DEPARTMENT OF HEALTH AND HUMAN SERVICES

OMNIBUS SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, AND FOOD AND DRUG ADMINISTRATION FOR SMALL BUSINESS INNOVATION RESEARCH (SBIR) GRANT APPLICATIONS

NEW INITIATIVES AND IMPORTANT REMINDERS IN THIS SOLICITATION

- **Reinvention Laboratory**. The Department of Health and Human Services (HHS) has designated the National Institutes of Health (NIH) a "reinvention laboratory." One reinvention objective is to simplify and improve each stage in the grant process: application, review, award, and administration. The Small Business Innovation Research (SBIR) program is part of an experiment to determine how to reduce the administrative burden in applying for an SBIR grant without compromising the information needed by the initial peer review group to assess the scientific and technical merit, feasibility, and potential for commercialization of the proposed project and the reasonableness of the proposed budget. Therefore, some of the instructions contained in the "Introduction and Application Instructions" portion of this SBIR Phase I Solicitation refer to items that have been modified and others that should not be completed at the time of submission of the application, **but will be requested by the awarding component if the application has a likelihood for funding**.

- **"Fast-Track" Pilot Initiative**. The following NIH awarding components are inaugurating a Fast-Track pilot initiative to expedite the decision and award of SBIR Phase II funding for scientifically meritorious applications for projects that have a high potential for commercialization:

  National Institute on Alcohol Abuse and Alcoholism (NIAAA)
  National Institute of Allergy and Infectious Diseases (NIAID)
  National Cancer Institute (NCI)
  National Institute of Child Health and Human Development (NICHD)
  National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
  National Institute of Environmental Health Sciences (NIEHS)
  National Institute of General Medical Sciences (NIGMS)
  National Heart, Lung, and Blood Institute (NHLBI)
  National Institute of Mental Health (NIMH)
  National Center for Human Genome Research (NCHGR)

The SBIR program is intended to support small business innovative research that results in commercial products or services that benefit the public. Innovation and probability of commercial success are both important factors in funding decisions. Allocation of a small business concern's funds and/or resources (and/or those of an investor or partner organization) is viewed as an important and meaningful commitment to a project's commercial success and as a mechanism for leveraging federal SBIR investment.

Fast-Track is a parallel review option available to those small business concerns (applicant organizations) whose applications satisfy additional criteria which enhance the probability of the project's commercial success. Applications that do not meet these criteria may be redirected for review through the standard review procedures described in this Solicitation under section VII, Method of Selection and Evaluation Criteria.

Fast-Track offers two major advantages:

1. Concurrent peer review of both Phase I and Phase II projects.

   Fast-Track SBIR applications for both Phase I and Phase II must be submitted together for concurrent initial peer review and evaluation. In order to identify the applications as such, the words "Fast-Track" must be shown in item 2 on the face page of the Phase I application. The Phase I application must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II. Failure to provide clear, measurable goals may be sufficient reason for the peer review committee to exclude the Phase II application from Fast-Track review. The peer review committee will evaluate the goals and may suggest other milestones that should be achieved prior to Phase II funding. The Phase I and Phase II applications will receive a single priority score. Following the initial peer review, Fast-Track applications will receive secondary review by the respective advisory council or board of the respective NIH awarding component named above.

2. Minimal or no funding gap between Phase I and Phase II.

   Fast-Track Phase II applications may be funded following submission of the Phase I progress report and other documents necessary for continuation. Phase II applications will be selected for funding based on the project's scientific and technical merit (priority score); the awarding component's assessment of the Phase I progress report and determination that the Phase I goals were achieved; an update and verification of the Commitment and Product Development Plans as described below; the project's potential for meeting the mission of the awarding component and for commercial success; and the availability of funds.

SBIR applications are eligible for the Fast-Track review process upon meeting the following criteria:

1. The Phase II application must be accompanied by a commitment(s) for funds and/or resources for commercialization of the product(s) or service(s) resulting from the SBIR grant. Although a specific level of commitment is not specified, funds or resources matching or greater than the Phase II award are encouraged. Any commitment(s) from an investor or partner organization must be described in a letter of agreement or contract signed by an official of the investor or partner organization with the authority to legally bind the organization. Details of the commitment(s) must be included in a **Commitment Appendix** to the Phase II application.

2. The **Commitment Appendix** must specify the amount of funds and/or nature of resources that will be dedicated to activities directly related to the SBIR project and must describe those activities. Non-federal commitments may support additional research and development on the project or activities that are beyond the scope of federal SBIR funding, such as market research. The activities supported by the commitment(s) should begin in

Phase II and provide for a smooth transition into Phase III commercialization.

3. Because of the risk involved, the commitment(s) may be contingent upon the small business concern receiving the Phase II award, achieving technical objectives, and the technology continuing to be scientifically and economically viable in the marketplace. Details of commitment contingencies must be described in the **Commitment Appendix**. Withdrawal of the commitment(s) may be considered sufficient reason by the participating awarding component to remove the Phase II application from consideration under Fast-Track or withhold further Phase II support.

4.. The small business concern must submit a concise Product Development Plan (limited to five pages) as a **Product Development Plan Appendix** to the Phase II application addressing 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 IV of this Solicitation for definition of "commercialization").

   b. Value of SBIR project, including lay description of key technology objectives, current competition, and advantages 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.

Before submitting applications under the Fast-Track pilot initiative, applicant organizations and investigators are strongly encouraged to consult with the program staff named below for specific details relevant to that awarding component.

Dr. Laurie Foudin
National Institute on Alcohol Abuse and Alcoholism
Willco Building, MSC 7003
6000 Executive Blvd., Suite 402
Bethesda, MD 20892-7003
Phone: (301) 443-4224
Fax: (301) 594-0673
E-mail: lf29z@nih.gov

Dr. Gregory Milman
Chief, Pathogenesis and Basic Research Program
Division of Acquired Immunodeficiency Syndrome
National Institute of Allergy and Infectious Diseases
Solar Building, Room 2C06 - MSC 7620
Bethesda, MD 20892-7620
Phone: (301) 496-8378
Fax: (301) 402-3211
E-mail: gm16s@nih.gov

Ms. Jo Anne Goodnight
Special Assistant for Program Coordination
Division of Cancer Biology
National Cancer Institute
6130 Executive Boulevard, Room 500 - MSC 7380
Bethesda, MD 20892-7380
Phone: (301) 496-5307
Fax: (301) 496-8656
E-mail: jg128w@nih.gov

Dr, Danuta Krotoski
Chief, Biological Sciences, Bioengineering, and Health Maintenance Branch
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
6100 Executive Boulevard., Room 2A03 - MSC 7510
Bethesda, MD 20892-7510
Phone: (301) 402-2242
Fax: (301) 402-0832
E-mail: dk58p@nih.gov

Mr. John R. Garthune
Assistant Director for Grants
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Building 45, Room 6AS49E - MSC 6600
Bethesda, MD 20892-6600
Phone: (301) 594-8842
Fax: (301) 480-3504
E-mail: jg60d@nih.gov

Dr. Michael Galvin
National Institute of Environmental Health Sciences
P.O. Box 12233, MD 3-03, North Campus
Research Triangle Park, NC 27709
Phone: (919) 541-7825
Fax: (919) 541-3843
E-mail: mg63c@nih.gov

Dr. Michael R. Martin
National Institute of General Medical Sciences
Building 45, Room 2AN-32K
45 Center Drive - MSC 6200
Bethesda, MD 20892-6200
Phone: (301) 594-3910
Fax: (301) 480-1852
E-mail: mm72k@nih.gov

Dr. John T. Watson
Head, Bioengineering Research Group
Division of Heart and Vascular Diseases

National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 9178 - MSC 7940
Bethesda, MD 20892-7940
Phone: (301) 435-0513
Fax: (301) 480-1336
E-mail: jw53f@nih.gov

Dr. Michael F. Huerta
National Institute of Mental Health
Room 11-103, 5600 Fishers Lane
Rockville, MD 20857
Phone: (301) 443-5625
Fax: (301) 443-1731
E-mail: mh38f@nih.gov

Dr. Carol Dahl
Program Director, Sequencing Technology Branch
National Center for Human Genome Research
Building 38A, Room 604 - MSC 6050
Bethesda, MD 20892-6050
Phone: (301) 496-7531
Fax: (301) 480-2770
E-mail: cd41x@nih.gov

- **Award Levels**. Award amounts for Phase I and Phase II should not exceed the statutory guidelines of $100,000 and $750,000, respectively.

- **Receipt of Phase II Applications**. Phase II applications may be submitted on any of the three scheduled receipt dates identified in section VI., Submission of Grant Applications, **EITHER BEFORE OR AFTER EXPIRATION OF THE PHASE I BUDGET PERIOD**. Applicant organizations (small business concerns) are reminded that Phase II funding is based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. **Applicants are cautioned that applications not demonstrating sufficient results in Phase I may be designated as " noncompetitive" in the peer review process** (see section VII., Method of Selection and Evaluation Criteria).

- "**Type Size**." Specifications for proper type size must be observed throughout the application (see page 181).

- "**Reminder Sheet.**" A reminder sheet has been included on the page opposite the Mailing Label (inside back cover) to aid applicant organizations in assuring that the requirements for submission of the application have been met.

I. SMALL BUSINESS INNOVATION RESEARCH PROGRAM

The "Small Business Research and Development Enhancement Act of 1992" (Public Law 102-564, signed October 28, 1992) requires the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration and certain other federal agencies reserve a specified amount of their extramural budgets for research or

research and development (R&D) for a Small Business Innovation Research (SBIR) program. The legislation is intended to:

- expand and improve the SBIR program;
- emphasize increased private sector commercialization of technology developed through federal SBIR R&D;
- increase small business participation in Federal R&D; and
- foster and encourage participation of socially and economically disadvantaged small business concerns and women-owned small business concerns in the SBIR program.

The SBIR program consists of the following three phases:

Phase I: The objective of this phase is to establish the technical merit and feasibility of proposed research or R&D efforts and to determine the quality of performance of the small business grantee organization prior to providing further federal support in Phase II.

Phase II: The objective of this phase is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II application. **(Only Phase I grantees are eligible to apply for Phase II funding and Phase II applications may be submitted either before or after expiration of the Phase I budget period.)**

Phase III: The objective of this phase, where appropriate, is for the small business concern to pursue with non-federal funds the commercialization of the results of the research or R&D funded in Phases I and II. In some federal agencies, Phase III may involve follow-on non-SBIR funded R&D or production contracts for products or processes intended for use by the United States government.

Purpose of Solicitation: The purpose of this SBIR Phase I Solicitation is to invite grant applications from domestic small business concerns that have the technological expertise to contribute to the R&D mission(s) of the NIH, CDC, and/or FDA.

This Solicitation outlines the objectives of the agencies' SBIR grants program, the eligibility requirements for those small business concerns wishing to participate, and the application and review processes. It also provides both general program information as well as specific research topics and subtopics that may be of interest to small business concerns.

Although areas of special programmatic interest or priority are described in the PROGRAM DESCRIPTIONS/RESEARCH TOPICS section of this Solicitation, **grant applications will be considered in any area within the mission of the participating agencies unless otherwise specifically excluded**. **SMALL BUSINESS CONCERNS ARE ENCOURAGED TO SUBMIT GRANT APPLICATIONS FOR PROPOSED RESEARCH IN ANY PROGRAM AREA THAT FALLS WITHIN THE PURVIEW OF THE AGENCIES.**.

Those small business concerns that are interested in submitting contract proposals should consult the Contract Solicitation which will be released in September 1996. Unlike grant applications, contract proposals will be accepted only if they respond to a specific research

topic identified in the SBIR Contract Solicitation of the participating agencies.

SBIR Phase II grant applications must be submitted on form PHS 6246-2, which will be mailed to Phase I grantees shortly after issuance of the Phase I Notice of Grant Award.

Amount and Period of Support

Phase I: Awards should not exceed $100,000 for direct costs, indirect costs, and fixed fee for a period normally not to exceed six months.

Phase II: Awards should not exceed $750,000 for direct costs, indirect costs, and fixed fee for a period normally not to exceed two years. **Phase II grant awards are non-renewable and only one Phase II award may be made for any SBIR project**.

II. ELIGIBILITY

Organizational Criteria:

Each organization submitting a grant application under the SBIR program must qualify as a small business concern in accordance with the definition given in section IV.H. In determining whether an applicant is a small business concern, an assessment will be made of several factors, including whether or not it is independently owned and operated and whether or not it is an affiliate of a larger organization whose employees, when added to those of the applicant organization, exceed 500. In conducting this assessment, all appropriate factors will be considered, including common ownership, common management, and contractual relationships.

In accordance with Title 13 Code of Federal Regulations (CFR) Part 121.4, affiliation exists when either directly or indirectly "(i) one concern controls or has the power to control the other, or (ii) a third party or parties controls or has the power to control both." One of the circumstances that would lead to a finding that an organization is controlling or has the power to control another organization involves sharing common office space and/or employees and/or other facilities (e.g., laboratory space). Although access to special facilities or equipment in another organization is permitted (as in cases where the SBIR grantee has entered into a subcontractual agreement with another organization for a specific, limited portion of the research project), **research space occupied by an SBIR grantee must be space which is not shared generally with another organization and over which the SBIR grantee has exclusive control. A letter from the organization providing the research space, certifying that the SBIR grantee will have exclusive control over the research space, must be submitted with the grant application.** Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether or not such sharing constitutes control or the power to control. 13 CFR 121.4 also states that control or the power to control exists when "key employees of one concern organize a new concern .... and serve as its officers, directors, principal stockholders, and/or key employees, and the one concern is furnishing or will furnish the other concern with subcontracts, financial or technical assistance, bid or performance bond indemnification, and/or other facilities, whether for a fee or otherwise."

All SBIR grant applications will be reviewed with the above considerations in mind. **If it appears that an applicant organization does not meet eligibility requirements, a size determination of the organization will be requested from the cognizant Small Business Administration (SBA) regional office. The review of the application for scientific merit will be deferred until a determination is provided by the SBA.**

Principal Investigator Criteria

As defined in 42 CFR 52, the principal investigator is the "single individual designated by the grantee in the grant application ... who is responsible for the scientific and technical direction of the project." When the proposed principal investigator clearly does not have sufficient qualifications to assume this role, the application will be "noncompetitive" (see section VII.B., Review Process). The primary employment of the principal investigator 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 principal investigator's time is spent in the employ of the applicant small business concern. **Primary employment with a small business concern precludes full-time employment at another organization**.

In the event that the principal investigator (l) is a less-than-full-time employee of the small business concern, (2) is concurrently employed by another organization, or (3) gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position, at the time of submission of application, **it is essential that documentation be submitted with the application to verify his/her eligibility.** That is to say, if the principal investigator is employed or appears to be employed by an organization other than the applicant organization (for example, a university, non-profit research institute, or another company), **a letter must be provided by each employing organization confirming that the principal investigator, if an SBIR grant is awarded to the applicant organization, 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 principal investigator is employed by a university, such a letter must be provided by the **Dean's office or equivalent**; if the principal investigator is employed by another for-profit organization, the letter must be signed by a **corporate official**.

Documentation is required to establish eligibility of the Principal Investigator when any portion of the application (biographical sketch/curriculum vitae, research plan, etc.) indicates a commitment such as Research Fellow, Consultant, and courtesy appointments, including Adjunct Professor, Clinical Professor, Clinical Research Professor or Associate. It also applies to those individuals engaged currently as the principal investigator on an active SBIR project. **ALL CURRENT EMPLOYMENT AND ALL OTHER APPOINTMENTS OF THE PRINCIPAL INVESTIGATOR MUST BE IDENTIFIED IN HIS/HER "BIOGRAPHICAL SKETCH" REQUIRED AS PART OF THE APPLICATION** (see page 189 of this Solicitation). **BE CERTAIN THAT CORRECT BEGINNING AND ENDING DATES ARE INDICATED FOR EACH EMPLOYMENT RECORD LISTED**. Documentation is required for **every** application that is submitted, even one that is a revision of a previously submitted application.

In cases where the applicant organization (the small business concern) fails to provide adequate documentation regarding organizational eligibility OR the principal investigator fails to establish evidence of primary employment with the applicant organization, THE APPLICATION WILL BE RETURNED WITHOUT REVIEW.

Performance Site Criteria

For both Phase I and Phase II, the research or R&D project activity must be performed in its entirety in the United States (see section IV.L., Definitions).

Market Research

The participating agencies will not support any market research under the SBIR program. Neither will they support studies of the literature that will lead to a new or expanded statement of work. Literature searches where the commercial product is a database are acceptable.

For purposes of the SBIR program, "market research" is the systematic gathering, editing, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the research project. It includes various types of research, such as the size of potential market and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

III. AGENCY CONTACT FOR INFORMATION

Hard copies of this SBIR Phase I Program Solicitation **are available directly from the following office ONLY**:

NIH SBIR/STTR Solicitation Office
13687 Baltimore Avenue
Laurel, MD 20707-5096
Phone: (301) 206-9385
Fax: (301) 206-9722
E-mail: a2y@cu.nih.gov

In addition, the Solicitation is available electronically through the NIH Home Page on the World Wide Web (http://www.nih.gov). This does not include SBIR application forms, which should be obtained in hard copy from the NIH SBIR/STTR Solicitation Office above.

Section X, Grants-Program Descriptions/Research Topics, includes names, addresses, and communication numbers of persons for each NIH, CDC, and FDA awarding component that should be contacted for the following purposes:

- For additional information regarding research topics, a program administrator(s) is identified. **APPLICANTS ARE ENCOURAGED TO QUERY PROGRAM ADMINISTRATORS PERIODICALLY VIA E-MAIL TO LEARN OF NEW OR EMERGING SCIENTIFIC INTERESTS OF THE AWARDING COMPONENTS.**

- For administrative and business management questions **that are not answered in the Solicitation**, a grants management officer is identified.

IV. DEFINITIONS

A. Commercialization. The process of developing markets and producing and delivering products for sale (whether by the originating party or by others); as used here, commercialization includes both Government and commercial (private sector) markets.

B. Contract. An award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to provide payment therefor.

C. Essentially equivalent work. This term is meant to identify “scientific overlap,” which occurs

when (1) substantially the same research is proposed for funding in more than one proposal (grant application or contract proposal) submitted to the same federal agency; OR (2) substantially the same research is submitted to two or more different federal agencies for review and funding consideration; OR (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

D. Grant. A financial assistance mechanism whereby money and/or direct assistance is provided to carry out approved activities.

E. Grantee. For purposes of the SBIR program, this term means the small business concern (applicant organization) to which the grant is awarded and which is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project.

F. Innovation. Something new or improved, including research for (1) development for new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For purposes of PHS programs, an example of "innovation" would be new medical or biological products, for improved value, efficiency, or costs.

G. Key Personnel Engaged on Project. This term is meant to identify those individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salariess are requested.

H. Prototype. A model of something to be further developed and includes designs, protocols, questionnaires, software, devices, etc.

I. Research or Research and Development (R/R&D). Any activity that is:

1. A systematic, intensive study directed toward greater knowledge or understanding of the subject studied.

2. A systematic study directed specifically toward applying new knowledge to meet a recognized need.

3. A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

J. Small Business Concern. A small business concern is one that, at the time of award of Phase I and Phase II, meets the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States and is organized for profit;

2. Is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens;

3. Has, including its affiliates, a number of employees not exceeding 500, and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than

investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, et seq., are affiliates of one another when either directly or indirectly;

(a) one concern controls or has the power to control the other; or

(b) a third party or parties controls or has the power to control both.

Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.401. The term "number of employees" is defined in 13 CFR 121.407. **BUSINESS CONCERNS INCLUDE, BUT ARE NOT LIMITED TO, ANY INDIVIDUAL, PARTNERSHIP, CORPORATION, JOINT VENTURE, ASSOCIATION, OR COOPERATIVE.**

K. Socially and Economically Disadvantaged Individual. A member of any of the following groups:

(1) Black Americans
(2) Hispanic Americans
(3) Native Americans
(4) Asian-Pacific Americans
(5) Subcontinent Asian Americans
(6) Other groups designated from time to time by SBA to be socially disadvantaged; or
(7) Any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act,15 U.S.C. 637(a).

L. Socially and Economically Disadvantaged Small Business Concern. A socially and economically disadvantaged small business concern:

1. Is one that is at least 51 percent owned by (i) an Indian tribe or a native Hawaiian organization, or (ii) one or more socially and economically disadvantaged individuals; and

2. Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

M. Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government awardee calling for supplies or services required solely for performance of the funding agreement.

N. United States. The 50 states, the territories and possessions of the U.S., the Commonwealth of Puerto Rico, the Federated States of Micronesia, the Republic of Palau, the Republic of the Marshall Islands, and the District of Columbia.

O. Women-Owned Small Business Concern. A small business concern that is at least 51 percent owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

V. PREPARATION OF GRANT APPLICATIONS

Application form PHS 6246-1 (Rev. 1/95) and instructions for completion and submission are contained in the back of this Solicitation. Since this Solicitation is valid for all three of the calendar year (CY) 1996 SBIR application receipt dates identified in section VI. below, **the entire application form PHS 6246-1 may be photocopied freely for usage as drafts and as original forms for future submissions in CY 1996.** This material must be used in applying for SBIR Phase I grants.

Potential applicants are encouraged to contact program staff for pre-application guidance and/or for more specific information on the research topics described in this Solicitation. **See section X, Grants-Program Descriptions/Research Topics, for the names, addresses, and communication numbers of appropriate program staff.**

VI. SUBMISSION OF GRANT APPLICATIONS

The following schedule applies to the receipt, review, and award of SBIR applications:

Receipt Date	National Technical Merit Review	Earliest Adv. Council/ Board Review	Possible Award
April 15	June/July	Sept/Oct	November
August 15	Oct/Nov	Jan/Feb	March
December 15*	Feb/March	May/June	July

Applications must be **RECEIVED** by the Division of Research Grants (DRG), NIH, by the above dates. If the receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following work day. The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter with the signed, completed application. **No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.**

* Applications to the Centers for Disease Control and Prevention and the Food and Drug Administration may be submitted on the December 15, 1996, receipt date ONLY.

VII. METHOD OF SELECTION AND EVALUATION CRITERIA

All Phase I and Phase II grant applications will be evaluated and judged on a competitive basis. Applications will be screened for completeness and adherence to eligibility criteria described under Section II and those found to be incomplete in any way or programmatically unrelated to the agency's mission will be returned to the applicant. Those passing the screening will be reviewed for technical and scientific merit. Each application will be judged individually, as described below. The participating agencies are under no obligation to fund any application or make any specific number of awards in a given research topic area. Also, they may elect to fund several or none of the proposed projects within a given topic area.

A. Assignment of Grant Applications

It is the responsibility of the Division of Research Grants (DRG) of the National Institutes of Health (NIH) to assign all appropriately completed applications received that fall within the overall mission of the funding agency. The DRG will assign applications to the initial review groups (commonly referred to as "IRGs" or "study sections") that will perform scientific merit review and will assign each application to the agency awarding component that is the potential funding component.

When the scientific areas and the research proposed in a grant application are sufficiently relevant to the program responsibilities of two awarding components, DRG may assign the application to both components. The component that has the more relevant program responsibility is designated as the primary assignee. The other component that has an interest in the application is designated as the secondary assignee. If the application is eligible for funding and the primary assignee does not intend to make an award, the secondary assignee will be given the opportunity to do so.

B. Review Process

Grant applicartions are subjected to a peer review process involving two sequential steps, both of which are required by law. The first step is performed by the IRGs, composed primarily of non-federal scientists selected for their competence in particular scientific fields. The task of the IRGs is to evaluate applications for scientific and technical merit. Each application will receive a priority score ranging from best (100) to worst (500), unless the IRG determines that an application should be "not recommended for further consideration" (NRFC). NRFC means that an application does not have "significant and substantial merit." For those applications receiving a priority score (that is, those that are NOT designated "NRFC"), the reviewers suggest a funding level and duration of support and make recommendations related to the hypothesis, scope, direction, and conduct of the proposed research or R&D effort. The second level of review is made by the National Advisory Council or Board of the awarding component to which the grant application is assigned. These groups, composed of scientists, physicians, and leaders in public affairs, are chosen for their expertise, interest, or activity in matters related to the awarding component's mission. If the council or board recommmends an action other than that recommended by the IRG, the awarding component will send a letter to the principal investigator indicating the action and its rationale. Subsequent decisions concerning the funding of applications will take into account elements such as the relevance of the goals of the proposed research to the mission of the awarding component, program balance, overlapping support from other sources, and the availability of funds. The awarding component will notify the principal investigator and the applicant organization of the final disposition of the application.

C. Review Criteria

In considering the scientific and technical merit of each application, the following criteria will be used:

1. The soundness and technical merit of the proposed approach.

2. The qualifications of the proposed principal investigator, supporting staff, and consultants.

3. The scientific, technical, or technological innovation of the proposed research.

4. The potential of the proposed research for commercial application.

5. The appropriateness of the budget requested.

6. The adequacy and suitability of the facilities and research environment.

7. Where applicable, the adequacy of assurances detailing the proposed means for (a) safeguarding human or animal subjects and/or (b) protecting against or

minimizing any adverse effect on the environment.

D. Funding Decisions

When making funding decisions, the awarding components take into consideration the following: (1) ratings resulting from the scientific and technical evaluation process; (2) areas of high program relevance; (3) program balance (that is, balance among areas of research); (4) available funds; and (5) the extent of commercialization status where the small business concern has received more than 15 Phase II awards in the prior five (5) fiscal years, if applicable (see this application requirement under "Prior SBIR Phase II Awards" found in the “Introduction and Application Instructions” portion of the Solicitation).

E. Release of Grant Application Review Information

l. On applications submitted to NIH and CDC -

Following evaluation of grant applications by the IRGs but prior to National Advisory Council or Board action, summary statements (with priority scores) will be sent automatically to principal investigators. A summary statement documents the evaluation of an application by the IRG and conveys the group's recommendations to the awarding component and its Council or Board. **No one other than the Principal Investigator may receive the summary statement and priority score.**

2. On applications submitted to FDA -
Summary statements will be automatically sent to principal investigators following National Advisory Council review of grant applications. If an investigator wishes to obtain a copy of his/her summary statement following the IRG meeting but prior to Council review, he/she must submit a written request to the Privacy Act Coordinator of the FDA. Prior to Council review, summary statements sent to investigators shall have priority scores deleted.

F. Revision and Resubmission of Grant Applications

Grant applications that are not funded may be revised for resubmission at a future receipt date. **Revised applications without substantive changes will not be accepted.** The application **MUST** address the issues identified in the previous summary statement of the unfunded application. **Revised sections must be clearly marked as described in the “Introduction and Application Instructions” portion of the Solicitation.** Upon acceptance of a revised application by the DRG, the prior version will be withdrawn from further consideration by the awarding component. Acceptance of the revised application will generally mean that it will fall into a later review and award cycle.

Resubmission of an application that duplicates a previous application is not acceptable and the duplicate application will be returned without review.

G. Submission of Similar Grant Applications by the Applicant Organization

The submission to the DRG of similar grant applications by the same applicant organization is strongly discouraged. Principal investigators are cautioned not to prepare multiple grant applications with essentially the same research focus, that is, a product or technology that, with non-substantive modifications, can be applied to a variety of purposes. In evaluating groupings of applications with a common scientific focus or

objective (for example, implantation sensors/sensor materials, medical applications of lasers, immunology/immunoassays), IRGs (see section VII. B. above) are in a position to easily identify multiple grant applications from the same organization for essentially the same project. In these cases, the HHS will give funding consideration to only one application.

VIII. CONSIDERATIONS

A. Awards

1. Approximate number of Phase I grant awards to be issued under this Solicitation:

   - NIH - 700 awards
   - CDC - 10 awards
   - FDA - 2 awards

2. The primary award mechanism will be the grant instrument.

3. The average dollar amount of Phase I awards (composed of direct costs, indirect costs, and fixed fee) to be issued under this Solicitation is estimated to be approximately $100,000.

4. The average dollar amount of Phase II awards (composed of direct costs, indirect costs, and fixed fee) to be issued to continue the research or R&D efforts initiated in Phase I, is estimated to be approximately $700,000.

B. Payment Schedule

Once an SBIR grant is awarded, the grantee will receive information and forms from the Payment Management System of the Department of Health and Human Services regarding requests for cash, manners of payment, and associated reporting requirements. Payment may be made on a cost-reimbursement or advance basis.

C. Limited Rights Information and Data

1. Proprietary Information. Information contained in unfunded grant applications will remain the property of the applicant. The Government may, however, retain copies of all applications. Public release of information in any application will be subject to existing statutory and regulatory requirements.

   If proprietary information provided in an application constitutes trade secrets or proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law, provided this information is clearly identified by the appropriate page numbers under the Notice of Proprietary Information on the Face Page of the SBIR grant application form. Any other Notice may be unacceptable to the Government and may constitute grounds for return of the application without further consideration and without assuming any liability for inadvertent disclosure. Where possible, the Government will limit dissemination of such proprietary information to within official channels.

2. Title to Equipment and Supplies. Title to equipment and supplies acquired by a for-profit organization as a grantee or subcontractor under a grant awarded by the

agencies participating in this Solicitation, shall vest, upon acquisition, in the grantee or subcontractor, respectively.

3. Rights to Data Developed Under SBIR Funding Agreement. Rights to data, including software developed under the terms of any funding agreement resulting from a grant application submitted in response to this Solicitation, shall remain with the grantee, except that the Government shall have the limited right to use such data for internal Government purposes and shall not release such data outside the Government without permission of the grantee for a period of four years from completion of the project from which the data were generated.

4. Copyrights. The grantee may normally copyright and publish (consistent with appropriate national security considerations, if any) material developed with PHS support. The awarding component receives a royalty-free license for the Federal Government and requires that each publication contain an acknowledgement of agency support and disclaimer statement, as appropriate. An acknowledgement shall be to the effect that "This publication was made possible by grant number _____ from (NIH/CDC/FDA awarding component)" **or** "The project described was supported by grant number _____ from (NIH/CDC/FDA awarding component). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the (NIH/CDC/FDA awarding component)."

5. Patents. Small business concerns normally retain the principal worldwide patent rights to any invention developed with Government support. Under existing regulations, 37 CFR 401, the Government receives a royalty-free license for Federal Government use, reserves the right to require the patent-holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States. Information about additional requirements imposed by 37 CFR 401 should be obtained from local counsel or from the Division of Extramural Inventions and Resource Technologies, NIH, 6701 Rockledge Drive, Room 3188, MSC 7750, Bethesda, MD 20892-7750, phone: (301) 435-1986; fax: (301) 480-0272; e-mail: so7k@nih.gov. To the extent authorized by 35 U.S.C. 205, the Government will not make public any information disclosing a Government-supported invention for a four-year period to allow the grantee a reasonable time to file a patent application, nor will the Government release any information that is part of that application.

   Inventions must be reported promptly to the Division of Extramural Inventions and Resource Technologies, NIH, at the address above. This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the small business concern, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

D. Profit or Fee

A reasonable fixed fee is available to small business concerns receiving awards under the

SBIR program. The amount of the fee approved by the agencies participating in this Solicitation normally will not exceed seven (7) percent of total costs (direct and indirect) for each phase (I and II) of the project. Applicant organizations are reminded that SBIR Phase I awards may not exceed $100,000 for direct costs, indirect costs, and negotiated fixed fee. See page 187 for additional information.

E. Joint Ventures and Limited Partnerships

Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern in accordance with the definition included in this Solicitation.

F. Performance of Research and Analytical Work by the Applicant Organization

l. In Phase I, normally, a minimum of two-thirds or 67 percent of the research or analytical effort must be carried out by the small business concern, that is, consultant fees and contracts to third parties for portions of the scientific/technical effort generally may not exceed 33 percent of the total proposed budget, including direct and indirect costs.

2. In Phase II, normally, a minimum of one-half or 50 percent of the research or analytical effort must be carried out by the small business concern, that is, consultant fees and contracts to third parties for portions of the scientific/technical effort generally may not exceed 50 percent of the total proposed budget, including direct and indirect costs.

G. Terms and Conditions of Award

Upon acceptance of a grant award, the grantee must comply with the terms and conditions contained or referenced in the Notice of Grant Award document. These terms and conditions, constituting legal requirements imposed on a awardee by statute, regulations, administrative policy, or the award document itself, are either "standard" or "special", as follows:

Standard Terms and Conditions. Those that are required by policy to be incorporated by reference in Notices of Grant Award through citations of specific documents which contain requirements applicable to the grant.

Special Terms and Conditions. Those that are judged necessary to attain the objectives for which the grant is being awarded, facilitate post-award administration, conserve grant funds, or otherwise protect the interests of the Federal Government. They are stated in full on the Notice of Grant Award.

Grant awards must be administered in accordance with the PHS Grants Policy Statement and with the following regulations and policy.

9CFR 1,2,3	Animal Welfare
37 CFR 401	Rights to Inventions Made by Non-profit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative agreements
42 CFR 52	Grants for Research Projects

45 CFR 46	Protection of Human Subjects
45 CFR 74	Administration of Grants
45 CFR 80	Nondiscrimination Under Programs Receiving Federal Assistance Through DHHS Effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR 84	Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting from Federal Financial Assistance
45 CFR 91	Nondiscrimination on the Basis of Age in Programs and Activities Receiving or Benefiting from Federal Financial Assistance
P.L.99-158	Public Health Service Policy on Humane Care and Use of Laboratory Animals
Section 495	"Animals in Research"

H. American-Made Equipment and Products

When purchasing equipment or a product under the SBIR award, the small business concern should purchase only American-made items whenever possible.

I. Additional Information

1. This Omnibus Solicitation is intended for informational purposes and reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR funding agreement, the terms of the funding agreement are controlling.

2. Prior to award of an SBIR funding agreement, the Government may request the applicant to submit certain organizational, management, personnel, and financial information in order to assure responsibility of the applicant.

3. This Omnibus Solicitation is not an offer by the Government and does not obligate the Government to make any specific number of awards. Awards under this Program are contingent upon the scientific/technical merit of an application and the availability of funds for research and development. The Government is not responsible for any monies expended by the applicant before award of any funding agreement.

4. If an award is made pursuant to a grant application submitted in response to this Omnibus Solicitation, the grantee may be required to certify that it has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government.

5. If an award is made under this Omnibus Solicitation for a project, some of whose elements are being or will be supported by another federal agency, the awarding component and the applicant will negotiate a budget that reflects the elimination of any overlapping support.

IX. SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Health science research literature is available at academic and health science libraries throughout the United States. Information retrieval services are available at these libraries and Regional Medical Libraries through a network supported by the National Library of Medicine. A list of Regional Medical Libraries and information about network services may be requested from the Public Information Office, National Library of Medicine, Bethesda, MD 20894, telephone: (301) 496-6308.

Other sources that provide technology search and/or document services include the organizations listed below. They should be contacted directly for service and cost information.

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 487-4600

Mid-Atlantic Technology Applications Center
University of Pittsburgh
823 William Pitt Union
Pittsburgh, PA 15260
(412) 648-7000
(412) 648-7003 (fax)
(800) 257-2725 (toll-free US)

Mid-Continent Technology Transfer Center
The Texas A&M University System
College Station, TX 77843-3401
(409) 845-8762
(409) 845-3559 (fax)

Far West Regional Technology Transfer Center
University of Southern California
3716 South Hope Street, Suite 200
Los Angeles, CA 90007-4344
(213) 743-2353
(213) 746-9043 (fax)
(800) 642-2872 (CA only)
(800) 872-7477 (outside CA)

Center for Technology Commercialization
Massachusetts Technology Park
100 North Drive
Westborough, MA 01581
(508) 870-0042

Southern Technology Applications Center
University of Florida
College of Engineering
Box 24
One Progress Boulevard
Alachua, FL 32615
(904) 462-3913
(800) 225-0308 (outside FL)

Great Lakes Industrial Technology Center
25000 Great Northern Corporate Center
Suite 260
Cleveland, OH 44070-5310
(216) 734-0094
(216) 734-0686 (fax)

National Technology Transfer Center
Wheeling Jesuit College
316 Washington Avenue
Wheeling, WV 26003-6295
(800) 678-6882 (toll-free US)
(All services at no cost)

X. GRANTS - PROGRAM DESCRIPTIONS/RESEARCH TOPICS

NATIONAL INSTITUTES OF HEALTH (NIH)

The mission of the NIH is to improve human health trough biomedical and behavioral research, research training, and communications. The programs of the NIH are oriented principally towards basic and applied scientific inquiry related to the causes, diagnosis, prevention, treatment, and rehabilitation of human diseases and disabilities; the fundamental biological processes of growth, development, and aging; and the biological effects of the environment. In addition, the NIH sponsors training of research personnel; career development of new and established scientists; evaluation and dissemination of new information about medicine and health; construction and renovation of research facilities and provision of other research resources; and improvements in biomedical communications.

To carry out these responsibilities, the NIH is organized into awarding components. Those components that have an extramural element, that is, provide funds for research and research training activities in organizations external to the NIH, are shown below.

National Institute on Aging (NIA) 22

National Institute on Alcohol Abuse and Alcoholism (NIAAA) 28

National Institute of Allergy and Infectious Diseases (NIAID) 34

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) 40

National Cancer Institute (NCI) 42

National Institute of Child Health and Human Development (NICHD) 66

National Institute on Drug Abuse (NIDA) 80

National Institute on Deafness and Other Communication Disorders (NIDCD) 92

National Institute of Dental Research (NIDR) 95

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) 100

National Institute of Environmental Health Sciences (NIEHS) 110

National Eye Institute (NEI) 112

National Institute of General Medical Sciences (NIGMS) 114

National Heart, Lung, and Blood Institute (NHLBI) 118

National Institute of Mental Health (NIMH) 128

National Institute of Neurological Disorders and Stroke (NINDS) 145

National Institute of Nursing Research (NINR) 148

National Center for Research Resources (NCRR) 149

National Center for Human Genome Research (NCHGR) 153

National Library of Medicine (NLM) 156

Trans-NIH Research Programs 157

The Fogarty International Center, which provides support only for conferences, postdoctoral fellowships for research in the United States and abroad, and senior scientist exchanges between the United States and other countries, does not participate in the SBIR program.

Although all of the components listed above may use the grant and contract mechanisms, the primary funding instrument is the grant mechanism.

The research topics shown below represent program areas that may be of interest to small business concerns (applicant organizations) in the development of projects that have potential for commercialization. Small business concerns are encouraged to submit SBIR applications in these areas; however, **SBIR applications will be considered in ANY area within the mission of the NIH awarding components identified below.**

APPLICANTS ARE ENCOURAGED TO QUERY PROGRAM ADMINISTRATORS PERIODICALLY VIA E-MAIL TO LEARN OF NEW OR EMERGING SCIENTIFIC INTERESTS OF THE NIH AWARDING COMPONENTS.

OMB No. 0925-0195
Expiration Date 2/28/98

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Small Business Research Program

PHASE I GRANT APPLICATION FORM (PHS 6246-1)

INTRODUCTION

The applicant organization and the principal investigator are jointly responsible for the accuracy and validity of all the administrative, fiscal and scientific information in the application. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions such as withdrawal of an application or the suspension and/or termination of an award, as well as possible criminal penalties.

The Public Health Service (PHS) requests the information described in these instructions pursuant to its statutory authorities for awarding grants. Lack of sufficient information may hinder the ability of the PHS to review an application and to monitor the awardee's performance. Therefore, such information must be submitted if an application is to receive due consideration for an award.

The Privacy Act requires that individuals be informed that provision of the Social Security number is voluntary. No individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose the Social Security number. The PHS requests the Social Security number for the purpose of accurate identification, referral, and review of the application and for efficient management of PHS grant programs. This information is requested pursuant to authority in the Public Health Service Act, as amended (42 USC 241a and 42 USC 288).

The PHS makes information available to the public on awarded grants, including the title and the abstract of the project, the awardee institution, the principal investigator and the amount of the award. In addition, the Freedom of Information Act (FOIA), 5 USC 552, requires that records in the government's hands be released to requestors, unless certain exemptions apply. The exemptions permit the deletion, among other things, of trade secrets and confidential commercial or financial ("proprietary") information, or information that would invade personal privacy if revealed. The final decision on whether exemptions apply will be made by the funding agency. Awardees will be notified about any release of information from an application.

Grant records are maintained under Privacy Act systems of records 09-25-0112 and 09-25-0036. These systems allow the PHS to disclose grant records outside of DHHS for the following purposes: for audit; for defense in litigation; to a congressional office responding to an inquiry from a principal investigator; for processing of records in conjunction with evaluation or administration; and to the applicant organization. In addition, information which does not constitute trade secrets or privileged commercial or financial information may be disclosed to another Federal agency considering award of a grant or contract to the applicant or for research not inconsistent with limitations under which the information was provided. The PHS informs the National Technical Information Service, Department of Commerce of assignments of research investigators and project monitors on funded grants.

Under the provisions of the Privacy Act, principal investigators may request copies of their grant records as well as an accounting of disclosures of these records made outside of the Department of Health and Human Services (DHHS). In addition, principal investigators may request amendment of a record if they believe it is inaccurate, untimely, incomplete or irrelevant.

SUBMISSION

Type Size:

Type size specifications must be observed throughout the application, or the application will be returned without review. Adherence to these type size and line spacing requirements is necessary for several reasons. First, no applicant should have the advantage, by using small type characteristics, of providing more text in his/her application than other applicants. Second, small type may make it difficult for reviewers to read the application. Third, reviewers' inabilities to read text easily might impact adversely on the adequacy of the peer review process, thereby doing a disservice to the applicant.

The application must be clear, readily legible, and conform to the following three requirements: (1) The height of the letters must not be smaller than 10 point. (2) Type density must be no more than 15 characters per inch (cpi). (For proportional spacing, the average for any representative section of text must not exceed 15 cpi.) (3) Finally, there must be no more than 6 lines of type within a vertical inch. Type requirements should be checked on the printed document using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/printer combination. **The type size used throughout the application must conform to all three of these requirements.** (Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be clear and readily legible.)

Applications not meeting all three requirements stated in the preceding paragraph will be returned without review. The Referral Office, Division of Research Grants (DRG), NIH, has the responsibility and authority to make the final determination of legibility which is FINAL AND NOT APPEALABLE. Further inquiries should be directed to the Referral Office, DRG: phone: (301) 435-0715; fax: (301) 480-1987.

Page Limits and Mailing Instructions:

The complete application (including all "continuation" pages suggested by these instructions or application forms) may not exceed 25 pages, <u>excluding</u> cover letters, letters of commitment from collaborators/consultants, letters to determine eligibility, the CHECKLIST page, and the page(s) furnishing the information required under "Prior SBIR Phase II Awards" (see item immediately below), if applicable. No appendices may be submitted and, if submitted, they will not be considered in the review of the application for scientific and technical merit. Use English only and avoid jargon and unusual abbreviations. Type the application, single spaced, and stay within the margin limitations indicated on the forms. (Use one inch margins for all continuation pages.) Use standard size, black type that can be photocopied; do **not** use photoreduction. Draw all graphs, diagrams, tables, and charts in black ink. Do **not** include glossy photographs, or materials that cannot be photocopied in the body of the application. **Mail or deliver** the complete and signed typewritten, original of the application and two signed, exact, clear, single-sided photocopies, in one package, to the **DIVISION OF RESEARCH GRANTS, NATIONAL INSTITUTES OF HEALTH, 6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710, BETHESDA, MD 20892-7710.** (<u>NOTE</u>: This zip code is for centraol receipt of NIH mail. **Applicants who wish to use express mail or courier service should change the zip code to 20817.)** Do **not** bind or staple the sets, but secure them with rubber bands or paper clips. **Do not include more than one set of applications in each mailing envelope.**

Prior SBIR Phase II Awards:

A small business concern that submits an SBIR Phase I application and that has received more

than 15 Phase II SBIR awards during the preceding five (5) fiscal years must document the extent to which it was able to secure Phase III funding to develop concepts resulting from previous Phase II SBIR awards. The following information must be submitted in the Phase I application regarding each such prior Phase II award: (1) name of awarding agency; (2) award number and date; (3) amount of award; (4) title of project; (5) source, date, and amount of Phase III funding agreement; and (6) commercialization status of each Phase II award shown in (1) above.

Requests for Referral:

When submitting an application, the principal investigator may suggest in a cover letter an awarding component(s) to which it could be appropriately assigned for potential funding. Although these suggestions will be taken into consideration, the final determination will be made by the agencies participating in this Solicitation..

Incomplete Applications:

Do not submit an incomplete application. An application will be considered incomplete and will be returned if it is illegible, if it fails to follow the instructions, or if the material presented is insufficient to permit an adequate review.

Supplementary or Corrective Information:

Do not send supplementary or corrective material pertinent to the review of an application after the receipt date without its being specifically solicited by or agreed to through prior discussion with the Scientific Review Administrator of the initial review group.

Receipt Date:

Applications submitted under this Solicitation must be **RECEIVED** by the Division of Research Grants (DRG), NIH, by the receipt dates shown in section VI., Submission of Grant Applications. If the receipt date falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following work day. The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter with the signed, completed application. **No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.**

Notification of Receipt:

Usually within six weeks, the DRG, NIH, will send the principal investigator and the applicant organization the application's number and the name, address, and telephone number of the Scientific Review Administrator of the initial review group to which the application has been assigned. If this information is **not** received within that time, contact the **REFERRAL OFFICE, DIVISION OF RESEARCH GRANTS, NATIONAL INSTITUTES OF HEALTH, 6701 ROCKLEDGE DRIVE, ROOM 1040 -- MSC 7710, BETHESDA, MD 20892-7710, phone: (301) 435-0715; fax: (301) 480-1987.**

SPECIFIC INSTRUCTIONS

FACE PAGE (Form Page 1)

The information provided on the FACE PAGE of the application and all fiscal information, including the calculation of indirect costs, must be verified by the Official Signing for Applicant Organization.

Item 1. Title of Application. Choose a descriptive and specifically appropriate title. Do not exceed 56 typewritten spaces, including punctuation and spaces between words.

Item 2. Solicitation No. (filled in). These forms are to be used in applying for support under the SBIR program only.

Item 3. Principal Investigator. Check the "New Investigator" box **only** if the principal investigator has never received independent research grant or contract support from the agencies participating in this Solicitation.

Item 3a. Name of Principal Investigator. Name the **ONE** person responsible to the applicant organization for the scientific and technical direction of the project. **(Reminder: More than one-half of the Principal Investigator's time must be spent with the applicant organization at the time of award and during the conduct of the proposed project. The application must include evidence of primary employment with the applicant organization [see section II., Eligibility]. APPLICATIONS THAT FAIL TO PROVIDE SUCH DOCUMENTATION WILL BE CONSIDERED INCOMPLETE AND WILL BE RETURNED WITHOUT REVIEW.)** The concept of co-principal investigator is not formally recognized. Agency staff conduct offical business only with principal investigators and officials of the applicant organizations (small business concerns).

Item 3b. Degree(s). Indicate up to three academic and professional degrees or other credentials, such as licenses (for example, R.N.).

Item 3c. Social Security Number. The agencies participating in this Solicitation request Social Security Numbers for accurate identification, referral, and review of applications and for management of their grant programs. Provision of the Social Security Number is voluntary. No individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose his or her Social Security Number. The Social Security Number is requested under sections 301(a) and 487 of the PHS Act as amended (42 USC 241a and USC288).

Item 3d. Position Title. Provide the professional title of the principal investigator. If more than one title, indicate the one most relevant to the proposed project, such as Director of Research or Group Leader.

Item 3e. Mailing Address. Provide complete information (including room number, building and street address) necessary for postal delivery. All written communications with the principal investigator will use this address. For electronic mail, enter the appropriate e-mail address.

Item 3f. Telephone and FAX Numbers. Provide a daytime telephone number and, if available, a FAX number.

Items 4-5. Human Subjects and Vertebrate Animals. If Human Subjects and/or Vertebrate Animals are involved in the proposed project, refer to the information on these items on pages 189 and 190, respectively, before proceeding.

Item 6. Dates of Project Period. Normally, SBIR Phase I may not exceed six (6) months.

Item 7. Costs Requested

Item 7a. Direct Costs. Insert total direct costs from form page 3. (Do not include amount requested for fixed fee.)

Item 7b. Total Costs. Enter the sum of (a) the total direct costs on form page 3; (b) the amount requested for fixed fee on form page 3; and (c) the indirect costs derived from the CHECKLIST (form page 5). **(NOTE**: The total costs, including the fixed fee, should not exceed $100,000.

Item 8. Performance Sites. Indicate where the work described in the RESEARCH PLAN will be conducted. If there is more than one performance site, list all the sites and provide an explanation on form page 4, RESOURCES. One of the sites indicated must be that of the applicant organization.

NOTE: The research or R&D project activity must be performed in its entirety in the United States (see section IV, Definitions).

Item 9. Appicant Organization. Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award.

Item 10. Entity Identification Number. Enter the 12-digit number assigned to the applicant organization by the Department of Health and Human Services (HHS) for payment and accounting purposes. That number is an expansion of the 9-digit "employer identification number" (EIN) assigned to the applicant organization by the Internal Revenue Service (IRS). If an HHS number has not yet been assigned, the applicant organization should enter either (1) the EIN assigned to it by the IRS or (2) the words "Applied for" to indicate that the organization does not have an EIN but has applied to the local office of the IRS for one. **An individual's social security number is not appropriate for this item.** Also, be sure to fill in the Congressional District in the space provided.

Item 11. Small Business Certification. The applicant organization must certify that it is a small business concern by checking the first box. Check the second and/or third boxes if applicable. (See the definitions for a small business concern as provided in section IV of this Solicitation.) Please note that capture of information on socially and economically disadvantaged small business concerns and women-owned small business concerns is strictly for statistical purposes (as requested by the Small Business Administration).

Item 12. Notice of Proprietary Information. Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets or information that is commercial or financial and confidential or privileged, identify the pages in the application which contain such information. In addition, mark those paragraphs or lines containing such information with an asterisk (*) in the left-hand margin.

Item 13. Disclosure Permission Statement. Self-explanatory.

Item 14. Official Signing for Applicant Organization. Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. For electronic mail, enter the appropriate e-mail address.

Item 15. Principal Investigator Assurance. An original signature in ink is required. "Per" signatures are not acceptable. Date of signature must be included.

Item 16. Applicant Organization Certification and Acceptance. An original signature in ink is required. "Per" signatures are not acceptable. Date of signature must be included. In signing the application face page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying the accurancy, validity, and conformity with the most current organizational guidelines of all the administrative, fiscal, and scientific information in the application, including information pertaining to indirect costs. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, and debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the apprpriate use of any funds awarded and for the performance of the grant supported project or activities resulting from this application. The grantee organization may be liable for the reimbursement of funds associated with any inappropriate or

fraudulent conduct of the project activity.

ABSTRACT OF RESEARCH PLAN (Form Page 2). Follow the instructions for the information requested. The Abstract of Research Plan is limited to 200 words. If the application is funded, this description, as is, will become public information. Therefore, **do not include proprietary or confidential information in the abstract**.

BUDGET FOR PHASE I (Form Page 3)

For the reasons indicated on the first page of this SBIR Solicitation, certain of the following items have been modified and others should not be completed for the submission of the application, **but will be requested by the awarding component if the application has a likelihood for funding**.

Form page 3, Budget for Phase I Direct Costs Only, is completed by the applicant organization (small business concern) and reflects the total direct costs requested for Phase I, which includes the total costs (direct and indirect) of any "contractual costs." The amount requested by the small business concern for "fixed fee" is not a "cost" and should not be included within "Total Direct Costs" on form page 3.

The following items pertain individually to the completion of budget form pages 3 and 4.

Personnel

Name. List the names of **all** organizational personnel to be involved in the project during the Phase I budget period regardless of whether a salary has been requested. Starting with the Principal Investigator whose signature appears on the face page of the application, include all collaborating investigators, individuals in training, and support staff. The concept of co-principal investigators is not formally recognized..

Role on Project. Identify the role of each individual listed on the project. Describe their specific functions under Budget Justification on form page 4.

Type of Employment. Do not complete at the time of application. The following information will be requested by the awarding component if the application has a likelihood for funding. When requested to do so, list the number of months per year reflected in an individual's employment agreement with the organization. If employment is less than full time (for example, 13/25 time or 3/4 time), enter an asterisk (*) after the number of months and provide a full explanation under Budget Justification on form page 4.

Percent Effort on Project. Percent of effort on project indicates the percentage of each individual's employment at the organization to be spent on **this** project. If an individual engages in other corporate responsibilities, such as management, the **total** percentage devoted to **all** research activities by the individual must be less than 100 percent.

Institutional Base Salary. Do not complete at the time of application. The following information will be requested by the awarding component if the application has a likelihood for funding. The institutional base salary is defined as the annual compensation that the organization pays for the individual's employment, whether that individual's time is spent on research, administration, or other activities. Base salary excludes any income the individual may be permitted to earn outside of duties to the organization. Base salary **may not** be increased as a result of replacing corporate salary funds with grant funds.

Dollar Amount Requested

Salary. Do not complete at the time of application. The following information will be requested by the awarding component if the application has a likelihood for funding. When requested to do so, enter the dollar amounts for each position for which funds are requested. The maximum salary

that may be requested is calculated by multiplying the individual's institutional base salary, defined above, by the percent of effort on this project. Congress has imposed and may continue to impose salary caps. Organizations should request appropriate salary support without regard to Congressional salary caps. Any amount requested for salary that may be in excess of a salary cap will be adjusted at the time an award is issued. Calculate the totals for each position and enter the subtotals in each column where indicated.

Fringe Benefits. **Do not complete at the time of application.** The following information will be requested by the awarding component if the application has a likelihood for funding. Fringe benefits may be requested as a direct cost to the extent that they are treated consistently by the organization as a direct cost to all sponsors. As an alternative, fringe benefits may be included in the calculation of the organization's indirect costs.

Totals. Do not complete at the time of application.

Subtotals. Show amounts in total for all organizational personnel for whom a salary is requested.

Consultant Costs. The total amount of all consultant costs and contractual costs normally may not exceed 33 percent of the total costs requested. Provide the names and organizational affiliations of any consultants, **other than those involved in contractual arrangements**, who have agreed to serve in that capacity. Include consultant physicians in connection with patient care. **Reminder**: Letters of commitment from collaborators and consultants must be submitted with the application, but are excluded from the 25-page limitation. **If this category exceeds $10,000 and/or a consultant(s) is identified as "Key Personnel Engaged on Project" on form page 2**, briefly describe on form page 4 the services to be performed, including the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs. See section IV for definition of "Key Personnel Engaged on Project."

Equipment. Provide the total dollar amount requested. Itemize and justify according to the following instructions only if this category exceeds $15,000. List separately each item of equipment with a unit acquisition cost of $5,000 or more; and justify the request on form page 5. Explain the need for any item that appears to duplicate or to be equivalent to those listed in the RESOURCES portion on form page 5.

Supplies. Provide the total dollar amount requested. Itemize and justify according to the following instructions only if this category exceeds $15,000. Itemize supplies in separate categories such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are involved, state how many are to be used, their unit purchase cost, and their unit care cost.

Travel. Provide the total dollar amount requested. Itemize and justify according to the following instructions only if this category exceeds $5,000. Describe the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that agency policy requires that less than first class air travel be used. Justify foreign travel in detail on form page 4, describing its importance to the accomplishment of the project.

Patient Care Costs. The applicant organization may be reimbursed for inpatient and outpatient charges incurred incident to the proposed research. Provide the names of the hospitals to be used and the amounts requested for each. Indicate in detail the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment.

Patient care costs do not include travel, lodging, and subsistence; request these costs in the "Other Expenses" category. Request consultant physician fees in the "Consultant Costs" category.

Contractual Costs. **The total amount of all contractual costs and consultant fees normally may not exceed 33 percent of the total costs requested**. Contractual arrangements for scientific

or technical services, such as the laboratory testing of biological materials, clinical services, etc, may involve costs such as personnel, supplies, and any other allowable expenses, including indirect costs. Such contracts may be sufficient scope to warrant a categorical breakdown of costs. Enter the total direct costs and indirect costs, if any, separately for each contractor. Use photcopies of form page 3 to itemize separate detailed budgets for each contractor. Itemize any indirect costs and provide the basis for the rate in the “Other Expenses” category of the supplementary budget pages. Insert the supplementary budget pages after form page 4 and number them sequentially.

Other Expenses. **Provide the total dollar amount requested. Itemize and justify according to the following instructions <u>only</u> if this category exceeds $5,000**. Itemize other expenses, such as computer charges, donor fees, rentals and leases, equipment maintenance, etc., by category and unit cost. Justify all items on form page 4.

Fixed Fee. The amount requested for fixed fee must be reasonable. The amount of the approved fee normally will <u>not</u> exceed seven (7) percent of total costs (direct <u>and</u> indirect) for each phase (I and II) of the project. Explain the basis for the amount of fixed fee under Budget Justification on form page 4.

On the Face Page of the application, enter the amount for "Direct Costs," item 7a., as indicated on form page 3. Enter the amount requested for "Total Costs" (direct costs, indirect costs, <u>and</u> fixed fee) in item 7b. to reflect the total amount of support requested for the proposed project. Applicant organizations are reminded that SBIR Phase I awards should not exceed $100,000, <u>including</u> negotiated fixed fee.

Other Support (Form Page 3). **Do not complete this item at the time of application**. The following information will be requested by the NIH awarding component if the application has a likelihood for funding.

<u>Policy</u>

The information on "Other Support" assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that (1) sufficient and appropriate levels of effort are committed to the project; (2) there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and (3) funds not otherwise necessary to the conduct of the approved project are not included in the award. The Principal Investigator is responsible for being aware of any changes in the other support of key personnel identified on form page 2 and for notifying the appropriate grants management office of such changes. Updated information on other support may be requested at the time of award (1) when there is a substantial amount of pending support; (2) when there has been a significant time lapse since the time of application; or (3) when potential overlap has been identified.

<u>Definitions</u>

"Other Support" is defined as **all financial resources**, whether Federal (including SBIR), non-Federal, organizational, or other industrial, **available in direct support of an individual’s research endeavors**, including but not limited to, research grants, cooperative agreements, contracts, and awards from industrial sources.

Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration; or (2) a specific research objective and the experimental design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

Budgetary overlap occurs when duplicate or equivalent budgetary items (for example, salary, equipment) are requested in an application but are already funded or provided for by another source.

Commitment overlap occurs when any project personnel has time commitments exceeding 100 percent. This is the case whether or not the grant or contract includes salary support for the effort. It is important to note that while information on other support is requested only for key personnel, no individual on the project may have commitments in excess of 100 percent.

Resolution of Overlap

Although applicant organizations are requested to identify potential overlap, the actual resolution of overlap occurs at the time of award in conjunction with applicant organization officials, including the Principal Investigator, and awarding agency staff. Potential overlap is to be addressed by the initial review groups only by its identification in an Administrative Note in the Summary Statement (see section VII.E., Release of Grant Application Review Information).

Instructions (**Do not complete this item at the time of application.** The information below will be requested by the awarding component if the application has a likelihood for funding.)

There is no "form page" for Other Support. If none, check the box marked "NO" at the foot of form page 3. Otherwise, check the box marked "YES" and for **each** of the key personnel named on form page 2 (**excluding** consultants), use continuation pages to list in separate groups: (1) all currently active research support, and (2) all applications and proposals pending review or funding (do not list **this** application). In a separate group, list any other active or pending support to the applicant organization (small business concern) for work related to **this** project. For all groups, specifically identify projects under the SBIR program and the Small Business Technology Transfer (STTR) program. If the support is provided under a subcontract arrangement or is part of a multiproject award, identify the principal investigator and provide the data below for both the parent and the subproject.

For each item, provide: (a) source of funding, identifying number, title, and inclusive dates of the project as approved (for active awards) or proposed (for pending support); (b) brief statement of overall objectives of the project, subproject, or subcontract; (c) annual direct costs as approved or proposed; and (d) percentage of effort on the project. After listing all OTHER SUPPORT, summarize for each individual any potential overlap with active or pending projects and **this** application in terms of the science, budget, or an individual's committed effort. (See the definitions above for the three types of overlap.) Any necessary resolution of overlap due to this application being funded will occur in conjunction with the applicant organization and the awarding component staff at the time of award.

> **WARNING** -- While it is permissible, with proposal notification, to submit identical proposals or proposals containing a significant amount of essentially equivalent work (as defined in this Solicitation) for consideration under numerous federal program solicitations, **it is unlawful to enter into grants or contracts requiring essentially equivalent effort**. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award.

For each continuation page, show the name of the Principal Investigator for **this** application at the top, number the pages sequentially, and insert them after form page 4.

RESOURCES (Form Page 4). All performance sites identified in item 8 on the Face Page of the application should be described under "Facilities." Attach a continuation page(s) if necessary. One of the sites indicated must be that of the small business concern (applicant organization).

BIOGRAPHICAL SKETCH AND BIBLIOGRAPHY (Use continuation pages)

Provide the following information for each "key professional" listed on form page 2, beginning with the principal investigator: name, title, birthdate and education (including institution(s) and location, degree(s) and year(s) conferred, and field(s) of study). (See section IV of the Solicitation for definition of "Key Personnel Engaged on Project.") List, in reverse chronological order, previous employment, experience and honors. Provide dates and places of employment as well as some information about the nature of each position or professional experience. **Indicate current or most recent employment.** List, in chronological order, the titles and complete references to those publications most pertinent to this application. (The 25-page limitation includes all biographical sketches.)

RESEARCH PLAN (Use continuation pages)

Include sufficient information to facilitate an effective review without reference to any previous application. Be specific and informative and avoid redundancies. **The complete application may not exceed 25 pages, excluding cover letters, letters of commitment from collaborators/consultants, letters to determine eligibility, the CHECKLIST page, and the page(s) furnishing the information required under "Prior SBIR Phase II Awards", if applicable. No appendix may be submitted.**

Introduction: Include an introduction **only** when submitting a revised application. Do not exceed one page. This page is in addition to the 25-page limitation of the application.

Revised Application. Acceptance of a REVISED application automatically withdraws the prior version. In the Introduction, summarize any substantial additions, deletions, and changes that have been made. Include responses to criticisms in the previous summary statement. Identify these changes within the text of the RESEARCH PLAN by appropriate bracketing, indenting, or changing of typography. Incorporate any work done since the prior version was submitted. **A revised application will be returned if substantial revisions are not clearly apparent.**

The suggested format for the **Research Plan** is as follows:

A. **Specific Aims.** State concisely and realistically what the proposed research is intended to accomplish in terms of its potential for technological innovation and commercial application.

B. **Significance.** Briefly sketch the background to the present grant application, critically evaluate existing knowledge, and specifically identify the commercial opportunities which 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.

C. **Relevant Experience.** Describe the principal investigator's research experience pertinent to the project, including any information that will help establish the competence of the investigator to pursue the proposed project.

D. **Experimental Design and Methods.** Discuss in detail the experimental design, procedures and protocols to be used, and the means by which the data will be analyzed and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. **Discuss the criteria that will be used to determine if feasibility has been demonstrated.** Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. **Information regarding the Inclusion of Women and Minorities in Research Involving Human Subjects MUST be included in this portion of the Research Plan (see page 204.) No SBIR grant will be awarded that does not comply with this policy.**

E. **Human Subjects.** If Item 4 on the FACE PAGE of the application has been marked "YES" and exemptions from the regulations are designated, provide sufficient information to allow a determination that the designated exemptions are appropriate.

If Item 4 on the FACE PAGE of the application has been marked "YES" and an exemption from the regulations is not designated, address the following six points. Be sure to consult information under "**Checklist**."

1. Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the Experimental Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion. **If women and/or minorities are not included in a given study, provide a clear rationale for their exclusion.** All research projects involving human subjects are subject to the policy, whether or not they are exempt from human subject protections and IRB review requirements. Explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, human in vitro fertilization, prisoners or other institutionalized individuals, or others who are likely to be vulnerable.

2. Identify the sources of human research material, such as specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data. Indicate whether the source of these materials will be from individually identifiable living human subjects whose identity may be readily ascertained by the investigator or collaborators under the investigator's direction.

3. Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the method of documenting consent. If the applicant is an MPA institution, state if the IRB has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. If the applicant is not an MPA institution, state if the IRB will be requested to grant a modification or waiver of the elements of consent or the requirement for documentation of consent. The consent form should be submitted to the PHS only on request. Neither IRB review nor approval is required as a condition of application unless the applicant organization is an MPA institution.

4. Describe any potential risks-physical, psychological, social, legal, or other-and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for insuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to insure the safety of subjects.

6. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the FDA.

F. **Vertebrate Animals.** If item 5 on the FACE PAGE of the application has been marked "YES", address the following five points. Be sure to consult information under "**Checklist**."

1. Provide a detailed description of the proposed use of the animals in the work previously outlined in the Experimental 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 used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and their 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 euthanasia method 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 justification for not following the recommendations.

G. **Consultants**. Attach appropriate letters from each individual confirming his or her role in the project. Include biographical sketches for each consultant. (**Reminder**: The 25-page limitation of the application includes biographical sketches but not letters of commitment from collaborators and consultants.)

H. **Contractual Arrangements**. Provide a detailed explanation of the programmatic and fiscal arrangements made between the applicant organization and the contractor. Provide a statement that the applicant organization and the contractor either have established or are prepared to establish in writing the required contractual agreement. Attach confirming letters or copies of the contract, if available.

I. **Literature Cited**. List literature citations at the end of the RESEARCH PLAN. Each citation must include the names of all authors, the name of the book or journal, volume number, page numbers, and year of publication. Be judicious in compiling a relevant and current bibliography. It need not be exhaustive.

CHECKLIST. This must be the last page of the application and should be numbered accordingly. **Complete "Type of Application," "Indirect Costs," and "Smoke-Free Workplace" portions only at the time of application**. Information on the other two parts ("Assurances and Certifications" and "Program Income") will be requested by the awarding component if the application has a likelihood for funding.

CHECKLIST

This must be the last page of the application and should be numbered accordingly.

ASSURANCES AND CERTIFICATIONS

In signing the application Face Page, the Official Signing for Application Organization (small business concern) certifies that the applicant organization will comply with the following:

HUMAN SUBJECTS

A. Policy

The Department of Health and Human Services (DHHS) regulations for the protection of human subjects provide a systematic means, based on established internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations require that applicant organizations establish and maintain appropriate policies and procedures for the protection of

human subjects. These regulations, 45 CFR 46, **Protection of Human Subjects**, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, MD 20892-7507, (301) 496-7041.

The regulations stipulate that an applicant organization bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations define "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 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. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

Exempt from coverage by the regulations are activities in which the only involvement of human subjects will be in one or more of the following six categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) (b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data,documents, records, pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

An applicant organization proposing to conduct non-exempt research involving human subjects does not need to file an assurance of compliance (Assurance) with the OPRR at the time of application. However, no DHHS award for non-exempt research involving human subjects will be

made to an applicant organization unless that organization is operating in accord with an approved Assurance and provides certification that the Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the DHHS regulations.

If an award is to be made, an Assurance will be requested prior to issuance of the award. As part of this Assurance, which commits the applicant organization to comply with the DHHS regulations, the applicant organization must appoint an IRB, which is required to review and approve all non-exempt research activities involving human subjects. Specific instructions for small businesses regarding Assurances and IRB reviews and approvals are contained in B. Instructions below.

Research investigators are entrusted with an essential role in assuring the adequate protection of human subjects. In activities they conduct or which are conducted under their direction, they have a direct and continuing responsibility to safeguard the rights and the welfare of the individuals who are or may become subjects of the research. Investigators must comply with the DHHS regulations, with the applicant organization's Assurance, and with the requirements and determinations of the IRB concerning the conduct of the research. Investigators must avoid unnecessary risks to subjects by using procedures which are consistent with sound research design and acceptable medical practice. Whenever appropriate, investigators should use procedures already being performed on the subjects for diagnostic or treatment purposes. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. Investigators must obtain the legally effective informed consent of each subject or of the subject's legally authorized representative before involving the subject in the research, to the extent required by and in accordance with 45 CFR 46, or as required by applicable Federal, State, or local law. The consent form must be approved by the IRB.

Investigators who conduct research involving fetuses, pregnant women, children, human *in vitro* fertilization, or prisoners must follow the provisions of the regulations in Subparts B, C and D of 45 CFR 46, which describe the additional protections required for these subjects.

B. Instructions

If activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check the box marked **"YES." at item 4.** If the activities are designated to be exempt from the regulations, insert in item 4a the exemption number(s) corresponding to one or more of the six exemption categories listed above. **Inappropriate designations of the non-involvement of human subjects or of exempt categories of research may result in delays in the review of an application. The PHS will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the RESEARCH PLAN.**

If the planned activities involving human subjects are not exempt, complete the remaining parts of item 4a. If the applicant organization does not have on file with OPRR an approved Multiple Project Assurance (MPA), insert "NONE" in item 4b. In this case, the applicant organization, by the signatures on the face page, is declaring that it will comply with 45 CFR 46 (the regulations for Protection of Human Subjects). **APPLICANT ORGANIZATIONS THAT DO <u>NOT</u> HAVE AN MPA ON FILE WITH OPRR ARE <u>NOT</u> REQUIRED TO SUBMIT AN ASSURANCE OR TO HAVE THE PROPOSED RESEARCH APPROVED BY AN IRB AT THE TIME THE APPLICATION IS SUBMITTED. When the awarding component determines that the application has a likelihood for funding, the awarding component will request OPRR to contact the applicant organization. OPRR will provide detailed instructions on filing an Assurance to the applicant organization, even if a subcontract organization has an Assurance on file with OPRR. APPLICANT ORGANIZATIONS ARE REMINDED THAT IT IS THEIR RESPONSIBILITY TO RESPOND TO OPRR IN A TIMELY MANNER ONCE THE INSTRUCTIONS ON FILING AN ASSURANCE HAVE**

BEEN RECEIVED.

If the applicant organization has an approved MPA on file with the OPRR that covers the specific activity, insert the Assurance identification number and the latest date of approval by the IRB of the proposed activities. This date must be no earlier than one year before the receipt date for which the application is submitted. **The information in item 4 and the signatures on the Face Page fulfill the requirement for certification of IRB approval.**

The applicant organization may be an MPA institution. If so, IRB review is best completed prior to submission of the application. This will help to avoid delays in the review of the application. However, if the IRB review is unavoidably delayed beyond the submission of the application, enter "pending" at item 4a. A follow-up certification of IRB approval from the Corporate Official must then be sent to and received by the Scientific Review Administrator of the initial review group within 60 days after the receipt date for which the application is submitted. This follow-up certification format must include: application number, title of the application project, name of the principal investigator and institution, MPA number, date of IRB approval, and appropriate signatures. Any modifications in the Research Plan section of the application required by the IRB must be submitted with the follow-up certification. Occasionally, PHS initial review may be scheduled to occur before the end of the 60-day grace period. In these special cases of accelerated review, the follow-up certification will be requested earlier. **Otherwise, it is the responsibility of the applicant organization to submit the follow-up certification. The PHS does not guarantee that it will remind the applicant organization or the principal investigator to provide this missing information. If certification of IRB approval is not received when due, i.e., within 60 days after the official application receipt date, the application will be considered incomplete and deferred to the next review cycle.**

The name and address of the Scientific Review Administrator of the initial review group will be sent to the principal investigator and the applicant organization as soon as possible after the receipt date, usually within 6 weeks. To avoid delays in review, do not send the follow-up information to any other addresses.

For assistance and guidance on issues related to the protection of human subjects, small business concerns should contact OPRR staff at the National Institutes of Health, Bethesda, MD 20892-7507, (301) 496-7041, identifying themselves as SBIR applicants.

VERTEBRATE ANIMALS

A. Policy

The PHS Policy on Humane Care and Use of Laboratory Animals (Policy) requires that applicant organizations establish and maintain appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used In Testing, Research, and Training and requires that institutions use the **Guide for the Care and Use of Laboratory Animals (Guide)** as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations which impose more stringent standards for the care and use of laboratory animals. **All** institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.), and other Federal statutes and regulations relating to animals. The PHS Policy and Guide are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, MD 20892-7507, (301) 496-7163.

The Policy stipulates that an applicant organization bears responsibility for the humane care and use of animals in PHS-supported research activities. The PHS Policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes". An applicant organization proposing to use vertebrate animals in PHS-supported activities must file an Animal Welfare Assurance (Assurance) with the

OPRR. As part of this Assurance, which commits the applicant organization to comply with the PHS Policy, the applicant organization must appoint an Institutional Animal Care and Use Committee (IACUC), which is required to review and approve those sections of applications for PHS support that involve vertebrate animals.

No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accord with an approved Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with the PHS Policy. Applications may be referred by the PHS back to the applicant organization for further review by the IACUC in the case of apparent or potential violations of the PHS Policy. Copies of the approved Assurance are available to every researcher at the applicant organization. No award to an individual will be made unless that individual is affiliated with an organization that accepts responsibility for compliance with the PHS Policy and has filed the necessary Assurance with OPRR.

Research investigators are entrusted with an essential role in assuring the humane care and use of animals. In activities they conduct or which are conducted under their direction, they have a direct and continuing responsibility to see that animals are adequately cared for and used. Investigators must comply with the PHS Policy, with the applicant organization's Assurance, and with the requirements and determinations of the **IACUC** concerning the conduct of the research. Investigators must ensure that discomfort, distress, pain and injury to the animals are avoided or minimized, consistent with sound research design; that no more animals are used than are necessary to reach sound scientific conclusions; and that, when appropriate, animals are painlessly killed in accordance with methods of euthanasia recommended by the Panel on Euthanasia of the American Veterinary Medical Association.

B. Instructions

If activities involving vertebrate animals are planned **at any time** during the proposed project period, either at the applicant organization or any other performance site or collaborating institution, check the box marked **"YES"** at item 5.

If the applicant organization does not have on file with OPRR an approved Assurance, insert "NONE" in item 5b. In this case, the applicant organization, by the signatures on the face page, is declaring that it will comply with PHS policy regarding the care and use of animals by submitting an Assurance and verification of IACUC approval **when requested to do so by OPRR**. **When the awarding component determines that the application has a likelihood for funding, the awarding component will request OPRR to contact the applicant organization. OPRR will provide detailed instructions on filing an Assurance to the applicant organization, even if a subcontract organization has an Assurance on file with OPRR. APPLICANT ORGANIZATIONS ARE REMINDED THAT IT IS THEIR RESPONSIBILITY TO RESPOND TO OPRR IN A TIMELY MANNER ONCE INSTRUCTIONS ON FILING AN ASSURANCE HAVE BEEN RECEIVED.**

If the applicant organization has an approved Assurance on file with OPRR, insert at item 5a the date of approval by the IACUC of those sections of the application related to the care and use of animals. Insert at item 5b the Assurance identification number. **The information in item 5 and the signatures on the Face Page fulfill the requirement for verification of IACUC approval.**

To ensure against delays in the review of the application, IACUC review is best completed prior to submission of the application. However, if the IACUC review is unavoidably delayed beyond the submission of the application, enter "pending" at item 5a. A follow-up verification of IACUC approval from the Official Signing for Applicant Organization must then be sent to and received by the Scientific Review Administrator of the initial review group within 60 days after the receipt date for which the application is submitted. The follow-up verification format must include: application number, title of application project, name of principal investigator and institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures.

Any modifications of the Research Plan section of the application required by the IACUC must be submitted with the follow-up verification. Occasionally, PHS initial review may be scheduled to occur before the end of this 60-day grace period. In these special cases of accelerated review, the follow-up verification will be requested earlier. **Otherwise, it is the responsibility of the applicant organization to submit the follow-up verification.**

The PHS does not guarantee that it will remind the applicant organization or the principal investigator to provide this missing information. If verification of IACUC approval is not received when due, i.e., within 60 days after the official application receipt date, the application will be considered incomplete and deferred to the next review cycle.

The name and address of the Scientific Review Administrator of the initial review group will be sent to the principal investigator and applicant organization as soon as possible after the receipt date, usually within 6 weeks. To avoid delays in review, do not send the follow-up information to any other addresses.

For assistance and guidance on issues related to animal welfare, small business concerns should contact OPRR staff at the National Institutes of Health, Bethesda, MD 20892-7507, (301) 496-7163, identifying themselves as SBIR applicants.

DEBARMENT AND SUSPENSION. Executive Order 12549, "Debarment and Suspension," mandated development of a **Governmentwide** debarment and suspension system for nonprocurement transactions with Federal Agencies. "Nonprocurement" transactions include grants, cooperative agreements, and fellowships. HHS regulations implementing Executive Order 12549 are provided in 45 CFR 76, "Governmentwide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-free Workplace (Grants)." Accordingly, before a grant award can be made, the applicant organization must make the following certification (Appendix A of the HHS regulations):

"(1) The prospective primary participant certifies to the best of its knowledge and belief that it and its principals (including research personnel):

> "(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
>
> "(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgement rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
>
> "(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and
>
> "(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

"(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal."

Grantees are required to obtain a similar certification from most subawardees, called "lower tier participants." (See 45 CFR 76, Appendices A and B.)

DRUG-FREE WORKPLACE. The Drug-Free Workplace Act of 1988 (Public Law 100-690,Title V, Subtitle D) requires that all grantees receiving grants from any Federal agency certify to that agency

that they will maintain a drug-free workplace. HHS regulations implementing the Act are provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the applicant organization must make the certification set forth below (Appendix C of the HHS regulations). The certification is a material representation of fact upon which reliance will be placed by the PHS awarding component. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or **Governmentwide** suspension or debarment.

The applicant organization certifies "that it will or will continue to provide a drug-free workplace by:

"(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

"(b) Establishing an ongoing drug-free awareness program to inform employees about:

"(1) The dangers of drug abuse in the workplace;

"(2) The grantee's policy of maintaining a drug-free workplace;

"(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

"(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

"(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a).

"(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will;

"(1) Abide by the terms of the statement; and

"(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction.

"(e) Notifying the agency in writing within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

"(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted;

"(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

"(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

"(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f)."

For purposes of paragraph (e) regarding agency notification of criminal drug convictions, the HHS has designated the following central point for receipt of such notices:

Division of Grants Management and Oversight
Office of Management and Acquisition
Department of Health and Human Services
Room 517-D
200 Independence Avenue, S.W.
Washington, DC 20201

DELINQUENT FEDERAL DEBT. In accordance with Office of Management and Budget Memorandum M-87-32, "Certification of Nondelinquency by Applicants for Federal Assistance," the applicant organization must certify that it is **not** delinquent on the repayment of any Federal debt before a grant award can be made. The certification applies to the applicant organization, **not** to the Official Signing for Applicant Organization (unless they are the same) **nor** to the Principal Investigator .

Where the applicant organization discloses delinquency on debt to the Federal Government, the PHS shall (1) take such information into account when determining whether the prospective grantee organization is responsible with respect to that grant, and (2) consider not making the grant until payment is made or satisfactory arrangements are made with the agency to whom the debt is owed. Therefore, it may be necessary for the PHS to contact the applicant small business concern before a grant can be made to confirm the status of the debt and ascertain the payment arrangements for its liquidation. Applicants who fail to liquidate indebtedness to the Federal Government in a business-like manner place themselves at risk of not receiving financial assistance from the PHS.

RESEARCH MISCONDUCT

Each organization which receives or applies for a research, research training or research-related grant or cooperative agreement under the Public Health Service Act must certify that the organization has established administrative policies required by the Final Rule (42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," and that it will comply with those policies and the requirements of the Final Rule.

The signature of the Official Signing for Applicant Organization on the Face Page of the application serves as certification that:

(a) the organization will comply with the requirements of the PHS regulations on responsibilities of awardee and applicant organizations for dealing with and reporting possible misconduct, 42 CFR Part 50, Subpart A;

(b) the organization has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A;

(c) the organization will provide its policies and procedures to the Office of Research Integrity upon request; and

(d) at the end of each calendar year all organizations with research, research training, or research-related grants will make a submission (PHS form 6349) comprising an aggregate report on their allegations, inquiries, and investigations handled in the previous year. (Form 6349 will be sent automatically to all PHS awardee organizations by the Office of Research Integrity at the end of each calendar year.)

Research Misconduct is defined by the Public Health Service as fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or

honest differences in interpretation or judgements of data.

Falsification, fabrication or plagiarism in the grant application is considered per se research misconduct unless the principal investigator or other responsible person shows, following the exercise of due care, that the falsification, fabrication or plagiarism was due to honest error or honest differences in interpretation or judgements of data.

For further information, contact the Office of Research Integrity, Division of Policy and Education, Rockwall II, Suite 700, 5515 Security Lane, Rockville, MD 20852, phone: (301) 443-5300; fax: (301) 594-0042.

ASSURANCE OF COMPLIANCE (Civil Rights, Handicapped Individuals, Age Discrimination)

Before a grant award can be made, the applicant organization must certify that it has filed with the HHS Office for Civil Rights an Assurance of Compliance (form HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88-352, as amended) which prohibits discrimination on the basis of race, color or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended) which prohibits discrimination on the basis of handicaps; and the Age Discrimination Act of 1975 (P.L. 94-135) which prohibits discrimination on the basis of age.
The Assurance of Compliance form HHS 690 is available from the Grants Information Office, Division of Research Grants, National Institutes of Health, Bethesda, MD 20892, phone: (301) 594-7248; fax: (301) 594-7384.

Review of the application for scientific and technical merit will **not** be affected if form HHS 690 has not been filed with the HHS Office for Civil Rights; however Assurance of Compliance form HHS 690 must be filed appropriately **before a grant award can be made**.

PROGRAM INCOME

Public Health Service (PHS) policy requires applicants for PHS research grants to include in their grant applications an estimate of the amount and source of program income (defined below) expected to be generated as a result of the project for which funding is being sought. The specific policies that govern the treatment of program income under research grants are set forth in the PHS Grants Policy Statement. "Program income" means gross income earned by a grant recipient during the budget period of the grant as a result of activities supported by the grant award. The PHS Grants Policy Statement contains a detailed explanation of program income, the ways in which it may be generated and accounted for, and the various options for its use and disposition.

Program income includes, but is not limited to:

- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing;

- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds;

- Funds generated by the sale of products developed under the grant which include but are not limited to drugs, assays, devices, instrumentation, software, laboratory techniques/methodologies, and testing/training devices or systems; and

- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals.

Generally, SBIR awardees that earn program income may be authorized to have such income added to the grant account and used to further the objectives of the research project. Authorization must be requested from the Grants Management Officer of the appropriate PHS awarding component.

If no program income is anticipated during the period(s) for which grant support is requested, check the box marked "NO" in item 2 of the **Checklist** page. No other action is necessary.

If the response to this item is "YES", check the appropriate box and follow the prescribed format to reflect, by budget period, the amount and source(s) of anticipated program income. If the application is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income. (See PHS Grants Policy Statement for PHS policy on the treatment of program income earned under research grants.)

Applicants with questions concerning any aspect of this topic are encouraged to contact the Grants Management Officer of the appropriate PHS awarding component or the Grants Policy Office of the National Institutes of Health, phone: (301) 496-5967; fax: (301) 480-8443.

All program income earned during the budget period must also be identified on the Financial Status Report.

INDIRECT COSTS

The Financial Advisory Services Branch (FASB), Division of Contracts and Grants, NIH, is the office authorized to negotiate indirect cost rates with small business concerns receiving NIH SBIR awards.

Upon request of the NIH, the applicant organization should provide FASB with an indirect 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, proposals showing estimated rates and support for same should be submitted.

To facilitate preparation of an indirect cost proposal, shown below are (1) some definitions of the term "indirect costs," (2) a brief discussion of indirect cost rate structures and a simple example of an indirect cost rate computation, (3) a listing of data that should accompany your proposal submission, and (4) a listing of unallowable/unallocable costs extracted from Federal cost principles for commercial organizations, that is, the Federal Acquisition Regulation (FAR Part 31.2).

Indirect Costs (definition extracted from FAR Part 31.2)

> An indirect cost is any cost not directly identified with a single, final cost objective, but identified with two or more final cost objectives or an intermediate cost objective. It is not subject to treatment as a direct cost. After direct costs have been determined and charged directly to the contract or other work, indirect costs are those remaining to be allocated to the several cost objectives. An indirect cost shall not be allocated to a final cost objective if other costs incurred for the same purpose in like circumstances have been included as a direct cost of that or any other final cost objective.

In simpler terms, indirect costs are those costs not readily identified with a specific project or organizational activity but incurred for the joint benefit of both projects and other activities. Indirect costs are usually grouped into common pools and charged to benefiting objectives through an allocation process/indirect cost rate.

An indirect cost rate is simply a device for determining fairly and expeditiously the proportion of general (non-direct) expenses that each project will bear. It is the ratio between the total indirect costs of an applicant and some equitable direct cost base.

$$\frac{\text{Indirect Cost Pool}}{\text{Direct Cost Base}} = \text{Indirect Cost Rate}$$

Indirect costs include costs which are frequently referred to as overhead expenses (for example,

rent and utilities) and general and administrative expenses (for example, officers' salaries and accounting and payroll costs). Indirect costs may also include fringe benefits Applicable to employees whose salaries are charged as direct costs to projects. The indirect cost base or bases (that is, the denominator(s) of the fraction producing a rate) should be selected so as to permit an equitable distribution of indirect costs to the benefiting cost objectives.

Generally, indirect cost rate structures for commercial organizations follow a single, two-rate (for example, fringe and overhead rates), or three-rate (for example, fringe, overhead, and General and Administrative expense rates) system. A single rate structure is illustrated below.

Direct Cost Base	
Direct Labor Costs (Salaries and Wages excluding vacation, holiday and sick leave)*	$100,000 (a)
Other Direct Costs*	40,000
Total Direct Costs	$140,000 (b)
Indirect Cost Pool	
Vacation, Holiday and Sick Leave	$ 15,000
Health Insurance	8,000
FICA Taxes	8,000
Pension Costs	4,000
Indirect Salaries	40,000
Facility Rental Costs	15,000
Equipment Depreciation	5,000
Utilities	3,500
Indirect Supplies	2,500
Legal Fees	2,000
Accounting Fees	2,000
Total Indirect Costs	$105,000 (c)

*Includes costs associated with independent (self-sponsored) research and development (IR&D) activities.

Indirect Rate - Based on Direct Labor (c/a)	105%
Indirect Rate - Based on Total Direct Costs (c/b)	75%

The indirect cost proposal, based on company-wide cost data, should be accompanied by the following supporting information:

1. The profit and loss statement and balance sheet for the applicant organization's most recently completed fiscal year. Certified statements prepared by a CPA engaged to conduct an annual audit should be submitted, if available. The indirect cost proposal should include a reconciliation with the income statement; that is, there should be a cross-referencing from amounts on the income statement to amounts shown in the proposal, and a clear identification of individual elements (labor, materials, other expenses, etc.) of independent (self-sponsored) research and development (IR&D) expenses. **IR&D costs are not allowable under NIH awards.**

2. A listing of categories of costs normally classified and claimed as direct costs on Federal awards and non-Federally supported projects or activities.

3. An explanation of how the organization accounts for paid absences (vacation, holiday, and sick leave).

In determining what costs should be included in the proposed indirect cost pool(s), the applicant organization should refer to the following list of unallowable/unallocable costs.

FAR REFERENCE	Unallowable/Unallocable Costs
31.205-1	Advertising Costs - "Advertising" means the use of media to promote the sale of products and/or services.
31.205-3	Bad Debts Costs - Losses arising from uncollectible accounts receivable and other claims.
31.205-6	Compensation for Personal Services - The reasonableness of executive compensation, any individual element or the sum of individual elements, may be challenged. Where such challenges occur, the small business concern must demonstrate the reasonableness of compensation items in question.
31.205-7	Contingencies - Contingency costs are costs associated with a possible future event or condition, the outcome of which is undeterminable at the present time.
31.205-8	Contributions or Donations - Such costs include cash, property or services, and are unallowable regardless of recipient.
31.205-10	Cost of Money - Cost of money is an imputed cost determined by applying a cost-of-money rate to facilities capital employed in contract performance. Such costs are unallowable charges to HHS grants.
31.205-14	Entertainment Costs - Costs of social activities and any directly associated costs including tickets to shows or sporting events, meals, lodging, gratuities, etc.
31.205-15	Fines and Penalties - Such costs result from violations of, or failure to comply with, Federal, State, local or foreign laws. Such costs would be allowable if incurred to comply with specific terms and conditions of the contract.
31.205-18	Independent Research and Development Costs - Such costs include research and development expenditures not sponsored by, or required in, the performance of a HHS contract or grant.
31.205-19	Insurance Costs - Costs of insurance on the lives of officers, partners, or sole proprietors where the contracting organization is the beneficiary.
31.205-20	Interest and Other Financial Costs - Include interest on borrowings however represented, costs of refinancing capital, fees paid in connection with preparing prospectuses, issuing stock rights, etc.
31.205-22	Legislative Lobbying Costs - These costs are almost always unallowable. Contractor must submit with its annual indirect cost proposal a certification that the requirements and standards of 31.205-22 have been complied with.
31.205-27	Organization Costs - Includes expenditures associated with planning or executing the organization or reorganization of the corporate structure of the business, or raising capital.
31.205-30	Patent Costs - Unallowable except for general counseling services on patent matters, and patent costs required by the terms of the grant.
31.205-35	Relocation Costs - Costs associated with relocating an employee who resigns within twelve (12) months for reasons within the employee's control.

31.205-37 Royalty Costs - Such costs include royalties paid where the Government has royalty free use of the patent, or in cases where the patent is invalid, unenforceable, or expired.

31.205-41 Taxes - Such costs include Federal income and excess profits taxes and taxes associated with financing, refinancing, or reorganizations.

31.205-46 Travel Costs - Costs for meals, lodging and incidental expenses which exceed maximum per diem rates which apply to travel by Federal employees in the performance of Government business.

Costs of contractor-owned or leased automobiles are allowable if reasonable and to the extent they are used for company business. That portion of the cost of company-furnished automobiles that relates to personal use by employees (including transportation to and from work) is considered compensation to the employee and is unallowable in accordance with 31.205-6(m)(2).

31.205-51 Alcoholic Beverage Costs - Costs of alcoholic beverages are unallowable.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from section 492B of Public Law 103-43, "The National Institutes of Health Revitalization Act of 1993," dated June 10, 1993, and supersedes and strengthens the previous NIH policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies. All research projects involving human subjects are subject to the policy, whether or not they are exempt from human subject protections and IRB review requirements.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research", which have been published in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994, and in the Federal Register, Volume 59, Number 59, Monday, March 28, 1994, at pages 14508-14513. **Investigators may obtain copies from these sources or from the program contact persons found in section X. Grants - Program Descriptions/Research Topics. Program staff may also provide additional relevant information concerning the policy.**

PUBLIC HEALTH SERVICE METRIC PROGRAM

Consistent with governmentwide implementing regulations issued at 15 CFR Part 19, Subpart B and/or any other governmentwide requirements, it is Public Health Service (PHS) policy to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards.

Effective October 1, 1991, proposals for grants, cooperative agreements, and other financial assistance submitted to PHS awarding components are required to use metric units. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

RECOMBINANT DNA

The current NIH Guidelines for Research Involving Recombinant DNA Molecules and announcements of modifications and changes to the Guidelines are available from the Office of

Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, MD 20892, phone: (301) 496-9838; fax: (301) 496-9839. All research involving recombinant DNA techniques that is supported by the Department of Health and Human Services must meet the requirements of these Guidelines. As defined by the Guidelines, recombinant DNA molecules are either: (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of those described in (1) above.

FINANCIAL CONFLICT OF INTEREST (APPLICABLE TO SBIR PHASE II ONLY)

The information provided below is applicable **ONLY** to small business concerns (hereinafter referred to as the "applicant organization") applying for grant support under **PHASE II** of the Public Health Service (PHS) SBIR program. It is being presented in this PHS SBIR Phase I Grant Solicitation in order to give advance notice to SBIR Phase II applicant organizations of the Financial Conflict of Interest regulatory requirements that must be accomplished as a condition of applying for SBIR Phase II grant support.

Each applicant organization applying for grant support under Phase II of the PHS SBIR program must certify that it has established administrative policies as required by the Final Rule, Title 42 Code of Federal Regulations Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought." A similar rule applies to PHS SBIR Phase II **contracts** under Title 45 Code of Federal Regulations Part 94, "Responsible Prospective Contractors." These regulations are required under Public Law 103-43, "The National Institutes of Health Revitalization Act of 1993," dated June 10, 1993.

The signature of the Official Signing For Applicant Organization on the Face Page of the SBIR Phase II grant application (form PHS 6246-2 (Rev. 1/95) serves as certification that:

(a) there is in effect at that applicant organization an administrative process to identify and resolve Significant Financial Interests consistent with Subpart 50.604 with respect to all research projects for which funding is sought from the PHS;

(b) the applicant organization agrees to make information available to the PHS regarding all Significant Financial Interests identified by the applicant organization of the type described in Subpart 50.604 and how those interests have been resolved to protect the research from bias; and

(c) the applicant organization will otherwise comply with 42 CFR Part 50, Subpart F.

Significant Financial Interests is defined by PHS as either (I) a financial interest the value of which exceeds $10,000 for one business enterprise or other single entity when combined for the Investigator, Investigator's spouse and each dependent of the Investigator, or (ii) a financial interest based on an equity or ownership interest that is five percent (5%) or more for one business enterprise or other single entity when combined for the Investigator, Investigator's spouse and each dependent of the Investigator. "Investigator" means the principal investigator and any other person at the applicant organization who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. "Investigator" includes the Investigator's spouse and dependent children. Where the financial interest is an equity interest with an identifiable value, so that both clause (I) and clause (ii) apply, the interest will be a Significant Financial Interest unless the value of the interest is $10,000 or less and the equity interest is less than five percent of the total equity of the business enterprise. A "Financial interest" means anything of monetary value, including but not limited to salary or other payment for services such as a consulting fee or honorarium; equity interests such as stocks, stock options, or other ownership interests; intellectual property rights such as patents, copyrights, and royalties from such rights; and other financial benefits. A "Financial interest" **does not include**: (a) salary or other remuneration, including royalties, the Investigator receives as part of his or her compensation from the applicant organization for PHS research funding; (b) an ownership interest in any SBIR applicant organization; (c) grants or other types of support to the applicant

organization, including industry support, for the project for which PHS research funding is sought, so long as the Investigator does not receive any direct compensation; (d) income from lectures or teaching at public or nonprofit private entities; or (e) income from service on advisory committees or review panels for public or nonprofit private entities.

REMINDER SHEET

AFTER HAVING READ ALL INSTRUCTIONS IN THIS SOLICITATION, DOES THE APPLICATION MEET THE REQUIREMENTS FOR SUBMISSION?

- **Have you typed the application according to the "Type Size" specifications (see page 181) that must be observed throughout the application?**

- **Does the application contain no more than 25 allowable pages as described in "Page Limits and Mailing Instructions" on page 181?**

- **Has all documentation necessary to establish the "primary" employment of the proposed Principal Investigator with the applicant organization (small business concern) been included with the application, as discussed in detail on page 8? Are you employed by other than the applicant organization? If so, have you submitted a letter(s) from that other employing organization(s)? Do you have a courtesy appointment(s)? If so, have you submitted a letter(s) from the organization(s) conferring that appointment(s)? Have you updated the Biographical Sketch information (see page 189) to reflect current employment? You are reminded that the application will be returned without review in cases where the proposed Principal Investigator fails to establish evidence that (1) his or her primary employment is <u>currently</u> with the small business concern, or (2) his or her primary employment <u>will be</u> with the small business concern at the time of award and during the conduct of the proposed project.**

- **Have you completed all items on the Face Page of the application?**

- **Have you completed the CHECKLIST page of the application?**

- **The grant application should be assembled in the following order:**
  - **COVER LETTER -- not a requirement.**
  - **FACE PAGE -- first page of application.**
  - **ABSTRACT OF RESEARCH PLAN -- form page 2.**
  - **BUDGET FOR PHASE I -- form page 3.**
  - **BUDGET JUSTIFICATION -- form page 4.**
  - **CONTINUATION PAGES -- as appropriate and numbered sequentially:**
    - **BIOGRAPHICAL SKETCH AND BIBLIOGRAPHY**
    - **RESEARCH PLAN (includes LITERATURE CITED)**
    - **LETTERS FROM CONSULTANTS AND COLLABORATORS**
    - **LETTERS OF ELIGIBILITY, INCLUDING RENTAL OF RESEARCH SPACE**
  - **CHECKLIST -- last page of application.**

- **Questions regarding the acceptability of the application for submission under this Solicitation should be directed to the Referral Office, Division of Research Grants, National Institutes of Health, phone: (301) 435-0715; fax: (301) 480-1987.**

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Reminder Sheet

All grant recipients are encouraged to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the mission of the Health Agencies to protect and advance the physical and mental health of the American people.

Public reporting burden for this collection of information is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Office, 6701 Rockledge Drive, MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-0195). Do not return the completed form to this address.

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