



SBIR/STTR Programs Information Handbook

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Handbook

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SBIR Program

SBIR: GENERAL COMMENTS

The SBIR program seeks to provide funding to small businesses in order to facilitate the commercialization of innovative technologies. There is \$1.6 billion in total SBIR Program funding, individual grants/contracts up to \$100,000 in Phase I and up to \$750,000 in Phase II. Only Phase I recipients can apply for Phase II funding.

The SBIR program is best suited for companies (primarily technology-based) with a committed R & D program/strategy and long-term focus (years not months). It is not generally a good option for individual inventors or to meet short-term funding needs.

WHAT'S ENTAILED IN DOING IT

- Extensive 25-page proposal with solid technical and commercial background and strong grantsmanship. The proposal usually requires 150-200 professional hours to complete.
- Applicants are expected to know the STATE OF THE ART in the field. Consider that the reviewers are volunteers who are generally academics with expertise in the field of study, therefore...
- Homework before and during the proposal period is essential, including: knowledge of current literature and related prior successful proposals, and...
- Knowledge of current solicitations. "Get to know your customer (the specific agency) and their specific need or problem".

ADMINISTRATIVE REALITIES

- There are basic guidelines to the SBIR program, however, there are ten different funding agencies and multiple sub-agencies, all with somewhat different timetables and different rules governing the solicitations, proposals and funding.
- Accounting rules and administrative details are very important and proposal procedures vary somewhat with each specific agency. Some agencies will reject for simple errors.
- Some offer "contracts" while others offer "grants and it is important to be aware of the implications of each for things like intellectual property rights and the purchase/ownership of capital equipment.
- Some of the agencies will not consider unsolicited proposals. Others have open categories which allow companies to define the problems and "sell" their solutions.

THINGS YOU NEED IN ORDER TO BE COMPETITIVE

- A strong principal investigator is critical, i.e., credentials and/or proven track record. Preferably both.
- Good innovative science with some significant work to be done (a technical barrier to overcome)
- A well-written, clear, concise proposal. Grantsmanship is an essential. “Bad ideas will not win awards because of good grantsmanship, but good ones do lose because of bad grantsmanship”.
- A product or process that will make a technical and/or economic impact. A “platform” technology or a product with strong potential.
- Specific commercialization strategy with clear and measurable milestones.
- Outside funding sources to leverage resources and validate commercial potential.
- A strong internal and/or external team. Strategic partners to fill any weakness, add credibility and validate technical/commercial potential. The commercial viability will be judged by the same academics evaluating the science. Perception is important.
- Written business plan is necessary for Phase II but important for Phase I as well.

ADVOCACY

- The program is for small business and is designed specifically to keep big companies and university researchers out. It is a reasonably level playing field. Official numbers indicate that one in seven to 12 proposals gets funded. However, within some agencies the odds for awards for truly competitive proposals are as good as one in three or four for Phase I and even better for Phase II.

STTR Program

STTR PROGRAM (SMALL BUSINESS TECHNOLOGY TRANSFER)

STTR is an important new small business program that expands funding opportunities in the federal innovation research and development arena. Central to the program is expansion of the public/private sector partnership to include the joint venture opportunities for small business and the nation's premier nonprofit research institutions. STTR's most important role is to foster the innovation necessary to meet the nation's scientific and technological challenges in the 21st century.

STTR is a highly competitive program that reserves a specific percentage of federal R&D funding for award to small business and nonprofit research institution partners. Small business has long been where innovation and innovators thrive. But the risk and expense of conducting serious R&D efforts can be beyond the means of many small businesses.

Conversely, nonprofit research laboratories are instrumental in developing high-tech innovations. But frequently, innovation is confined to the theoretical, not the practical. STTR combines the strengths of both entities by introducing entrepreneurial skills to high-tech research efforts. The technologies and products are transferred from the laboratory to the marketplace. The small business profits from the commercialization, which, in turn, stimulates the U.S. economy.

QUALIFICATIONS

Small businesses must meet certain eligibility criteria to participate in the STTR Program.

- American-owned and independently operated
- For-profit
- Principal researcher need not be employed by small business
- Company size limited to 500 employees

(No size limit for nonprofit research institution)

The nonprofit research institution must also meet certain eligibility criteria.

- Located in the US
- Meet one of three definitions
- Nonprofit college or university
- Domestic nonprofit research organization
- Federally funded R&D center (FFRDC)

AGENCY PARTICIPATION

Each year, five federal departments and agencies are required by STTR to reserve a portion of their R&D funds for award to small business/nonprofit research institution partnerships.

- Department of Defense
- Department of Energy
- Department of Health and Human Services
- National Aeronautics and Space Administration
- National Science Foundation

These agencies designate R&D topics and accept proposals.

THREE PHASE PROGRAM

Following submission of proposals, agencies make STTR awards based on small business/nonprofit research institution qualification, degree of innovation, and future market potential. Small businesses that receive awards or grants then begin a three-phase program.

- Phase I is the startup phase. Awards of up to \$100,000 for approximately one year fund the exploration of the scientific, technical, and commercial feasibility of an idea or technology.
- Phase II awards of up to \$500,000, for as long as two years, expand Phase I results. During this period, the R&D work is performed and the developer begins to consider commercial potential. Only Phase I award winners are considered for Phase II.
- Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace. No STTR funds support this phase. The small business must find funding in the private sector or other non-STTR federal agency funding.

Proposal Development Comments

HOW TO WRITE A COMPETITIVE PROPOSAL

OVERVIEW

- Proposal should be focused on one main idea or concept.
Avoid the “shopping bag” of ideas approach.
Need to keep reviewers attention on one theme.
- Proposal should address high-quality research or research and development.
Must be at the “cutting-edge” of the subject to be investigated.
Literature review or market surveys are not appropriate.
- Proposal should involve an advanced concept related to an important scientific problem or opportunity.
Avoid small improvement in a mature technology.
- Proposal concept should have significant commercial potential.
Idea or concept that leads to the penetration of many markets is most attractive, e.g., electronic devices, software, batteries, etc.

PROPOSAL CONCEPT OR IDEA

MUST BE:

- New and innovative.
- Not a simple extension of earlier work.
- Not already in the Public Domain.
- Carefully developed.

You should have a broad knowledge of the technical fields associated with the proposal concept or idea.

Use publicly accessible technical library facilities.

Discuss concept or idea with technical colleagues.

MOST SUCCESSFUL PROPOSALS ARE COMPLETED ACCORDING TO A TIME SCHEDULE

- Provide sufficient time to think the project through.

- Adequately research background.
- Develop and rework research approach.
- Define technical objectives.
- Work Plan should be adequate to satisfy technical objectives.
- Prepare a complete draft of the proposal and leave it for a few days.
- Review proposal. Make changes that will give rise to significant improvements.
- Prepare final draft.

COMMERCIAL POTENTIAL

- Who/What will benefit from the success of this work?
- Develop either a general or specific pathway to commercial use.
- Provide cost analysis data:
 1. Have solid data for the conventional technology.
 2. Provide an estimate of how new process costs-out.
- Introduce future plans:
 1. Give an outline of where you go after this project.
 2. Develop a plan to how you will interface with an industry partner.

PROJECT PERSONNEL A KEY INGREDIENT TO SUCCESS

- Convince the reviewer that YOU are the BEST QUALIFIED to carry out the project.
- Involve one or more expert consultants in your project.
- Identify and obtain support from an industrial partner.
- Principal Investigator:
You are responsible for the project.
How and why you are qualified must be described.

Provide related work experiences.

COMMON SENSE OFTEN FORGOTTEN

- If you are not a “Real Expert” or have a “Real Innovation” do not waste your time. If you cannot reference prior publications, research, and/or hardware in the specific proposal area you will not be perceived as a “Real Expert”.
- There needs to be a “Real Company”.
- Get to the innovation and significance of the effort concisely, quickly and accurately.
- Accurately and fairly discuss what others have done and why the innovation is an improvement to the state-of-the-art.
- Deliver hardware and/or demonstrate the innovation in Phase I.
- Do not waste the reviewers’ time with fluff and boilerplate.
- Do not clone proposals and/or reuse proposals.

COMMON PROPOSAL CRITICISMS

1. Poorly written and presented.
2. Principal Investigator lacks necessary technical expertise.
3. Insufficient literature review.
4. Insufficient technical information.
5. Cannot be completed in six months.
6. Inadequate bibliographical information.
7. Lacks letters from consultants.
8. Research already done by others.
9. Too vague and unfocused.
10. Failure to indicate where project would go in Phase II.

11. Poor commercialization potential.
12. Doubtful economic prospects.
13. Inadequate detail in experimental plan.
14. Too much research done at university.
15. Need to engage consultants to add expertise in area where Principal Investigator is deficient.

Online Proposal Preparation Handbook

U.S. Small Business Administration Website

www.sbaonline.sba.gov/gopher/Innovation-And-Research/SBIR-Pro-Prep/

SBA Gopher

*** Innovation and Research - SBIR and STTR *** **Handbook for SBIR Proposal Preparation**

U.S Small Business Administration

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Program and Proposal Preparation

Refer to:

<http://www.sbt dc.org/technology/SBIR%20Intro.ppt>

SBIR Newsletter

Published Monthly by the NC SBTDC

Refer to archive at:

<http://www.sbtcd.org/technology/news.asp>

Sign up for the SBIR newsletter by contacting the SBIR Program Specialist via email: sbir@sbtcd.org

ZYN.com Website

An SBIR Portal

www.zyn.com/sbir

Solicitation Searches
Agency News and Links
National Calendar of Events



The Most Comprehensive and Easy to Use SBIR Information Site

EZ Solicitation Search

Resources

[SBIR Agency Links](#)

[Solicitation Dates](#)

[SBIR Events Calendar](#)

[State Newsletters](#)

[About SBIR Funding](#)

[Federal Laboratories](#)

[EPSCoR Program](#)

[Other Grant Info](#)

[SBA Policy Directive](#)

[SBA FAST Winners](#)

[Contact Us](#)

News Items

[View Latest SBIR News](#)

News Updated 08/05/03

[HHS/NIH Opens SBIR Contracts Solicitation](#)

PHS 2004-1 NIH/CDC Closes Nov 14, 2003

[NASA Opens SBIR & STTR Solicitations](#)

Opened 07/07/03 - Closes 09/9/03

[USDA FY-2004 SBIR Now Open](#)

Opened 06/26/03 - Closes 08/29/03

National SBIR Conferences

[Cleveland OH * October 27 - 30, 2003](#)

National SBIR Fall Conference 2003

Registration Now Open!!

[Atlanta GA * April 26 - 29, 2004](#)

National SBIR Spring Conference 2004

[View SBIR Conference Calendar](#)

Includes State & Regional Events

Search Services

[Open SBIR/STTR Solicitation Topics](#)

Includes All Agencies Open SBIR/STTR Topics

[Closed SBIR/STTR Solicitation Topics](#)

Topics often recycled for future solicitations

[Past SBIR/STTR Awards](#)

Searches the SBA Tech-Nef Database

[Federal Laboratory R&D Resources](#)

Keyword search for federal tech resources

Help & Assistance Services

[Find a Partner](#)

For an SBIR/STTR or related project

[State & Local Assistance Services](#)

They're here to help you

[3rd Party Assistance Services](#)

Non-Government for profit services

[Venture Capital Organizations](#)

Links to various VC and related organizations



[DOC-NOAA SBIR Page](#)

[DOC-NIST Home Page](#)

[DOD SBIR Home Page](#)

[Air Force SBIR/STTR](#)

[Army SBIR/STTR](#)

[DARPA SBIR Program Home Page](#)

[DTIC-Defense Technical Information Center](#)

[MDA \(formerly BMDO\) SBIR Program Home Page](#)

[DTRA-Defense Threat Reduction Agency](#)

[Navy SBIR/STTR](#)

[NIMA-National Imagery and Mapping Agency](#)

[SOCOM-Special Operations Command](#)

[DOE SBIR Home Page](#)

[DOT SBIR Home Page](#)

[ED \(Dept. of Education\)](#)

[EPA SBIR Home Page](#)

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Frequently Asked Questions

SBIR Frequently Asked Questions (FAQs):

From: <http://www.sba.gov/sbir/indexfaq.html>

Q. What is the SBIR Program?

The Small Business Innovation Research (SBIR) Program is a highly competitive three-phase award system which provides qualified small business concerns with opportunities to propose innovative ideas that meet the specific research and research and development needs of the Federal Government.

Q. What are the three phases of the SBIR Program?

Phase I is a feasibility study to evaluate the scientific and technical merit of an idea. Awards are for periods of up to six months in amounts up to \$100,000.

Phase II is to expand on the results of and further pursue the development of Phase I. Awards are for periods of up to two years in amounts up to \$750,000.

Phase III is for the commercialization of the results of Phase II and requires the use of private sector or non-SBIR Federal funding.

Q. Do you have to be a Phase I awardee in order to be considered for Phase II of a project?

Yes.

Q. What is the small business size standard for purposes of the SBIR Program?

A small business concern for purposes of award of any funding agreement under the SBIR Program is one which, including its affiliates, has a number of employees not exceeding 500.

Q. How can a small business concern obtain funding under SBIR?

A small business can obtain funding under SBIR by being the recipient of a competitively awarded SBIR funding agreement.

Q. What is an SBIR funding agreement?

An SBIR funding agreement is a contract or grant entered into between an SBIR participating Federal agency and a small business concern for the performance of experimental, developmental, or research work funded by the Federal Government.

Q. Does the Small Business Administration make any awards under the SBIR Program?

No. The SBA has authority and responsibility for monitoring and coordinating the Government-wide activities of the SBIR Program and reporting its results to Congress.

The Federal agencies participating in SBIR have the responsibility for:

- (a) selecting SBIR topics
- (b) releasing SBIR solicitations
- (c) evaluating SBIR proposals
- (d) awarding SBIR funding agreements on a competitive basis

Q. Who are the participants in the SBIR Program?

The following Federal agencies are eligible to participate:

- Department of Agriculture
- Department of Commerce
- Department of Defense
- Department of Education
- Department of Energy
- Department of Health and Human Services
- Department of Transportation
- Environmental Protection Agency
- National Aeronautics and Space Administration
- National Science Foundation

Q. Can a firm go directly to a Phase II award without having to compete for Phase I?

No. The SBIR Program was created for NEW innovations to meet existing Federal R&D needs. The results of a Phase I are a determining factor in deciding whether there will be a Phase II award to continue the effort.

Q. Does SBA designate any of the topics cited in SBIR solicitations or make any awards under SBIR?

No. The legislation governing the SBIR Program gives unilateral authority and responsibility for these functions to each of the Federal agencies participating in the program.

Q. Since SBIR is a program to assist small business innovators, can SBA or the other Federal participating agencies provide direct funding for a project which a firm has initiated on its own?

No. SBA does not fund SBIR projects and such an endeavor would be considered an unsolicited proposal, which is outside the scope of the SBIR Program.

Q. Is a small US firm still eligible to compete for an SBIR award if it forms a 50-50 joint venture with a nonprofit or foreign firm?

No.

Q. Are foreign-based firms eligible for SBIR awards?

No. To be eligible for award of SBIR funding agreements, a small business concern has to meet the following qualifications:

- be independently owned and operated
- principal place of business is located in the United States
- at least 51 percent owned or in the case of a publicly owned business, at least 51% of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens.

Q. Are nonprofit concerns eligible for SBIR awards?

No.

Q. May a portion of an SBIR award be subcontracted?

For Phase I, a minimum of two thirds of the research and/or analytical effort must be performed by the proposing firm, and for Phase II, a minimum of one-half of the research and/or analytical effort must be performed by the proposing firm.

Q. Can a Federal agency other than the one originating the Phase I award make the Phase II award under the same SBIR topic?

No. Awards of this type would be the result of an unsolicited proposal, and therefore, would be considered outside the scope of the SBIR Program.

Q. What is the difference between SBIR solicitations and the SBIR Pre-Solicitation Announcement?

SBIR solicitations are specific Requests for Proposals released by the Federal agencies participating in the program which may result in the award of Phase I SBIR funding agreements.

SBIR Pre-Solicitation Announcements, released by SBA, contain pertinent data on SBIR solicitations that are about to be released by the participating Federal agencies.

Q. Will SBA provide funds for SBIR commercialization?

No. Private sources of capital should be used. However, SBIR awardees are encouraged to seek information on all of the services that SBA makes available to the small business community.

STTR Frequently Asked Questions (FAQs):

Q. What is the STTR Program?

STTR is a highly competitive three-phase program that reserves a specific percentage of Federal research and development funding for award to small businesses in partnership with nonprofit research institutions to move ideas from the laboratory to the marketplace, to foster high-tech economic development and to address the technological needs of the Federal Government.

Q. What are the three phases of the STTR Program?

Phase I is the startup phase for the exploration of the scientific, technical, and commercial feasibility of an idea or technology. Awards are for periods of up to one year in amounts up to \$100,000. Phase II is to expand Phase I results. During this period the R&D work is performed and the developer begins to consider commercialization potential. Awards are for periods of up to two years in amounts up to \$500,000. Phase III is the period during which Phase II innovation moves from the laboratory into the marketplace. There is no STTR funding in this phase.

Q. Must you be an established business when you propose?

No. However, you must be organized as a business at the time of award.

Q. Who can propose?

Only small for-profit businesses can propose.

Q. What is size criteria?

A small business concern with 500 or fewer employees including subsidiaries and/or affiliates. The size of the nonprofit collaborator is not relevant.

Q. How are future rights to projects developed under STTR determined?

The small business concern and the research institution must develop a written agreement prior to a Phase I award. This agreement must be submitted to the awarding agency if requested.

Q. Who are the Federal participants in the STTR Program?

The following five Federal departments and agencies are eligible to participate: Department of Defense Department of Energy National Aeronautics and Space Administration Department of Health and Human Services National Science Foundation

Q. Can I skip Phase I and begin at Phase II?

No. Phase II awards can only be awarded to firms having successfully completed Phase I at the same awarding agency.

Q. Does SBA make any STTR awards?

No. The five participating Federal agencies have unilateral procurement authority.

Q. Can you subcontract in STTR -- either party or both?

Yes. Either party may subcontract or they may jointly fund a subcontractor.

Q. Can a small business concern participate in both SBIR and STTR simultaneously at the same or differing agencies?

Yes, but they may not perform the same or essentially similar work under more than one contract or grant. Collecting funds more than once for the same work is fraud.

Q. Must a successful Phase I small business concern use the same institution in Phase II?

No. The small business concern can change research institutions in Phase II.

Q. Will an unsolicited proposal be accepted in the STTR Program?

No. Proposals must respond to the solicitation as published by one or more of the participating agencies.

Q. Who is the prime contractor or grantee?

The small business concern.

Q. Must the small business concern and/or the research institution be located in the United States?

Yes. Both the small business concern and the institution must be on U.S. soil.

Q. Can a Phase III follow-on contract for funding be made, without competition, to the firm that successfully completes Phase I and II.

Yes, the firm may be given a sole source contract in Phase III for further work or production.

Q. What is the minimum percent breakout for small firms and institutions in conducting research?

Small business concerns must perform at least 40% and research institutions must perform at least 30% of the work.

Q. Who resolves problems concerning STTR topics, awards, audits, etc.?

The agency issuing the Program Solicitation. SBA handles program policy for across the board uniformity, reporting to Congress and program oversight.

Q. Where can I go for further information on how I get started or if there is other assistance available?

Information can be obtained from SBA Online Bulletin Board by dialing: 1-800-697-4636.

NIH - FREQUENTLY ASKED QUESTIONS

Q. What Forms/Instructions do I use?

A. You must use the PHS 398 forms and the PHS 398 Instructions to prepare the forms. The SBIR/STTR SPECIFIC instructions are located in CHAPTER VI of the PHS 398. Please DO NOT BEGIN PREPARING YOUR APPLICATION UNLESS YOU HAVE READ CHAPTER VI. See <http://grants.nih.gov/grants/funding/phs398/phs398.html>

Q. I am submitting a revised application. What are the page limits on an introduction?

A. Yes. For Phase I, you also need to include a one-page Introduction Page just before the Research Plan.

For **Phase IIs**, you are **allowed a 3-page introduction**. See the instructions on Revised Applications.

For **Fast Track Applications**, include a one page Introduction in the Phase I (just before the Research Plan) and no more than 3 pages of Introduction in the Phase II application (just before the Research Plan).

Q. If I am using an overnight courier, does the postmark date still apply?

A. Yes. A 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 date 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**.

Q. Do I need to include letters from consultants and collaborators with my application?

A. Yes.

Q. Must the Principal Investigator be a U.S. citizen?

A. No, the PI, the individual who is responsible for the scientific and technical direction of the project, is not required to have US citizenship BUT the PI must be here legally in the United States and must be available to perform the research proposed for the duration of the project. The responsibility to meet these requirements for individuals who do not have permanent resident status in the U.S. rests with the small business concern. NOTE: The applicant small business concern MUST be at least 51 percent owned and controlled by one or more

individuals who are **citizens of, or permanent resident aliens in, the United States** and must also meet the other eligibility criteria as described in the Solicitation.

Q. How do I know what the estimated start date of my project is?

A. To select an appropriate beginning date for a **new** application, consult the following schedule:

**SBIR and STTR
Receipt Dates
Phase I and Phase II Estimated**

Award Date

April 1 November 1
August 1* March 1
December 1 July 1

PHS awarding components may not always be able to honor the requested start date. No commitments or obligations should be made until confirmation of the actual start date by the awarding component.

Q. Is it permissible to submit a budget that deviates from the time and dollars normally awarded to Phase I or Phase II?

A. Yes. Deviations from the guidelines are acceptable, but must be well justified. We recognize that not all types of biomedical/behavioral research can be conducted under the prescribed amounts of time and dollars. Propose a reasonable budget and project period that is appropriate for completion of the research project and justify the need to go beyond the "norm." **You are encouraged to discuss budgetary deviations with [NIH Program Staff](#) prior to submission of the application.** (CDC and FDA do not make awards greater than the stated guidelines.)

Q. Do I need to identify an Institute or Center to submit the application to?

A. No. We have an entire office, the Center for Scientific Review/Receipt and Referral Office, that refers applications to the appropriate Institute/Center (IC). If you know that your proposed research overlaps with several ICs, then include a cover letter and request that your application be assigned to those ICs. CSR makes the final call as to assignments.

Q. What do I enter in Line 2 on the face page, which asks if our grant is in "Response to Specific Request for Applications or Program Announcement of Solicitation?"

A. Check Yes (This is in response to the SBIR/STTR Solicitation) Enter in Line 2 "PHS 2002-2 SBIR" (or STTR).

Do not type PHS 398 in this line.

For Phase II SBIR/STTR applications, check "Yes" and type PHS 2002-2 "Phase II SBIR" or "Phase II STTR," as appropriate.

(If you are submitting an application in response to a special NIH Guide Announcement, then enter THAT Announcement number (e.g., PA-02-025) and type in the title of the Announcement.)

Q. Do I enter the same numbers in Item 8 as I did for 7 ?

A. Phase I : For Phase I SBIR/STTR applications that do not exceed one year, the direct and total costs for the entire "proposed period of support" (Item 8) will be the same as the direct and total costs for the "initial budget period" (Item 7).

Q. Item 8b request Total Costs... what does this include ?

A. This is the SUM of (a) the total direct costs from Form Page 5 (or Modular Budget); (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 (F&A) derived from the Checklist Form Page.

Q. Do I use \$250,000 as the threshold for Modular Grants?

A. NOOOOOO. The \$250,000 threshold does not apply to SBIR/STTR Applications. IF YOU ARE REQUESTING A TOTAL BUDGET (Direct+F/A+Fee) OF \$100,000 OR LESS, THEN YOU FOLLOW THE MODULAR FORMAT AS DESCRIBED IN CHAPTER VI OF THE PHS 398.

http://grants.nih.gov/grants/funding/phs398/section_6.html#4_modular

In this case, you do not submit FP4 and FP5; you only submit the Modular Budget Format Page for your budget.

IF YOU ARE REQUESTING A TOTAL BUDGET OF MORE THAN \$100,000, THEN YOU FOLLOW THE NON-MODULAR BUDGET FORMAT AS DESCRIBED IN CHAPTER VI.

http://grants.nih.gov/grants/funding/phs398/section_6.html#4_modular

This means that you will need to submit FP 4 and FP5.

Q. Do I need to include Form Pages 4 and 5 for my subcontractors?

A. If you are non-modular, then YES. Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period (Form Page 4) and the entire proposed project period (Form Page 5).

If you are non-modular, then NO. The subcontracts/consultant costs are discussed on the Modular Budget Page.

Q. Do I REALLY only enter Total DIRECT Costs on the Modular Budget Page?

A. YES. The table on the Modular Budget Page requests Total Direct Costs. If your total direct costs are \$64,524, then enter this amount. (The \$25,000 increments do NOT Apply to SBIR/STTR Modular Budgets)

Q. I am submitting a Phase I for 6 months. I entered \$74,652 in the box for "Initial Budget Period" to reflect my Direct Costs. What do I enter in the other boxes on the Modular Budget Table?

A. Nothing. You enter only the Direct Costs in the far left box for "Initial Budget Period" and enter the same amount in the box for "Total Direct Costs Requested for Entire Budget Period" since your budget request does not exceed one year. Provide a narrative justification for Personnel, Consultant/Contractual/Consortium Costs and Fee as described in the instructions.

Q. Where do I enter F&A (Indirect) Costs?

A. The Checklist Page. See Chapter VI, Checklist Instructions.
http://grants.nih.gov/grants/funding/phs398/section_6.html#11_checklist

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.

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.

See the Policy in this section also :

http://grants.nih.gov/grants/funding/phs398/section_6.html#11_checklist

Q. Where do I show the TOTAL (Direct +F&A (Indirect)+ Fee) Costs that I am requesting?

A. On the Face Page, you enter in 7b the Total Costs for the Initial Period and in 8b you enter the total costs for the entire proposed project period.

Q. What is Fee/Profit?

A. A reasonable profit/fee is available to small business concerns receiving awards under the SBIR/STTR program; **however, this profit/fee must be included in your budget request at the time of application.** *. The amount of the fee approved by the agencies participating in this solicitation normally will not exceed 7% of total costs (direct and indirect) for each Phase (I and II) of the project.* The fee is not a "cost" item and may be used by the small business concern for any purpose, including additional effort under the SBIR/STTR award. The fee is intended to be a reasonable profit factor available to for-profit organizations, consistent with normal profit margins provided to profit-making firms for research and development work. The profit/fee applies solely to the small business concern receiving the SBIR/STTR award and not to any other participant in the project. However, the grantee may pay a profit/fee to a contractor providing routine goods or services in accordance with normal commercial practice.

Q. The Biographical Sketch seems to include Research Support, but the instructions say NOT to include "Other Support." Is there a difference?

A. Yes. Research Support includes selected ongoing and completed (during the last three years) research projects (federal or non-federal support). Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. **Do not include percent of effort or direct costs.**

Other Support goes beyond this information and includes all active and pending support AND requires that you provide percent effort and costs associated with each grant/award.

Our reviewers do not review how well-supported you are (\$\$\$) or how much effort you have... since this latter item changes between submission and

award. THESE ARE ADMINISTRATIVE DETAILS WITH WHICH NIH STAFF (not Peer

Review) WILL BE CONCERNED.

Q. How many copies do I submit? What if my application overlaps with more than one IC?

A. The original plus 5 copies. PERIOD. We make all the other copies if your application is assigned to more than one IC.

Q. I will be subcontracting ALL of the Human Subjects work to a University, so do I still need to address the points delineated in Section E. of the Research Plan?

A. YES.YES. YES. This is the one area that, if not addressed, will result in your application being returned.

See http://grants.nih.gov/grants/funding/phs398/section_1.html#e_humansubs

and follow these instructions to the 'T'.

You do NOT need to have IRB approval or an assurance at the time of submission, *but you do need to address the 4 points under section ' e ' of the Research Plan.*

Q. I will be using Human Subjects in my research but do not have approval by an Institutional Review Board yet. Is this required at the time of submission?

A. No. Your company will be required to obtain an Assurance (typically a Single Project Assurance) by the time an award is made. Our NIH staff will initiate that process if you do not have an assurance, and you will work closely with your Program director and OHRP staff to negotiate such an assurance.

Q. I will be using vertebrate animals in my research. Do I need to have an IACUC approval at the time of submission or within 60 days of submission?

A. No. This is also done prior to award. The certification of IACUC approval is not required at the time of application, **but you must address the points under the Vertebrate Animal section of the Research Plan.** IACUC approval may be submitted in a "just-in-time" fashion prior to award (as is now permitted for IRB

approval.) Additional information is available on the following NIH Guide Notice:
<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-064.html>

Note: DO NOT TYPE IN THE IACUC NUMBER OF COLLABORATING INSTITUTIONS.

Q. I am submitting a Phase I STTR that is Non-Modular (>\$100,000). What forms does the Small Business and the Research Institution need to include?

A. The Small Business completes/submits Form Page 4 and Form Page 5. I completes/submits the STTR Research Institution Budget Form Page. See http://grants.nih.gov/grants/funding/phs398/section_6.html#4_modular

Q. I am submitting a Phase II STTR that is Non-Modular (>\$100,000). What forms does the Small Business and the Research Institution need to include?

A. The Small Business completes/submits Form Page 4 and Form Page 5. The RI completes/submits the STTR Research Institution Budget Form Page (for the Initial Year of the Budget) and Form Page 5 (for the out years). See http://grants.nih.gov/grants/funding/phs398/section_6.html#4_modular