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Agency for Healthcare
Research and Quality
2101 East Jefferson Street
Rockville, Maryland 20852

OMB No. 0990-0115
Request for Proposal
No. AHRQ-01-0014

Date Issued: 31 January 2001
Date Due: 19 March 2001

LADIES AND GENTLEMEN:

You are invited to submit a proposal to the Agency for Healthcare Research and Quality (AHRQ) for Request for Proposal (RFP) No. AHRQ-01-0014, entitled "Small Business Innovative Research (SBIR) Program". Your proposal must be developed and submitted in accordance with the requirements and instructions of this RFP.

Your proposal shall be signed by an official authorized to bind your organization and must be received in our Contracts Office **no later than 3:00 p.m., local prevailing time, on 19 March 2001 .** Your proposal must be mailed to the following address:

Agency for Healthcare Research and Quality
Division of Contracts Management
2101 E. Jefferson Street, Suite 601
Rockville, Maryland 20852
Attention: Sherry Baldwin

Handcarried proposals may be dropped off at the above location. The Division of Contracts Management office is located in Suite 601 in the East Wing of the 6th Floor.

The RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

Requests for any information concerning this RFP should be referred to the Sherry Baldwin, who may be called on area code (301) 594-7190.

Sincerely yours,

Jacquelyn C. Carey
Contracting Officer
Division of Contracts Management
Agency for Healthcare Research and Quality

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Streamlining the Contracting Process

With the Federal Acquisition Streamlining Act of 1994 and the Federal Acquisition Reform Act of 1996, a number of terms and conditions that previously applied to contracts under $100,000 are no longer applicable. Under the Small Business Innovation Research (SBIR) program, Phase I awards, which normally may not exceed $100,000, will reflect the streamlined contract document.

I. SMALL BUSINESS INNOVATION RESEARCH PROGRAM

The Small Business Research and Development Enhancement Act of 1992 requires the agencies of the Public Health Service (PHS), Department of Health and Human Services (HHS), and certain other federal agencies to reserve 2.5 percent of their current fiscal year extramural budgets for research or research and development (R&D) for an 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 determine the scientific, technical, and commercial merit and feasibility of the proposed research or R&D efforts and the quality of performance of the small business concern, prior to providing further Federal support in Phase II. Phase I awards normally may not exceed $100,000 for direct costs, indirect costs, and profit for a period normally not to exceed 6 months.

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 proposal. Phase II awards normally may not exceed $750,000 for direct costs, indirect costs, and negotiated fixed fee for a period normally not to exceed 2 years, that is, generally, a 2-year Phase II project may not cost more than $750,000 for that project. **Only one Phase II award may be made for a single SBIR project.** Only Phase I contractors are eligible to apply for Phase II funding, and Phase II proposals may only be submitted upon the **request of the Contracting Officer only**.

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 U.S. Government.

Purpose of Solicitation

The purpose of this Solicitation is to invite Phase I **contract proposals** from small business concerns that have the expertise to contribute to the mission of the Agency for Healthcare Research and Quality.

Within this Solicitation are instructions for preparing contract proposals, a description of the proposal review process, and some conditions of a contract award. **Contract proposals will be accepted only if they respond specifically to a research topic within this Solicitation** (see section XIV, Research Topics). Otherwise, they will be returned to the offeror(s) without evaluation.

To apply for an SBIR grant rather than a contract, use the *Omnibus Solicitation of the Public Health Service for Small Business Innovation Research Grant Applications*, where the majority of PHS programs are described.

ELIGIBILITY

Organizational Criteria: Each organization submitting a proposal under the SBIR program must qualify as a small business concern in accordance with the definition given in section III. In determining whether an offeror 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 offeror organization, exceed 500. In conducting this assessment, all appropriate factors will be considered, including common ownership, common management, and contractual relationships.

In accordance with 13 CFR 121.3, affiliation exists when "...one concern controls or has the power to control the other ...control may be affirmative or negative and it is immaterial whether it is exercised so long as the power to control exists." 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). 13 CFR 121.3 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 one concern is furnishing or will furnish the other concern with sub-contracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise."

Access to special facilities or equipment in another organization is permitted (as in cases where the SBIR awardee has entered into a subcontractual agreement with another institution for a specific, limited portion of the research project). However, **research space occupied by an SBIR contractor organization must be space that is available to and under the control of the SBIR contractor for the conduct of its portion of the project.** 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. Whenever a proposed SBIR project is to be conducted in facilities other than those of the offeror organization, a letter must be submitted **with** the proposal stating that leasing/rental arrangements have been

negotiated for appropriate research space (i.e., space that will be available to and under the control of the SBIR contractor organization.) This letter, **to be signed by an authorized official of the organization whose facilities are to be used for the SBIR project,** must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the offeror organization.

All SBIR contract proposals will be reviewed with the above considerations in mind. **If it appears that an offeror organization does not meet eligibility requirements, the PHS will request a size determination of the organization from the cognizant Small Business Administration (SBA) regional office. The evaluation of the proposal for scientific merit will be deferred until a determination is provided by the SBA.**

Principal Investigator Criteria**:** The primary employment of the principal investigator must be with the offeror at the time of award and during the conduct of the proposed project. PHS policy defines a principal investigator as the single individual designated in the contract proposal with responsibility for the scientific and technical direction of the project. Primary employment means that **more than one half** of the principal investigator's time is spent in the employ of the small business concern. **Primary employment with a small business concern precludes full-time employment at another organization.**

In the event that the principal investigator (1) is a less-than-full-time employee of the small business, (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 the proposal, **it is essential that documentation be submitted with the proposal to verify his/her eligibility.** That is to say, if the principal investigator is also employed or appears to be employed by an organization other than the offeror organization (e.g., a university, a nonprofit research institute, another company), a letter must be provided by the **non-offeror organization** confirming that the principal investigator will, if awarded an SBIR contract, 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**; if the principal investigator is employed by another for-profit organization, the letter must be signed by a **corporate official.** This documentation is required for **every** proposal that is submitted, even one that is a revision of a previously submitted proposal. In cases where the principal investigator fails to provide adequate documentation, the proposal will be returned to the offeror organization without evaluation.

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 III, Definitions).

Market Research: **The PHS will not support any market research under its SBIR program.** Neither will it 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, 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.

II. AGENCY CONTACT FOR INFORMATION

Questions on the administration of the AHRQ SBIR contract program should be directed to the contracting officer listed in section XII, Contracting Officer and Address for Mailing and Delivery of Proposals.

III. DEFINITIONS

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.

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.

Cooperative Agreement. A financial assistance mechanism to be used in lieu of a grant when substantial Federal programmatic involvement with the recipient during performance is anticipated by the PHS awarding component.

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 (contract proposal or grant application) 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.

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

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.

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 salaries are requested.

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

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.

. 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 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t). **Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative.**

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).

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.

Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government prime contractor calling for supplies or services required solely for the performance of the prime contract or another subcontract.

United States. The 50 states, the territories and possessions of the U.S., the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.

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.

IV. PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS

Note: Any research proposal involving surveys or interviews of more than 9 respondents will require clearance by the U. S. Office of Management and Budget. Therefore, it is not practical to propose such an activity for Phase I, which normally has only a 6-month duration.

Limitations on Length of Proposal

SBIR Phase I proposals shall not exceed a total of 25 single-spaced standard size (8 l/2" X 11") pages, including the cover sheet, cost breakdown, and all enclosures or attachments. Excluded from the 25-page limitation are cover letters, letters of commitment from collaborators and consultants and letters to determine eligibility. The proposal must meet the following requirements for type size: 1) The height of the letters must be no smaller than 10 point; 2) Type density must be no more than 15 characters per inch; 3) No more than 6 lines of type must be within a vertical inch. No appendices may be submitted and, if submitted, they will not be considered in the evaluation of

scientific and technical merit.

. **Proposal Cover Sheet**

Photocopy and complete the form identified as Appendix A and use it as the first page of each proposal. No other cover sheet should be used.

! Topic Number: Provide the appropriate numerical designator of the research topic for which your proposal is being submitted. If your proposal is responsive to a subtopic, provide both the topic and subtopic numbers. (Each topic and subtopic is preceded by a numerical or alphabetical designator.)

! Project Title: Select a title that reflects the substance of the project. **Do not use the title of the topic that appears in the solicitation.**

Abstract of Research Plan

Photocopy and complete the form identified as Appendix B and insert it as the second page of each proposal.

. **Research Plan**

Beginning on page three of the proposal, discuss the following elements in the order indicated below.

1. Identification and Significance of the Problem or Opportunity. Provide a clear statement of the specific technical problem or opportunity addressed.

2. Technical Objectives. State the specific objectives of the Phase I effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

3. Work Plan. Provide a detailed plan for the R&D to be carried out, including the experimental design, procedures, and protocols to be used. This plan should address the objectives and the questions stated in 2. above. The methods to be used to achieve each objective or task should be discussed in detail.

4. Related Research or R&D. Describe significant research or R&D that is directly related to the proposal, including any conducted by the principal investigator/project manager or by the proposing firm. Describe how it relates to the proposed effort and any planned coordination with outside sources. **The principal investigator/project manager must persuade reviewers of his or her awareness of recent significant research or R&D conducted by others in the same scientific field.**

5. Relationship with Future R&D.

    a. State the results expected from the proposed approach.

    b. Discuss the significance of the Phase I effort in providing a foundation for Phase II.

6. Potential Commercial Applications. Describe why the proposed project appears to have potential commercial applications.

7. Key Personnel and Bibliography of Directly Related Work. Identify key personnel, including their directly related education, experience, and bibliographic information. Where vitae are extensive, summaries that focus on the most relevant experience or publications are desired. **Provide dates and places of employment** and some information about the nature of each position or professional experience. Curriculum vitae must identify the current or most recent position.

8. Consultants. Involvement of consultants in the planning and/or research stages of the project is permitted. If such involvement is intended, it should be described in detail. If consultants are to be used, attach appropriate letters from each individual confirming his/her role in the project.

9. Facilities and Equipment. Indicate where the proposed research will be conducted. **One of the performance sites must be the offeror organization.** Describe the facilities to be used; identify the location; and briefly indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Include clinical, computer, and office facilities of the offeror and those of any other performance sites to be used in the project. List the most important equipment items already available for this project, noting location and pertinent capabilities of each.

Current Awards and Pending Proposals/Applications

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 contracts or grants requiring essentially equivalent effort. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award.

If a firm elects to submit identical proposals or proposals containing a significant amount of essentially equivalent work under other federal program solicitations, a statement must be included in each such proposal indicating the information requested in items 1-10 set forth below.

In addition, provide the information requested in items 1-10 on (a) active funding through contracts, grants, and cooperative agreements from public or private sponsors; (b) contract proposals and grant and cooperative agreement applications pending review or funding; and (c) contract proposals and grant and cooperative agreement applications about to be submitted.

1. Name and address of the funding source.

2. Type of award (contract, grant, cooperative agreement) and identifying number.

3. Title of research project.

4. Name and title of principal investigator or project manager.

5. Hours per week on the project by the principal investigator or project manager.

6. Annual costs proposed or awarded.

7. Entire period of support.

8. Date of proposal/application submission or date of award.

9. Title, number, and date of solicitations under which proposals or applications were submitted or awards received.

10. The specific applicable research topic for each SBIR proposal or application submitted or award received.

Specifically identify those projects that are SBIR.

Since the PHS uses both contracts and grants in its SBIR program, please note the following:

> **A small business concern may not submit both a contract proposal and a grant application for essentially the same project to the same or a different awarding component(s) of the PHS.** The only exception would be the submission of a grant application after the equivalent contract proposal has been evaluated and found unacceptable for consideration.

Proposed Cost Breakdown

Photocopy and complete the form identified as Appendix C (Contract Pricing Proposal). The cost breakdown should appear as the last section of the proposal. If some items on this form do not apply to the proposed project, they need not be completed.

- Under "Supplies and/or Services to be Furnished," provide the title of the proposed project.

- Under "Government Solicitation No.," enter "AHRQ-01-0014.

- If materials/supplies are proposed, provide the quantities and the price per unit.

- Under "Direct Labor," **list all key personnel by name.** However, support personnel may be consolidated into categories or labor classes, e.g., research assistants, data processing clerks, etc.

- If travel is proposed, provide the following details on "Exhibit A-Supporting Schedule": destination(s); duration of trip(s); number of travelers; and cost per trip, broken down by cost elements, e.g., airfare, lodging, meals, etc.

- If consultants are proposed, provide name(s), rate(s), and number of hours/days.

- If a subcontract is proposed, provide the same type of detailed cost breakdown. **Also provide a copy of the subcontractual agreement.**

- Use "Exhibit A-Supporting Schedule" to itemize and justify all major cost elements.

- **Normally, at least two-thirds or 67% of the entire research or analytical effort must be carried out by the offeror**, that is., subcontracts for portions of the scientific/technical effort and consultant fees normally may not exceed 33% of the total cost breakdown.

V. INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the AHRQ that women and members of minority groups and their subpopulations must be included in all AHRQ-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

Address the inclusion of women and members of minority groups and their subpopulations in developing a research design appropriate to the scientific objectives of the project. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a description of proposed outreach programs for recruiting women and minorities as participants. Provide a compelling rationale and justification for requesting any exclusions noted above.

All research projects involving human subjects are subject to the policy, whether or not they are exempt from human subject protections and Institutional Review Board (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 contracting officer found in section XII. of this Solicitation.**

VI. REQUIREMENT FOR ADEQUATE ASSURANCE OF PROTECTION OF HUMAN SUBJECTS

The HHS regulations for the Protection of Human Subjects, 45 CFR 46 (as amended), provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS. The requirement is that an approved assurance of compliance with the regulations must be on file with the Office for Protection from

Research Risks (OPRR), NIH, before an HHS award can be made.

When an offeror proposes research that involves human subjects, but the offeror does not have a Multiple Project Assurance (MPA) on file with OPRR, on request of the awarding component, OPPR will contact the offeror and provide detailed instructions for filing the necessary document. **Neither an Institutional Review Board (IRB) review nor an OPRR-approved Assurance is required at the time the proposal is submitted.**

Institutions having an MPA with OPRR are encouraged to have an IRB review before submitting the proposal and should furnish certification of IRB approval with the proposal. However, an MPA organization may submit the certification of IRB review 60 days after submission of the proposal or before the Initial Technical Review is initiated. If certification is not received before the Initial Technical Review meeting, the awarding component will not allow the review of the proposal.

The regulations define a "human subject" as a "living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue, 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 (as amended).

Inappropriate designations of the non-involvement of human subjects in an SBIR project may result in delays in the review of a proposal. The OPRR, on behalf of HHS, 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 proposal.

Any SBIR contract involving human subjects that is awarded as a result of a proposal submitted in response to this Solicitation will include the following clauses:

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 (as amended) and with the Contractor's current Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), Public Health Service. The Contractor further agrees to provide certification at least annually that the institutional review board has reviewed and approved the procedures which involve human subjects in accordance with 45 CFR Part 46 (as amended) and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and

will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OPRR, NIH, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Health and Human Services Human Subject Assurances.

In doubtful cases, prior consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, MD 20892 (telephone: [301] 496-7041) may be of assistance.

VII. BAN ON HUMAN EMBYRO RESEARCH

Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes, or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the Act, that is derived by fertilization, parthenogenesis, cloning, or any other means form one or more human gametes.

VIII. REQUIREMENT FOR ADEQUATE ASSURANCE OF COMPLIANCE WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

The *PHS Policy on Humane Care and Use of Laboratory Animal* (Policy) establishes a number of requirements in research activities involving live, vertebrate animals. It stipulates that an offeror organization, whether domestic or foreign, 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 offeror organization proposing to use animals in PHS- supported activities must file a written Animal Welfare Assurance with the Office for Protection from Research Risks (OPRR). When an offeror proposes research that involves animals, but the offeror does not have an Animal Welfare Assurance on file with OPRR,

on request of the awarding component, OPRR will contact the offeror and provide detailed instructions for filing the necessary document. **Neither an Institutional Animal Care and Use Committee (IACUC) nor an OPRR-approved Assurance is required at the time the proposal is submitted.**

Institutions having an Assurance with OPRR are encouraged to have an IACUC review before submitting the proposal and should furnish verification of IACUC approval with the proposal. However, an Assured organization may submit the verification of IACUC review 60 days after submission of the proposal or before the Initial Technical Review is initiated. If verification is not received before the Initial Technical Review meeting, the awarding component will not allow the review of the proposal.

No PHS award for research involving animals will be made to an offeror organization unless that organization is operating in accord with an approved Animal Welfare Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with PHS Policy.

48 CFR Part PHS 352 requires that any contract involving live, vertebrate animals, awarded as a result of a proposal submitted in response to this Solicitation include the following clauses:

(a) Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the Contracting Officer.

(b) The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the *PHS Policy on Humane Care and Use of Laboratory Animals*, the current Animal Welfare Assurance, the *Guide for the Care and Use of Laboratory Animals* prepared by the Institute of Laboratory Animal Resources, and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OPRR, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Public Health Service

Animal Welfare Assurances.

NOTE: The Contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program, may be obtained by contacting: **Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737, phone: (301) 734-4980.**

Offerors proposing research that involves live, vertebrate animals will be contacted by OPRR and given detailed instructions on filing a written Animal Welfare Assurance with the PHS. **OPRR may be contacted at the National Institutes of Health, Bethesda, MD 20892, phone: (301) 496-7163.**

IX. METHOD OF SELECTION AND EVALUATION CRITERIA

All Phase I and Phase II proposals will be evaluated and judged by a peer review committee. Contract proposals will be initially screened to determine their compliance with the administrative requirements of this Solicitation and their applicability to the research topic selected by the offeror. Those passing the initial screening will be evaluated for technical and scientific merit to determine the most promising approaches. Each proposal will be judged on its own merits within the broad framework of the Technical Evaluation Criteria described below. The agency is not under any obligation to fund any proposal or make any specific number of contract awards in a given research topic area. The agency may also elect to fund several or none of the proposals received within a given topic area. The SBIR contract projects do not require establishing a competitive range or requesting best and final offers before reaching source selection decisions.

Evaluation Process

Contract proposals are subjected to peer review by panels of scientists selected for their competence in relevant scientific and technical fields. The task of the evaluation panel is to evaluate proposals for scientific and technical merit and to perform a concept review, if one was not accomplished previously. The evaluation panel provides a rating, makes specific recommendations related to the scope, direction and/or conduct of the proposed research, and for those proposals recommended for award, provides a commentary about the funding level, labor mix and duration of the proposed contract project. A second level of review may also be made by Agency program staff. Recommendations of the evaluation panel and program staff are based on judgments about not only the technical merit of the proposed research but also its relevance and potential contributions to the mission and programs of the Agency.

AHRQ may award a contract only if the corresponding proposal has been recommended as technically acceptable by the peer review panel. Funding for acceptable proposals is not guaranteed.

. **Technical Evaluation Criteria**

In considering the technical merit of each proposal, the following factors will be assessed:

Phase I Proposals

Factors	Weight
1. The soundness and technical merit of the proposed approach.	40%
2. The qualifications of the proposed principal investigator, supporting staff, and consultants.	30%
3. The potential of the proposed research for technological innovation.	10%
4. The potential of the proposed research for commercial application.	10%
5. The adequacy and suitability of the facilities and research environment.	10%

Award Decisions

For proposals recommended for award, the Agency considers the following:

1. ratings resulting from the scientific/technical evaluation process;
2. areas of high program relevance;
3. program balance (i.e., balance among areas of research); and
4. available funds.

. **Proposal Debriefing**

Offerors will be notified when they are no longer being considered for award and when final award decisions have been made. Debriefings can be requested within 3 days of the receipt of either notification. Generally, more information is available at a postaward debriefing. Offerors are entitled to no more than one debriefing.

X. CONSIDERATIONS

Awards

1. Approximate number of Phase I contract awards:

   Agency for Healthcare Research and Quality (AHRQ): 2-3

2. The award instrument will be the contract.

3. A profit or fixed fee may be included in the proposal and the fee will be negotiated.

4. Phase I awards will be firm fixed price contracts. Normally, Phase II awards will be cost-plus-fixed-fee contracts.

5. The average dollar value of Phase I contracts to be awarded will be approximately $100,000. Phase II contracts normally may not exceed $750,000, including direct costs, indirect costs, and negotiated fixed fee.

Final Report

A final report is required of all Phase I contractors. It should include a detailed description of the project objectives, the activities that were carried out, the results obtained, and an in-depth discussion of whether such results provided a foundation for a Phase II effort. An original and five copies of this report must be submitted to the contracting officer not later than the expiration date of the Phase I contract.

Payment

Payments made by the Government, including invoice and contract financing payments, may be made by check or electronic funds transfer (EFT) at the option of the Government. As a condition to any payment, the contractor is required to provide information required to make payment by EFT unless the payment office determines that submission of the information is not required. Until January 1, 1999, if the contractor certifies that it does not have an account with a financial institution or an authorized payment agent, payments must be made by other than EFT. For any payment after January 1, 1999, the contractor shall provide EFT information. Payments on Phase I contracts will be made on a monthly advance basis.

Invoices/financing requests submitted for cost incurred under Phase II cost reimbursement contracts will be on a monthly basis unless otherwise authorized by the contracting officer.

Limited Rights Information and Data Proprietary Information.

Information contained in unsuccessful proposals will remain the property of the offeror. The Government may, however, retain copies of all proposals. Public release of information in any proposal will be subject to existing statutory and regulatory requirements.

The Department of Health and Human Services (HHS) recognizes that, in responding to this Solicitation, offerors may submit information that they do not want used or disclosed for any purpose other than for evaluation. Such data might, for example, include trade secrets, technical data, and business data (such as commercial information, financial information, and cost and pricing data). The use or disclosure of such information may be restricted if offerors identify it and the Freedom of Information Act (FOIA) does not require its release. For information to be protected, offerors must identify in the Notice of Proprietary Information (on the Proposal Cover Sheet) the page(s) on which such information appears. Any other Notice may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration without assuming any liability for inadvertent disclosure.

Unless disclosure is required by the FOIA, as determined by FOI officials of the HHS, data contained in those portions of a proposal that have been identified as containing restricted information, in accordance with the Notice of Proprietary Information, shall not be used or disclosed except for evaluation purposes.

The HHS may not be able to withhold data that has been requested pursuant to the FOIA, and the HHS FOI officials must make that determination. The Government is not liable for disclosure if the HHS has determined that disclosure is required by the FOIA.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of a proposal, the Government shall have the right to use or disclose the data to the extent provided by law. Proposals not resulting in a contract remain subject to the FOIA.

Title to Equipment.

Title to equipment purchased by the SBIR awardee in relation to project performance vests upon acquisition in the Federal Government. However, such title may be transferred to an SBIR awardee upon expiration of the project where the transfer would be more cost-effective than recovery of the property by the Government.

Rights to Data Developed Under SBIR Funding Agreement.

Rights to data, including software developed under the terms of any funding agreement resulting from a contract proposal submitted in response to this Solicitation, shall remain with the awardee, 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 awardee for a period of four years from completion of the project from which the data was generated.

Copyrights

The awardee 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 contract number from (PHS awarding component)" or "The project described was supported by contract number _____ from (PHS awarding component)."

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 Technology Resources, NIH, 6701 Rockledge Drive, Room 3188, MSC 7750, Bethesda, MD 20892-7750, phone: (301) 402-0850, fax: (301)

480-8443.

To the extent authorized by 35 USC 205, the Government will not make public any information disclosing a Government-supported invention for a four-year period to allow the awardee 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 Technology Resources, 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.

Profit or Fee

A fixed fee may be proposed and negotiated with the awarding component. A profit or fee is considered to be any amount in excess of actual direct and indirect costs incurred in the conduct of a project.

Joint Ventures or Limited Partnerships

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

Performance of Research and Analytical Work by Awardee Organization

1. In Phase I projects, normally a minimum of two-thirds or 67% of the research or analytical effort must be carried out by the small business concern.

2. In Phase II projects, normally a minimum of one-half or 50% of the research or analytical effort must be carried out by the small business concern.

Contractor Commitments

Upon entering into a contract, the contractor agrees, in accordance with the terms and conditions of the contract, to accept certain legal commitments embodied in the clauses of Phase I and Phase II contracts. The list that follows is illustrative of the types of clauses to which the contractor would be committed. This list is not a complete list of clauses to be included in Phase I and Phase II contracts, nor does it contain specific wording of such clauses. Copies of complete terms and conditions are available upon request.

The following clauses apply to Phase I contracts not exceeding $100,000.

1. Standards of Work. Work performed under the contract must conform to high professional standards.

2. Inspection. Work performed under the contract is subject to Government inspection and evaluation at all times.

3. Termination for Convenience. The contract may be terminated at any time by the Government for convenience if it deems termination to be in its best interest, in which case the contractor will be compensated for work performed and for reasonable termination costs.

4. Disputes. Any dispute concerning the contract which cannot be resolved by agreement shall be decided by the contracting officer with right of appeal.

5. Equal Opportunity. The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

6. Affirmative Action for Veterans. The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era.

7. Affirmative Action for Handicapped. The contractor will not discriminate against any employee or applicant for employment because he or she is physically or mentally handicapped.

8. Gratuities. The contract may be terminated by the Government if any gratuities have been offered to any representative of the Government to secure the contract.

9. American-made Equipment and Products. When purchasing equipment or products under an SBIR contract award, the contractor shall purchase only American-made items whenever possible.

In addition to the foregoing clauses, **the following clauses apply to contracts expected to exceed $100,000**

10. Examination of Records. The Comptroller General (or a duly authorized representative) shall have the right to examine any directly pertinent records of the contractor involving transactions related to this contract.

11. Default. The Government may terminate the contract for default if the contractor fails to perform the work described in the contract and such failure is not the result of excusable delays.

12. Contract Work Hours. The contractor may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (i.e., overtime pay).

13. Covenant Against Contingent Fees. No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees or commercial agencies maintained by the contractor for the purpose of securing business.

14. Patent Infringement. The contractor shall report each notice or claim of patent

infringement based on the performance of the contract.

Additional Information

1. This 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 contract, the terms of the contract are controlling.

2. Prior to award of an SBIR contract, the Government may request the offeror to submit certain organizational, management, personnel and financial information to assure responsibility of the offeror to receive an award.

3. The Government is not responsible for any expenditures of the offeror in advance and in anticipation of an award. In a cost reimbursement contract, reimbursement of costs by the Government may be made only on the basis of costs incurred by the contractor after award and during performance.

4. This 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 proposals and the availability of funds.

5. The SBIR program is not intended as a mechanism to invite unsolicited proposals. Unsolicited proposals shall not be accepted under the SBIR program in either Phase I or Phase II.

6. If an award is made pursuant to a proposal submitted in response to this SBIR Solicitation, the contractor will be required to certify that he or she has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government.

XI. INSTRUCTIONS FOR PROPOSAL SUBMISSION

Receipt Date

The deadline for receipt of all proposals submitted in response to this Solicitation is **3:00 p.m., Eastern Time,19 March 2001.** Any proposal received at the offices designated below after the exact time specified for receipt will not be considered unless it is received before award is made and:

1. it was sent by registered or certified mail not later than the fifth calendar day prior to the date specified for receipt of proposals;

2. it was sent by mail and it is determined by the Government that the late receipt was due solely to mishandling by the Government after receipt at the Government installation;

3. it was transmitted through an electronic commerce method authorized by the solicitation and was received at the initial point of entry to the Government infrastructure not later than 3:00 p.m. one working day prior to the date specified for receipt of proposals;

4. it is the only proposal received, or;

5. it is received in the office designated for receipt of proposals on the first work day on which normal Government processes are resumed following an emergency or anticipated event which interrupts normal Government processes so that proposals cannot be received by the exact time specified in the solicitation.

Despite the specified receipt date above, a proposal received after that date may be considered if it offers significant costs or technical advantages to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

Number of Copies

An original and 2 copies of each proposal must be submitted. The original must be signed by the principal investigator and a corporate official authorized to bind the offeror. The 2 copies of the proposal may be photocopies of the original.

Binding and Packaging of Proposal

Please do not use special bindings or covers. Staple the pages in the upper left corner of each proposal. All copies of a proposal must be sent in the same package.

XII. Contracting Officer and Address for Mailing or Delivery of Proposals

! Proposals to the Agency for Healthcare Research and Quality

Ms. Sherry Baldwin
Division Contracts Management
Agency for Healthcare Research and Quality
2101 East Jefferson Street, Suite 601
Rockville, MD 20852
Phone: (301) 594-7190
Fax: (301) 443-7523

XIII. 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, (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

Center for Technology Commercialization
Massachusetts Technology Park

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)

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

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)

Far West Regional Technology Transfer Center
University of Southern California
3716 South Hope Street, Suite 200
Los Angeles, CA 90007-4344
(213) 743-6132
(213) 746-9043 (fax)
(800) 642-2872 (CA only)
(800) 872-7477 (outside CA)

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**)

XIV. RESEARCH TOPICS

NOTE: Any small business concern that intends to submit an SBIR contract proposal under this Solicitation should provide the appropriate contracting officer(s) with early, written notice of its intent, giving its name, address, telephone, and topic number(s). If a topic is modified or canceled before this Solicitation closes, only those companies that have expressed such intent will be notified.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

The mission of the Agency for Healthcare Research and Quality (AHRQ), formerly known as the Agency for Health Care Policy and Research (AHCPR), is to enhance the quality, appropriateness and effectiveness of health services and to provide access to such services. AHRQ achieves its mission through the application of broad-based scientific research designed to (1) improve clinical practice; (2) improve the health care system's ability to provide access to and deliver high-quality, high-value health care; and (3) provide policymakers with the ability to assess the impact of system changes on outcomes, quality, access, cost, and use of health services.

This solicitation invites proposals in the following area:

Topic: Developing Tools to Enhance Quality and Patient Safety Through Medical Informatics

The Institute of Medicine recently estimated that between 44,000 and 98,000 people die in American hospitals each year because of medical errors. Many of these errors could be prevented through the use of modern information technology. Technology applications can also be used to provide evidence-based decision support to providers at the time and point-of-service, provide evidence-based information to patients, enhance shared decision-making and self-care, increase access to care for patients living in remote or underserved areas, facilitate sharing of important clinical data among providers in disparate locations, and improve the overall quality of care. Examples of such technology include biomedical databases, electronic medical records, computerized order entry, handheld wireless computers, Internet applications, and computerized decision-support systems.

The Agency seeks Phase I SBIR proposals to 1) develop informatics tools that enhance patient safety by reducing medical errors and injuries; 2) develop Internet or other computer applications that enhance patient-provider communication and shared decision-making; 3) develop applications that allow providers to share medical records and other medical information with their patients; or 4) develop handheld or other portable device applications for patients and providers. Proposals must address how the use of these technologies can improve quality of care and patient safety.

In Phase I, investigators should propose an approach or combination of approaches for identifying factors important in the development of these tools and devices. Potential approaches may include patient and provider focus groups, comprehensive literature reviews, secondary data analysis, and other techniques appropriate for Phase I contracts. The contractor will be expected to develop prototype devices and interventions, such as

web-based technologies that interactively link patients with their health care providers and health care systems.

In Phase II, the investigators will be expected to expand upon the prototype developed during Phase I and begin implementation and testing of the prototype devices and interventions. Phase II must include an assessment of the intervention's impact on important measurable outcomes such as a reduction in medication errors, increase in compliance with recommended treatment guidelines, etc. Beta testing is to be completed at the end of the Phase II period. The final product should be applicable and adaptable to a variety of health care populations, conditions, and settings.