if appropriate.

Form Page 2

ABSTRACT

Write your Abstract last. Make it a clear, succinct summary of your Phase I or Phase II application, and stay within the space provided. In your abstract, state your long-term commercial objectives, why the research is important and innovative, plans and methods for accomplishing Phase I goals, potential problems and solutions, and a brief discussion of plans for Phase II and III. Remember, if your project is funded, the Abstract becomes public information. Therefore, do not include proprietary or confidential information in the Abstract!

PERFORMANCE

List all sites where the work will take place. This list must match the information in the Resources Format Page, which details which facilities are completing which aspects of the project.

KEY PERSONNEL

List all key persons involved with the project and briefly state their role. Begin with the principal investigator, then list in alphabetical order all other people, including consultants, who are contributing substantively to the research. Each person listed should have a biosketch, which goes on the Biographical Sketch Format Page.

Form Page 3

Complete the table of contents, Form Page 3 when you're finished writing and printing everything.

Double check to make sure all items and page numbers correspond to those in the body of the application.

Form Page 4

Tips on Preparing a Budget

- *Although budget pages come at the beginning of your application, complete them after you have written your Research Plan and have a good idea of costs.*
- *SBIR Phase I Applications requesting ≤ $100,000 (Modular): Submit the Modular Budget Format Page. Include a Budget Narrative for Personnel, Fixed Fee, Consultant Costs and Contractual Costs. Use continuation pages if necessary.*
- *STTR Phase I Applications requesting ≤ $100,000: Submit Modular Budget Format Page. Include a Budget Narrative for Personnel, Fixed Fee, Consultant Costs and Contractual Costs. Use continuation pages if necessary. The "Total Cost" (direct and F&A costs) for the Research Institution is included in the Direct Costs of the Small Business Concern's budget. In addition to the Modular Budget Format Page, also submit the STTR Research Institution Certification Format Page (RTF or PDF). Do NOT include the Research Institution Budget Page since this is used for non-modular budgets.*
- *Budget Requests >$100,000 (non-modular grants): Always prepare a well-justified budget. This is particularly important for Phase II applications and for all requests that deviate from the statutory guidelines. Use continuation pages if you need more space, but remember these are included in the Phase I 25-page limit. Reviewers evaluate a budget for whether it is realistic and justified by the aims and methods of the project. The budget page should include only the funds requested from NIH.*
- *Concisely describe the role of all staff (professional and nonprofessional) even when not requesting salary. Reviewers will closely consider estimates of the time each person will work on each experiment or task. Make sure time estimates do not exceed 100 percent for an individual.*

- *Consider renting rather than purchasing expensive equipment, or consider using a lease-purchase arrangement. Reviewers delete requested funds for equipment that APPEARS to duplicate what should be available to you.*
- *Avoid expenses that might APPEAR to be extravagant, such as unwarranted travel.*
- *Thoroughly justify your consultants. Describe exactly what tasks they will do and include a detailed, justified budget for their work.*
- *You may request a fee/profit in an amount not to exceed 7% of total costs (direct and indirect).*

The Salary Cap

*Make sure the PI's salary takes into account the current NIH-statutory cap of **$166,700** per year. The salary cap can be a problem for highly paid scientists. For example, let's say a PI who makes $200,000 as a university physician scientist is devoting 10 percent effort to the SBIR project. The PI would probably like to charge $20,000 to the grant, but s/he can charge only $16,670 (10 percent of $166,700) for his or her work on the SBIR grant.*

Consultant Costs and Contractual Arrangements

- The total of SBIR consultant fees AND contractual costs normally may not exceed 33% of Phase I and 50% of Phase II total costs. *If your research warrants a deviation from this guideline, discuss the issue with NIH program staff and include a strong justification in your application.*
- Careful selection, addition and justification of consultants can add credibility to your application and greatly improve its quality. Also, remember to include letters from consultants agreeing to participate in the project and describing their specific roles.

Modular Grant Application and Award

*Please be sure to follow the instructions in Chapter VI of the PHS 398 for "Modular Applications" since only **some** features of the standard NIH **Modular Grant Application and Award** procedures apply under the SBIR/STTR programs. Whether you are "modular" or "non-modular" boils down to one thing: is your total budget (direct, indirect and fee) less than or more than $100,000. Follow the formats described below.*

Modular Format: SBIR/STTR Phase I budget is $100,000 Total Costs or Less

- Used ONLY for SBIR/STTR applications requesting up to $100,000 total costs (direct costs, F&A/indirect costs, and profit/fee).
- Do not use Form Pages 4 and 5. Use as internal "worksheets" only in the development of the total direct costs.
- Use only the Modular Budget Format Page (RTF or PDF)
- Budget requests are NOT made in increments of $25,000 (as they are for other research grant mechanisms such as R01, R03, R15, and R21).
- Under certain circumstances, additional budget information will be requested by the awarding component.

If the total cost (direct costs, indirect costs, and fixed fee) of your SBIR/STTR Phase I budget is **$100,000 or less,** use the Modular Budget Format Page (RTF PDF). Provide, in narrative format, the following information on Personnel, Consultant Costs, Contractual Costs and Fee. Use continuation page(s), if necessary. Samples are available at http://grants.nih.gov/grants/funding/phs398/phs398.html#forms. Enter the total amount requested for direct costs on line 7a and 8a of the PHS 398 Face Page. Present the total cost requested (direct, indirect and fee) on line 7b and 8b of the PHS 398 Face Page. **Do not submit detailed budget pages (Form Page 4 and Form Page 5). These are to be used as internal "worksheets" only.**

Scientific Review Groups (SRG) will evaluate the budget on the basis of a general, expert estimate of the total effort and resources required to carry out the proposed research, rather than on the basis of detailed categorical costs. Under certain circumstances, additional budget information may be requested.

Non-Modular Format: SBIR/STTR Phase I budget exceeds $100,000

- Used for grant applications requesting more than $100,000 total costs (direct, indirect and profit/fee)
- Use Form Page 4 and Form Page 5

If the total cost of your budget exceeds **$100,000 total costs** (direct costs, indirect costs, and fee), use the "Detailed Budget for Initial Budget Period- Direct Costs Only" (Form Page 4 [RTF PDF]) and the "Budget for Entire Proposed Project Period (Form Page 5 [RTF PDF]), and justify this request using "Budget Justification."

Administrative Supplement Requests

An administrative supplement provides additional funding to meet increased costs that are within the scope of your approved application, but that were unforeseen when the new or noncompeting continuation application was submitted. **If you are contemplating supplemental funding, you must consult in advance with your designated Grants Management Officer and Program Director. It is important for you to submit a request before your grant expires.** *To be considered for an administrative supplement, you will need to submit a request in writing, signed by the Principal Investigator and the authorized Business Official, describing the need for additional funding. In your letter, also be sure to point out what you will NOT be able to accomplish if such a request is denied.*

Biographical Sketch Pages

This section is your chance to showcase the knowledge, skills, and abilities of the key personnel and consultants involved in the project. Read the instructions carefully and include what is required. This section must contain the biographical sketches of all KEY personnel including consultants following the order as listed on Form Page 2. **Biographical sketch pages are excluded from the "25-page" limitation.**

Complete the educational block at the top of the format page, and complete sections A, B, and C.

A. **Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

B. Selected peer-reviewed publications or manuscripts in press (in chronological order). Include accepted manuscripts but not those that are submitted, unaccepted, or in preparation.

C. Research Support. List both selected ongoing and completed (during the last three years) research projects (federal or non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. If you're a beginning investigator, it's OK if you haven't had research support. **Note: Do not include percent of effort or direct costs.**

Don't confuse Research Support with "Other Support." Though they sound similar, these parts of the application are very different. As part of the biosketch section of the application, "Research Support" highlights your accomplishments, and those of your colleagues, as scientists. It's used by reviewers for the 'investigator' review criterion.

In contrast, "Other Support" lets NIH make sure the research you are proposing has not already been Federally- funded. You send your other support information to NIH just before we're ready to make an award. For more on what constitutes other support, see Section 3B of the 398. Do not include any pending support in that part of the application.

A sample biographical sketch is available at (http://grants.nih.gov/grants/funding/phs398/biosketchsample.pdf).

Resources

The Resources section of your proposal is a critical part of an SBIR or STTR application. In this section of your application, you'll need to convince reviewers you have the equipment, space, staff, and facilities to conduct the research. Use continuation pages if you need more space to illustrate why your environment is outstanding.

If your science is elegant but you don't have the resources to carry it out, your application is not likely to fare well in review. Don't assume that reviewers know your facilities have gas, vacuum, centrifuges, scintillation counters, gel apparatus, computers, autoclaves, shop, animal facilities, secretarial and financial support, or anything else you need for research. Indicate the essential resources that you have or have access to, such as animal facilities or sophisticated equipment. Make sure the resources you list match the Performance Sites section of form page 2. Describe which facilities will be used to complete which parts of the project.

Checklist

The section of the Checklist that poses the most questions is the section on Facilities and Administrative (F&A) Costs.

*First, it's important to understand what F&A costs are. These are defined as costs that are incurred by a grantee for common or joint objectives and that, therefore, **cannot** be identified specifically with a particular project or program. F&A costs were previously known as "indirect costs."*

Second, it's important to know where to find more information about calculating your F&A costs. The Division of Financial Advisory Services' (DFAS) website has a wealth of information that you can access at: http://ocm.od.nih.gov/dfas/dfas.htm. If you're still confused, don't be shy about calling the staff in that office (301-496-2444.)

The DFAS office is the office authorized to negotiate F&A cost rates with small business concerns receiving NIH SBIR/STTR awards. Upon request of the NIH, you should provide DFAS with an F&A cost proposal and supporting financial data for the most recently completed fiscal year. If financial data is not available for the most recently completed fiscal year, then you should submit proposals showing estimated rates and support for same.

Next it is important to understand the importance of actually requesting F&A costs, how to do so and how much is allowable. Request your F&A costs by completing Section 3 on the Checklist.

If you do not have currently effective negotiated F&A cost rates with a Federal agency, then you should **propose estimated F&A costs** at a rate **not to exceed 40% of the total direct costs.**

Phase I applicants

1. Complete line 3a (Initial Budget Period) and, if applicable (e.g., 2-year Phase I), complete subsequent year(s).

2. Under "Explanation", insert "Estimated F&A costs allocable (applicable) to this project are shown in line 3a" if you do not have a currently negotiated F&A costs rate with a Federal Agency.

3. If you have a currently effective negotiated F&A costs rate with a Federal agency, it should be used when calculating proposed F&A costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services.

Only actual F&A costs are to be charged to projects not to exceed the rate of 40%.

Phase II applicants

1. Complete line 3a (Initial Budget Period) for first 12-month budget period, line 3b (-02 Year) for second budget period, and subsequent year(s) as appropriate.

2. Under "Explanation", insert "Rate to be negotiated with NIH" if you do not have a currently negotiated F&A cost rate with a Federal Agency.

3. If you have a currently effective negotiated F&A cost rate with a Federal agency, it should be used when calculating proposed F&A costs.

If you request an F&A rate of **25 percent or less**, F&A costs will be awarded at the requested rate. However, remember that only actual F&A costs are to be charged to projects.

If you request an F&A rate that is **greater than 25 percent**, NIH will request additional information prior to award.

III. FAST-TRACK SBIR/STTR APPLICATIONS

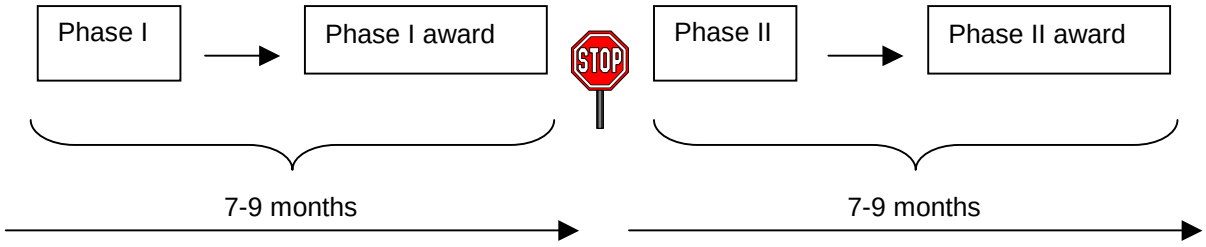
The SBIR/STTR "Fast-Track" procedures described below are designed to expedite the decision and award of Phase II funding for scientifically meritorious applications for projects that have a high potential for commercialization. Fast-Track is a review option available to those small business concerns (applicant organizations) whose applications satisfy additional criteria that enhance the probability of the project's commercial success. Applications that do not meet these criteria may be unscored or they may be redirected for review through the standard review procedures described above.

Fast-Track offers two major advantages over the standard SBIR or STTR review mechanism:

1. Single submission, peer review and scoring of both Phase I and Phase II projects.
2. Minimal or no funding gap between Phase I and Phase II.

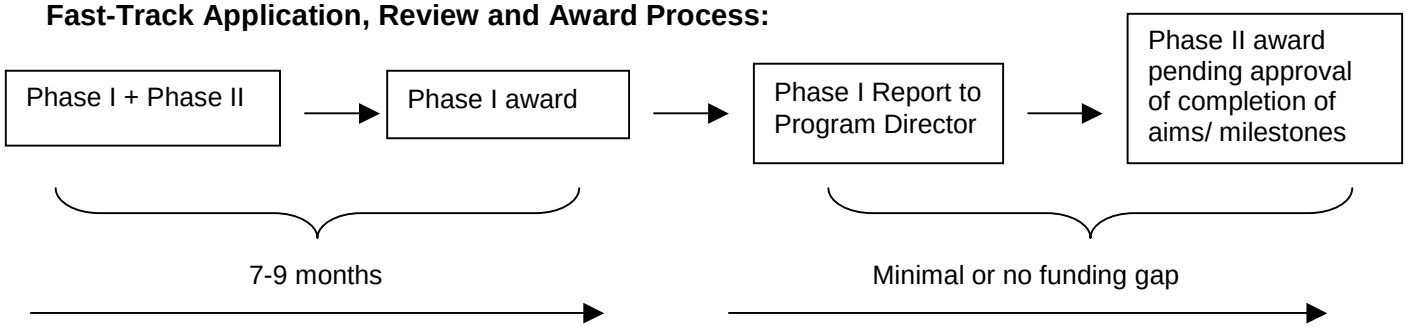
Fast-Track is intended for high-quality applications with sufficient preliminary data to clearly define milestones for proof of feasibility. Before submitting a Fast-Track application, you are strongly encouraged to consult with Program staff (listed at the end of the Research Topics in the SBIR/STTR Solicitation) for specific details relevant to the Institute or Center. If your application does not meet or exceed the stringent Fast-Track requirements, consider submitting your application under the standard SBIR/STTR Phase I program.

Standard Application, Review and Award Process:



The timeline from submission of your Phase I to receipt of your Phase II award could be as long as 18 months….

Fast-Track Application, Review and Award Process:



The timeline under the Fast-Track option could be as short as 9 months….

If Fast-Track is not the best avenue for you to take, following are several alternative strategies to minimize the Phase I/Phase II funding gap:

- You may submit the Phase II grant application at any time after award of Phase I.
- You may be eligible for supplemental funding to the Phase I project- discuss this option with your program director.
- You may incur, at your own risk, 90-day pre-award costs without prior approval - discuss this option with your grants management specialist.

You may stagger the submission of grant applications so the project start and end dates overlap.

SBIR/STTR Fast-Track Application Instructions and Requirements

(See PHS 398 Instructions, Chapter VI and the Fast Track Reminder Sheet before submitting the application.)

1. Submit a complete Phase I and Phase II application, including **for each**, the Face Page, Form Page 2 (Description/Abstract), Form Page 3 (Table of Contents), Budget Pages, Biographical Sketch Pages, Resources Page, Checklist Form Page, and Research Plan (including letters of support from consultants and collaborators). Only one Personal Data Form Page is needed. Place this page as the last page of the Phase II application. The Product Development Plan is required for the Phase II portion only. **Incomplete Fast Track Applications will be returned without review.**

2. Prepare the Fast-Track application in accordance with specific Phase I and Phase II grant application instructions and requirements. Use the PHS 398 forms, and refer to Chapter VI of the PHS 398 instructions, which are available electronically at http://grants.nih.gov/grants/funding/phs398/phs398.html.

3. Identify the application by typing the words "Fast Track: Phase I" in Item 2 on the Face Page of the Phase I and "Fast Track: Phase II" in Item 2 on the Face Page of the Phase II application.

4. Submit the completed Phase I and Phase II applications together in a single envelope or box.

5. Prepare the Research Plan in accordance with specified page limitations for items a-d in each Phase (15 pages for Phase I; 25 pages for Phase II).

6. Specify in the Phase I application clear, appropriate measurable goals (milestones) that should be achieved prior to initiating Phase II. The scientific peer review group will evaluate the goals and may suggest other milestones that should be achieved prior to Phase II funding.

7. Submit a concise Product Development Plan (limited to ten pages). Label this section clearly and include it at the end of the Research Plan (Item J). Address each of the following areas:

    a. Company information: including size; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding, regulatory experience,

and subsequent commercialization (see Section III of this solicitation for definition of "commercialization").

b. Value of SBIR/STTR project, including lay description of key technology objectives, current competition, and advantages compared to competing products or services.

c. Commercialization plans, milestones, target dates, market analyses of market size, and estimated market share after first year sales and after five years.

d. Patent status or other protection of project intellectual property.

You are ENCOURAGED to seek commitment(s) of funds, letters of interest, and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. **Place relevant letters following letters from consultants and collaborators.**

Typically Fast-Track applications will receive a single rating. Failure to provide clear, measurable goals may be sufficient reason for the scientific review group to exclude the Phase II application from Fast-Track review. In this case, only the Phase I application will receive a score. Following the initial peer review, Fast-Track applications will receive secondary review by the advisory council or board of the NIH awarding component that is the potential funding component.

IV. SUBMITTING YOUR APPLICATION

Once you have completed your application, make sure you follow the specific submission instructions.

Where to Send Your Application

The NIH's Center for Scientific Review (CSR) is the single receiving point for all NIH, CDC, and FDA SBIR/STTR grant applications. Even if your application is relevant to more than one awarding component, you need only submit the original application and five copies to the address noted below, and CSR will assign the application to all such components.

Center for Scientific Review, NIH
6701 Rockledge Drive, Room 1040-MSC 7710
Bethesda, MD 20892-7710
Use zip code 20817 for express mail or courier service. The telephone number is (301) 435-0715.

Use the mailing labels provided at the end of the forms (RTF or PDF). Until further notice, all applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the USPS. Applications delivered by individuals to the Center for Scientific Review will no longer be accepted.

Number of Copies to Submit

Send the **original and five** signed, exact, single-sided photocopies. If the receipt date falls on a weekend or holiday, then the application must be received by the following workday. If you cannot meet the application deadline, consider delaying submission to the next receipt date.

When to Send Your Application: Receipt Dates

Your grant application submitted under this SBIR/STTR Phase I Grant Solicitation will be considered on time if it is received by or mailed **on or before the published receipt dates below** and a proof of mailing is provided. Proof of timely mailing consists of one of the following: a legibly dated U.S. Postal Service **postmark** or a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable.

Table 2. Receipt, Review, and Award Dates

SBIR/STTR Application Receipt Dates	AIDS and AIDS-related Application Receipt Dates	Scientific Merit Review (Study Section)	Secondary Review (Advisory Council)	Earliest Award
Apr 1	May 1	Jun – Jul	Sep - Oct	Nov
Aug 1	Sept 1	Oct – Nov	Jan - Feb	Mar
Dec 1	Jan 2	Feb – Mar	May - Jun	Jul

The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter with the signed, completed application.

NOTE: SBIR/STTR applications in response to Request for Applications (RFAs) or Program Announcements (PAs) with specified receipt dates OTHER THAN THE STANDARD (Apr 1, Aug 1, Dec 1) receipt dates must be received by the specified dates. These RFAs/PAs are issued separately through the NIH Guide for Grants and Contracts.

Phase II Grant Application Submissions

You may apply for Phase II support at ANY time after the award of Phase I. To maintain eligibility to seek Phase II support, the Phase I grantee organization should submit an application for Phase II funding **within six receipt dates** following expiration of the Phase I budget period. *If you have the zeal to pursue a Phase II, but you are beyond the 2-year timeframe, discuss submission possibilities with your Phase I Program Director.*

Cover Letter

You are encouraged to include a cover letter with the submission of your grant application to request an assignment and referral to an institute and study section, to list of people who should not review your application and why, and/or to identify requisite scientific expertise or disciplines involved, if multidisciplinary.

Request an assignment and referral to an institute and study section. *The research you propose may cut across the scientific interests of multiple institutes/centers (ICs). Therefore, you can, and are encouraged to, request assignment or referral to appropriate primary and/or multiple ICs. While the NIH does give your request serious consideration, the final decision rests with the NIH Center for Scientific Review. If you feel your assignment is not appropriate, call the program director in the IC you think should be included on your assignment. This assignment is important since the SBIR and STTR set-aside amounts vary among ICs. Therefore, if you have multiple IC assignments and your primary IC exhausts its SBIR or STTR budget, one of the other assignees may consider your application for funding (assuming it has scientific and technical merit.)*

List of people who should not review your application and why. *In your cover letter, include the names of people you don't want to review your application, e.g., a competitor or someone with whom you have a long-standing scientific disagreement. Give the reasons for your objections but focus on the positive where possible, for example, by stating the skills needed to review the application. Remember that the first level of review is conducted by your peers…. So be judicious as you prepare such a list.*

Identify requisite scientific expertise or disciplines involved, if multidisciplinary. *Use your cover letter to indicate a specific area of scientific expertise that should be included on your study section. For multidisciplinary work, state the disciplines involved. This helps CSR properly assign your application to an IRG, if you are not requesting assignments.*

V. REVIEW OF SBIR AND STTR APPLICATIONS

Assignment to an NIH Institute or Center (IC) and Integrated Review Group

After you've mailed your application to NIH, CSR gives it a unique identifier. In addition, CSR assigns your application to an Integrated Review Group (IRG) for review, and makes a primary assignment to one of the ICs and secondary assignments to other ICs whose missions are relevant to the proposed project. You can let CSR referral officers determine where the application will go (using their referral guidelines), or you can request these assignments in your application Cover Letter. To see areas covered by the CSR study sections, go to CSR's Scientific Areas of Integrated Review Groups.

Having your application assigned to the right IRG can help make sure the right people review your application and exclude your competitors. Asking for an IRG lets you choose a group of study sections that may be friendly to your type of research. Since SBIR/STTR study sections (special emphasis panels) are assembled ad hoc, you will not know exactly who is on your review committee. This is all the more reason to include a cover letter to request that your "enemies" are excluded from the review committee. NIH generally honors such requests. Even if you're a new investigator, consider requesting an IRG assignment.

Frame your request in positive terms. Say that a study section has several people who are interested in your area and qualified to judge your work. Never suggest reviewers. If you do, they are immediately disqualified!

After you are notified of the assignment but before a review, you can check the committee's roster on the Web. At that point, you can call the SRA if there is a major problem, for example, a conflict of interest or no one on the committee is competent to review the application. It is often better to defer the review than be reviewed by the wrong reviewers.

Peer Review: The General Process

Applications are reviewed by a scientific review group (SRG) or "study section" composed of scientists from both academic and for-profit organizations who meet for one to three days, three times a year, to evaluate grant applications. SBIR and STTR study sections review applications that fit the overall missions of more than one IC. The study section is organized by a CSR Scientific Review Administrator (SRA). The SRA is a scientist who handles the administrative details of the meeting and is responsible for preparing a report of the reviewers' comments (summary statement) after the meeting. The summary statement, once prepared, is forwarded to the appropriate program director in the IC to which the application was assigned. The program director then forwards the summary statement to the applicant. Summary statements for applications that were "Not Scored" are automatically mailed to the applicant by CSR. (See below for more details on summary statements.)

For the review meeting, each SRA assembles a panel of reviewers with specific scientific expertise, according to the mix of applications received. This provides for a fair review of a broad range of applications.

A continually changing roster sometimes is a concern to applicants submitting revised applications. Often, the reviewers of an amended application will differ from those of the first

review. However, to provide continuity, the study section has access to prior summary statements.

At the Peer Review Meeting

Your application's most significant test is the initial peer review. Your peers -- successful scientists in your field and related ones -- will gather together to evaluate your proposal and give it a rating indicating their judgment of its quality. They use the information you have provided in your grant application to assess the quality of the science you've proposed and your ability as the PI to get the work done. Review materials are confidential. Reviewers are not allowed to divulge any information outside the meeting, and at the end of the meeting, NIH staff collects and destroys all materials used in the review. Additionally, reviewers sign conflict of interest statements showing they don't have a financial or other interest in your work.

The first task of the SRGs is to evaluate each SBIR/STTR application for scientific and technical merit and potential for commercialization, and to make an SRG recommendation for each application on the basis of this evaluation. When assessing the scientific merit of an application, all NIH review committees use the same criteria:

- Significance: ability of the project to improve health
- Approach: feasibility of your methods and appropriateness of the budget
- Innovation: originality of your approach
- Investigator: training and experience of investigators
- Environment: suitability of facilities and adequacy of support from your institution

Guess what? These are the same review criteria you were encouraged to use in preparing your application. The questions that follow each of these criteria in Chapter VI of the PHS 398 are also there to assist you in the writing of the various sections of your application. Though weights are not assigned to each of these criteria, the criteria are gauges for assessing scientific merit and feasibility. In writing your application, aim to convince peer reviewers that your research is important, your approach is logical and innovative, you have the resources to do the job, and you and your collaborators are qualified to accomplish the research.

Several weeks before the study section meets, the SRA sends each study section member a copy of the applications to be reviewed. The SRA assigns at least two study section members to be the reviewers and to write critiques prior to the meeting. These are the people who read your application thoroughly. The SRA may also ask one or more members to serve as readers, who identify strengths and weaknesses of the application. The SRA will also ask one or more members to serve as readers, who identify strengths and weaknesses of applications. However, the discussion usually involves many more study section members than those assigned to review it.

A streamlined procedure is employed in which, prior to the meeting, reviewers are asked to categorize applications assigned to a study section as either in the *approximate* “upper (more meritorious) half” or “lower (less meritorious) half” based on a priority score range from 1.0 (most meritorious) to 5.0 (least meritorious). Applications in the “upper half” are given full discussion at the study section meeting, receive a priority score, and are routinely taken to advisory council for second-level review. Streamlined applications in the “lower half” are not

discussed or numerically scored at the study section meetings. A few days prior to the study section meeting, all study section members receive a list from the scientific review administrator (SRA) identifying applications proposed by at least two assigned reviewers/readers to be excluded from the “upper half,” so that all members might give additional attention to these. In both cases, all applications are reviewed and applicants are provided with the reviewers’ essentially unedited comments as part of the summary statement.

Discussion during the review meeting focuses on the more meritorious applications, which are more likely to be funded. However, any review group member may identify an application that he or she believes should be discussed at the meeting. At the beginning of the meeting, the list is read aloud for final concurrence by the entire study section. If any member of the study section questions the rating or wishes to comment on an application, the study section will discuss and consider it in the normal sequence of review.

The Chairperson of the SRG introduces each application proposed for discussion and calls upon the reviewers assigned by the SRA to present their written comments. The assigned discussants are then called upon for their comments and group discussion follows. If the study section determines that the application being discussed should be moved to the “lower half,” it may recommend that the application not be scored. Such a designation requires unanimous agreement of the scientific review group. Otherwise, after sufficient discussion the Chairperson calls for a priority rating to be assigned to the application.

For applications that are scored, each member records a numerical rating to two significant figures (e.g., 1.2) to reflect the member's opinion of the merit of the application. The individual scores are averaged and then multiplied by 100 to yield a single overall score for each scored application (e.g., 123.) Abstaining members and those not present during the discussion do not assign a numerical rating and are not counted in calculating the average of the individual ratings. A score of 1.0 signifies the highest scientific and/or technical merit. Under the currently employed streamlining procedures, a rating of 3.0 would be considered the median score for the cohort of applications that a scientific review group might review. If a reviewer believes that a scored application ranks in the lower half of applications generally considered by that study section, a score greater than the median may be assigned to the application by that reviewer.

The second task of the SRG is to make budget recommendations concerning time and dollar amounts that are appropriate for the work proposed. *Phase I applications typically fall under the modular format, so there is not extensive discussion about the budget. Phase I budgets that exceed the $100,000 guideline and Phase II budgets receive much more scrutiny. Justify your budgets thoroughly or the reviewers will make budget reductions that could impact your ability to conduct the research you have proposed.*

Additional information on the peer review procedures and streamlining process used at NIH may be found in a document entitled "Streamlined Review Procedures Used in CSR" (available at http://www.csr.nih.gov/REVIEW/streamln.htm), and in a document entitled "New Scoring Procedure to be Used by CSR Study Sections" (http://www.csr.nih.gov/REVIEW/scoring.htm).

After the Peer Review Meeting

After the meeting, the SRA prepares a summary statement for each application. All grant applications, whether categorized in the “upper half” and scored or in the “lower half” and unscored, receive a summary statement. You will normally receive your summary statement within four to six weeks following the study section meeting in which it was reviewed. After the

review meeting occurs, you are encouraged to address inquiries to your IC Program Director, rather than to review staff.

Summary statements yield tangible results for each application. You will receive essentially unedited reviewer comments, a summary of the deliberations (for scored applications), an average priority score, recommended changes in budget, and administrative issues that need to be resolved, if any. In addition, reviewers may reflect their concerns about human subjects, animals, or biohazards. These concerns will be translated into a code on your summary statement, and it means we can't give you an award until the issue is resolved. Call your program director listed on your summary statement for advice if this happens to you.

The summary statement will list the reviewers who participated in the meeting but will not indicate which were primary reviewers or readers or which were absent from the review due to a conflict of interest. The NIH awarding components and other agencies that are serviced by CSR, such as the FDA and the CDC, receive copies of the relevant summary statements for the applications in their portfolios. *It is best to review your summary statement before calling your Program Director to learn if your application is likely to be funded.*

The summary statements for applications that are discussed will present the priority score, a resume and summary of discussion concerning the application at the study section meeting, a description of the proposed research, written critiques from the reviewers, and the roster of review panel members. The summary statements for grant applications that are streamlined and, consequently, not discussed at the study section meeting, will present a ranking of "**" to designate unscored and will incorporate the reviewers' critiques, essentially unaltered, along with a paragraph briefly describing the review process and the resultant summary statement.

If your application was not scored, it doesn't necessarily mean it was a terrible application. It could have had a serious but fixable flaw that resulted in placement in the lower half of the applications. Your task is to figure out the seriousness of the problems. Read the reviewers critiques carefully, and get advice from your Program Director and experts in your company.

Whether you have an outstanding score or an unfundable score, read the reviewers' comments to understand the strengths and weaknesses of your application. It is not unusual for reviewers to include useful and important information in their critiques that you need to consider before submission of a Phase II application.

If you believe that the review of your application is seriously flawed, e.g., bias or conflict of interest (not for cases of differences of scientific opinion), contact your Program Director to discuss your options*. It is possible that he or she was present as an observer at the review meeting to hear the discussion of your application, and, therefore, can provide information based on the discussions that took place around the table.*

How Funding Is Decided

Each IC considers SBIR and STTR applications for funding based on quality (as judged by the study section) and on the relevance of the application to the IC's mission. Some ICs set a "payline" where all applications with priority scores better (lower) than the payline are funded. The payline is likely to vary among NIH ICs since each IC has its own SBIR allocation equal to 2.5% of its extramural R&D budget.

Based on these considerations extramural Program staff prepare a prioritized list of applications for consideration by an IC's SBIR and STTR secondary review group. This review group may

be the IC's Advisory Council or it may be a different group. At the secondary review group meetings, which occur three times a year, members consider the prioritized list and summary statements of grant applications forwarded by the Program staff. The group may also consider complaints or other information from applicants regarding the quality of the review. Applications "not scored" are not considered by the second level review group.

Following that meeting, ICs take one of four actions:

1. The application may be approved for funding.
2. The primary responsibility for an application may be transferred for funding to another IC who agrees to fund it.
3. The application may be deferred for later decision, usually at the end of the fiscal year.
4. The application is not funded. See the next section on "Revised Applications".

VI. REVISED APPLICATIONS

If at first you don't succeed…re-search… re-think… re-vise… re-submit. About one-third of our Phase I applicants and 40-45% of our Phase II applicants are funded, so there is a good chance that you will have to revise and resubmit your application. The good news is that more people succeed on their second try than on their first; and still more on their third. Over half of all NIH applicants eventually get funded. The reason that you were not funded may be as simple as availability of funds….the "well" ran dry. There is a finite amount of money in this program, and the funds do eventually become exhausted.

Whatever the reason, revising is your opportunity to respond to the criticisms of the Scientific Review Group and use their comments and suggestions to improve your grant application. FIRST, talk with your Program Director to review your summary statement and obtain advice.

NIH allows two revisions of an application within a period of two years from the receipt date of the original, unamended application. If you submit a revised application, you must include an Introduction **(limited to one page for Phase I ; 3 pages for Phase II.**) Insert this section just before the Research Plan. Summarize any substantial additions, deletions and changes, and respond to criticisms in the previous summary statement. Clearly distinguish revised sections in the grant application by indenting, bracketing, underlining, or changing the type of revised text.

Common Reasons For Unscoring An Application

There are a number of common reasons for not scoring an application, but many are fixable:

Problem: Lack of innovative ideas
Solution: Beef up where the innovation in your technology lies. Is it something new or an improvement of an existing technology? Consider showing comparison charts of your technology and that of your competitor's, if it's an improvement.

Problem: Lack of defined test of feasibility
Solution: Define the metrics by which the success of your project is measured. How will you know the point at which you have established feasibility?

Problem: Significance not convincingly stated or absence of acceptable scientific rationale
Solution: Enhance that section; show importance to NIH mission. Discuss societal/public health benefit.

Problem: Lack of sufficient experimental detail
Solution: Assess what's missing; add it to the research plan.

Lack of knowledge of published relevant work
Solution: Do your homework and re-write your literature citation section.

Lack of experience in essential methodology
Solution: Hire consultants and collaborators with the required expertise. Collaborate with universities and other research institutions.

Questionable reasoning in experimental approach
Solution: Discuss what you'll do if you get negative results or an approach doesn't pan out; include decision trees.

Problem: Overly ambitious
Solution: If this is a Phase I, determine exactly what you need to complete to demonstrate feasibility. Save the rest for your Phase II.

Problem: Poor writing or Unfocused, diffuse, or superficial research plan
Solution: Rewrite, get help from experienced grantees and from NIH Program staff.

Inability to demonstrate the goals of Phase I were accomplished (Phase II applications)
Solution: Review your specific aims and milestones. Review your Progress Report data and make sure it maps to your goals. If not, you may need to conduct some additional research. Discuss this issue with your Program Director for advice.

Keep in mind that even if you respond adequately to all the criticisms in the summary statement, you are not guaranteed an award. This may happen because you run the risk of introducing new problems when you make changes. Even if the areas are not changed, it is possible that new concerns be raised since each application gets a "fresh" look. Finally, a summary statement is not meant to be an exhaustive critique; some problems discussed by the reviewers may not appear in it.

VII. WHAT TO DO WHEN YOU HAVE BEEN APPROVED FOR AN AWARD

Congratulations! You have just learned that you will be receiving an SBIR or STTR award from NIH. What's next? New awardees receive a "Welcome Wagon" memorandum with lots of important information on what to do. **Read it carefully** and also note the following tips. **File it in a place where you can easily access it.**

Required Documentation

If you know you are in the queue for an award, it is a good idea to contact your grants management specialist to find out what types of documentation you need prior to funding.

Pre-award Activities

After funding decisions are made, program directors complete their review of each application selected for funding. As a result of this review, program directors may contact you to request additional or updated information regarding your other sources of support or overlap with other projects or to resolve scientific concerns expressed by the initial reviewers regarding the involvement of human subjects, the use of live vertebrate animals, minority and gender representation, or potential biohazard problems. Grants management staff may contact you to request additional information regarding assurances and certifications or missing application documentation.

Program directors document their review and resolution of problems by completing, signing, and forwarding to the grants management specialist a documentation control form for each application to be funded. The grants management specialist and program director work together during this preaward phase of the award process.

If the application has a likelihood for funding, items that will be routinely requested by the awarding component "just in time" to make the grant award are:

- Documentation to establish the "primary employment" of the principal investigator with the applicant small business concern.
- Documentation regarding the performance site(s) of the applicant small business concern, as shown on the face page of the application, if that site is not owned by the applicant organization.
- Information regarding "Other Support" for the principal investigator and the other "Key Personnel Engaged on Project" named on form page 2, excluding consultants.

Further, there are several items NIH absolutely **must** have before it can issue an award, including **an animal welfare assurance** and/or **human subjects assurance**, and documentation of review and approval by the IACUC and/or Institutional Review Board **if item 4 or 5 on the Face Page of the application has been marked "YES"**. Instructions for submitting these assurances (if not already on file with OHRP or OLAW) will be sent to your institution in order that the assurances are completed before the anticipated date of funding. *It is a good idea to begin working on these items as soon as you learn that your score is in a range that may be fundable. Call your Program Director for advice.*

Human Subjects

To obtain information regarding the use of human subjects, visit the OHRP website at:

http://ohrp.osophs.dhhs.gov/.

To obtain information concerning a human subjects assurance, contact the Division of Human Subject Protections at the following address:

Office for Human Research Protections
Department of Health and Human Services
6100 Executive Boulevard, Suite 3B01, MSC-7507
Rockville, MD 20892-7507 NOTE: For Express or Hand Delivered Mail, Use Zip Code 20852
Phone: (301) 496-7041 E-mail: ohrp@od.nih.gov

To assist institutional review board (IRB) members, researchers, and institutional administrators, OHRP produced a 1993 publication entitled, *Protecting Human Research Subjects: Institutional Review Board Guidebook*. It is available online at:
http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm

To obtain additional instructional materials from OHRP, visit the following website:

http://ohrp.osophs.dhhs.gov/educmat.htm.

Laboratory Animals

Information regarding animal welfare assurance requirements, including the publication *Public Health Service Policy on Humane Care and Use of Laboratory Animals*, is available electronically at the following URL: http://grants.nih.gov/grants/olaw/olaw.htm.

Grants Management Review

Upon receiving a signed paylist and documentation control form from the program director, the grants management staff begin the process of developing an award. This involves a cost analysis of the proposed budget; a review for administrative compliance with DHHS and NIH policies; and, finally, negotiations with the grantee business official and/or the principal investigator. Examples of these activities are outlined below.

Financial Review

NIH is more likely to perform a financial review if your firm has not had previous Federal funding. Even so, information may be requested such as the previous year's statement of assets and liabilities (balance sheet), how your company handles its payroll and purchasing, and its accounting methods. *It is helpful to provide NIH with the name of your accounting firm.*

- *Companies with heavy liabilities raise concerns by NIH grants administrators. NIH looks at the firm's asset to liability ratio, calculated by dividing assets by liabilities. The ratios are viewed as follows: 2:1 is desirable; 1:1 is acceptable, less than 1:1 indicates insolvency.*

- If a company's ratio is less than 1:1, NIH may request a cash flow forecast covering the first budget period and evidence of a bank line of credit that can cover capital shortages. Also, if

a company lists unbilled accounts receivable under its assets, NIH may request more detailed information.

- *What if you are a new company with little or no assets or liabilities? This is not necessarily a problem. Showing a bank line of credit often will be enough to ensure the NIH that a new company has the means to pursue the research.*

COST ANALYSIS

The grants management specialist reviews the application for:

- Reasonableness of costs.
- Adherence to cost principles.
- Relationship of costs to the proposed project.
- The applicant institution's financial management capabilities.
- Similarity to, or duplication of, existing programs or projects being supported by other sources, to the extent that this can be ascertained.
- Eligibility requirements established by the SBIR or STTR Program

The extent of this analysis is a matter of judgment, based on factors such as:

- The applicant's previous experience in managing grant funds.
- IC's experience with the grantee.
- The dollar amount of the grant.
- The complexity of the grant.
- The financial history of the project.
- IC program concerns.

ADMINISTRATIVE REVIEW

In addition to analyzing the budget, the grants management specialist determines that all necessary assurances and reporting requirements have been met and that the applicant is in compliance with NIH and DHHS requirements and with other appropriate rules and policies. The following is a brief itemization of some of the issues that must be addressed, when appropriate, before an award can be issued:

- 45 CFR Part 46, "Protection of Human Subjects" compliance.
- Humane Care and Use of Laboratory Animals by Awardee Institutions compliance.
- Civil rights, handicapped individuals, and sex and age discrimination assurances.
- Debarment, suspension, and voluntary exclusion certification.

- Drug-free workplace certification.
- DHHS-approved entity identification number (EIN) for the applicant institution.
- Facilities and Administrative costs.
- Invention statements.
- Lobbying certification and disclosure.
- Assessment of applicant institution's management capability.
- Appropriate choice of mechanism (grant/contract/cooperative agreement).
- Misconduct in science assurance.
- Non-delinquency on Federal debt certification.
- Peer-review recommendations.
- Administrative notes from peer reviewers on the summary statement.
- Program income.
- Availability of proposed project staff.
- Recombinant DNA compliance.
- Scientific and budgetary overlap with other support.
- Time and effort over-commitment.

Negotiation

The primary purpose of negotiating an award is to establish the appropriate funding level, resolve identified problems, and agree on specialized terms and conditions of award, if needed. The degree and form of the negotiation depend on a variety of factors, such as the dollar amount and complexity of the project and the nature of the problems identified. The grants management specialist can usually complete negotiations and obtain needed information by telephone or through correspondence.

Preparation of Awards and Obligation of Funds

The Notice of Grant Award (NGA) is the official notification to the applicant that the project is being funded. The NGA document has recently been changed to a letter format and is transmitted electronically by the Grants Management Officer.

The Notice of Grant Award contains:

- The name and address of the grantee institution.
- The title of the project.

- The name of the principal investigator under whose direction the research is to be carried out.
- The period of grant support.
- The amount recommended for future years of support.
- Any special grant terms and conditions of award.
- In addition, all competing award notices and all noncompeting award notices, except those in the streamlined noncompeting application population (SNAP), show the authorized direct costs by budget category (e.g., personnel, supplies), thereby constituting prior approval for the expenditure of funds for specific purposes and items described in the grant application and/or agreed upon during negotiations. Facilities and Administrative costs are also included on the NGA.

If the awarding office has determined that a prospective grantee is financially unstable, has a history of poor performance, or has a management system that does not meet the agency's standards, the awarding office may impose special conditions more restrictive than those prescribed by standard grant policy, or may delay issuing the award until it is satisfied that the agency's standards have been met.

The Grants Management Officer certifies in signing the grant award that:

- The choice of the award mechanism is proper under applicable policy.
- The application on which the award is based was properly peer reviewed.
- The award amount is accurate and appropriate for the grant-supported activity.
- The applicant organization (your company) is judged to have (or is expected to acquire) adequate business management capability to administer the grant and account for Federal funds.
- The award is being made under the terms and conditions specified for the particular program and is consistent with appropriate review recommendations.
- The award is consistent with governing legislation, regulations, and policies.

All review and award actions are clearly documented in the official grant files.

The award amount is forwarded to the Office of Financial Management, NIH, where it is recorded as an obligation in the NIH official accounting records. A copy of the NGA letter is transmitted to the grantee business office. Internal copies are distributed to appropriate NIH and NCI offices.

Terms and Conditions of Award

The National Institutes of Health Grants Policy Statement (NIHGPS) is included as part of the Welcome Wagon packet to all new institutions. Acceptance of the award means that you agree to be bound by the “Terms and Conditions” of the award. To learn more about these, you may access it on the Internet at http://grants.nih.gov/grants/policy/policy.htm. The current GPS was issued in March 2001.

Post-Award Administration

Getting Paid

To get paid, you first must have an Employer Identification Number (EIN), which you obtain from the U.S. Internal Revenue Service (IRS). You will retain the same EIN for other grants.

As a grantee, your organization will be paid by electronic transfer of funds directly into its bank account as you report incurred expenses.

To minimize the impact of cash withdrawals on the public debt level and to reduce related financing costs, the U.S. Department of the Treasury has issued regulations governing the flow of cash to recipient organizations. Specifically, grantees should not request funds until actually needed for disbursement purposes. Grant payments are administered by the DHHS Payment Management System (PMS.) PMS will assign you a 12-digit EIN for payment and accounting purposes (this number is an expansion of the 9-digit EIN assigned by the IRS) and payment is primarily made by Electronic Funds Transfer. You can request DHHS grant funds by telephoning the Division of Payment Management to use the CASHLINE process or by accessing SMARTLINK II via a computer modem connection. Funds are deposited directly into the recipient's bank account on the next business day.

Information on the Payment Management System is available from:

Division of Payment Management

P.O. Box 6021

Rockville, Maryland 20852

(301) 443-1660.

What You Can and Cannot Pay for on a Grant

The allowableness, allocability, reasonableness, and necessity of direct and indirect costs that may be charged to Public Health Service (PHS) awards are outlined in the Federal Acquisition Regulations (FAR) 48 Subpart 31.2. A copy of this document may be obtained from the NIH Office of Contracts Management (301) 496-2444 or on the Internet at http://www.gsa.gov/far/. In addition, you may want a copy OMB Circular A-133, which describes administrative standards and audit requirements for organizations receiving Federal assistance.

Briefly, your grant can pay for the actual costs of research proposed in the grant application (direct costs) plus an appropriate percentage of the allowed amount of your organization’s other expenses (indirect costs) that are not specifically identified with a project.

You may propose estimated indirect costs at a rate not to exceed 40 percent of the total direct costs for your Phase I grant. This is the ceiling for all Phase I grants to organizations that do not have a formal, currently negotiated indirect cost rate agreement.

An indirect cost rate not to exceed 25 percent of the total direct costs for Phase II projects will also be allowed without formal NIH negotiation. However, if you propose a rate greater than 25 percent of the total direct costs for your Phase II SBIR/STTR grant, you will have to separate your expenses into direct and indirect costs and establish an "indirect cost rate" through a formal agreement between your organization and the Federal Government.

Instructions on indirect cost determinations may be found in the SBIR and STTR solicitations but you will probably want to leave the details to an accountant who is knowledgeable about negotiating Federal indirect cost rates. You will probably want to ask an accounting firm familiar with Federal funding to help you understand and comply with regulations. Also, you may need help from them to determine the best method to address tax issues related to receipt of grant funds.

You may obtain more information on indirect rates from the following office:

Chief, Division of Financial Advisory Services
Office of Contracts Management, NIH
6100 Executive Boulevard, Room 6B05
MSC 7540
Bethesda, MD 20982-7540
(301) 496-2244

Reporting Requirements

You are required to submit the following reports within 90 days of the end of the grant support period unless an extension is granted by the Grants Management Office (GMO):

- Financial Status Report (OMB 269)
- Final Progress Report (no form)
- Final Invention Statement and Certification (HHS 568)
- Annual Invention Utilization Reports

Failure to submit timely final reports may affect future funding to your organization or awards with the same Principal Investigator.

FINANCIAL STATUS REPORT.

This is a way of accounting for your funds. You are required to submit a Financial Status Report (FSR) on Standard Form (SF) 269 or 269A to report expenditures and remaining funds at the end of Phase I and Phase II. This form is available at: http://www.whitehouse.gov/OMB/grants/index.html. You may be asked to submit an FSR at the end of the first year of Phase II for Fast-Track SBIR grants. For information contact:

National Institutes of Health
Office of Financial Management
Government Accounting
Building 31, Room B1B05 MSC 2050
Bethesda, MD 20892-2052
(301) 402-9123

Alternatively, NIH has established a system for the electronic transmittal of FSRs, which allows participants to submit FSRs electronically. You can contact the office listed above to learn how to use this system.

PROGRESS REPORT

The recommended length for the narrative portion is 10 pages.

All NIH awards require an annual progress report, which usually is submitted with the application for continuation support. You will usually include your Phase I progress report with your application for Phase II funding. However, if you will not be submitting a Phase II application, or if you will be submitting a Phase II application more than 90 days after the end of Phase I, you will need to submit a final progress report within 90 days after the termination of the Phase I grant.

There is not a specific "form page" for the Phase I Final Progress Report. However, items to be covered should include

a) beginning and ending dates for the period covered by the Phase I grant;

b) list of all key personnel;

c) their titles, dates of service, and number of hours devoted to the Phase I project;

d) summary of specific aims of the Phase I grant;

e) succinct account of published and unpublished results, indicating progress toward their achievement;

f) summary of the importance of the findings;

g) specific changes in the specific aims;

h) list of titles and complete references to publications, manuscripts accepted for publication, patents, invention reports, and other printed materials, if any, that resulted from the Phase I effort. Submit **the original plus one copy**, with the exception of patent and invention reports, which are submitted as an Appendix **(1 copy)**. No-Cost Time Extension to Complete Research

Sometimes you need additional time to complete your research. First, talk with your Program Director. Then submit a request in writing to the Grants Management Specialist in charge of your grant at your IC. The name of your Grants Management Specialist is listed on your Notice of Grant Award. You must explain why an extension is needed, identify the specific research that needs to be completed, the reason it is delayed, and the amount of unexpended funds to be used. The request must be signed by both the Principal Investigator and your company's business office. This request should be submitted 30 days prior to the end of the project period. *Use the budget page form from your grant application as a guide to help you provide the necessary budget information.*

NOTE: Phase II grants do not require prior approval of a no-cost extension but do require that NIH be notified in writing 10 days prior to the expiration date of project period.

FINAL INVENTION STATEMENT AND CERTIFICATION (HHS-568)

You must submit to the IC that funded your grant a Final Invention Statement and Certification (HHS-568), whether or not an invention(s) results from work under the grant. The URL to

access this form is http://grants.nih.gov/grants/hhs568.pdf. We have dedicated an entire Chapter (Chapter VII) to assist you in understanding your requirements.

IMPORTANT: All inventions made in the course of, or under, any NIH research grant, including SBIR/STTR awards, must be promptly and fully disclosed to NIH within 2 months after the inventor provides written disclosure to the grantee's authorized official.

ANNUAL UTILIZATION REPORT

You must submit an annual utilization report when you have elected title to an invention or when royalties or licensing fees are generated for inventions that are not patented. NIH has developed an optional online Extramural Invention Information Management System, known as "IEdison," to facilitate grantee compliance with the disclosure and reporting requirements of 37 CFR 401.14(h). The URL for IEdison is http://www.iedison.gov. Information from these reports is not made publicly available.

For a summary of grantee/contractor invention responsibilities, which provides you with information on time limits placed by law and identifies specific invention reporting actions that you must take, go to http://www.iedison.gov/timeline.html.

Reasons You Could Lose Your Grant

Though it doesn't happen often, a company may lose its small business grant if 1) the company goes out of business or appears to be insolvent; 2) the PI leaves and there is no suitable replacement; or 3) the PI takes the grant to another company (both companies must agree).

If the business no longer qualifies as a small business (e.g., purchase by a larger non-qualifying company), the award may be retained, but a Phase II application may not be submitted following completion of a Phase I.

VIII. REQUIREMENTS FOR FINANCIAL AND BUSINESS MANAGEMENT SYSTEMS FOR SBIR/STTR AWARDEES

If the pending application is funded the organization must have the following financial and business management systems in place. This requirement will be referenced in a term (condition) of award. **It is important for your organization to be aware that an awardee's failure to follow the applicable laws, regulations and policies in the National Institutes of Health Grants Policy Statement (NIH GPS), October 1998, could result in audit disallowance, suspension, and/or termination of an award(s) and could jeopardize any future funding. This includes, but is not limited to, compliance with the policies, procedures and systems described below.**

The electronic copy of the NIH GPS is available on the NIH Home Page at http://grants.nih.gov/grants/policy/nihgps**.**

As the awardee, you must have records that document the following:

General Information

1. The organization meets the criteria to qualify as a "small business," as defined in the Omnibus Solicitation of the National Institutes of Health for SBIR Grant and Cooperative Agreements Applications and the Omnibus Solicitation of the National Institutes of Health for STTR Grant Applications.
2. Lines of authority and responsibility of officers and key personnel.
3. Recent audits by a government agency and/or independent public accountant other than financial statements.
4. Names of officials with authority to sign for the organization.

Financial Stability

1. The most recently audited financial statement; or if the organization does not have an audited financial statement, a current balance sheet.
2. If the working capital ratio (total current assets divided by total current liabilities) on the financial statement or balance sheet is less than 1:1.
   a) A cash flow forecast for the organization covering the entire budget period.
   b) A bank line of credit or other source of funds that could be accessed to cover working capital shortages.
   c) Information regarding any outstanding loans.

Accounting System: Is a Double-entry System

1. Maintains the basic books of account; e.g., cost journal, general ledger, project ledger, chart of accounts.
2. Identifies individual receipts and expenditures for each grant or contract.
3. Maintains a separate ledger for indirect costs and separate ledgers for each project.
4. Maintains documentation supporting accounting entries; e.g., purchases orders, vouchers, vendor payments, etc.
5. Records expenditures for each program by required budget cost categories.
6. Provides for the timely billing and payment of accounts receivable and payable.

Internal Controls

1. All accounting entries are supported by appropriate documentation.
2. All checks are approved by an authorized official before they are signed.
3. All checks are prenumbered and accounted for when the general-purpose bank account is reconciled.
4. Safeguards are in place to prevent misuse of any petty cash funds.
5. Employees who handle funds are required to be bonded against loss by fraud or dishonesty.

Personnel

1. How salary levels are established; e.g., comparability survey (Employee compensation should be comparable to the compensation for employees with similar skills in the same geographical area);
2. Salaries of personnel supported by Government projects are not higher than salaries of personnel in similar positions supported by the institution's funds.

Time and Effort Reporting

The policy on the time and effort reporting system for professional and nonprofessional staff, including the position of staff approving/certifying time and effort and the frequency of the after-the-fact certification process. *NOTE: Commercial grantees should comply with industry standards and maintain daily time records identifying hours expended on individual projects and/or activities. Manual reports should be signed by the employee and by a supervisory official with first-hand knowledge of the activities performed. The time and attendance system should be positive, reflecting the total number of hours worked and hours absent each day.* See FAR 31.205-46 at http://www.arnet.gov/far/

Consultant Services (if applicable)

1. A written policy must describe the internal process for establishing the need for consultants, their selection, and the rates to be paid. Procedures must require consultants to sign

consulting agreements outlining services to be rendered, duration of engagement, pay rates, and procedures for monitoring or reporting progress. These agreements should also address compliance with applicable Federal regulations and NIH policies.

2. The organization must be able to support charges for consultants to grants with documentation and information required in the NIH Grants Policy Statement, October 1998, pp. II 40/41.

Equipment/Property Management System

1. Property records that outline the description, cost, including information necessary to calculate the percentage of Federal participation in the ownership, acquisition date, source of property, location, use and condition, and ultimate disposition data.

2. Written procedures for screening proposed purchases of equipment to avoid unnecessary or duplicate purchases.

3. Identification procedure for tags or labels on equipment purchased with Federal funds to indicate Government ownership and a records system that identifies the grant under which the equipment was acquired.

4. Written procedures for identifying equipment purchased with Federal funds and for conducting an annual physical inventory of equipment.

5. Controls to ensure adequate safeguards to prevent loss, damage, or theft of the equipment.

6. Maintenance program to keep the equipment in good use and working condition.

   NOTE: Title to equipment acquired by a recipient with grant funds is vested in the recipient. The management, control, and disposition of property will be governed by the rules and regulations, which are set forth in 45 CFR Part 74.34. Further information is available upon request from the Chief, Property Accountability Section, Personal Property Branch, NIH; Telephone: (301) 496-6467; FAX: (301) 496-8428.

Travel (if applicable)

1. Written travel policies that comply with requirements in the *NIH Grants Policy Statement*, October1998, pp II 50/51. *NOTE: If there is no written travel policy, Federal Travel Regulations must be used, including the maximum per diem rates and subsistence rates prescribed in those regulations, to determine the amount for travel costs.*

2. Written travel requests that show the purpose of the trip and that are reviewed and approved by an authorized organizational official prior to the trip.

3. Receipts are required for lodging and meals if reimbursement is based on actual costs.

   NOTE: Regardless of organizational policy, for-profit organizations may not charge travel cost to grants that exceed Federal travel limitations. The GSA Federal Travel Regulations are available on the Internet at
   http://www.policyworks.gov/org/main/mt/homepage/mtt/ftr/ftrhp.shtml

Consortium Arrangements (if applicable)

1. A written inter-institutional agreement with consortium institutions that complies with the NIH requirements for consortium agreements which are set forth in the NIH Grants Policy Statement, October 1998, pp. III 64-66.

2. Written procedures for monitoring compliance with Federal regulations and NIH Policies at cooperating institutions if research involving human subjects or live vertebrate animals is being conducted at cooperating institutions.

Procurement

1. Who has the responsibility for purchasing?

2. Purchase orders for all equipment and services.

3. How quality, cost, source selection, etc., are considered.

4. How partial deliveries are handled.

5. When competitive bids are required.

6. How invoices are checked and authorized for payment.

7. The procedure to screen subcontractors to insure that debarred or suspended individuals or entities are not utilized.

8. Procedures that assure that minority firms, women-owned firms, and labor surplus area firms are used whenever possible as required in *NIH Grants Policy Statement*, October 1998, pp. II 75/76.

Program Income (if applicable)

1. Who is responsible for identifying program income?

2. How program income is generated.

3. Record keeping procedures for recording the earning, receipt, and disposition of the program income for which the institution is accountable.

4. A management system that adequately identifies and reports program income for each government project.

Standards of Conduct

NIH grants are subject to requirements intended to ensure that organizations are responsible in their handling of Federal awards, and to minimize the opportunity for improper financial gain on the part of employees, consultants, members of governing bodies, and others who may be involved in grant-supported activities, and to limit the potential for research results to be tainted by possible financial or other gain. In addition, NIH grantees are expected to provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research. Written administrative policies ensuring the ethical and safe conduct in

Science and organizational operations must be in accordance with the *NIH Grants Policy Statement*, October 1998, pp.II-12 through II-17.

Laboratory Notebooks

We recommend that organizations develop and implement a written policy covering laboratory notebook procedures. While not subject to Federal requirements, laboratory notebooks are vitally important as evidence for intellectual property rights to secure adequate patent rights. On the rare occasions when the laboratory notebook must be produced, it is absolutely necessary that it be a record that is sufficiently complete that another scientist can understand and reproduce the work, and that there is a witness who can give corroborating testimony if needed.

SBIR/STTR Policy Regarding Indirect Costs

PHASE I GRANTS

If your company has currently effective negotiated indirect costs rates with a Federal agency, such rates should be used when calculating proposed indirect costs. (However, these rates must be adjusted for independent [self-sponsored] research and development expenses, which are not allowable by the Department of Health and Human Services. A full discussion of "Indirect Costs" is contained in the SBIR and the STTR solicitations.) *If your company does not have currently effective negotiated indirect costs rates with a Federal agency, you may propose estimated indirect costs at a rate not to exceed actual or 40 percent of the total direct costs, whichever is less. However, remember that only actual indirect costs are to be charged to projects.* The Financial Advisory Services Branch, NIH, which is the office responsible for negotiating indirect cost rate agreements with for-profit institutions, will not negotiate indirect cost rates for Phase I awardees.

PHASE II GRANTS

If your company does not have currently effective negotiated indirect costs rates with a Federal agency, the applicant organization should propose estimated actual indirect costs. *If being considered for an award, you would be asked to submit detailed documentation justifying the proposed rate if it exceeded 25 percent of the total direct costs. However, you are reminded that only actual indirect costs are to be charged to projects.* If the proposed rate exceeds 25 percent of the total direct costs, you will be contacted by the Financial Advisory Services Branch, NIH, which is the office responsible for negotiating indirect cost rate agreements with for-profit institutions.

Research Involving Human Subjects and/or Live Vertebrate Animals

If your application includes research involving human subjects in non-exempt categories under 45 CFR Part 46 and/or live vertebrate animals and the organization does not have approved assurance(s) of compliance with the Office for Human Research Protection (OHRP), DHHS, that cover the research, your organization will be contacted by OHRP if the pending application is selected for funding. We urge your prompt attention to this matter since the NIH cannot issue an award until OHRP has approved the required assurance(s). The telephone number for OHRP is (301) 496-7041 (Human subjects) and 301 496-7163 (Vertebrate Animals). Additional information is available on OHRP's homepage at http://ohrp.osophs.dhhs.gov/.

Clarification of Audit Requirements for For-profit Organizations Including SBIR/STTR Grantees

http://grants.nih.gov/grants/funding/sbir_policy.htm#audit

Be aware that you may be audited. Audit requirements for Federal award recipients are defined in OMB Circular A-133, except that recipients of SBIR Phase I awards receiving no more than $100,000 in cumulative Federal awards **in a given year** are exempt. However, your organization must have all necessary records available for review by NIH should NIH elect to do so. For technical assistance pertaining to A-133, call the Department of Health and Human Services (DHHS) regional office in Kansas City on (800) 732-0679 or (816) 374-6714.

HHS has specified the requirements for non-Federal audits of for-profit organizations in 45 CFR 74.26(d). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of $300,000 or more under one or more HHS awards and at least one of those awards is an HHS grant (as a direct grantee and/or under a consortium agreement). 45 CFR 74.26(d) essentially incorporates the thresholds and deadlines of OMB Circular A-133 but provides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements. The grantee may either have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), GPO stock # 020-000-00-265-4, of all the HHS awards; or (2) an audit that meets the requirements of OMB Circular A-133.

OMB Circular A-133 is available electronically at http://www.whitehouse.gov/OMB/circulars/a133/a133.html.

The Government Auditing Standards are available electronically at http://www.ignet.gov/ignet/internal/manual/yellow/yellow.html.

Audits shall be completed and submitted to the following office within a period of time that is the earlier of (1) 30 days after receipt of the auditor's report(s), or (2) 9 months after the end of the audit period, i.e., the organization's fiscal year. The address is:

National External Audit Resources
HHS Office of Audit Services
323 West 8th Street
Lucas Place, Room 514
Kansas City, MO 64105

For-profit organizations **spending less than $300,000 a year** (calculated as above) are not required to have an annual audit for that year but must make their grant-related records available to NIH or other designated officials for review or audit.

IX. GRANTEE RESPONSIBILITIES FOR INVENTION REPORTING

The Bayh-Dole Act

The Bayh-Dole Act (Public Law 96-517) of 1980 requires that inventions made with Federal funds must be reported. This regulation, which was promulgated by the Department of Commerce, encourages researchers to patent and market their inventions. It is applicable to all agencies and it applies to all funding agreements, including contracts, grants, and cooperative agreements. Its objective is to use the patent system to promote the use of inventions arising from federally supported research; encourage participation of small business firms in federally supported research and development; promote collaboration between commercial and nonprofit organizations; ensure that inventions made by nonprofit organizations and small business firms are used in a manner that promotes free competition and enterprise; promote commercialization and public availability of inventions made in the U.S. by U.S. industry and labor; and ensure that the Government obtains sufficient rights to provide the reasonable use of inventions.

The Bayh-Dole Act grants first rights to an invention fully or partially funded by a Federal agency to the grantee/contractor organization. However, to obtain these rights, the inventor and the organization must meet several reporting requirements that protect the rights of the Government. Table 6 summarizes these required actions and when they are due.

Additional information about invention reporting requirements may be obtained from:

Extramural Inventions and Technology Resources Branch, OPERA, NIH
6705 Rockledge Drive, Room 1140A, MSC 7750
Bethesda, MD 20892-7980
(301) 435-1986; Fax (301) 435-0272
E-mail: edison@od.nih.gov
Interagency-Edison Home Page: http://www.iedison.gov

DEFINITION OF AN INVENTION

> "Any invention or discovery that is or **may be** patentable or otherwise protectable under title 35 or any novel variety of plant which is or may be protected under the plant variety protection act (7 USC 2321 et seq.)"

According to this definition from the U.S. Code, it is clear that an invention need not be patentable to be reported to NIH, as it may not be known whether it is patentable until a patent application has been filed and prosecuted.

Inventions That Must Be Reported

A reportable invention or "Subject Invention" as defined in the Bayh-Dole Act is any invention conceived or first actually reduced to practice with funds from an NIH grant. An invention could still be reportable, even after an initial patent application has been filed. The fact that you may have filed a patent application prior to applying for an NIH grant does not mean it is not reportable particularly if the invention is first reduced to practice in the performance of work on

the grant. If you are unsure whether the discovery is a subject invention and if you are concerned that the invention is particularly valuable, you may wish to obtain an opinion from an outside patent counsel.

NIH has an electronic system for reporting inventions on the Internet, called Interagency Edison. You can log in at http://www.iedison.gov/

The awardee organization is responsible for the following:

- Disclosing an invention to the NIH in writing within two months of the inventor's initial report to the organization. This disclosure must be complete in technical detail to convey a clear understanding of the invention. There is no standardized format.

- Electing title to invention within two years of disclosure to NIH. Sometimes election is made at the time of disclosure of the invention when it is clear that a grantee/contractor plans to file a patent application. **For inventions that have been disclosed to the public, notify NIH sixty days prior to the statutory bar date, which is usually one year after the date of publication, sale, or public use.**

- Informing NIH when the grantee/contractor organization does not wish to take title to an invention. For inventions not disclosed to the public, NIH should be notified at least sixty days prior to the end of the two-year period after disclosure.

- Filing a patent application within one year of election of title or public disclosure, whichever is earlier. The patent application must include the Federal support statement: "This invention was made with U.S. Government support under (grant or contract number) awarded by (agency). The U.S. Government has certain rights in the invention." The page of the patent application that contains the Federal support clause must be sent to NIH.

- Providing NIH with a nonexclusive, nontransferable, irrevocable paid-up license to make or use the invention throughout the world. This is available electronically at http://www.iedison.gov/

- Providing NIH with patent number and issue date at time of issuance of the patent.

- Reporting utilization annually subsequent to electing title.

- Completing a final invention statement prior to closeout of the NIH grant or contract. This form [HHS 568] is to be submitted directly to the awarding NIH institute or center (IC).

Except for the Form HHS 568 all information should be sent to Extramural Invention Reporting, National Institutes of Health, Rockledge I, Room 1140A, Bethesda, MD 20892-7980.

CONSEQUENCES OF FAILING TO COMPLY

Failure to report inventions appropriately is usually caused by "ignorance of the law" or a misunderstanding of the legislation and its implementing regulations. This oversight is based on the incorrect premise that the Government will inappropriately interfere with the commercialization of subject inventions. In fact, the Bayh-Dole Act provides very few restrictions on commercial development.

As long as government funded inventions are reported and commercially viable inventions are being reasonably developed by the organization (which is in everyone's interest), Government

involvement is limited to retaining its confirmatory, nonexclusive license. On the other hand, failure to comply with the reporting requirements of the Standard Patent Rights Clause [37 CFR 401.14(d)] can result in loss of the recipient's rights to an invention or the use of the Government's right to march-in. In addition, the latest version of the PHS Form 398 grant application (revised 1995) includes a penalty clause for the improper reporting of an invention or failure to report an invention.

For further information and to obtain a "License to the United States Government" form, contact:

Division of Extramural Invention and Technology Resources
National Institutes of Health
6701 Rockledge Drive MSC 7750
Bethesda, MD 20892-7750
Telephone: (301) 435-1986
FAX (301) 480-0272

Counsel on Intellectual Property
Office of the General Counsel
National Institutes of Health
Building 31, Room 2B-50
Bethesda, MD 20892
Telephone: (301) 496-4108
FAX (301) 402-1034

RIGHTS OF GRANTEES FOR INVENTIONS MADE WITH NIH FUNDS

SBIR grantees may retain title to subject inventions throughout the world provided the government is granted a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention. Occasionally a firm will argue that it does not want to accept a grant if its inventions will be subject to a license to the Government. **Nonetheless, it should be noted that under 28 USC 1498, all U.S. patents are subject to a license to the Government, although reasonable compensation must be provided.**

MODEL AGREEMENTS FOR ALLOCATION OF RIGHTS

A sample of an NIH STTR Agreement can be found in the STTR Omnibus Solicitation at http://grants1.nih.gov/grants/funding/sbirsttr1/STTRModelAgreement.rtf

Table 6. Action and Timing of Invention Reporting Requirements

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. EDISON	NIH CONTACT
Employee Agreement to Disclose All Inventions: The agreement to be obtained by the grantee/contractor organization is that the employee will abide by the terms of the patent rights clause.	At time of employment— term of employment.	Grantee/contractor organizations must have policies in place regarding ownership of intellectual property, including conflict of interest issues.	401.14(f)(2)		Extramural Inventions & Technology Resources Branch, OPERA
Invention Report: A report of an invention that identifies inventor(s), federal agency grant or contract number, and date of any public disclosure. Date of submission establishes time frames for all future actions. Must be complete in technical detail. The term "subject invention" means any invention of a grantee or contractor organization conceived or first actually reduced to practice in the performance of work under a federal funding agreement.	Within 2 months of inventor's initial report to the grantee/contractor organization.	There is no single format for disclosure, acceptable in any form. Cover letter stating existence of invention, and written technical detail, signed by the inventor. Must be in writing, fax copy acceptable.	401.14(a)(2) 401.14(c)(1)	Notification of existence of invention done electronically, invention disclosure document (signed by inventor) accepted via fax.	Extramural Inventions & Technology Resources Branch, OPERA
Rights to Inventions on Subcontracts: Subcontractors retain rights to their subject inventions.	Same reporting responsibilities, obligations and time frames as prime grantee/ contractor organization.	Prime grantee/contractor organization cannot require ownership of subcontractor's subject invention(s).	401.14(g)(1) 401.14(g)(2)		Grants or Contracts Management Office
Election of Title to Invention: Grantee/contractor organization notifies NIH that it will retain ownership of invention and take steps to commercialize the invention.	Within 2 years of reporting to NIH. If disclosed publicly, this period is decreased.		401.14(b) 401.14(c)(2) 401.14(f)(1)	Election of title handled electronically using Edison, otherwise a signed paper document is required.	Extramural Inventions & Technology Resources Branch, OPERA
Non-election of Title to Invention: Grantee/contractor organization notifies NIH that it will not retain ownership of an invention, or grantee/contractor does not elect to retain title within 2 years from date invention is reported. Title then vests with the government.	Within 2 years of reporting to NIH. If disclosed publicly, this period is decreased.	Effectively a waiver to the government. Cognizant NIH Technology Development Coordinator may elect title on behalf of the government.	401.14(c)(2) 401.14(d)	Handled electronically through Edison, otherwise a signed document is required.	Extramural Inventions & Technology Resources Branch, OPERA
File Patent Application	Within 1 year after election of title.	Time frame may vary if invention made public.	401.14(c)(3)		File with U.S.Patent and Trademark Office
Assignment to Third Party: Grantee/contractor organization must first waive rights to the invention. NIH Office of Technology Transfer must	Action must be taken during the 2 year	If waiver approved, third party has 1 year to file patent and is bound by	401.14(k) for non-profits.	Information available on Edison Home	Extramural Inventions &

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. EDISON	NIH CONTACT
decide whether to take title on behalf of the government, allow a third party to obtain rights, or move the invention into the public domain. Decision must be coordinated through cognizant NIH Technology Development Coordinator and OPERA. Note: Non-profits cannot assign rights without the government's permission.	disclosure period, plus any extensions in time.	same conditions imposed on grantee/contractor organization. If not filed, government takes title. Third party responsible for keeping government informed.	Note the distinction between small businesses and non-profit organizations.	Page. Require signatures of grantee/contractor organization and third party. At present, this cannot be done entirely electronically.	Technology Resources Branch, OPERA
Inventor Certification: Documentation needed when a grantee/contractor organization waives rights to the invention and the inventor is interested in pursuing the invention. The government must waive its rights before any other party can elect title. The inventor or third party has the same responsibilities as the grantee/contractor organization. Grantee/contractor organization can waive rights to the inventor directly with permission of the NIH Office of Technology Transfer, after consultation with the grantee/contractor. The inventor must actively pursue development (i.e., patent rights and commercialization) of the invention.	At the time the grantee/contractor organization elects not to pursue title and the inventor requests rights in the invention.	First, the grantee/contractor organization must elect not to retain rights in the invention. Second, the inventor must agree to all terms associated with invention reporting as detailed in 37 CFR 401 and must pursue patent and commercialize. Must be in writing, fax copy acceptable. See: http://www.iedison.gov/Edison/INVCERPR1.html	401.14(k)(1) non-profits	Status indicated using Edison; all other issues (such as outstanding documents required) should be resolved prior to proceeding further, paper receipt (via fax) of inventor certification.	OPERA assisted by: Office of Technology Transfer and Technology Development Coordinator
Issued Patent: Provide NIH with patent filing date, number, title of patent, issue date and government support clause.	At the time of issue.	Patent must include government support clause.	401.5(f)(2) 401.14(f)(4)	All data received electronically if using Edison, otherwise information required in writing.	Extramural Inventions & Technology Resources Branch, OPERA
Request for Extension of Time: For election of title, or filing a patent application.	Prior to any statutory bar.	The first extension is preapproved. Additional extensions need written approval from OPERA, with good cause shown in writing.	401.14(c)(4)	Can be requested electronically if using Edison; otherwise request must be in writing.	Extramural Inventions & Technology Resources Branch, OPERA
Discontinuance of Patent Application: Payment of Maintenance Fees, or Defense in a Reexamination or Opposition proceeding on a Patent: Must notify NIH and provide relevant information and documents (e.g., patent application or patent) such that a determination to protect government interests can be made.	At anytime in the process, but prior to established deadlines.	NIH has the option to pursue the patent application or the patent if not being properly pursued or maintained.	401.14(f)(3) 401.6	Indication may be made via Edison or through written correspondence.	Extramural Inventions & Technology Resources Branch, OPERA
Annual Utilization Report: Required for all inventions that have other than provisional patent filings or are licensed without a patent (applicable to inventions where NIH is the Primary Agency only). Report includes latest stage of development, date of first commercial sale or use, gross royalties and other income, number of licenses (small business, exclusive, non-exclusive, domestic manufacture waiver), and gross sales of any products developed from the invention .	Annually.	For grants and contracts, due October 31st. No standardized format as long as minimum required information is supplied for each invention. Data is for each federal fiscal year, October 1 through September 30 of the following year. Report license count information for	401.14(h)	Can be submitted electronically using Edison, otherwise submission may be made of the same data in writing.	Extramural Inventions & Technology Resources Branch, OPERA

ACTION	WHEN	DISCUSSION	37 CFR REFERENCE	COMPARISON PAPER VS. EDISON	NIH CONTACT
		all licenses in force for any part of the fiscal year, and royalties and sales information for income or sales made during that fiscal year.			
Annual Invention Statement (on continuation grant application; specific to grants only): Grantee organizations must certify whether a subject invention was made or reduced to practice during the previous budget period. This includes non-competing continuation (PHS 2590) and competing continuation (PHS 398) applications.	Part of the preaward application submission and review process.	For grants, response to question on the face page of the PHS 2590 grant application or as a check list item on the PHS 398 grant application. Additional details may be included in the body of the application.	401.5(f)(3)	An invention reported on a continuation application must ultimately be established in the Edison system. Use either hardcopy of electronic entry.	Grants Management Office and Extramural Inventions & Technology Resources Branch, OPERA
Final Invention Statement and Certification (Form HHS 568): For grants and contracts, report all subject inventions derived or reduced to practice during the performance of the grant or contract. If none, submit a negative report. Submit all reports to the awarding unit grants or contracts management office.	Due 90 days after the project ends.	Must be reconciled by grants/contracts management and OPERA with previously submitted information. Information available on Edison web site regarding HHS 568 submission.	401.5(f)(1)	At present, this final closeout form is paper-based .	Extramural Inventions & Technology Resources Branch, OPERA Grants or Contracts Management Office

X. USEFUL WEB SITES FOR SMALL BUSINESSES

NIH SBIR/STTR FUNDING OPPORTUNITIES SITE
http://grants.nih.gov/grants/funding/funding.htm

GENERAL INFORMATION

- SBIR/STTR Solicitations for Grants and Contracts
  http://grants.nih.gov/grants/funding/sbir.htm#sol
- Special Initiatives (Pas and RFAs)
  http://grants.nih.gov/grants/funding/sbir_announcements.htm
- Success Stories
  http://grants.nih.gov/grants/funding/sbir_successes/sbir_successes.htm
- Policy and Grantsmanship and Information
  http://grants.nih.gov/grants/funding/sbir_policy.htm
- SBIR/STTR Abstracts (NIH CRISP System) and Award Data
  http://grants.nih.gov/grants/funding/sbir.htm#data
- Collaborative Opportunities and Research Partnerships
  http://grants.nih.gov/grants/funding/collab.pdf

FORMS AND INSTRUCTIONS

- SBIR and STTR Phase I Application Instructions and Forms (PHS 398)
  http://grants1.nih.gov/grants/funding/phs398/phs398.html
- SBIR and STTR Phase II Application Instructions and Forms (PHS 398)
  http://grants1.nih.gov/grants/funding/phs398/phs398.html

  http://grants1.nih.gov/grants/funding/sbir2/index.htm

NIH Office of Extramural Research

BIOETHICS RESOURCES
http://www.nih.gov/sigs/bioethics/

BIOHAZARDS (HEALTH AND SAFETY GUIDELINES)
http://www4.od.nih.gov/oba/

CONFLICT OF INTEREST
http://grants.nih.gov/grants/policy/nihgps/part_ii_2.htm#conflictint

CONFLICT OF INTEREST SUMMARY
http://odoerdb2.od.nih.gov/gmac/topics/object_summary.html

CONSORTIUM
http://grants.nih.gov/grants/policy/nihgps/part_ii_4.htm#selectcost

CONSULTANT
http://grants.nih.gov/grants/policy/nihgps/part_ii_4.htm#selectcost

COSTS

- Cost Analysis
  http://grants.nih.gov/grants/policy/nihgps/part_ii_1.htm#costanal
- Cost Considerations
  http://grants.nih.gov/grants/policy/nihgps/part_ii_3.htm#costconsid
- Division of Payment Management
  http://grants.nih.gov/grants/policy/nihgps/part_ii_3.htm#payment
- Indirect Costs
  http://www4.od.nih.gov/ocm/dfas/dfas.htm

EXPANDED AUTHORITY
http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#expandauth

FINANCIAL REPORTING REQUIREMENTS
http://grants.nih.gov/grants/policy/nihgps/part_ii_6.htm#finreps

FREQUENTLY ASKED QUESTIONS
http://grants.nih.gov/grants/policy/coifaq.htm

INVENTION REPORTING
http://www.iedison.gov

MISCONDUCT IN SCIENCE/DHHS OFFICE OF RESEARCH INTEGRITY
http://ori.dhhs.gov/

NIH GRANTS POLICY
http://grants.nih.gov/grants/policy/nihgps/

NIH GUIDE FOR GRANTS AND CONTRACTS
http://grants.nih.gov/grants/guide/index.html

NIH HOME PAGE
http://www.nih.gov

NIH INFORMATION FOR NEW GRANTEES
Welcome Wagon Memorandum
http://grants.nih.gov/grants/funding/welcomewagon.htm

NIH News and Events/Press Releases
http://www.nih.gov/news/

Objectivity in Research
http://grants1.nih.gov/grants/guide/notice-files/not95-179.html

SNAP - Streamline Noncompeting Application
http://grants.nih.gov/grants/forms.htm

OHRP and OLAW (Humans and Animals)

- Office for Human Research Protections (OHRP), DHHS
  http://ohrp.osophs.dhhs.gov/index.htm
- Office of Laboratory Animal Welfare (OLAW), NIH
  http://grants.nih.gov/grants/olaw/olaw.htm

NIH Small Business Office for Contracting Opportunities (Procurement)

- Small Business Office for Contracting Opportunities
  http://sbo.od.nih.gov/
- e-PIC (E-Portals in Commerce)
  http://epic.od.nih.gov

SBA SBIR/STTR Site

Small Business Administration
http://www.sba.gov/SBIR

SBIR FAQS (and answers!)
http://www.sba.gov/SBIR/indexfaqs.html

Other Business Sites of Interest

Audit Information

- OMB Circulars
  http://www.whitehouse.gov/OMB/circulars
- OMB Circular A-133
  http://www.whitehouse.gov/OMB/circulars/a133/a133.html
- Audits/DCCA Information for Contractors
  http://web.deskbook.osd.mil/reflib/DDCAA/0048p/001/0048p001DOC.HTM

- Government Auditing Standards
  http://www.gao.gov/govaud/ybhtml/

FEDERAL ACQUISITION REGULATION
http://www.arnet.gov/far/

NATIONAL SBIR CONFERENCE CENTER WEBSITE
http://www.sbirworld.com

SBIR GATEWAY
http://www.zyn.com/sbir/

SBIR STATE SUPPORT ENTITIES
http://www.ed.gov/offices/OERI/SBIR/statelink.html

U. S. BUSINESS ADVISOR
http://www.business.gov/