U.S. Small Business Administration Office of Investment and Innovation



Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program

Policy Directive

Effective: May 2, 2019

Table of Contents

1.	Purpose
2.	Summary of Statutory Provisions53
3.	Definitions
4.	Phased Structure of Programs67
5.	Program Solicitation Process81
6.	Eligibility and Application (Proposal) Requirements83
7.	Program Funding Process91
8.	Terms of Agreement Under SBIR/STTR Awards101
9.	Responsibilities of SBIR/STTR Agencies and Departments111
10.	Reporting Requirements for Participating Agencies, Applicants and Awardees130
11.	Responsibilities of SBA150
12.	Supporting Programs and Initiatives153

1. Purpose

(a) Sections 9(j) and 9(p) of the Small Business Act (the Act) require that the Small Business Administration (SBA) issue Policy Directives for the general conduct of the SBIR and STTR programs within the Federal Government.

(b) This Policy Directive fulfills SBA's statutory obligation to provide guidance to the participating Federal agencies for the general operation of the SBIR and STTR programs. Because most of the policy for the SBIR and STTR program is the same, SBA issues a single Policy Directive for both programs. Unless one of the programs is specifically mentioned, the term "program" or "programs" refers to both the SBIR and STTR programs. In addition, "SBIR/STTR" is used throughout to refer to both programs.

(1) The following sections pertain only to the STTR program: § 3(cc) - Definition of "Research Institution," § 7(k) - Management of the STTR Project, § 8(c) - Allocation of Intellectual Property Rights in STTR Award, and § 12(e) - Phase 0 Proof of Concept Partnership Pilot Program.

(2) The following sections pertain only to the SBIR program: § 3(b) - Definition of "Additionally Eligible State," § 3(1) - Definition of "Covered Small Business,"
§ 4(b)(1)(ii) – Direct to Phase II Awards, § 6(a)(6) – Majority-Owned by Multiple VCOCs, Hedge Funds or Private Equity Firms, § 6(b)(1)(iii) – Registration and Certifications for Proposal and Award for Majority-Owned by Multiple VCOCs, Hedge Funds or Private Equity Firms, and Appendix I - Certifications for Proposal and Award for Majority-Owned by Multiple VCOCs, Hedge Funds or Private Equity Firms, and Appendix I - Certifications for Proposal and Award for Majority-Owned by Multiple VCOCs, Hedge Funds or Private Equity Firms, and Appendix I - Certifications for Proposal and Award for Majority-Owned by Multiple VCOCs, Hedge Funds or Private Equity Firms.

(3) Additional or modified instructions may be issued by SBA as a result of public

comment or experience. With this directive, SBA fulfills the statutory requirement to simplify and standardize the program proposal, selection, contracting, compliance, and audit procedures for the programs to the extent practicable, while allowing the Participating Agencies flexibility in the operation of their individual programs. Wherever possible, SBA has attempted to reduce the paperwork and regulatory compliance burden on small business concerns (SBCs) applying to and participating in the SBIR/STTR programs, while still meeting the statutory reporting and data collection requirements.

(c) The statutory purpose of the SBIR program is to strengthen the role of innovative SBCs in Federally-funded research or research and development (R/R&D). Specific program purposes are to: (1) stimulate technological innovation; (2) use small business to meet Federal R/R&D needs; (3) foster and encourage participation by socially and economically disadvantaged SBCs (SDBs), and by women-owned SBCs (WOSBs), in technological innovation; and, (4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity and economic growth.

(d) In addition to the broad goals of the SBIR program, the statutory purpose of the STTR program is to stimulate a partnership of ideas and technologies between innovative SBCs and non-profit Research Institutions. By providing awards to SBCs for cooperative R/R&D efforts with Research Institutions, the STTR program assists the U.S. small business and research communities by supporting the commercialization of innovative technologies.

(e) Federal agencies participating in the programs (Participating Agencies) are obligated

to follow the guidance provided by this Policy Directive. Each Participating Agency is required to review its rules, policies, and guidance on the programs to ensure consistency with this Policy Directive and to make any necessary changes in accordance with each agency's normal procedures. This is consistent with the statutory authority provided to SBA concerning the SBIR/STTR programs.

2. <u>Summary of Statutory Provisions</u>

(a) The SBIR program is codified at § 9 of the Act, 15 U.S.C. 638. The SBIR program is authorized until September 30, 2022, or as otherwise provided in law subsequent to that date.

(b) Each Federal agency with an extramural budget for R/R&D in excess of \$100,000,000 must participate in the SBIR program and spend (obligate) a minimum percentage of their extramural R/R&D budgets (obligations) of not less than 3.2% of such budget in fiscal year 2017 and for the percentage required by statute for each fiscal year after for awards to SBCs for R/R&D under the SBIR program.

A Federal agency may exceed this minimum percentage.

(c) The STTR program is also codified at § 9 of the Act, 15 U.S.C. 638. The STTR program is authorized until September 30, 2022, or as otherwise provided in law subsequent to that date.

(d) Each Federal agency with an extramural budget for R/R&D in excess of

\$1,000,000,000 must participate in the STTR program and spend (obligate) a minimum percentage of their extramural R/R&D budgets (obligations) of not less than 0.45% of such budget in fiscal year 2016 and for the percentage required by statute for each fiscal year after on awards to SBCs under the STTR program.

A Federal agency may exceed this minimum percentage.

(e) In general, each Participating Agency must make SBIR/STTR awards for R/R&D through the following uniform, three-phase process:

(1) Phase I awards to determine, insofar as possible, the scientific and technical merit and feasibility of ideas that appear to have commercial potential.

(2) Phase II awards to further develop work from Phase I that meets particular program needs and exhibits potential for commercial application.

(3) Phase III awards where commercial applications of SBIR/STTR program-funded R/R&D are funded by non-Federal sources of capital; or where products, services or further research intended for use by the Federal Government are funded by non-SBIR/STTR sources of Federal funding.

(f) Participating Agencies must report to SBA on the calculation of the agency's extramural R/R&D budget, for the purpose of determining SBIR/STTR program funding, within four months of enactment of each agency's annual Appropriations Act.
(g) The Act explains that agencies are authorized and directed to cooperate with SBA in order to carry out and accomplish the purpose of the programs. As a result, each Participating Agency shall provide information to SBA for SBA to monitor and analyze each agency's SBIR/STTR program and to report annually to the Committee on Small Business and Entrepreneurship of the Senate and to the Committee on Small Business and the Committee on Science, Space, and Technology of the House of Representatives. For more information on the agency's reporting requirements, including the frequency for specific reporting requirements, see § 10 of the Policy Directive.

(h) SBA establishes databases and websites to collect and maintain, in a common format,

information that is necessary to assist SBCs and assess the SBIR/STTR programs.

(i) SBA implements the Federal and State Technology (FAST) Partnership Program to strengthen the technological competitiveness of SBCs, to the extent that FAST is authorized by law.

(j) The competition requirements of the Armed Services Procurement Act of 1947 (10
U.S.C. 2302, <u>et seq</u>.) and the Federal Property and Administrative Services Act of 1949
(41 U.S.C. 3101, <u>et seq</u>.) must be read in conjunction with the procurement notice
publication requirements of § 8(e) of the Act (15 U.S.C. 637(e)). The following notice
publication requirements of § 8(e) of the Act apply to SBIR/STTR Participating Agencies
using contracts as a SBIR or STTR Funding Agreement.

(1) Any federal executive agency intending to solicit a proposal to contract for property or services valued above the amounts set forth in Federal Acquisition Regulations (FAR) § 5.101, must transmit a notice of the impending solicitation to the Government wide point of entry (GPE) for access by interested sources. See FAR § 5.201. The GPE, located at www.fbo.gov, is the single point where Government business opportunities, including synopses of proposed contract actions, solicitations, and associated information, can be accessed electronically by the public. In addition, an agency must not issue its solicitation for at least 15 days from the date of the publication of the GPE. The agency must establish a deadline for submission of proposals in response to a solicitation in accordance with FAR § 5.203.

(2) The contracting officer must generally make available through the GPE those solicitations synopsized through the GPE, including specifications and other pertinent information determined necessary by the contracting officer. See FAR § 5.102.

(3) Any executive agency awarding a contract for property or services must synopsize the award through the GPE in accordance with FAR subpart 5.3.

(4) The following are exemptions from the notice publication requirements:

(i) In the case of agencies intending to solicit Phase I proposals for contracts in excess of \$25,000, the head of the agency may exempt a particular solicitation from the notice publication requirements if that official makes a written determination, after consulting with the Administrator of the Office of Federal Procurement Policy (OFPP) and the SBA Administrator, that it is inappropriate or unreasonable to publish a notice before issuing a solicitation.

(ii) The SBIR/STTR Phase II award process.

(iii) The SBIR/STTR Phase III award process.

3. <u>Definitions</u>

(a) <u>Act</u>. The Small Business Act (15 U.S.C. 631, <u>et seq</u>.), as amended.

(b) <u>Additionally Eligible State</u>. (SBIR only) A State in which the total value of funding agreements awarded to SBCs under all agency SBIR programs is less than the total value of funding agreements awarded to SBCs in a majority of other States, as determined by SBA's Administrator in biennial fiscal years and based on the most recent statistics compiled by the Administrator.

(c) <u>Affiliate</u>. This term has the same meaning as set forth in 13 CFR part 121—Small Business Size Regulations, § 121.103, "How Does SBA Determine Affiliation?". Further information about SBA's affiliation rules and a guide on affiliation is available at www.SBIR.gov and www.SBA.gov/size.

(d) Applicant. The organizational entity that qualifies as an SBC at all pertinent times

and that submits a contract proposal or a grant application for a funding agreement under the SBIR/STTR programs.

(e) <u>Awardee</u>. The organizational entity that receives an SBIR or STTR Phase I, Phase II, or Phase III award. An "SBIR/STTR Awardee."

(f) <u>Commercialization</u>. The process of developing products, processes, technologies, or services and the production and delivery (whether by the originating party or others) of the products, processes, technologies, or services for sale to or use by the Federal Government or commercial markets.

(g) <u>Computer Database</u>. A collection of data recorded in a form capable of being processed by a computer. The term does not include Computer Software.

(h) <u>Computer Programs</u>. A set of instructions, rules, or routines recorded in a form that is capable of causing a computer to perform a specific operation or series of operations.

(i) <u>Computer Software</u>. Computer Programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled.
 Computer Software does not include Computer Databases or Computer Software Documentation.

(j) <u>Computer Software Documentation</u>. Owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the Computer Software or provide instructions for using the software.

(k) <u>Covered Small Business Concern</u>. (SBIR only) A small business concern that: (1) was not majority-owned by multiple venture capital operating companies (VCOCs),

hedge funds, or private equity firms on the date on which it submitted an application in response to a solicitation under the SBIR program; and (2) is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms on the date of the SBIR award.

(1) <u>Data</u>. All recorded information, regardless of the form or method of recording or the media on which it may be recorded. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(m) <u>Essentially Equivalent Work</u>. Work that is substantially the same research, which is proposed for funding in more than one contract proposal or grant application submitted to the same Federal Agency, or submitted to two or more different Federal Agencies for review and funding consideration; or work where a specific research objective and the research design for accomplishing the objective are the same or closely related to another proposal or award, regardless of the funding source.

(n) Extramural R/R&D Budget/Obligations. The sum of the total obligations for R/R&D minus amounts obligated during a given fiscal year for R/R&D activities by employees of a Federal Agency in or through Government-owned, Government-operated facilities. For the Agency for International Development, the "extramural budget" does not include amounts obligated solely for general institutional support of international research centers or for grants to foreign countries. For the Department of Energy, the "extramural budget" does not include amounts obligated for atomic energy defense programs solely for weapons activities or for naval reactor programs. (See also § 7(j) of this Policy Directive for additional exemptions related to national security.)

(o) <u>Federal Agency</u>. An executive agency as defined in 5 U.S.C. 105, and a military department as defined in 5 U.S.C. 102 (Department of the Army, Department of the Navy, Department of the Air Force), except that it does not include any agency within the Intelligence Community as defined in Executive Order 12333, § 3.4(f), or its successor orders.

(p) <u>Federal Laboratory</u>. As defined in 15 U.S.C. 3703, means any laboratory, any federally funded research and development center, or any center established under 15 U.S.C. 3705 and 3707 that is owned, leased, or otherwise used by a Federal Agency and funded by the Federal Government, whether operated by the Government or by a contractor.

(q) Form, Fit, and Function Data. Data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For Computer Software it means data identifying source, functional characteristics, and performance requirements, but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

(r) <u>Funding Agreement</u>. Any contract, grant, or cooperative agreement entered into between any Federal Agency and any SBC for the performance of experimental, developmental, or research work, including products or services, funded in whole or in part by the Federal Government.

(s) <u>Government Purpose</u>. Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense

organizations or sales or transfers by the United States Government to foreign governments or international organizations. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Technical Data or Computer Software for commercial purposes or authorize others to do so.

(t) <u>Innovation</u>. Something new or improved, having marketable potential, that includes the development of new technology, the refinement of existing technology, or the development of new applications for existing technology.

(u) <u>Intellectual Property</u>. The separate and distinct types of intangible property that are referred to collectively as "Intellectual Property," including but not limited to: patents, trademarks, copyrights, trade secrets, and mask works.

(v) Joint Venture. See 13 CFR 121.103(h).

(w) <u>Key Individual</u>. The Principal Investigator/Project Manager and any other person named as a "key" employee in a proposal submitted in response to a Program Solicitation.

(x) <u>Operations, Maintenance, Installation, or Training Purposes (OMIT) Data</u>. Data that is necessary for operation, maintenance, installation, or training purposes (but not including detailed manufacturing or process data).

(y) <u>Participating Agency(ies)</u>. A federal agency with an SBIR or STTR program. An "SBIR/STTR Agency."

(z) <u>Principal Investigator/Project Manager</u>. The one individual designated by the Applicant to provide the scientific and technical direction to a project supported by the Funding Agreement.

(aa) <u>Program Solicitation</u>. A formal solicitation for proposals issued by a Federal Agency that notifies the small business community of its R/R&D needs and interests in broad and selected areas, as appropriate to the agency, and requests for proposals from SBCs in response to these needs and interests.

(bb) <u>Prototype</u>. A product, material, object, system, or process, or a model thereof, that is in development, regardless of whether it is in tangible, electronic, graphic or other form, at any stage of development prior to its intended ultimate commercial production and sale. The term "Prototype" includes Computer Programs embedded in hardware or devices.

(cc) <u>Research Institution</u>. One that has a place of business located in the United States, which operates primarily within the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor, and is: (1) A non-profit institution as defined in section 4(3) of the Stevenson-Wydler Technology Innovation Act of 1980 (that is, an organization that is owned and operated exclusively for scientific or educational purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual); or (2) A Federally-funded R/R&D center (FFRDC) as identified by the National Science Foundation (NSF) in accordance with the Federal Acquisition Regulation issued in accordance with section 35(c)(1) of the Office of Federal Procurement Policy Act (or any successor regulation). A non-profit institution can include hospitals and military educational institutions, if they meet the definition above.

(dd) <u>Research or Research and Development (R/R&D)</u>. Any activity that is: (1) a systematic study directed toward greater knowledge or understanding of the subject

studied; (2) a systematic study directed specifically toward applying knowledge and innovation to meet a recognized but unmet need; or (3) a systematic application of knowledge and innovation 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.

(ee) <u>SBIR/STTR Computer Software Rights</u>. The Federal Government's rights during the SBIR/STTR Protection Period in specific types of SBIR/STTR Data that are Computer Software.

(1) The Federal Government may use, modify, reproduce, release, perform, display, or disclose SBIR/STTR Data that are Computer Software within the Federal Government. The Government may exercise SBIR/STTR Computer Software Rights within the Government for:

(i) Use in Government computers;

(ii) Modification, adaptation, or combination with other Computer Software,
 provided that the Data incorporated into any derivative software are subject to the
 rights in paragraph (ee) and that the derivative software is marked as containing
 SBIR/STTR Data;

(iii) Archive or backup; or

(iv) Distribution of a computer program to another Government agency, without further permission of the Awardee, if the Awardee is notified of the distribution and the identity of the recipient prior to the distribution, and a copy of the SBIR/STTR Computer Software Rights included in the Funding Agreement is provided to the recipient prior to the distribution. The agency in receipt of the distributed SBIR/STTR Data is subject to the data rights provisions in the SBIR/STTR Awardees SBIR/STTR funding agreement.

(2) The Government shall not release, disclose, or permit access to SBIR/STTR Data that is Computer Software for commercial, manufacturing, or procurement purposes without the written permission of the Awardee. The Government shall not release, disclose, or permit access to SBIR/STTR Data outside the Government without the written permission of the Awardee unless:

(i) The non-Governmental entity has entered into a non-disclosure agreement with the Government that complies with the terms for such agreements outlined in § 8 of this Policy Directive; and

(ii) The release or disclosure is—

(A) To a Government support service contractor or their subcontractor in the performance of a Government support services contract for internal Government use or activities, including evaluation, diagnosis and correction of deficiencies, and adaptation, combination, or integration with other Computer Software, provided that SBIR/STTR Data incorporated into any derivative software are subject to the rights in paragraph (ee), and provided that the release is not for commercial purposes or manufacture; or

(B) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul.

(ff) <u>SBIR/STTR Data</u>. All Data developed or generated in the performance of an SBIR or STTR award, including Technical Data and Computer Software developed or generated in the performance of an SBIR or STTR award. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(gg) <u>SBIR/STTR Data Rights.</u> The Government's license rights in properly marked SBIR/STTR Data during the SBIR/STTR Protection Period as follows: SBIR/STTR Technical Data Rights in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software and SBIR/STTR Computer Software Rights in SBIR/STTR Data that is Computer Software. Upon expiration of the protection period for SBIR/STTR Data, the Government has a royalty-free license to use, and to authorize others to use on its behalf, these Data for Government Purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these Data by third parties, except that any such Data that is also protected under a subsequent SBIR/STTR award shall remain protected through the protection period of that subsequent award. The Government receives Unlimited Rights in all Form, Fit, and Function Data, OMIT Data, and unmarked SBIR/STTR Data.

(hh) <u>SBIR/STTR Protection Period</u>. The period of time during which the Government is obligated to protect SBIR/STTR Data against unauthorized use and disclosure in accordance with SBIR/STTR Data Rights. The SBIR/STTR Protection Period begins at award of an SBIR/STTR Funding Agreement and ends not less than twenty years from that date. (See § 8(b)(4) of this Policy Directive).

(ii) SBIR/STTR Technical Data Rights. The Federal Government's rights during the

SBIR/STTR Protection Period in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software.

(1) The Government may, use, modify, reproduce, perform, display, release, or disclose SBIR/STTR Data that are Technical Data within the Federal Government; however, the Federal Government shall not use, release, or disclose the data for procurement, manufacture or commercial purposes; or release or disclose the SBIR/STTR Data outside the Government except as permitted by paragraph (2) below or by written permission of the Awardee.

(2) SBIR/STTR Data that are Technical Data may be released outside the Federal Government without any additional written permission of the Awardee only if the non-Governmental entity or foreign government has entered into a non-disclosure agreement with the Federal Government that complies with the terms for such agreements outlined in § 8 of this Policy Directive and the release is:

(i) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul;

(ii) To a Government support services contractor in the performance of a Government support services contract for internal Government use or activities, including evaluation, diagnosis or modification provided that SBIR/STTR
Technical Data incorporated into any derivative Data are subject to the rights in paragraph (ii), and the release is not for commercial purposes or manufacture;
(iii) To a foreign government for purposes of information and evaluation if

required to serve the interests of the U.S. Government; or

(iv) To non-Government entities or individuals for purposes of evaluation.

(jj) <u>Small Business Concern (SBC)</u>. A concern that meets the SBIR/STTR program eligibility requirements set forth in 13 CFR 121.702, "What size and eligibility standards are applicable to the SBIR and STTR programs?".

(kk) <u>Socially and Economically Disadvantaged Individual</u>. <u>See</u> 13 CFR 124.103 and 124.104.

(ll) <u>Socially and Economically Disadvantaged SBC (SDB)</u>. <u>See</u> 13 CFR. part 124, subpart B.

(mm) <u>Student/Faculty-owned SBC</u>. A small business that is majority-owned by a faculty member or a student of an institution of higher education as defined in 20 U.S.C. 1001.
(nn) <u>Subcontract</u>. Any agreement, other than one involving an employer-employee relationship, entered into by an Awardee of a Funding Agreement calling for supplies or services for the performance of the original Funding Agreement.

(oo) Technology Development Program.

(1) the Established Program to Stimulate Competitive Research (EPSCoR) of the National Science Foundation as established under 42 U.S.C. 1862g;

(2) the Defense Established Program to Stimulate Competitive Research (DEPSCoR) of the Department of Defense;

(3) the Established Program to Stimulate Competitive Research (EPSCoR) of the Department of Energy;

(4) the Established Program to Stimulate Competitive Research (EPSCoR) of the Environmental Protection Agency; (5) the Established Program to Stimulate Competitive Research (EPSCoR) of the National Aeronautics and Space Administration;

(6) the Institutional Development Award (IDeA) Program of the National Institutes of Health; and

(7) the Agriculture and Food Research Initiative (AFRI) of the Department of Agriculture.

(pp) <u>Technical Data</u>. Recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including Computer Software Documentation and Computer Databases). The term does not include Computer Software or financial, administrative, cost or pricing, or management information, or other data incidental to contract or grant administration. The term includes recorded Data of a scientific or technical nature that is included in Computer Databases.
(qq) <u>United States</u>. The 50 states, the territories and possessions of the Federal Government, the Commonwealth of Puerto Rico, the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau.
(rr) <u>Unlimited Rights</u>. The Federal Government's rights to use, modify, prepare derivative works, reproduce, release, perform, display, disclose, or distribute Data in

whole or in part, in any manner and for any purpose whatsoever, and to have or authorize others to do so.

(ss) <u>Women-Owned SBC (WOSB)</u>. An SBC that is at least 51% owned by one or more women, or in the case of any publicly owned business, at least 51% of the stock is owned by women, and women control the management and daily business operations.

4. <u>Phased Structure of Programs</u>

The SBIR/STTR programs employ a phased process, uniform throughout the Federal Government, of soliciting proposals and awarding Funding Agreements for R/R&D, production, services, or any combination, to meet stated agency needs or missions. Agencies must issue SBIR/STTR awards pursuant to competitive and merit-based selection procedures. Agencies may not use investment of venture capital or investment from hedge funds or private equity firms as a criterion for an SBIR/STTR award. Although cost sharing or matching funds cannot be required for Phase I or Phase II awards, agencies may require a small business to have matching funds for certain special awards (e.g., to reduce the gap between a Phase II and Phase III award). In order to stimulate and foster scientific and technological innovation, including increasing Commercialization of Federal R/R&D, the program must follow a uniform competitive process of the following three phases, unless an exception applies:

(a) <u>Phase I</u>. Phase I involves a solicitation of contract proposals or grant applications to conduct feasibility-related experimental or theoretical R/R&D related to described agency requirements. These requirements, as defined by agency topics contained in a solicitation, may be general or narrow in scope, depending on the needs of the agency. The object of this phase is to determine the scientific and technical merit and feasibility of the proposed effort and the quality of performance of the SBC with a relatively small agency investment before consideration of further Federal support in Phase II.

(1) Several different proposed solutions to a given problem may be funded.

(2) Proposals will be evaluated on a competitive basis. Agency criteria used to evaluate SBIR/STTR proposals must give consideration to the scientific and technical merit and feasibility of the proposal along with its potential for Commercialization.

Considerations may also include program balance with respect to market or technological risk or critical agency requirements.

(3) Agency benchmarks for progress towards Commercialization must be met to be eligible to participate in Phase I of the program. See § 6(a) of this Policy Directive for a description of this Phase I eligibility requirement.

(4) Agencies may require the submission of a Phase II proposal as a deliverable item under Phase I.

(b) <u>Phase II</u>.

(1) The object of Phase II is to continue the R/R&D effort from the completed Phase

I. Unless an exception set forth in paragraphs (i) or (ii) below applies, only

SBIR/STTR Phase I Awardees are eligible to participate in Phase II.

(i) A Federal Agency may issue an SBIR Phase II award to an STTR Phase I Awardee to further develop the work performed under the STTR Phase I award. Similarly, an agency may issue an STTR Phase II award to an SBIR Phase I Awardee to further develop the work performed under the SBIR Phase I award. The agency must base its decision upon the results of work performed under the Phase I award and the scientific and technical merit and commercial potential of the Phase II proposal. The Phase I Awardee must meet the eligibility and program requirements of the Phase II program from which it will receive the award in order to receive the Phase II award.

(ii) [SBIR only] The National Institutes of Health (NIH), Department of Defense(DoD) and the Department of Education (DoEd) may issue a Phase II SBIR awardto an SBC that did not receive a Phase I SBIR or STTR award for that R/R&D.

Prior to such an award, the heads of those agencies, or designees, must issue a written determination that the small business has demonstrated the scientific and technical merit and feasibility of the ideas that appear to have commercial potential. The determination must be submitted to SBA prior to issuing the Phase II award. This pilot program shall terminate on September 30, 2022, unless otherwise extended.

(iii) [SBIR only] A Federal Agency must implement a Commercialization Assistance Pilot Program, under which SBCs may apply to receive a third Phase II award to carry out further commercialization activities. Awards made under this pilot program may not exceed the limitation on size of awards and shall be disbursed during the performance of a Phase II award. The funds awarded may only be used for research and development activities that build on the Phase II work and ensure it is rapidly progressing towards commercialization. The head of each Participating Agency may be allocated not more than 5 percent of the funds allocated to the SBIR program of that agency for the purpose of making awards under this pilot program. SBA may determine a covered agency has a sufficiently similar program, and thus is not required to implement the pilot program.

(A) To be selected to receive an award under this pilot program, an SBC shall submit to the Participating Agency implementing the program an application at such time, in such manner, and containing such information as the Participating Agency may require, including:

- a. An updated Phase II commercialization plan; and
- b. The source and amount of the required matching funding

- (B) Eligible SBCs has received:
 - a. A Phase II award under an SBIR program; and
 - A Sequential Phase II ("second Phase II") from the covered agency to which the SBC is apply for a third Phase II award under this pilot program.
- (C) Matching funding from an eligible third party is required. The matching amount (excluding any fees collected by the SBC) must be equal to the amount of the award. SBCs may not use funding from ineligible sources to meet the matching requirement.
 - a. Eligible third-party investors include:
 - i. a SBC other than the eligible SBC;
 - ii. venture capital firms;
 - iii. individual investors;
 - iv. a non-SBIR federal, state, or local government;
 - v. or any combination thereof.
 - b. Ineligible sources include:
 - The eligible SBC's internal research and development funds;
 - ii. Funding in forms other than cash (such as in-kind or other tangible assets);
 - iii. Funding from the owners of the eligible SBC, or the family members or affiliates of such owners; or
 - iv. Funding attained through loans or other forms of debt

obligations.

- (D)Agencies shall consider the following when making awards under this pilot program:
 - a. The extent to which such award could aid the eligible entity in commercializing the research funded under the eligible entity's Phase II program;
 - b. Whether the updated Phase II commercialization plan provides a sound approach for establishing technical feasibility that could lead to commercialization of such research;
 - c. Whether the proposed activities to be conducted under such updated Phase II commercialization plan further improve the likelihood that such research will provide societal benefits;
 - d. Whether the small business concern has progressed satisfactorily in Phase II to justify receipt of a subsequent Phase II SBIR award;
 - e. The expectations of the eligible third-party investor that provides matching funding; and
 - f. The likelihood that the proposed activities to be conducted under such updated Phase II commercialization plan using matching funding provided by such eligible third-party investor will lead to commercial and societal benefit.
- (E) The pilot under this subsection shall terminate on September 30, 2022, unless otherwise extended.

(2) Funding must be based upon the results of work performed under a Phase I award and the scientific and technical merit, feasibility and commercial potential of the Phase II proposal. Phase II awards may not necessarily complete the total research and development that may be required to satisfy commercial or Federal needs beyond the SBIR/STTR program. The Phase II Funding Agreement with the Awardee may, at the discretion of the awarding agency, establish the procedures applicable to Phase III agreements. The Government is not obligated to fund any specific Phase II proposal.

(3) The SBIR/STTR Phase II award decision process requires, among other things, consideration of a proposal's commercial potential. Commercial potential includes the potential to transition the technology to private sector applications, Government applications, or Government contractor applications. Commercial potential in a Phase II proposal may be evidenced by:

(i) the SBC's record of successfully commercializing SBIR/STTR or other research;

(ii) the existence of Phase II funding commitments from private sector or other non-SBIR/STTR funding sources;

(iii) the existence of Phase III, follow-on commitments for the subject of the research; and

(iv) other indicators of commercial potential of the idea.

(4) Agencies may not use an invitation, pre-screening, or pre-selection process foreligibility for Phase II. Agencies must note in each solicitation that all Phase IAwardees may apply for a Phase II award and provide guidance on the procedure for

doing so.

(5) A Phase II Awardee may receive one additional, sequential Phase II award to continue the work of an initial Phase II award. The additional, sequential Phase II award has the same guideline amounts and limits as an initial Phase II award. (6) Agencies may offer special SBIR/STTR awards, such as Phase IIB awards, that supplement or extend Phase II awards. For example, some agencies administer Phase IIB awards that differ from the base Phase II in that they require third party matching of the SBIR/STTR funds. Each such supplemental award must be linked to a base Phase II award (the initial Phase II, or the second sequential Phase II award). Any SBIR/STTR funds used for such special or supplementary awards are aggregated with the amount of the base Phase II to determine the size of that Phase II award. Therefore, while there is no limit on the number of such special/supplementary awards, there is a limit on the total amount of SBIR/STTR funds that can be administered through them -- the amounts of these awards count towards the size of the initial Phase II or the sequential Phase II, each of which has a guideline amount of \$1 million and a limit of \$1.5 million. (Note that Phase IIB awards under the NIH SBIR program are administered as second, sequential Phase II awards, not supplemental awards. As such, they are base Phase II awards and subject to the Phase II guideline amounts and limits of \$1 million and \$1.5 million). (7) A concern that has received a Phase I award from an agency may receive a subsequent Phase II award from another agency if each agency makes a written determination that the topics of the relevant awards are the same and both agencies report the awards to the SBA including a reference to the related Phase I award and

initial Phase II award if applicable.

(8) Agencies may issue Phase II awards for testing and evaluation of products, services, or technologies for use in technical or weapons systems.

(c) <u>Phase III</u>. Phase III refers to work that derives from, extends, or completes an effort made under prior SBIR/STTR Funding Agreements, but is funded by sources other than the SBIR/STTR programs. Phase III work is typically oriented towards Commercialization of SBIR/STTR research or technology, including through further R/R&D work.

(1) <u>Phase III work:</u> Each of the following types of activity constitutes SBIR/STTR Phase III work:

(i) Commercial application (including R/R&D, testing and evaluation of products, services or technologies for use in technical or weapons systems) of SBIR/STTR-funded R/R&D that is financed by non-Federal sources of capital. (Note: The guidance in this Policy Directive regarding SBIR/STTR Phase III pertains to the non-SBIR/STTR federally-funded work described in (ii) and (iii) below. It does not address private agreements an SBIR/STTR firm may make in the Commercialization of its technology, except for a subcontract to a Federal contract that may be a Phase III.).

(ii) SBIR/STTR-derived products or services intended for use by the Federal Government, funded by non-SBIR/STTR sources of Federal funding.

(iii) Continuation of SBIR/STTR work, funded by non-SBIR/STTR sources of Federal funding including R/R&D.

(2) Data Rights. A Phase III award is, by its nature an SBIR/STTR award, has

SBIR/STTR status, and must include SBIR/STTR Data Rights protection. If an SBIR/STTR Awardee receives a Funding Agreement (whether competed, direct award, sole sourced or a subcontract) for work that derives from, extends, or completes efforts made under prior SBIR/STTR Funding Agreements, then the Funding Agreement for the new work must have all SBIR/STTR Phase III status and SBIR/STTR Data Rights.

(3) <u>Competition Requirement</u>. The competitions for SBIR/STTR Phase I and Phase II awards satisfy any competition requirement of the Armed Services Procurement Act, the Federal Property and Administrative Services Act, and the Competition in Contracting Act. An agency that wishes to fund an SBIR/STTR Phase III award, which is an extension of prior Phase I and/or Phase II awards, is not required to conduct another competition for the Phase III award in order to satisfy those statutory provisions. As a result, in conducting actions relative to a Phase III SBIR/STTR award, it is sufficient to state for purposes of a Justification and Approval, if one is deemed required by the agency, that the project is an SBIR/STTR Phase III award that is derived from, extends, or completes efforts made under prior SBIR/STTR Funding Agreements and is authorized pursuant to 15 U.S.C. 638(r)(4). Further justification is not needed.

(4) Phase III work may be for products, production, services, R/R&D, or any such combination.

(5) There is no limit on the number, duration, type, or dollar value of Phase III awards made to a business concern. There is no limit on the time that may elapse between a Phase I or Phase II award and Phase III award, or between a Phase III award and any

subsequent Phase III award. A Federal Agency may enter into a Phase III SBIR/STTR agreement at any time with a Phase II Awardee. Similarly, a Federal Agency may enter into a Phase III SBIR/STTR agreement at any time with a Phase I Awardee. A subcontract to a Federally-funded prime contract may be a Phase III award.

(6) <u>Size</u>. The small business size limits for Phase I and Phase II awards do not apply to Phase III awards.

(7) <u>Special acquisition requirement</u>. Agencies or their Government-owned, contractor-operated (GOCO) facilities, Federally-funded research and development centers (FFRDCs), or Government prime contractors that pursue R/R&D or production of technology developed under the SBIR/STTR program shall issue Phase III awards relating to the technology, including sole source awards, to the Awardee that developed the technology under an SBIR/STTR award, to the greatest extent practicable, consistent with an Agency's mission and optimal small business participation.

(i) <u>Implementing the requirement</u>. In recognition of the prior merit-based competitive selection of, and subsequent commitment of agency funds to SBIR/STTR Awardees and the broad intent of the program to promote the commercial success of these small businesses, Agencies must make a good faith effort to negotiate with such Awardees regarding the performance of the new, related, work and to issue Phase III awards for the work. When implementing this requirement, the agency will evaluate the work for consistency with its documented mission requirements and must consider the practicality of pursuing

the work with the Awardee through a direct follow-on award by performing market research to determine whether the firm is available, capable, and willing to perform the work. If an award is made, the Agency must identify the funding agreement as an SBIR or STTR Phase III. The Agency must act in ways consistent with the Congressional intent to support the Commercialization of an SBIR/STTR-developed technology by the SBIR/STTR Awardee, and all parties must proceed along these steps in good faith.

(ii) <u>Sole Source Awards</u>. If pursuing the Phase III work with the Awardee is found to be practicable, the agency must award a non-competitive contract to the firm.

(iii) <u>Other Preference.</u> If pursuing Phase III work with the Awardee on a sole source/non-competitive basis does not meet the requirements set forth in the above sections regarding availability, practicality and capability, the Agency must document the file and provide a copy of the decision, including the rationale, to the SBA. The agency should also use other means of affording preference for the Phase III work, especially when the request is for a large acquisition program, which may not be best suited for an SBIR/STTR Award. Examples include reference to the SBIR/STTR Awardee's brand-name as a required deliverable in the request for proposals, requiring the prime awardee to use evaluation factors favoring subcontracting to SBIR/STTR Concerns, or providing other incentives to the prime contractor for utilizing SBIR/STTR Awardees as subcontractors, as referenced in 15 U.S.C. § 638(y).

(iv) Agency Notice of Intent to Award. An agency, or its GOCOs or FFRDCs,

that intends to pursue Phase III work (which includes R/R&D, production, services, or any combination thereof of a technology developed under an SBIR/STTR award), with an entity other than the Phase I or Phase II SBIR/STTR Awardee, must notify SBA in writing prior to such an award. This notification must include, at a minimum:

(A) The steps the agency has taken to fulfill the special acquisitionrequirement (<u>e.g.</u>, a good faith effort to make the award to the SBIR/STTRAwardee).

(B) The reasons why a follow-on Funding Agreement with the SBIR/STTR Awardee is not practicable (e.g., SBIR/STTR Awardee was not willing or interested in the work, not capable of doing the work or functioning as a prime and subcontracting the work, or no longer in business).

(C) The identity of the entity with which the agency intends to make an award to perform the research, development, or production; the type of Funding Agreement to be used; and the amounts of the agreement.

(v) <u>SBA Notice of Intent to Appeal</u>. SBA may appeal a decision by an agency (or its GOCOs or FFRDCs) to pursue Phase III work with a business concern other than the SBIR/STTR Awardee that developed the technology to the head of the contracting activity.

(A) If SBA receives an agency's notice of intent to make an award under (iv)above, SBA may file a notice of intent to appeal with the Funding Agreementofficer no later than 5 business days after receiving the agency's notice of intent to

make award.

(B) If an agency is pursuing work that SBA has determined is Phase III work and has not complied with either of the reporting requirements above, SBA may notify the agency at any time of its intent to appeal the decision to proceed with the work. SBA makes such determinations based on all information it receives, including information presented directly to SBA by an SBIR/STTR Awardee.

(vi) <u>Suspension of Work</u>. Upon receipt of SBA's notice of intent to appeal, the Funding Agreement officer must suspend further action on the funding agreement until the head of the contracting activity issues a written decision on the appeal. The Funding Agreement officer may proceed with award only if he or she determines in writing that the award must be made to protect the public interest. The Funding Agreement officer must include a statement of the facts justifying such a determination and provide a copy of its determination to SBA.

(vii) <u>SBA Appeal</u>. Within 10 business days of SBA's notice of intent to appeal, SBA may file a formal appeal with the head of the agency. SBA's appeal will state with specificity SBA's conclusion that the agency's obligation to make a Phase III award "to the greatest extent practicable" has not been fulfilled.

(viii) <u>Agency Decision</u>. Within 30 business days of receiving SBA's appeal, the head of the agency's contracting or grant-making activity must render a written decision setting forth the basis of his or her determination. During this period, the agency should consult with SBA and review any case-specific information SBA believes to be pertinent.

(ix) SBA Case Report to Congress. SBA notifies Congress of all instances in which

an agency pursued Phase III R/R&D, or production of a technology developed under an SBIR/STTR award, with a business or entity other than the SBIR/STTR Awardee. SBA will notify Congress of such instances, of any agency determination or decision justifying an award to other than the Phase III SBIR/STTR Awardee, and of any SBA appeals of agency decisions under this section.

5. <u>Program Solicitation Process</u>

(a) <u>Topics/Subtopics.</u> At least annually, each agency must issue a Program Solicitation that sets forth a substantial number of R/R&D topics and subtopic areas consistent with stated agency needs or missions. Agencies may decide to issue joint solicitations. Both the list of topics and the description of the topics and subtopics must be sufficiently comprehensive to provide a wide range of opportunities for SBCs to participate in the agency R/R&D programs. Topics and subtopics must emphasize the need for proposals with advanced concepts to meet specific agency R/R&D needs. Each topic and subtopic must describe the needs in sufficient detail to assist in providing on-target responses, but cannot involve detailed specifications to prescribed solutions of the problems.
(b) <u>Master Schedule.</u> The Act requires issuance of SBIR/STTR Phase I Program Solicitations in accordance with a Master Schedule coordinated between SBA and the SBIR/STTR Participating Agency. The SBA office responsible for coordination is: Office of Innovation, U.S. Small Business Administration, 409 Third Street, SW,

Washington, DC 20416. Phone: (202) 205-6450. Fax: (202) 205-7754. E-mail:

technology@sba.gov. Website: www.SBIR.gov.

(c) <u>Coordination of Agency Schedules.</u> For maximum participation by interested SBCs, it is important that the planning, scheduling and coordination of agency Program

Solicitation release dates be completed as early as practicable to coincide with the commencement of the fiscal year on October 1. Bunching of agency Program Solicitation release and closing dates may prohibit SBCs from preparation and timely submission of proposals for more than one SBIR/STTR project. SBA's coordination of agency schedules minimizes the bunching of proposed release and closing dates. SBIR/STTR Agencies may elect to publish multiple Program Solicitations within a given fiscal year to facilitate in-house agency proposal review and evaluation scheduling. (d) Posting of Master Schedule. SBA posts a Master Schedule of release dates of Program Solicitations with links to the Participating Agency websites. For more information see § 10(c) of this Policy Directive.

(e) Simplified, Standardized, and Timely SBIR/STTR Program Solicitations

(1) The Act requires simplified, standardized and timely SBIR/STTR solicitations and for agencies to use a "uniform process" minimizing the regulatory burden for SBCs. Therefore, the instructions in Appendix I to this Policy Directive purposely depart from normal Government solicitation format and requirements. Furthermore, while all of Appendix I is applicable for Phase I and Phase II procurements, only §5(d) of Appendix I is applicable for Phase III procurements.

(2) Agencies must update <u>www.SBIR.gov</u> with information on each solicitation and modification no later than 5 days after the date of release of the solicitation or modification to the public. This must include any update to the website link for the Program Solicitation.

(3) SBA does not intend that the SBIR/STTR Program Solicitation replace or be used as a substitute for unsolicited proposals for R/R&D awards to SBCs. In addition, the

SBIR/STTR Program Solicitation procedures do not prohibit other agency R/R&D actions with SBCs that are carried on in accordance with applicable statutory or regulatory authorizations.

6. <u>Eligibility and Application (Proposal) Requirements</u>

(a) <u>Eligibility Requirements</u>

(1) <u>Certification</u>. To receive SBIR/STTR funds, each Awardee of a Phase I or Phase II award must qualify as an SBC at the time of award and at any other time set forth in SBA's regulations at 13 CFR 121.701-121.705. Each Phase I and Phase II Awardee must submit a certification stating that it meets the size, ownership and other requirements of the SBIR or STTR program at the time of award, and at any other time set forth in SBA's regulations at 13 CFR 121.701-121.705. SBA's size regulations for the SBIR/STTR program require that an Awardee be directly owned and controlled by individuals or SBCs; however, SBA is clarifying that an SBC directly owned and controlled by an Indian Tribe or by another SBC that is directly owned and controlled by an Indian Tribe may also be eligible to participate in the SBIR/STTR programs.

(2) <u>Performance of Work Requirements</u>. For SBIR Phase I, a minimum of two-thirds of the research or analytical effort must be performed by the Awardee. For SBIR Phase II, a minimum of one-half of the research or analytical effort must be performed by the Awardee. Occasionally, deviations from these SBIR requirements may occur, and must be approved in writing by the Funding Agreement officer after consultation with the agency SBIR/STTR program manager/coordinator. For STTR Phase I and Phase II, not less than 40 percent of the R/R&D work must be performed

by the SBC, and not less than 30 percent of the R/R&D work must be performed by a partnering Research Institution. Deviations from these STTR requirements are not allowed, as the performance of work requirements are specified in statute at 15 USC 638(e). An agency can measure this research or analytical effort using the total award dollars or labor hours, and must explain to the small business in the solicitation how it will be measured.

(3) Employment of the Principal Investigator/Project Manager. For both Phase I and Phase II, the primary employment of the Principal Investigator/Project Manager must be with the SBC (or the Research Institution – STTR only) 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/Project Manager's employment time is spent in the employ of the SBC (or Research Institution – STTR only). This precludes full-time employment with another organization. Occasionally, deviations from this requirement may occur, and must be approved in writing by the Funding Agreement officer after consultation with the agency SBIR/STTR program manager/coordinator. Further, an SBC may replace the Principal Investigator/Project Manager on an SBIR/STTR Phase I or Phase II award, subject to approval in writing by the Funding Agreement officer. For purposes of the SBIR/STTR programs, personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the Awardee. This is consistent with SBA's size regulations, 13 CFR 121.106, "How Does SBA Calculate Number of Employees?".

(4) Location of the work. For both Phase I and Phase II, the R/R&D work must be

performed in the United States. However, based on a rare and unique circumstance, agencies may approve a particular portion of the R/R&D work to be performed or obtained in a country outside of the United States, for example, if a supply or material or other item or project requirement is not available in the United States. The Funding Agreement officer must approve each such specific condition in writing. (5) Novated/Successor in Interested/Revised Funding Agreements. An SBIR/STTR Awardee may include, and SBIR/STTR work may be performed by, those identified via a "novated" or "successor in interest" or similarly-revised Funding Agreement. For example, in order to receive a Phase III award, the Awardee must have either received a prior Phase I or Phase II award or been novated a Phase I or Phase II award (or received a revised Phase I or Phase II award if a grant or cooperative grant). In addition, an SBIR/STTR Awardee may include those that have merely reorganized with the same key staff (e.g., reorganized from a partnership to an LLC), regardless of whether they have been assigned a different tax identification number. In cases where there is a novation or similarly revised Funding Agreement, agencies may require the original Awardee to relinquish its rights and interests in an SBIR/STTR project in favor of another Applicant as a condition for that Applicant's eligibility to participate in the programs for that project.

(6) <u>Majority-Owned by Multiple VCOCs, Hedge Funds or Private Equity Firms</u> [SBIR Only]. NIH, Department of Energy (DOE), and NSF may each award not more than 25% of the agency's SBIR funds to SBCs that are owned in majority part by multiple venture capital operating companies, hedge funds, or private equity firms through competitive, merit-based procedures that are open to all eligible SBCs. Any

other SBIR Participating Agency may award not more than 15% of the agency's SBIR funds to such SBCs. SBIR agencies may or may not choose to utilize this funding option. A table listing the agencies that are currently using this authority can be found at <u>www.SBIR.gov</u>. This authority is set forth in 13 CFR 121.701-121.705.

(i) Before permitting participation in the SBIR program by SBCs that are owned in majority part by multiple venture capital operating companies, hedge funds, or private equity firms, the SBIR agency must submit a written determination to SBA, the Senate Committee on Small Business and Entrepreneurship, the House Committee on Small Business and the House Committee on Science, Space, and Technology at least 30 calendar days before it begins making awards to such SBCs. The determination must be made by the head of the Federal Agency or designee and explain how awards to such SBCs in the SBIR program will:

(A) induce additional venture capital, hedge fund, or private equity firm funding of small business innovations;

- (B) substantially contribute to the mission of the Federal Agency;
- (C) address a demonstrated need for public research; and

(D) otherwise fulfill the capital needs of SBCs for additional financing for SBIR projects.

(ii) The SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms must register with SBA in the Company Registry Database, at <u>www.SBIR.gov</u>, prior to the date it submits an application for an SBIR award.

(iii) The SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms must submit a certification with its proposal stating, among other things, that it has registered with SBA.

(iv) Any agency that makes an award under this paragraph during a fiscal year shall collect and submit to SBA data relating to the number and dollar amount of Phase I awards, Phase II awards, and any other category of awards by the Federal Agency under the SBIR program during that fiscal year. <u>See</u> § 10 of this Policy Directive for the specific reporting requirements.

(v) If an agency awards more than the percentage of the funds authorized under § 6(a)(6) of this Policy Directive, the agency shall transfer from its non-SBIR and non-STTR R/R&D funds to the agency's SBIR funds any amount that is in excess of the authorized amount. The agency must transfer the funds not later than 180 days after the date on which the Federal Agency made the award that exceeded the authorized amount.

(vi) If a Federal Agency makes an award under a solicitation more than 9 months after the date on which the period for submitting applications under the solicitation ends, a Covered Small Business Concern is eligible to receive the award, without regard to whether it meets the eligibility requirements of the program for a SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms, if the Covered Small Business Concern meets all other requirements for such an award. In addition, the agency must transfer from its non-SBIR and non-STTR R/R&D funds to the agency's SBIR funds any amount that is so awarded to a Covered Small Business Concern.

The funds must be transferred not later than 90 days after the date on which the Federal Agency makes the award.

(7) Agency Benchmarks for Progress Towards Commercialization.

(i) Before making a new Phase I award to an Awardee that has won multiple prior SBIR/STTR awards, each agency must establish benchmarks for progress towards Commercialization and determine whether an Applicant meets those benchmarks. Agencies must apply two SBA-approved performance standards (benchmarks) addressing an Awardee's progress towards Commercialization: a Phase II Transition Rate that sets a minimum required rate of progress from Phase I to Phase II over a specified period, and a Commercialization Rate Benchmark that sets the minimum Commercialization results an Awardee must have realized from its prior SBIR/STTR awards over a specified period.

(ii) If an Awardee fails to meet either of the benchmarks, that Awardee is not eligible to submit a proposal for a new Phase I award (and any new Phase II award issued pursuant to paragraph 4(b)(1)(ii)) for a period of one year from the time of the determination.

(iii) For each benchmark, agencies establish a threshold number of prior awards an Awardee must have won for the benchmark requirement to be applied.
(iv) Using information received from the agencies and from SBIR/STTR Awardees, SBA identifies the companies that have won more than the threshold number of awards and calculates the Phase II Transition Rates and Commercialization Rates for those companies. The results of this assessment are used by each agency to determine if a company fails to meet a benchmark rate and is therefore not eligible to submit a proposal for a new Phase I award. Agencies must notify SBA of any applications denied because of failure to meet the benchmarks. The assessment results and eligibility determinations are not made public. Participating Agencies and SBA officials view the results through secure user accounts on <u>www.SBIR.gov</u>. Each participating company can view the results of the last benchmark assessment once it has created a Small Business User account on <u>www.SBIR.gov</u>. If an Awardee believes its assessment was made in error, it may provide SBA with the pertinent award information and request a reassessment.

(v) Current details of these requirements and the implementation processes used by the agencies are posted on <u>www.SBIR.gov</u> under the "Performance Benchmark Requirements" tab. Changes to these benchmarks requirements and procedures become effective when posted on <u>www.SBIR.gov</u>. Agencies must submit any changes to the benchmarks to SBA for prior approval. If approved, SBA will publish the benchmarks and allow for public comment at least 60 days before becoming effective.

(b) Proposal (Application) Requirements.

(1) <u>Registration and Certifications for Proposal and Award</u>.

(i) Each Applicant must register in SBA's Company Registry Database at <u>www.SBIR.gov</u> (see Appendix I) and submit a .pdf document of the registration and any required certifications with its application if the information cannot be transmitted automatically to the SBIR/STTR Agencies from <u>www.SBIR.gov</u>. Applicants must have updated their information on the Company Registry no

more than 6 months prior to the date of a proposal submission.

(ii) Agencies may request the SBIR/STTR Applicant to submit a certification at the time of submission of the application, which requires the Applicant to state that it intends to meet the size, ownership and other requirements of the SBIR/STTR program at the time of award of the Funding Agreement, if selected for award. <u>See</u> Appendix I for the required text of the certification.

(iii) [SBIR Only] For those agencies using the authority under § 6(a)(6) of this Policy Directive, each Phase I and Phase II Applicant that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms is required to submit a specific certification with its SBIR application to the SBIR agency (see Appendix I for the required text of the certification).

(2) <u>Commercialization Plan</u>. A succinct commercialization plan must be included with each proposal for an SBIR/STTR Phase II award. Elements of a commercialization plan will include the following, as applicable:

(i) <u>Company information</u>. Focused objectives/core competencies; specialization area(s); products with significant sales; and history of previous Federal and non-Federal funding, regulatory experience, and subsequent Commercialization.

(ii) <u>Customer and Competition</u>. Clear description of key technology objectives, current competition, and advantages compared to competing products or services; description of hurdles to acceptance of the innovation.

(iii) <u>Market.</u> Milestones, target dates, analyses of market size, and estimated market share after first year sales and after 5 years; explanation of plan to obtain market share.

(iv) <u>Intellectual Property.</u> Patent status, technology lead, trade secrets or other demonstration of a plan to achieve sufficient protection to realize the commercialization stage and attain at least a temporal competitive advantage.
(v) Financing. Plans for securing necessary funding in Phase III.

(vi) <u>Assistance and mentoring</u>. Plans for securing needed technical or business assistance through mentoring, partnering, or through arrangements with State assistance programs, SBDCs, Federally-funded research laboratories,

Manufacturing Extension Partnership centers, or other assistance providers.

(3) <u>Data Collection</u>. Each Phase I and II Applicant is required to provide information on <u>www.SBIR.gov</u> (see Appendix II as posted on www.SBIR.gov). Each SBC applying for a Phase II award is required to update its Commercialization information on <u>www.SBIR.gov</u> for all of its prior Phase II awards (<u>see</u> Appendix II as posted on www.SBIR.gov).

7. Program Funding Process

Because the Act requires a "simplified, standardized funding process," specific attention must be given to the following areas of SBIR/STTR program administration:

(a) <u>Timely Receipt of Proposals</u>. Program Solicitations must establish proposal submission dates for Phase I and may establish proposal submission dates for Phase II.
 However, agencies may also negotiate mutually acceptable Phase II proposal submission dates with individual Phase I Awardees.

(b) <u>Review of Proposals</u>. SBA encourages participating agencies to use their routine review processes for SBIR/STTR proposals whether internal or external evaluation is

used. A more limited review process may be used for Phase I due to the larger number of proposals anticipated. Where appropriate, "peer" reviews external to the agency are authorized by the Act. SBA cautions participating agencies that all review procedures must be designed to minimize any possible conflict of interest as it pertains to Applicant proprietary Data. The standardized SBIR/STTR solicitation advises potential Applicants that proposals may be subject to an established external review process and that the Applicant may include company designated proprietary information in its proposal.

(c) <u>Selection of Awardees</u>.

(1) <u>Time Period for Decision on Proposals.</u>

(i) NIH and NSF must issue a notice to an Applicant for each proposal submitted stating whether it was recommended or not for award no more than one year after the closing date of the solicitation. NIH and NSF agencies should issue the award no more than 15 months after the closing date of the solicitation. Pursuant to paragraph (iii) below, NIH and NSF are encouraged to reduce these timeframes.
(ii) All other Participating Agencies must issue a notice to an Applicant for each proposal submitted stating whether it was recommended or not for award no more than 90 calendar days after the closing date of the solicitation. Agencies should issue the award no more than 180 calendar days after the closing date of the solicitation.

(iii) Agencies are encouraged to develop programs or measures to reduce the time periods between the close of a Phase I solicitation/receipt of a Phase II application and notification to the Applicant as well as the time to the issuance of the Phase I and Phase II awards. As appropriate, agencies should adopt accelerated proposal,

evaluation, and selection procedures designed to address the gap in funding these competitive awards to meet or reduce the timeframes set forth above. With respect to Phase II awards, SBA recognizes that Phase II arrangements between the agency and Applicant may require more detailed negotiation to establish terms acceptable to both parties; however, agencies must not sacrifice the R/R&D momentum created under Phase I by engaging in unnecessarily protracted Phase II proceedings.

(iv) <u>Request for Waiver</u>.

(A) If the agency determines that it requires additional time between the solicitation closing date and the notification of recommendation for award, it must submit a written request for an extension to SBA. The written request must specify the number of additional calendar days needed to issue the notice for a specific Applicant and the reasons for the extension. If an agency believes it will not meet the timeframes for an entire solicitation, the request for an extension must state how many awards will not meet the statutory timeframes, as well as the number of additional calendar days needed to issue the notice and the reasons for the extension. The written request must be submitted to SBA at least 10 business days prior to when the agency must issue its notice to the Applicant. Agencies must send their written request to: Office of Innovation, U.S. Small Business Administration, 409 Third Street, SW, Washington, DC 20416. Phone: (202) 205-6450. Fax: (202) 205-7754. E-mail: technology@sba.gov.

(B) SBA will respond to the request for an extension within 5 business days, as practicable. SBA may authorize an agency to issue the notice up to 90 calendar days after the timeframes set forth in paragraphs (c)(1)(i) and (ii).

(C) Even if SBA grants an extension of time, the SBIR/STTR Participating Agency is required to develop programs or measures to reduce the time periods between the close of a Phase I solicitation/receipt of a Phase II application and notification to the Applicant as well as the time to the issuance of the Phase I and Phase II awards as set forth in paragraph (c)(1)(iii) above.

(D) If an SBIR/STTR Participating Agency does not receive an extension of time, it may still proceed with the award to the small business and must complete the requirements in (C) above.

(2) <u>Standardized Solicitation</u>.

(i) The standardized SBIR/STTR Program Solicitation must advise Phase I Applicants that additional information may be requested by the awarding agency to evidence Awardee responsibility for project completion and advise Applicants of the proposal evaluation criteria for Phase I and Phase II.

(ii) The SBIR/STTR Agency will provide information to each Phase I Awardee considered for a Phase II award regarding Phase II proposal submissions, reviews, and selections.

(d) <u>Essentially Equivalent Work</u>. SBIR/STTR Applicants often submit duplicate or similar proposals to more than one soliciting agency when the announcement or

solicitation appears to involve similar topics or requirements. However, Essentially Equivalent Work must not be funded in the SBIR/STTR or other Federal Agency programs, unless an exception to this rule applies. Agencies must verify with the Applicant that this is the case by requiring them to certify at the time of award and during the life cycle of the award that they do not have Essentially Equivalent Work funded by the same or another Federal Agency.

(e) <u>Cost Sharing</u>. Cost sharing can serve the mutual interests of the Participating Agencies and certain program Awardees by assuring the efficient use of available resources. Cost sharing on SBIR/STTR projects cannot be required of Applicants for Phase I and Phase II, although it may be encouraged for any phase award. However, cost sharing cannot be an evaluation factor in the review of Phase I proposals. The standardized SBIR/STTR Program Solicitation (Appendix I) will provide information to prospective program Applicants concerning cost sharing.

(f) Payment Schedules and Cost Principles.

(1) SBIR/STTR Awardees may be paid under an applicable, authorized progress payment procedure or in accordance with a negotiated/definitized price and payment schedule. Advance payments are optional and may be made under appropriate law. In all cases, agencies must make payment to recipients under SBIR/STTR Funding Agreements in full, subject to audit, on or before the last day of the 12-month period beginning on the date of completion of the Funding Agreement requirements.

(2) All SBIR/STTR Funding Agreements must use, as appropriate, current cost principles and procedures authorized for use by the Participating Agencies. By the time of award, agencies must have informed each Awardee of the applicable Federal

regulations and procedures that refer to the costs that, generally, are allowable under Funding Agreements.

(3) Agencies must, to the extent possible, shorten the amount of time between the notice of an award under the SBIR/STTR program and the subsequent release of funding with respect to the award.

(i) Pilot Program to Accelerate Department of Defense SBIR and STTR Awards

(A) The Under Secretary of Defense for Research and Engineering, acting through the Director of Defense Procurement and Acquisition Policy of the Department of Defense, shall establish a pilot program to reduce the time for awards under the SBIR and STTR programs of the Department of Defense, under which the Department of Defense shall—

(i) develop simplified and standardized procedures and model contracts throughout the Department of Defense for Phase I, Phase II, and Phase III SBIR awards;

(ii) for Phase I SBIR and STTR awards, reduce the amount of time between solicitation closure and award;

(iii) for Phase II SBIR and STTR awards, reduce the amount of time between the end of a Phase I award and the start of the Phase II award;(iv) for Phase II SBIR and STTR awards that skip Phase I, reduce the amount of time between solicitation closure and award;

(v) for sequential Phase II SBIR and STTR awards, reduce the amount of time between Phase II awards; and

(vi) reduce the award times described in clauses (ii), (iii), (iv), and (v) to

be as close to 90 days as possible.

(B) In carrying out the pilot program under subparagraph (A), the Director of Defense Procurement and Acquisition Policy of the Department of Defense shall consult with the Director of the Office of Small Business Programs of the Department of Defense.

(C) The pilot program under subparagraph (A) shall terminate on September30, 2022.

(g) <u>Funding Agreement Types and Fee or Profit</u>. Statutory requirements for uniformity and standardization require consistency in application of SBIR/STTR program provisions among SBIR/STTR Agencies. However, consistency must allow for flexibility by the various agencies in their missions and needs as well as the wide variance in funds required to be devoted to SBIR/STTR programs in the agencies. The following instructions meet all of these requirements:

(1) <u>Funding Agreement</u>. The type of Funding Agreement (contract, grant, or cooperative agreement) is determined by the awarding agency, but must be consistent with 31 U.S.C. 6301-6308. Contracting agencies may issue SBIR/STTR awards as fixed price contracts (including firm fixed price, fixed price incentive or fixed price level of effort contracts) or cost type contracts, consistent with the FAR and agency supplemental acquisition regulations. In some cases, small businesses seek progress payments, which may be appropriate under fixed-price R&D contracts and are a form of contract financing for firm-fixed-price contracts. However, for certain agencies, in order to qualify for progress payments or an incentive type contract, the small business's accounting system would have to be audited, which can delay award,

unless the contractor has an already approved accounting system. Therefore, SBIR/STTR Agencies should consider using partial payments methods or on a deliverable item basis or consider other available options to work with the SBIR/STTR Awardee.

(2) Fee or Profit. Except as expressly excluded or limited by statute, awarding agencies must provide for a reasonable fee or profit on SBIR/STTR Funding Agreements, consistent with normal profit margins provided to profit-making firms for R/R&D work.

(h) Periods of Performance and Extensions.

(1) In keeping with the legislative intent to make a large number of relatively small awards, modification of Funding Agreements to increase the dollar amount should be kept to a minimum, except for options in original Phase I or II awards.

(2) <u>Phase I</u>. Period of performance normally should not exceed 6 months for SBIR or
1 year for STTR. However, agencies may provide a longer performance period
where appropriate for a particular project.

(3) <u>Phase II</u>. Period of performance under Phase II is a subject of negotiation between the Awardee and the issuing Participating Agency. The duration of Phase II normally should not exceed 2 years. However, agencies may provide a longer performance period where appropriate for a particular project.

(i) <u>Dollar Value of Awards</u>.

(1) Generally, a Phase I award (including modifications) may not exceed \$150,000 and a Phase II award (including modifications) may not exceed \$1,000,000. Agencies may issue an award that exceeds these award guideline amounts by no more than 50%.

(2) SBA reviews these amounts every year for the effects of inflation and posts these inflation effects and any resulting adjustments on <u>www.SBIR.gov</u>. Adjusted guidelines are effective for all solicitations issued on or after the date of the adjustment, and may be used by agencies to amend the solicitation and other program literature. Agencies have the discretion to issue awards for less than the guidelines.
(3) There is no dollar limit associated with Phase III SBIR/STTR awards.

(4) Agencies may request a waiver to exceed the award guideline amounts established in paragraph (i)(1) by more than 50% for a specific topic. Agencies must submit this request for a waiver to SBA prior to release of the solicitation, contract award, or modification to the award for the topic. The request for a waiver must explain and provide evidence that the limitations on award size will interfere with the ability of the agency to fulfill its research mission through the SBIR or STTR program; that the agency will minimize, to the maximum extent practicable, the number of awards that exceed the guideline amounts by more than 50%; and that research costs for the topic area differ significantly from those in other areas. After review of the agency's justification, SBA may grant the waiver for the agency to exceed the award guidelines by more than 50% for a specific topic. SBA will issue a decision on the request within 10 business days. The waiver will be in effect for one fiscal year. (5) Agencies must maintain information on all awards exceeding the guidelines set forth in paragraph (i)(1), including the amount of the award, a justification for exceeding the guidelines for each award, the identity and location of the Awardee, whether the Awardee has received any venture capital, hedge fund, or private equity

firm investment, and whether the Awardee is majority-owned by multiple VCOCs, hedge funds, or private equity firms.

(6) The award guidelines do not prevent an agency from funding SBIR/STTR projects from other (non-SBIR/STTR) agency funds. Non-SBIR/STTR funds used on SBIR/STTR efforts do not count toward the award guidelines set forth in (i)(1).

(j) <u>National Security Exemption</u>. The Act provides for exemptions related to the simplified standardized funding process "if national security or intelligence functions clearly would be jeopardized." This exemption should not be interpreted as a blanket exemption or prohibition of SBIR/STTR participation related to the acquisition of effort on national security or intelligence functions except as specifically defined under § 9(e)(2) of the Act, 15 U.S.C. 638(e)(2). Agency technology managers directing R/R&D projects under the SBIR and STTR programs, where the project subject matter may be affected by this exemption, must first make a determination on which, if any, of the standardized proceedings clearly place national security and intelligence functions in jeopardy, and then proceed with an acceptable modified process to complete the SBIR/STTR action. SBA's SBIR/STTR program monitoring activities, except where prohibited by security considerations, must include a review of nonconforming SBIR/STTR actions justified under this public law provision.

(k) <u>Management of the STTR Project</u> [STTR only]. The SBC, and not its partnering Research Institution(s), is to provide satisfactory evidence that it will exercise management direction and control of the performance of the STTR Funding Agreement. Regardless of the proportion of the work or funding allocated to each of the performers under the Funding Agreement, the SBC is to be the primary party with overall

responsibility for performance of the project. All agreements between the SBC and the Research Institution cooperating in the STTR Funding Agreement, or any business plans reflecting agreements and responsibilities between the parties during performance of STTR Phase I or Phase II Funding Agreement, or for the Commercialization of the resulting technology, should reflect the controlling position of the SBC.

8. <u>Terms of Agreement Under SBIR/STTR Awards</u>

(a) <u>Proprietary Information Contained in Proposals</u>. The standardized SBIR/STTR Program Solicitation shall include provisions requiring the confidential treatment of any proprietary information, unless disclosure is otherwise required by law. The solicitation will require that all proprietary information be identified clearly and marked with a prescribed legend. Agencies may elect to require SBCs to limit proprietary information to that essential to the proposal and to have such information submitted on a separate page or pages keyed to the text. The Government, except solely for proposal review purposes, shall not use or disclose, or authorize any other person or entity to use or disclose, all proprietary information, regardless of type, submitted in a contract proposal or grant application for a Funding Agreement under the SBIR/STTR programs.

(b) <u>Rights in Data Developed under an SBIR/STTR Funding Agreement</u>.

(1) <u>General</u>. The Act provides for retention by an SBC Awardee of the rights to Data generated by the concern in the performance of an SBIR/STTR award. These data rights provide an incentive for SBCs to participate in Federally-funded research projects and contribute to the ability of small business Awardees to commercialize the technology developed under the program. The central purpose of SBIR/STTR Data Rights is to provide the Federal Government with the degree of access to an

Awardee's SBIR/STTR Data needed to evaluate the work and effectively utilize the results and at the same time ensure that the Federal Government or other concerns cannot use SBIR/STTR Data in ways (e.g., for commercial purposes or to produce future technical procurement specifications) that would inappropriately diminish the rights or associated economic opportunities of the small business that developed the Data. The SBIR/STTR Data Rights provisions and definitions provided in this Policy Directive are designed to ensure that, for properly marked SBIR/STTR Data, during the SBIR/STTR Protection Period, the Federal Government provides effective protection of the Data that is comparable to and at least as strong as the protection the Federal Government gives to delivered proprietary Data that is developed exclusively at private expense.

(2) <u>Application of SBIR/STTR Data Rights</u>. SBIR/STTR Participating Agencies must ensure that Awardees of an SBIR/STTR Funding Agreement retain appropriate proprietary rights for all SBIR/STTR Data generated in the performance of the award. In general, this results in the Government receiving SBIR/STTR Data Rights in all SBIR/STTR Data during the SBIR/STTR Protection Period, except for certain types of Data that are not subject to such data rights restrictions due to the nature of the data (e.g., Form, Fit, and Function Data or OMIT Data). SBIR/STTR Data Rights apply to all SBIR/STTR awards, including subcontracts or subgrants to such awards, that fall within the statutory definition of Phase I, II, or III of the SBIR/STTR programs, as described in § 4 of this Policy Directive. The scope and extent of the SBIR/STTR Data Rights applicable to Federally-funded Phase III awards are identical to the SBIR/STTR Data Rights applicable to Phases I and II SBIR/STTR awards.

SBIR/STTR Data Rights provide license rights to the Federal Government. SBIR/STTR Data Rights restrict the Federal Government's use and release of properly marked SBIR/STTR Data only during the SBIR/STTR Protection Period; after the protection period, the Federal Government has a royalty-free license to use, and to authorize others to use on its behalf, these data for Government Purposes, and is relieved of disclosure prohibitions related to such Government Purposes, and assumes no liability for unauthorized use of these data by third parties. There is one exception to the rule that all Federal agencies receive Government Purpose rights in SBIR/STTR Data after the protection period. This exception is limited to the U.S. Department of Energy (DOE), whose statutory authorities, it has argued, mandates that it release and disclose all Government funded SBIR/STTR Data after the protection period. These authorities are the Atomic Energy Act of 1954, Public Law 83-703, 42 U.S.C. 2013(b); Energy Reorganization Act of 1974 (ERA), Public Law 93-438, 42 U.S.C. 5813(7); and the Department of Energy Organization Act of 1977 (DEOA), 42 USC 7112(5). Based on these authorities, DOE receives Unlimited Rights in SBIR/STTR Data upon expiration of the SBIR/STTR Protection Period, and this exception is limited to DOE. The Federal Government receives Unlimited Rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data. (3) <u>SBIR/STTR Data Rights - Main Elements</u>:

(i) An SBC retains title and ownership of all SBIR/STTR Data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR Data that are not granted to the Government in accordance with this Policy Directive. These rights of the SBC do not expire.

(ii) The Government receives SBIR/STTR Data Rights during the SBIR/STTR Protection Period on all appropriately marked SBIR/STTR Data. These rights enable the Federal Government to use SBIR/STTR Data in limited ways within the Government, such as for project evaluation purposes, but are intended to prohibit uses and disclosures of the SBIR/STTR Data that may undermine the SBC's future Commercialization of the associated technology. The Government receives Unlimited Rights in Form, Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.

(iii) After the SBIR/STTR Protection Period has expired, the Federal Government may use, and authorize others to use on its behalf, for Government Purposes,
SBIR/STTR Data that was subject to SBIR/STTR Data Rights during the
SBIR/STTR Protection Period. However, SBIR/STTR Data developed under awards issued by DOE are subject to Unlimited Rights after the SBIR/STTR
Protection Period has expired.

(4) <u>SBIR/STTR Protection Period</u>. The SBIR/STTR Protection Period begins with award of an SBIR/STTR Funding Agreement and ends twenty years, or longer at the discretion of the Participating Agency, from the date of award of an SBIR/STTR Funding Agreement (either Phase I, Phase II, or Federally-funded SBIR/STTR Phase III) unless subsequent to the award, the agency and the SBC negotiate for some other protection period for the SBIR/STTR Data.

(5) <u>Marking Requirements, and Requirements for Omitted or Incorrect Markings</u>. To receive the protections accorded to SBIR/STTR Data pursuant to SBIR/STTR Data Rights, any SBIR/STTR Data that is delivered must be marked with the appropriate

SBIR/STTR Data Rights legend or notice, in accordance with agency procedures. The Government assumes no liability for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR Data without markings. If SBIR/STTR Data is delivered without the required legend or notice, the SBIR/STTR Awardee may, within 6 months of such delivery (or a longer period approved by the agency for good cause shown), request to have an omitted SBIR/STTR Data legend or notice, as applicable, placed on qualifying Data. If SBIR/STTR Data is delivered with an incorrect or nonconforming legend or notice, the agency may correct or permit correction at the Awardee's expense of such incorrect or nonconforming notice(s).

(6) Negotiated Rights.

(i) Specially Negotiated Licenses Authorized Only After Award. An agency must not, in any way, make issuance of an SBIR/STTR award conditional upon the Awardee negotiating or consenting to negotiate a specially negotiated license or other agreement regarding SBIR/STTR Data. The negotiation of any such specially negotiated license agreements shall be permitted only after award.
(ii) Following issuance of an SBIR/STTR award, the Awardee may enter into a written agreement with the awarding agency to modify the license rights that would otherwise be granted to the agency during the SBIR/STTR Protection Period. However, any such agreement must be entered into voluntarily and by mutual agreement of the SBIR/STTR Awardee and agency, and not a condition for additional work under the Funding Agreement or the exercise of options.

SBIR/STTR award (which award must include an appropriate SBIR/STTR Data Rights clause) has been signed. Any such specially negotiated license must be in writing under a separate agreement after the SBIR/STTR Funding Agreement is signed. A decision by the Awardee to relinquish, transfer, or modify in any way its rights in SBIR/STTR Data must be made without pressure or coercion by the agency or any other party. Any provision in a competitive non-SBIR or SBIR solicitation that would have the effect of diminishing SBIR/STTR Data Rights shall have no effect on the provision of SBIR/STTR Data Rights in a resulting Phase II, Phase III award.

(7) <u>SBIR/STTR Data Rights Clause</u>. To ensure that SBIR/STTR Awardees receive the applicable data rights, all SBIR and STTR solicitations and resulting Funding Agreements must fully implement all of the policies, procedures, and requirements set forth in this Policy Directive in appropriate provisions and clauses incorporated into the SBIR/STTR solicitations and awards. Paragraph (5)(d)(3) of Appendix I: Instructions for Preparation of SBIR/STTR Program Solicitations provides a sample SBIR/STTR Data Rights clause containing the key elements that must be reflected in the clause used in Federal Agency solicitations. SBA will report to the Congress any attempt or action by an agency, that it is aware of, to condition an SBIR or STTR award on the negotiation of lesser data rights or to exclude the appropriate data rights clause from the award.

(c) <u>Non-disclosure Agreement for Releases Outside the Government</u>. In accordance with the Government's SBIR/STTR Data Rights, the Government must enter into an appropriate non-disclosure agreement (NDA) with any non-Governmental entity that is

authorized to receive SBIR/STTR Data (that is subject to SBIR/STTR Data Rights) during the SBIR/STTR Protection Period, except as otherwise permitted by the Awardee asserting the SBIR/STTR Data Rights. The NDA must contain terms and conditions to ensure that the non-governmental entity:

Understands, acknowledges, and agrees that its use, modification, reproduction, release, display, disclosure, and distribution of the SBIR/STTR Data is permitted only for the specific activities authorized by the NDA (which must be authorized by SBIR/STTR Data Rights, or otherwise authorized by the SBIR/STTR Awardee);
 Is prohibited from further using, modifying, reproducing, releasing, displaying, disclosing, or distributing the Data unless it receives the written permission of the Federal Government (when authorized by the SBIR/STTR Awardee) or the written permission of the SBIR/STTR Awardee;

(3) Agrees to destroy (or return to the Federal Government at the request of the Government), all SBIR/STTR Data, and all copies in its possession, at or before the time specified in the agreement, and to notify the procuring agency that all copies have been destroyed (or returned as requested by the Government);

(4) Is prohibited from using the data for a commercial purpose unless it receives the written permission of the Federal Government (when authorized by the SBIR/STTR Awardee) or the written permission of the SBIR/STTR Awardee itself; and
(5) Ensures that its employees, subcontractors, and other entities that are authorized to receive SBIR/STTR Data are bound by use and non-disclosure restrictions consistent with the NDA prior to being provided access to such SBIR/STTR Data.

(d) [STTR only] Allocation of Intellectual Property Rights in STTR Award.

(1) An SBC, before receiving an STTR award, must negotiate a written agreement between the SBC and the partnering Research Institution, allocating Intellectual Property rights and rights, if any, to carry out follow-on research, development, or Commercialization. The SBC must submit this agreement to the awarding agency with the proposal. The SBC must certify in all proposals that the agreement is satisfactory to the SBC.

(2) The awarding agency may accept an existing agreement between the two parties if the SBC certifies its satisfaction with the agreement, and such agreement does not conflict with the interests of the Government. SBA will provide a model agreement to be adopted by the agencies and used as guidance by the SBC in the development of an agreement with the Research Institution. The model agreement will direct the parties to, at a minimum:

(i) State specifically the degree of responsibility, and ownership of any product, process, or other invention or Innovation resulting from the cooperative research.The degree of responsibility shall include responsibility for expenses and liability, and the degree of ownership shall also include the specific rights to revenues and profits.

(ii) State which party may obtain United States or foreign patents or otherwise protect any inventions resulting from the cooperative research.

(iii) State which party has the right to any continuation of research, including non-STTR follow-on awards.

(3) The Government will not normally be a party to any agreement between the SBC and the Research Institution. Nothing in the agreement is to conflict with any

provisions setting forth the respective rights of the United States and the SBC with respect to Intellectual Property rights and with respect to any right to carry out follow-on research.

(e) <u>Title Transfer of Agency-Provided Property</u>. Under the Act, the Federal Government may transfer title to property provided by the SBIR/STTR Participating Agency to the Awardee or acquired by the Awardee for the purpose of fulfilling the contract where such transfer would be more cost effective than recovery of the property.

(f) <u>Continued Use of Government Equipment</u>. Agencies must allow an SBIR/STTR Awardee participating in an SBIR/STTR Phase III award continued use, as a directed bailment, of any property transferred by the agency to the Phase II Awardee or acquired by the Awardee for the purpose of fulfilling the contract. The Phase II Awardee may use the property for a period of not less than 2 years, beginning on the initial date of the concern's participation in the third phase of the SBIR/STTR program.

(g) <u>Grant Authority</u>. The Act does not, in and of itself, convey grant authority. Each agency must secure grant authority in accordance with its normal procedures.

(h) <u>Conflicts of Interest</u>. SBA cautions Participating Agencies that awards made to SBCs owned by or employing current or previous Federal Government employees may create conflicts of interest in violation of FAR part 3 and the Ethics in Government Act of 1978, as amended. Each Participating Agency should refer to the standards of conduct review procedures currently in effect for its agency to ensure that such conflicts of interest do not arise.

(i) <u>American-Made Equipment and Products</u>. Congress intends that the Awardee of a Funding Agreement under the SBIR/STTR program should, when purchasing any

equipment or a product with funds provided through the Funding Agreement, purchase only American-made equipment and products, to the extent possible, in keeping with the overall purposes of this program. Each SBIR/STTR Agency must provide to each Awardee a notice of this requirement.

(j) <u>Certifications After Award and During Funding Agreement Life Cycle</u>.

(1) A Phase I Funding Agreement must state that the Awardee shall submit a new certification as to whether it is in compliance with specific SBIR/STTR program requirements at the time of final payment or disbursement.

(2) A Phase II Funding Agreement must state that the Awardee shall submit a new certification as to whether it is in compliance with specific SBIR/STTR program requirements prior to receiving more than 50% of the total award amount and prior to final payment or disbursement.

(3) Agencies may also require additional certifications at other points in time during the life cycle of the Funding Agreement, such as at the time of each payment or disbursement.

(k) <u>Updating www.SBIR.gov</u>. Agencies must require each Phase II Awardee to update the Commercialization information on the award through the company's account on <u>www.SBIR.gov</u> upon completion of the last deliverable under the Funding Agreement. In addition, the Awardee is requested to voluntarily update the Commercialization information on that award annually thereafter for a minimum period of 5 years.
(l) <u>Prototypes</u>. Participating Agencies must handle all Prototypes developed under an

SBIR/STTR award with caution during the SBIR/STTR Protection Period to prevent any use or disclosure of these items that has the potential to reveal the innovative aspects of

the technology in ways that may harm the Awardee's ability to commercialize the technology. In particular, reverse engineering of Prototypes may reveal, to a Government or non-Government entity, the SBIR/STTR Data that is applied or embodied in the item. While a Prototype may not itself be considered SBIR/STTR Data because it is not "recorded information," SBA cautions agencies that it is a violation of the purpose and intent of the Act to release or use a Prototype during the SBIR/STTR Protection Period in a way that harms the Awardee's ability to take advantage of the economic opportunities of its SBIR/STTR Data. SBA notes that the Defense Federal Acquisition Regulations Supplement (DFARS) Restricted Rights license granted to the Government for Computer Software prohibits non-Governmental entities from reverse-engineering, disassembly, or decompiling Computer Software (including computer software embedded within hardware), except in extremely limited circumstances.

9. <u>Responsibilities of SBIR/STTR Agencies and Departments</u>

(a) <u>General Responsibilities.</u> Each agency participating in the SBIR/STTR program must:

(1) Unilaterally determine the categories of projects to be included in its SBIR/STTR program, giving consideration to maintaining a portfolio balance between exploratory projects of high technological risk and those with greater likelihood of success. Further, to the extent permitted by the law, and in a manner consistent with the mission of that agency and the purpose of the SBIR/STTR program, each Federal agency must:

(i) give priority in the SBIR/STTR program to manufacturing-related research and development in accordance with Executive Order 13329. In addition, agencies

must develop an Action Plan for implementing Executive Order 13329, which identifies activities used to give priority in the SBIR/STTR program to manufacturing-related research and development. These activities should include the provision of information on the Executive Order on the agency's SBIR/STTR program website.

(ii) give priority to SBCs that participate in or conduct energy efficiency or renewable energy system research and development projects.

(iii) give consideration to topics that further one or more critical technologies as identified by the National Critical Technologies panel (or its successor) in reports required under 42 U.S.C. 6683, or the Secretary of Defense in accordance with 10 U.S.C. 2522.

(2) Release SBIR/STTR solicitations in accordance with the SBA master schedule.

(3) Unilaterally receive and evaluate proposals resulting from Program Solicitations, select Awardees, issue Funding Agreements, and inform each Awardee under such agreement, to the extent possible, of the expenses of the Awardee that will be allowable under the Funding Agreement.

(4) Require a succinct Commercialization plan with each proposal submitted for a Phase II award.

(5) Collect and maintain information from Applicants and Awardees and provide it to SBA to develop and maintain the database, as identified in § 11(c) of this Policy Directive.

(6) Administer its own SBIR/STTR Funding Agreements or delegate such administration to another agency. Such administrative services include the use of

assisted acquisition service providers under the terms and conditions of a properly executed Interagency Agreement.

(7) Include provisions in each SBIR/STTR Funding Agreement setting forth the respective rights of the United States and the Awardee with respect to Intellectual Property rights and with respect to any right to carry out follow-on research.

(8) Ensure that the rights in Data developed under each Federally-funded SBIR/STTRPhase I, Phase II, and Phase III award are protected properly.

(9) Make payments to Awardees of SBIR/STTR Funding Agreements on the basis of progress toward or completion of the Funding Agreement requirements and in all cases make payment to Awardees under such agreements in full, subject to audit, on or before the last day of the 12-month period beginning on the date of completion of such requirements.

(10) Provide an annual report on the SBIR/STTR program to SBA, as well as other information concerning the SBIR/STTR program. <u>See §10 of this Policy Directive</u> for further information on the agency's reporting requirements, including the frequency for specific reporting requirements.

(11) Include in its annual performance plan required by 31 U.S.C. 1115(a) and (b) a section on its SBIR/STTR program, and submit such section to the Senate Committee on Small Business and Entrepreneurship and to the House Committees on Science, Space and Technology and Small Business.

(12) Establish the agency's benchmarks for progress towards Commercialization and include the information necessary to implement the benchmarks in each solicitation. See § 6(a)(7) of the directive for further information.

(b) Discretionary Technical and Business Assistance to SBIR/STTR Awardees.

(1) Agencies may enter into agreements with 1 or more vendors to provide technical and business assistance to SBIR/STTR Awardees, which may include access to a network of scientists and engineers engaged in a wide range of technologies, assistance with product sales, intellectual property protections, market research, market validation, and development of regulatory plans and manufacturing plans, or access to technical and business literature available through on-line databases. For a term not to exceed 5 years, each agency may select 1 or more vendors from which small business concerns may obtain assistance. Such selection must be based on competitive and merit-based criteria.

(i) The purpose of this technical and business assistance is to assist SBIR/STTR Awardees in:

- (A) making better technical decisions on SBIR/STTR projects;
- (B) solving technical problems that arise during SBIR/STTR projects;
- (C) minimizing technical risks associated with SBIR/STTR projects; and
- (D) commercializing the SBIR/STTR product or process, including intellectual property protections.

(ii) An agency may not enter into a contract with the vendor if the contractamount provided for technical assistance is based upon the total number of PhaseI or Phase II awards, but may enter into a contract with the vendor based upon thetotal amount of awards for which assistance is provided.

(2) Each agency may provide up to \$6,500 of SBIR/STTR funds for the technical and business assistance described above in (b)(1) per year for each Phase I award, which

shall be in addition to the amount of the award. Each agency may provide up to \$50,000 of SBIR/STTR funds for technical and business assistance described above in (b)(1) per project for Phase II awards. The amount of technical and business assistance for Phase II awards, as determined appropriate by the head of the Federal agency, may be included as part of the recipient's award or be in addition to the amount of the recipient's award. The agency may not use SBIR/STTR funds for technical and business assistance unless a vendor provides the services to the SBIR/STTR Awardee.

(3) A small business concern may, by contract or otherwise, select 1 or more vendors to assist the small business concern in meeting the goals listed in paragraph (1). An SBIR/STTR Applicant may acquire the technical assistance services set forth in (b)(1)(i) above itself rather than through a vendor selected by the Federal Agency. The Applicant must request the authority to select its own technical and business assistance provider from the Federal Agency and demonstrate in its SBIR/STTR application that the individual or entity selected can provide the specific technical and business services needed. If the Awardee demonstrates this requirement sufficiently, the agency shall permit the Awardee to acquire such technical and business assistance itself, in an amount up to \$6,500 per year for Phase I awards and up to \$50,000 per award for Phase II awards, as an allowable cost of the SBIR/STTR award. The amount of technical and business assistance for Phase I awards shall be in addition to the amount of the award. Phase II awards, as determined appropriate by the head of the Federal agency, may be included as part of the recipient's award or be in addition to the amount of the recipient's award. The applicant may also seek business-related

services aimed at improving the commercialization success of a small business concern from an entity, such as a public or private organization or an agency of or other entity established or funded by a State that facilitates or accelerates the commercialization of technologies or assists in the creation and growth of private enterprises that are commercializing technology.

(4) SBA must establish a limit on the value of business and technical assistance services received or purchased by SBCs awarded multiple Phase II awards in a fiscal year. SBA will seek public comment to gather input on the appropriate limit and will provide guidance on www.SBIR.gov.

(5) A small business concern that receives technical or business assistance from a vendor during a fiscal year shall submit to the Federal agency contracting with the vendor a description of the technical or business assistance provided and the benefits and results of the technical or business assistance provided. The information required shall be collected by a Federal agency as part of a report required to be submitted by small business concerns engaged in SBIR or STTR projects of the Federal agency for which the requirement was in effect on August 13, 2018.

(6) Not later than the end of fiscal year 2019, the Administrator of the Small Business Administration shall –

(A) Conduct a survey of vendors providing technical or business assistance under section 9(q) of the Small Business Act (15 U.S.C. 638(q)), and small business concerns receiving the technical or business assistance; and
(B) Submit to the Committee on Small Business and Entrepreneurship of the Senate and the Committee on Small Business of the House of Representatives a

report reviewing the efficacy of the provision of the technical or business assistance.

(c) <u>Timelines for Awards.</u> Agencies must publish the information relating to timelines for awards of Phase I and Phase II Funding Agreements and performance start dates of the Funding Agreements that are reported to SBA in the agency's Annual Report (see § 10(a) of this Policy Directive). SBA will also publish this information on <u>www.SBIR.gov</u>.

(d) Interagency actions.

(1) Joint funding. An SBIR/STTR project may be financed by more than one Federal Agency. Joint funding is not required but can be an effective arrangement for some projects.

(2) <u>Phase II awards</u>. An SBIR/STTR Phase II award may be issued by a Federal Agency other than the one that made the Phase I award. Prior to award, the head of the Federal Agency for the Phase I and Phase II awards, or designee, must issue a written determination that the topics of the awards are the same. Both agencies must submit the report to SBA.

(3) <u>Participation by WOSBs and SDBs in the SBIR/STTR Program</u>. In order to meet statutory requirements for greater inclusion, SBA and the Participating Agencies must conduct outreach efforts to find and place innovative WOSBs and SDBs in the SBIR/STTR program. These SBCs will be required to compete for SBIR/STTR awards on the same basis as all other SBCs. However, SBIR/STTR Agencies are encouraged to work independently and cooperatively with SBA to develop methods to encourage qualified WOSBs and SDBs to participate in the SBIR/STTR program.
(4) <u>Interagency Assisted Acquisitions</u>. A Participating Agency may obtain assistance,

as needed to meet its mission, by entering into a properly executed Interagency Agreement with another Federal Agency for the provision of acquisition services to award and administer funding agreements.

(e) Limitation on use of funds.

(1) Each SBIR/STTR Agency must expend the required minimum percent of its extramural budget on awards to SBCs. Agencies may not make available for the purposes of meeting the minimum percent an amount of its extramural budget for basic research that exceeds the minimum percent required for that year. Funding Agreements with SBCs for R/R&D that result from competitive or single source selections other than an SBIR/STTR program must not be considered to meet any portion of the required minimum percent.

(2) An agency must not use any of its SBIR/STTR budget for the purpose of funding administrative costs of the program, including costs associated with program operations, employee salaries, and other associated expenses, unless the exception in paragraph (3) below or § 12(b)(4)(ii) of this Policy Directive applies.

(3) <u>Funding of Administrative, Oversight, and Contract Processing Costs.</u> Upon establishment by SBA of the agency-specific performance criteria, SBA shall allow an SBIR Participating Agency to use no more than 3% of its SBIR budget for one or more specific activities, which may be prioritized by the Federal SBIR/STTR Interagency Policy Committee. The purpose of this program is to assist with the substantial expansion in commercialization activities, prevention of fraud/waste/abuse, expansion of reporting requirements by agencies and other agency activities required for the SBIR program. Funding under this program is not intended

to and must not replace current agency administrative funding in support of SBIR/STTR activities. Rather, funding under this program is intended to supplement such funds. The authority for this program shall terminate on September 30, 2022, unless otherwise extended.

(i) A Federal Agency may use this money to fund the following specific activities:

(A) SBIR and STTR program administration, which includes:

 (I) internal oversight and quality control, such as verification of reports and invoices and cost reviews, and waste/fraud/abuse prevention
 (including targeted reviews of SBIR/STTR Awardees that an agency determines are at risk for waste/fraud/abuse);

(II) carrying out any activities associated with the participation by small businesses that are majority-owned by multiple venture capital operating companies, hedge funds or private equity firms;

(III) contract processing costs relating to the SBIR or STTR program of that agency, which includes supplementing the current workforce to assist solely with SBIR or STTR Funding Agreements;

(IV) funding of additional personnel to work solely on the SBIR/STTR program of that agency, which includes assistance with application reviews; and

(V) funding for simplified and standardized program proposal, selection, contracting, compliance, and audit procedures for the SBIR/STTR program, including the reduction of paperwork and data collection. (VI) funding for improvements that increase commonality across data systems, reduce redundancy, and improve data oversight and accuracy(B) SBIR or STTR program-related outreach and related technical assistance

initiatives not in effect prior to commencement of this pilot, except significant expansion or improvement of these initiatives, including:

(I) technical assistance site visits;

(II) personnel interviews;

(III) national conferences;

(C) Commercialization initiatives not in effect prior to commencement of this pilot, except significant expansion or improvement of these initiatives.

(D) For DoD and the military departments, carrying out the

Commercialization Readiness Program set forth in § 12(b) of this Policy Directive, with emphasis on supporting new initiatives that address barriers in bringing SBIR/STTR technologies to the marketplace, including Intellectual Property issues, sales cycle access issues, accelerated technology development issues, and other issues.

(ii) Agencies must use this money to attempt to increase participation by SDBs and WOSBs in the SBIR/STTR program, and small businesses in states with a historically low level of SBIR/STTR awards. The agency may submit a written request to SBA to waive this requirement. The request must explain why the waiver is necessary, demonstrate a sufficient need for the waiver, and explain that the outreach objectives of the agency are being met and that there has been

increased participation by small businesses in states with a historically low level of SBIR/STTR awards.

(iii) SBA will establish performance criteria each fiscal year by which use of these funds will be evaluated for that fiscal year. The performance criteria will be metrics that measure the performance areas required by statute against the goals set by the agencies in their work plans. The performance criteria will be based upon the work plans submitted by each agency for a given fiscal year and will be agency-specific. SBA will work with the SBIR/STTR Agencies in creating a simplified template for agencies to use when making their work plans. (iv) Each agency must submit its work plan to SBA at least 30 calendar days prior to the start of each fiscal year for which the pilot program is in operation. Agency work plans must include the following: a prioritized list of initiatives to be supported; the estimated percentage of administrative funds to be allocated to each initiative or the estimated amounts to be spent on each initiative; milestones for implementing the initiatives; the expected results to be achieved; and the assessment metrics for each initiative. The work plan must identify initiatives that are above and beyond current practice and which enhance the agency's SBIR/STTR program.

(v) SBA will evaluate the work plan and provide initial comments within 15 calendar days of receipt of the plan. SBA's objective in evaluating the work plan is to ensure that, overall, it provides for improvements to the SBIR/STTR program of that particular agency. If SBA does not provide initial comments within 30 calendar days of receipt of the plan, the work plan is deemed to be

approved. If SBA does submit initial comments within 30 calendar days, agencies must amend or supplement their work plan and resubmit to SBA. Once SBA establishes the agency-specific performance criteria to measure the benefits of the use of these funds under the work plan, the agency may begin using the SBIR funds for the purposes set forth in the work plan. Agencies can adjust their work plans and spending throughout the fiscal year as needed, but must notify SBA of material changes in the plan.

(vi) Agencies must coordinate any activities in the work plan that relate to fraud, waste, and abuse prevention, targeted reviews of Awardees, and implementation of oversight control and quality control measures (including verification of reports and invoices and cost reviews) with the agency's Office of Inspector General (OIG). If the agency allocates more than \$50,000,000 to its SBIR program for a fiscal year, the agency may share this funding with its OIG when the OIG performs the activities.

(vii) Agencies shall report to the Administrator of the SBA on use of funds under this authority as part of the SBIR/STTR Annual Report. See § 10 generally and § 10(i) of this Policy Directive.

(4) An agency must not issue an SBIR/STTR Funding Agreement that includes a provision for subcontracting any portion of that agreement back to the issuing agency, to any other Federal Government agency, or to other units of the Federal Government, except as provided in paragraph (e)(5) below. SBA may issue a case-by-case waiver to this provision after review of an agency's written justification that includes the following information:

(i) An explanation of why the SBIR/STTR research project requires the use of the Federal facility or personnel, including data that verifies the absence of non-Federal facilities or personnel capable of supporting the research effort.
(ii) Why the Federal Agency will not and cannot fund the use of the Federal facility or personnel for the SBIR/STTR project with non-SBIR/STTR money.
(iii) The concurrence of the SBC's chief business official to use the Federal facility or personnel.

(5) An agency may issue an SBIR/STTR Funding Agreement to an SBC that intends to enter into an agreement with a Federal Laboratory to perform portions of the award or has entered into a cooperative research and development agreement (see 15 U.S.C. 3710a(d)) with a Federal Laboratory, only if there is compliance with the following.

(i) The agency may not require that the SBC enter into an agreement with any Federal Laboratory to perform any portion of an SBIR/STTR award, as a condition for an SBIR/STTR award.

(ii) The agency may not issue an SBIR/STTR award or approve an agreement between an SBIR/STTR Awardee and a Federal Laboratory if the SBC will not meet the minimum performance of work requirements set forth in § 6(a)(4) of this Policy Directive.

(iii) The agency may not issue an SBIR/STTR award or approve an agreement between an SBIR/STTR Awardee and a Federal Laboratory that violates any SBIR/STTR requirement set forth in statute or this Policy Directive, including any SBIR/STTR Data Rights protections.

(iv) The Federal Agency and Federal Laboratory may not require any SBIR/STTR

Awardee that has an agreement with the Federal Laboratory to perform portions of the activities under the SBIR/STTR award to provide advance payment to the Federal Laboratory in an amount greater than the amount necessary to pay for 30 days of such activities.

(6) No agency, at its own discretion, may unilaterally cease participation in the SBIR/STTR program. R/R&D agency budgets may cause fluctuations and trends that must be reviewed in light of SBIR/STTR program purposes. An agency may be considered by SBA for a phased withdrawal from participation in the SBIR/STTR program over a period of time sufficient in duration to minimize any adverse impact on SBCs. However, the SBA decision concerning such a withdrawal will be made on a case-by-case basis and will depend on significant changes to extramural R/R&D 3-year forecasts as found in the annual Budget of the United States Government and NSF National Center for Science Engineering Statistics (NCSES) breakdowns of total R/R&D obligations as published in the Survey of Federal Funds for Research and Development. Any withdrawal of an SBIR/STTR agency from the SBIR/STTR program will be accomplished in a standardized and orderly manner in compliance with these statutorily mandated procedures.

(7) Any Federal agency which has an extramural R/R&D budget in excess of \$100,000,000 based on 3-year forecasts as found in the annual Budget of the United States Government and NSF NCSES Survey of Federal Funds for Research and Development should start participation in the SBIR program. Any Federal agency which has an extramural R/R&D budget in excess of \$1,000,000,000 based on 3-year forecasts as found in the annual Budget of the United States Government and NSF

NCSES Survey of Federal Funds for Research and Development should start participation in the STTR program. SBA will monitor the NCSES Survey of Federal Funds for Research and Development and notify a Federal agency if it appears to be required to begin participation in the SBIR and/or STTR program, but it is the responsibility of Federal agencies to implement the institution of its agency's SBIR and/or STTR program. Federal agencies not otherwise required to participate in the SBIR/STTR program may participate on a voluntary basis. Federal agencies seeking to participate in the SBIR/STTR program must first submit their written requests to SBA. Voluntary participation requires the written approval of SBA.

(f) Preventing Fraud, Waste, and Abuse.

(1) Agencies shall evaluate risks of fraud, waste, and abuse in each application, monitor and administer SBIR/STTR awards, and create and implement policies and procedures to prevent fraud, waste and abuse in the SBIR/STTR program. To capitalize on OIG expertise in this area, agencies must consult with their OIG when creating such policies and procedures. Fraud includes any false representation about a material fact or any intentional deception designed to deprive the United States unlawfully of something of value or to secure from the United States a benefit, privilege, allowance, or consideration to which an individual or business is not entitled. Waste includes extravagant, careless, or needless expenditure of Government funds, or the consumption of Government property, that results from deficient practices, systems, controls, or decisions. Abuse includes any intentional or improper use of Government resources, such as misuse of rank, position, or authority or resources. Examples of fraud, waste, and abuse relating to the SBIR/STTR

program include, but are not limited to:

(i) misrepresentations or material, factual omissions to obtain, or otherwise receive funding under, an SBIR/STTR award;

(ii) misrepresentations of the use of funds expended, work done, results achieved, or compliance with program requirements under an SBIR/STTR award;
(iii) misuse or conversion of SBIR/STTR award funds, including any use of award funds while not in full compliance with SBIR/STTR program requirements, or failure to pay taxes due on misused or converted SBIR/STTR award funds;

(iv) fabrication, falsification, or plagiarism in applying for, carrying out, or reporting results from an SBIR/STTR award;

(v) failure to comply with applicable federal costs principles governing an award;

(vi) extravagant, careless, or needless spending;

(vii) self-dealing, such as making a sub-award to an entity in which the PI has a financial interest;

(viii) acceptance by agency personnel of bribes or gifts in exchange for grant or contract awards or other conflicts of interest that prevent the Government from getting the best value; and

(ix) lack of monitoring, or follow-up if questions arise, by agency personnel to ensure that Awardee meets all required eligibility requirements, provides all required certifications, performs in accordance with the terms and conditions of the award, and performs all work proposed in the application.

(2) At a minimum, agencies must:

(i) Require certifications from the SBIR/STTR Awardee at the time of award, as well as after award and during the Funding Agreement life cycle (see § 8(i) and Appendix I for more information);

(ii) Include on their respective SBIR/STTR web page and in each solicitation, information explaining how an individual can report fraud, waste and abuse as provided by the agency's OIG (e.g., include the fraud hotline number or web-based reporting method for the agency's OIG);

(iii) Designate at least one individual in the agency to, at a minimum, serve as the liaison for the SBIR/STTR program, the OIG and the agency's Suspension and Debarment Official (SDO) and ensure that inquiries regarding fraud, waste and abuse are referred to the OIG and, if applicable, the SDO.

(iv) Include on their respective SBIR/STTR web page information concerning successful prosecutions of fraud, waste and abuse in the SBIR or STTR programs.
(v) Establish a written policy requiring all personnel involved with the SBIR/STTR program to notify the OIG if anyone suspects fraud, waste, and/or abuse and ensure the policy is communicated to all SBIR/STTR personnel.
(vi) Create or ensure there is an adequate system to enforce accountability
(through suspension and debarment, fraud referrals or other efforts to deter wrongdoing and promote integrity) by developing separate standardized templates for a referral made to the OIG for fraud, waste and abuse or the SDO for other matters, and a process for tracking such referrals.

(vii) Ensure compliance with the eligibility requirements of the program and the terms of the SBIR/STTR Funding Agreement.

(viii) Work with the agency's OIG with regard to its efforts to establish frauddetection indicators, coordinate the sharing of information between FederalAgencies, and improve education and training to SBIR/STTR program officials,Applicants and Awardees;

(ix) Develop policies and procedures to avoid funding Essentially Equivalent Work already funded by the same or another agency, which could include: searching <u>www.SBIR.gov</u> prior to award for the Applicant (if a Joint Venture, search for each party to the Joint Venture), Key Individuals of the Applicant, and similar abstracts; using plagiarism or other software; checking the SBC's certification prior to award and funding and documenting the Funding Agreement file that such certification evidenced the SBC has not already received funding for Essentially Equivalent Work; reviewing other agencies' policies and procedures for best practices; and reviewing other R&D programs for policies and procedures and best practices related to this issue; and

(x) Consider enhanced reporting requirements during the Funding Agreement.
(g) <u>Interagency Policy Committee</u>. The Director of the Office of Science and Technology Policy (OSTP) will establish an Interagency SBIR/STTR Policy Committee, which will include representatives from Federal Agencies with an SBIR or an STTR program and SBA. The Interagency SBIR/STTR Policy Committee shall review the following issues (but may review additional issues) and make policy recommendations on ways to improve program effectiveness and efficiency:

(1) The <u>www.SBIR.gov</u> databases described in section 9(k) of the Act (15 U.S.C.
638(k));

(2) Federal Agency flexibility in establishing Phase I and II award sizes, including appropriate criteria for exercising such flexibility;

(3) Commercialization assistance best practices of Federal Agencies with significant potential to be employed by other agencies and the appropriate steps to achieve that leverage, as well as proposals for new initiatives to address funding gaps that business concerns face after Phase II but before Commercialization.

(4) The need for a standard evaluation framework to enable systematic assessment of SBIR and STTR, including through improved tracking of awards and outcomes and development of performance measures for the SBIR program and STTR program of each Federal Agency.

(5) Identification and sharing of best practices and the leveraging of resources in support of increasing the participation of small businesses underrepresented in the SBIR and STTR programs, including outreach and technical assistance activities for Applicants, Awardees, and others.

(h) <u>National Academy of Science Report.</u> The National Academy of Sciences (NAS) will conduct a study and issue reports on the SBIR and STTR programs.

(1) Prior to and during the period of study, and to ensure that the concerns of small business are appropriately considered, NAS shall consult with and consider the views of SBA's Office of Investment and Innovation and the Office of Advocacy and other interested parties, including entities, organizations, and individuals actively engaged in enhancing or developing the technological capabilities of SBCs.

(2) The head of each agency with a budget of more than \$50,000,000 for its SBIR program for fiscal year 1999 shall, in consultation with SBA, and not later than 6

months after December 31, 2011, cooperatively enter into an agreement with NAS regarding the content and performance of the study. SBA and the agencies will work with the Interagency Policy Committee in determining the parameters of the study, including the specific areas of focus and priorities for the broad topics required by statute. The agreement with NAS must set forth these parameters, specific areas of focus and priorities, and comprehensively address the scope and content of the work to be performed. This agreement must also require the NAS to ensure there is participation by and consultation with, the small business community, the SBA, and other interested parties as described in paragraph (h)(1).

(3) NAS shall transmit to SBA, heads of agencies entering into an agreement under this section, the Committee on Science, Space and Technology, the Committee on Small Business of the House of Representatives, and to the Committee on Small Business of the Senate a copy of the report, which includes the results and recommendations, not later than 4 years after December 31, 2011, and every subsequent four years.

10.<u>Reporting Requirements – for Participating Agencies, Applicants</u> and Awardees

(a) <u>General</u>. The Act requires agencies to collect meaningful information from SBCs and ensure that reporting requirements are streamlined to minimize the burden on small businesses.

(1) SBA is required to collect data from Participating Agencies and report to the Congress information regarding applications by and awards to SBCs by each Federal Agency participating in the SBIR/STTR program. Participating Agencies report data using standardized templates that are provided, maintained, and updated by SBA on www.SBIR.gov.

(2) The Act requires a "simplified, standardized and timely annual report" from each Federal Agency participating in the SBIR/STTR program (see § 3 of the Policy Directive for the definition of Federal Agency), which is submitted to SBA. In addition, agencies are required to report certain items periodically throughout the year to SBA. Agencies may identify certain information, such as award data information, by the various components of each agency. SBA collects agency reports through the www.SBIR.gov portal. If the www.SBIR.gov databases are unavailable, then the report must be emailed to technology@sba.gov.

(3) To meet these requirements, the SBIR/STTR program has the following key principles:

(i) Make updating data available electronically;

(ii) Centralize and share certain data through secure interfaces to which only authorized Government personnel have access;

(iii) Have small business enter the data only once, if possible; and

(iv) Provide standardized procedures.

(b) Summary of SBIR/STTR Databases.

(1) The Act requires that SBA coordinate the implementation of electronic databases at the SBIR/STTR Agencies, including the technical ability of the agencies to share the data. In addition, the Act requires the reporting of various data elements, which are clustered together in the following subsections:

(i) Solicitations Database (to include the Master Schedule);

- (ii) <u>www.SBIR.gov</u>, which includes the following databases:
 - (A) Company Registry Database;
 - (B) Application Information Database;
 - (C) Award Information Database;
 - (D) Commercialization Database;
 - (E) Annual Report Database; and
 - (F) Other Reporting Requirements Database.

(2) The subsections below describe the data reporting requirements, including reporting mechanisms, the frequency of data collection and reporting, and whether this information is shared publicly or is protected and only available to authorized personnel. The table below summarizes the data collection requirements for each database; however, there may be some divergences at the individual data field level. Refer to Appendix II (as posted on <u>www.SBIR.gov</u>) for the detailed reporting requirements at the data field level. SBA notes that in fiscal year 2012, SBA began a phased implementation of this data collection.

Database	Reporting Mechanism	Collection/Reporting Frequency	Public/Government
Solicitations	Agency XML or manual upload to http://www.SBIR.gov	Within 5 business days of solicitation open date	Public.
Company Registry	SBC reports data to <u>www.SBIR.gov;</u> Agency receives .pdf from company.	Register or reconfirm at time of application.	Government only.
Application Information	Agency provides XML or manual upload to www.SBIR.gov	Quarterly	Government only.
Award Information	Agency provides XML or manual upload to www.SBIR.gov.	Quarterly	Public.
Commercialization	Agencies + companies report to <u>www.SBIR.gov.</u>	Agencies update in real time; SBC updates prior to subsequent award	Government only.

		application and voluntarily thereafter.	
Annual Report	Agency XML or manual upload to www.SBIR.gov.	Annually	Government only. Summary SBA Annual Report based on Agency- submitted Annual Report data is Public.
Other Reports	As set forth in the directive	As set forth in the directive	Public.

(3) SBIR/STTR Awardees will have user names and passwords assigned in order to access their respective awards information in the system. Award and Commercialization data maintained in the database can be changed only by the Awardee, SBA, or the awarding SBIR/STTR Participating Agency.

(c) Master Schedule and the Solicitations Database.

(1) SBA posts an electronic Master Schedule of release dates of Program Solicitations with links to Internet websites of agency solicitations on <u>www.SBIR.gov</u>.

(i) On or before August 1, each agency representative must notify SBA in writing or by e-mail of its proposed Program Solicitation release and proposal due dates for the next fiscal year. SBA and the agency representatives will coordinate the resolution of any conflicting agency solicitation dates by the second week of August. In all cases, SBA will make final decisions. Agencies must notify SBA in writing of any subsequent changes in the solicitation release and close dates.
(ii) For those agencies that use both general topic and more specific subtopic designations in their SBIR/STTR solicitations, the topic data should accurately describe the research solicited.

(iii) Agencies must post on their Internet websites the following information regarding each Program Solicitation:

(A) list of topics upon which R/R&D proposals will be sought;

 (B) agency address, phone number, or email address from which SBIR/STTR Program Solicitations can be requested or obtained, especially through electronic means;

(C) names, addresses, and phone numbers of agency contact points where SBIR/STTR-related inquiries may be directed;

(D) release date(s) of Program Solicitation(s);

(E) closing date(s) for receipt of proposals; and

(F) estimated number and average dollar amounts of Phase I awards to be made under the solicitation.

(2) SBA will manage a searchable public database that contains all solicitation and topic information from all SBIR/STTR Agencies. Agencies are required to update the Solicitations Database, (available at <u>www.SBIR.gov</u>), within 5 business days of a solicitation's open date for applications and/or submissions for SBCs. Refer to Appendix II (as posted on <u>www.SBIR.gov</u>) for detailed reporting requirements. The main data requirements include:

(i) type of solicitation – SBIR/STTR;

(ii) Phase – I or II;

(iii) topic description;

(iv) sub-topic description;

(v) website for further information; and

(vi) applicable contact information per topic or sub-topic, where applicable and allowed by law.

(d) Company Registry Database.

(1) SBA maintains and manages a company registry to track ownership and affiliation requirements for all companies applying to the SBIR/STTR program, including those that are majority-owned by multiple VCOCs, private equity firms, or hedge funds.
 (2) Each SBC applying for a Phase I or Phase II award must register on www.SBIR.gov prior to submitting an application. The SBC will report and/or update ownership information to SBA prior to each SBIR/STTR application submission. The SBC can view the ownership and affiliation requirements of the program on the registry site.

(3) Data collected in the Company Registry Database will not be shared publicly. Refer to Appendix II (as posted on <u>www.SBIR.gov</u>) for details on specific fields shared publicly.

(4) The SBC will save its information from the registration in a .pdf document and will append this document to the application submitted to a given agency unless the information can be transmitted automatically to SBIR/STTR Agencies.

(5) Refer to <u>www.SBIR.gov</u> for details on the required reporting fields. The main data requirements include:

(i) basic identifying information for the SBC;

(ii) the number of employees for the SBC;

(iii) whether the SBC has venture capital, hedge fund or private equity firm investment and if so, include:

(A) the percentage of ownership of the Awardee held by the VCOC, hedgefund or private equity firm;

(B) the registration by the SBC of whether or not it is majority-owned by VCOCs, hedge funds, or private equity firms. Please note that this may be auto-populated through the individual calculations of investments in the SBC already submitted.

- (iv) information on the Affiliates of the SBC, including:
 - (A) the names of all Affiliates of the SBC;
 - (B) the number of employees of the Affiliates;

(e) Application Information Database.

(1) SBA will manage an Application Information Database on information on applications to the SBIR/STTR program across agencies.

(2) Each agency must upload application data to the Application Information

Database at <u>www.SBIR.gov</u> at least quarterly.

(3) The data in the Application Information Database is only viewable to authorized

Government officials and not shared publicly.

(4) Refer to <u>www.SBIR.gov</u> for detailed reporting requirements. The main data

requirements for each Phase I and Phase II application include:

(i) name, size, and location of the Applicant, and the identifying number assigned;

(ii) an abstract and specific aims of the project;

(iii) name, title, contact information, and position in the small business of eachKey Individual that will carry out the project;

(iv) percentage of effort each Key Individual identified will contribute to the project;

(v) Federal agency to which the application is made and contact information for the person responsible for reviewing applications and making awards under the program.

(5) The Application Information Database connects and cross-checks information with the Company Registry and Government personnel can see connected data.

(f) Award Information Database.

(1) SBA manages a database on awards made within the SBIR/STTR program across agencies.

(2) Each agency must update the Award Information Database quarterly, if not more frequently.

(3) Most of the data available on the Award Information Database is viewable and searchable by the public on <u>www.SBIR.gov</u>.

(4) Refer to <u>www.SBIR.gov</u> for detailed reporting requirements. The data requirements for each Phase I and Phase II award include:

(i) information similar to the Application Information Database – if not already collected;

(ii) the name, size, and location of, and the identifying number assigned;

(iii) an abstract and specific aims of the project;

(iv) the name, title, contact information, and position in the small business of eachKey Individual that will carry out the project;

(v) the percentage of effort each identified Key Individual will contribute to the project;

(vi) the Federal agency making the award;

(vii) award amount;

(viii) Principal Investigator/Project Manager identifying information – including name, email address, and demographic information;

(ix) detailed information on location of company;

(x) whether the Awardee:

(A) has venture capital, hedge fund or private equity firm investment and if so, the amount of such investment received by SBC as of date of award and amount of additional capital Awardee has invested in SBIR/STTR technology;

(B) is a WOSB or has a woman as a Principal Investigator/Project Manager;

(C) is an SDB or has a Socially and Economically Disadvantaged Individual as a Principal Investigator/Project Manager;

(D) is owned by a faculty member or a student of an institution of higher education as defined in 20 U.S.C. 1001); and

(E) has received the award as a result of the Commercialization ReadinessPilot Program for Civilian Agencies set forth in §12(c) of this PolicyDirective.

(xi) an identification of any business concern or subsidiary established for the commercial application of a product or service for which an SBIR or STTR award is made.

(5) The Award Information Database connects and cross-checks information with the Company Registry and Application Information Database, and Government personnel can see connected data.

(g) Commercialization Database.

(1) The Commercialization Database stores information reported by Awardees on the commercial activity resulting from their past SBIR/STTR awards.

(2) Commercialization data is inputted to this database in two ways: Awardees enter

their Commercialization data directly into the Commercialization Database on

www.SBIR.gov, and agencies can upload to the database at www.SBIR.gov

Commercialization data they have collected from Awardees.

(3) The Commercialization Database is currently maintained by SBA.

(4) Awardees are required to update this information on their prior Phase II awards in

the Commercialization Database when submitting an application for an SBIR/STTR

Phase II award and upon completion of the last deliverable for that award.

(5) Commercialization data at the company level will not be shared publicly.

Aggregated data that maintains the confidentiality of companies may be reported in compliance with the statute.

(6) Refer to <u>www.SBIR.gov</u> for the specific Commercialization data reporting fields.The main data requirements include for every Phase II award:

(i) any business concern or subsidiary established for the commercial application of a product or service for which an SBIR/STTR award is made;

(ii) total revenue resulting from the sale of new products or services, or licensing agreements resulting from the research conducted under each Phase II award;

(iii) additional investment received from any source, other than Phase I or PhaseII awards, to further the research and development conducted under each Phase II award;

(iv) any contract with the Federal Government marked as an SBIR/STTR Phase III award; and

(v) any narrative information that a Phase II Awardee voluntarily submits to further describe the Commercialization efforts of its awards and related research.(7) The SBC may apportion sales or additional investment information relating to

more than one Phase II award among those awards, if it notes the apportionment for each award. Companies are requested to update their records in this database on a voluntary basis for at least 5 years following the completion of award.

(8) Awardees will update their information and add project Commercialization and sales data using their user names and passwords. SBA and SBIR/STTR Participating Agencies will coordinate data collection to ensure that small businesses will not need to report the same data more than once.

(9) Note that the Award Information and Commercialization Databases will contain the data necessary for agencies to determine whether an Applicant meets the agency's benchmarks for progress towards Commercialization.

(h) Participating Agency Annual Report to SBA.

(1) Participating Agencies must submit their report to SBA on an annual basis and will report for the period ending September 30 of each fiscal year. The report is due to SBA no later than March 15 of each year. For example, the report for FY 2017 (October 1, 2016 – September 30, 2017) must be submitted to SBA by March 15,

2018.

(2) SBA provides the Annual Report form to agencies through <u>www.SBIR.gov</u>. SBA reserves the right to modify the fields of the Annual Report data form beyond those identified in this directive.

(3) A number of the fields of the Annual Report template are pre-populated by SBA with data from the SBIR/STTR program database. SBA works with the agencies to resolve any data inconsistencies.

(4) The annual report includes the following:

(i) SBIR/STTR program dollars obligated through program Funding Agreements for Phase I, Phase II, and other uses of program funds, during the reporting fiscal year.

(ii) Number of topics and subtopics contained in each Program Solicitation.

(iii) Number of proposals received by the agency for each topic and subtopic in each Program Solicitation.

(iv) Agency total extramural R/R&D obligations for the reporting fiscal year
including an explanation of its calculation and how it differs, if at all, from the
amount reported to the NSF NCSES Survey of Federal Funds for Research and
Development pursuant to the annual Budget of the United States Government.
(v) The minimum dollar amount the agency is required to obligate per fiscal year
for the SBIR and STTR programs. This amount is calculated by applying the
statutory per centum to the agency's total extramural R/R&D obligations made
during the fiscal year (adjusted for the appropriate exclusions); and if the

explanation of how the agency plans to meet the requirement in the future. Agencies may provide an explanation of the specific budgeting process their agency uses to allocate funds for the SBIR/STTR programs and describe any issues they may see with the compliance determination procedure. Agencies may also indicate obligations made in the reporting year using prior fiscal years of appropriation within available funding obligation periods.

(vi) For all Applicants and Awardees in the applicable fiscal year – where applicable, the name and address, solicitation topic and subtopic, solicitation number, project title, total dollar amount of Funding Agreement, and applicable demographic information. The agency is not required to re-submit Applicant and Awardee information in the annual report that it has already reported to SBA through <u>www.SBIR.gov</u> as required.

(vii) Justification for the award of any Funding Agreement exceeding the award guidelines set forth in § 7(i) of this Policy Directive, the amount of each award exceeding the guidelines, the identity and location of the Awardee, whether the Awardee has received any venture capital, hedge fund, or private equity firm investment, and whether the Awardee is majority-owned by a venture capital operating company, hedge fund or private equity firm.

(viii) Justification for awards made under a topic or subtopic where the agency received only one proposal. Agencies must also provide the Awardee's name and address, the topic or subtopic, and the dollar amount of award. Awardee information must be collected quarterly in any case, but updated in the agency's annual reports.

(ix) All instances where the Phase II Awardee did not receive a Phase I award.
(x) All instances in which an agency pursued R/R&D, services, production, or any combination thereof of a technology developed under an SBIR/STTR award with an entity other than that Awardee. See § 10(i)(5) of this Policy Directive for minimum reporting requirements.

(xi) The number and dollar value of each SBIR/STTR and non-SBIR/STTR award (includes grants, contracts and cooperative agreements as well as any award issued under the Commercialization Programs) over \$10,000 and compare the number and amount of SBIR/STTR awards with awards to other than SBCs. (xii) Information relating to the pilot to allow for funding of administrative, oversight, and contract processing costs, including the money spent on each activity and any other information required in the approved work plan to measure the benefits of using these funds for the specific activities – especially, as it pertains to the goals outlined in the work plan. See § 9(e)(3) of this Policy Directive concerning the Pilot to Allow for Funding of Administrative, Oversight, and Contract Processing Costs.

(xiii) <u>Outreach</u>. A description and the extent to which the agency is increasing outreach and awards to SDBs and WOSBs.

(xiv) <u>VCOC-owned</u>. General information about the implementation of and compliance with the allocation of funds for Awardees that are majority-owned by multiple VCOCs, hedge funds or private equity firms.

(xv) <u>Phase III appeals</u>. Descriptive information on any appeals filed on Phase III awards pursuant to § 4(c)(7) of this Policy Directive and notices of noncompliance with the SBIR/STTR Policy Directive filed by SBA.
(xvi) <u>Phase III awards</u>. Information relating to each Phase III award made by that agency either as a prime or subcontract, including the name of the business receiving the Phase III award, the dollar amount, and the awarding agency or prime contractor.

(xvii) <u>Commercialization Programs</u>. An accounting of funds, initiatives, and outcomes under the commercialization programs set forth in § 12(b) and (c) of this Policy Directive.

(xviii) <u>Manufacturing</u>. Information relating to the agency's enhancement of manufacturing activities, if the agency awards more than \$50,000,000 under the SBIR and STTR programs combined in a fiscal year. The report must include:

(A) a description of efforts undertaken by the agency to enhance U.S. manufacturing activities;

 (B) a comprehensive description of the actions undertaken each year by the agency in carrying out the SBIR or STTR programs to support Executive Order 13329 (relating to manufacturing);

(C) an assessment of the effectiveness of the actions taken at enhancing the R/R&D of U.S. manufacturing technologies and processes;

(D) a description of efforts by vendors selected to provide discretionary technical assistance to help SBIR and STTR business concerns manufacture in the U.S.; and (E) recommendations from the agency's SBIR/STTR program managers/coordinators of additional actions to increase manufacturing activities in the U.S.

(xix) <u>Performance Areas and Metrics</u>. As part of agency work plans submitted pursuant to § 9(e) of this Policy Directive, SBA works with the agencies to establish the performance criteria and metrics used to measure agency performance. The Act establishes broad performance areas for the program, including Commercialization, streamlining, outreach, etc. Agencies must report their progress, using the SBA-approved performance criteria, at the end of each fiscal year as part of the annual report. The metrics and performance areas will evolve over time and can be found at www.SBIR.gov.

(i) Other Reporting Requirements.

(1) SBA will set forth a list of reports that agencies are required by statute to submit, in a table format, which will be available at <u>www.SBIR.gov</u>.

(2) SBA's SBIR/STTR program database will include a list of any individual or SBC that has received an SBIR/STTR award and that has been convicted of a fraud-related crime involving SBIR/STTR funds or found civilly liable for a fraud-related violation involving SBIR/STTR funds, of which SBA has been made aware.

(3) Program Funding Compliance. Agencies must submit to SBA's Administrator, not later than 4 months after the date of enactment of its annual Appropriations Act, a report on the agency's plan to meet the program funding requirement for the current fiscal year. SBA provides detailed guidance regarding this report on <u>www.SBIR.gov</u>. The report must include the following main elements: (A) an explanation of the calculation of total extramural R/R&D including an itemization of each research program excluded from the calculation including the dollar amount and a brief explanation of why it is excluded,

(B) a review of the agency's compliance with the funding requirement in the prior fiscal year to determine if the program funding process enabled the agency to meet the requirement, and

(C) a funding plan showing how the agency is budgeting its funds for the SBIR/STTR programs during the current fiscal year so as to meet or exceed the year's expected minimum obligations requirement for the program.

(4) Agencies must provide notice to SBA of any case or controversy before any Federal judicial or administrative tribunal concerning the SBIR/STTR program of the Federal agency. This does not include agency level protests of awards unless and until the protest is before a Federal court or administrative body. The agency must provide notice to SBA within 15 business days of the agency's written notification of the case or controversy.

(5) Agencies must provide notice of all instances in which an agency pursued research, development, production, or any such combination of a technology developed by an SBC using an award made under the SBIR/STTR program of that agency, where the agency determined that it was not practicable to enter into a follow-on non-SBIR/STTR Funding Agreement with that concern. The agency must provide notice to SBA within 15 business days of the agency's award. The report must include, at a minimum: (i) the reasons why the follow-on Funding Agreement with the concern was not practicable;

(ii) the identity of the entity with which the agency contracted to perform the research, development, or production; and

(iii) a description of the type of Funding Agreement under which the research, development, or production was obtained.

(6) Participating Agencies must provide information supporting the agency's achievement of the Interagency Policy Committee's policy recommendations on ways to improve program effectiveness and efficiency. This includes qualitative and quantitative data as appropriate, which would measure the agency's progress. The agency must provide this information to SBA at the end of each fiscal year. (7) Participating Agencies must provide an annual report to SBA, Senate Committee on Small Business and Entrepreneurship, House Committee on Small Business, and the House Committee on Science, Space, and Technology on SBIR and STTR programs and the benefits of these programs to the United States. Prior to preparing the report, the agency shall develop metrics to evaluate the effectiveness and benefit to the United States of the SBIR and STTR programs. The metrics must be sciencebased and statistically driven, reflect the mission of the agency, and include factors relating to the economic impact of the programs. The report must describe in detail the agency's annual evaluation of the programs using these metrics. The final report must be posted online so it can be made available to the public.

(8) NIH, DoD and the DoEd must provide the written determination to SBA any time it issues a Phase II award to an SBC that did not receive a Phase I award for that R/R&D. The determination must be submitted prior to award.

(9) SBA will compile data and report to Congress on the Federal and State Technology (FAST) Partnership Program, described in § 12 of this Policy Directive. If required by the FAST grant, the grantees will report a comprehensive list of the companies that received assistance under FAST, whether those companies received SBIR or STTR awards, and any information regarding mentors and Mentoring Networks, as required in the FAST Partnership Program.

(j) <u>Further Clarification on Availability of SBC Information</u>

(1) Unless stated otherwise, the information contained in the Company Registry Database, the Application Information Database, and the Commercialization Database is solely available to authorized Government officials, with the approval of SBA. This includes Congress, the Government Accountability Office (GAO), the SBIR/STTR Participating Agencies, Office of Management and Budget (OMB), OSTP, OFPP, and other authorized persons who are subject to an NDA with the Federal Government covering the use of the databases. These databases are used for the purposes of evaluating and determining eligibility for the SBIR/STTR program, in accordance with Policy Directives issued by SBA. Pursuant to 15 U.S.C. 638(k)(4), certain information provided to those databases is privileged and confidential and not subject to disclosure pursuant to 5 U.S.C. 552 (Government Organization and Employees); nor must it be considered to be publication for purposes of 35 U.S.C. 102 (a) or (b).

(2) Most of the information in the Award Information and Annual Reports Databases will be available to the public. Any information that will identify the confidential business information of a given SBC will not be disclosed to the public. Those databases are available at <u>www.SBIR.gov</u> and offer a vast array of user-friendly capabilities that are accessible by the public at no charge. The Award Information Database allows for the online submission of SBIR/STTR awards data from all SBIR/STTR Agencies. It also allows any end-user to perform keyword searches and create formatted reports of SBIR/STTR awards information, and for potential research partners to view research and development efforts that are ongoing in the SBIR and the STTR programs, increasing the investment opportunities of the SBIR/STTR SBCs in the high tech arena.

(k) <u>Waivers</u>.

(1) Participating Agencies must request an extension for additional time between the solicitation closing date and notification of recommendation for award. SBA will respond to the request for an extension within 5 business days, as practicable. See § 7(c)(1) of this Policy Directive for further information.

(2) Participating Agencies must request a waiver to exceed the award guidelines for Phase I and Phase II awards by more than 50% for a specific topic. See § 7(i)(4) of this Policy Directive for further information.

(3) Participating Agencies must request a waiver to not use their SBIR funds, as part of the pilot allowing for the use of such funds for certain SBIR-related costs, to increase participation by SDBs and WOSBs in the SBIR/STTR program, and small businesses in states with a historically low level of SBIR/STTR awards. See § 9(e)(3)(ii) of this Policy Directive for further information.

(4) Participating Agencies must request a waiver to issue a Funding Agreement that includes a provision for subcontracting a portion of that agreement back to the issuing agency if there is no exception to this requirement in the directive. See § 9(e)(4) of this Policy Directive for further information.

11. <u>Responsibilities of SBA</u>

(a) <u>Policy</u>.

(1) SBA establishes policy and procedures for the program by publishing and updating the SBIR/STTR Policy Directive and promulgating regulations. Policy clarification of any part or provision of the directive or regulations may be provided by SBA.

(2) It is essential that SBIR/STTR Agencies do not promulgate any policy, rule,
regulation, or interpretation that is inconsistent with the Act, this Policy Directive, or
SBA's regulations relating to the SBIR/STTR program. SBA's monitoring activity
will include review of policies, rules, regulations, interpretations, and procedures
generated to facilitate intra- and interagency SBIR/STTR program implementation.
(3) Waivers providing limited exceptions to certain policies can be found at § 10(k) of
this Policy Directive.

(b) <u>Outreach</u>. SBA conducts outreach to achieve a number of objectives including:
(1) Educating the public about the SBIR/STTR programs via conferences, seminars, and presentations;

(2) Highlighting the successes achieved in the program by publishing (via press releases and <u>www.SBIR.gov</u>) success stories, as well as hosting awards programs;
(3) Maintaining <u>www.SBIR.gov</u>, which is an online public information resource that provides comprehensive information regarding the SBIR/STTR programs. This information includes: a listing of solicitation information on currently available SBIR/STTR opportunities, award information on all Phase I and Phase II awards, summary annual award information for the whole program, and contact information for SBA and SBIR/STTR program managers/coordinators.

(c) <u>Collection and publication of program-wide data</u>. SBA collects and maintains program-wide data within the <u>www.SBIR.gov</u> data system. This data includes information on all Phase I and II awards from across all SBIR/STTR Agencies, as well as fiscal year Annual Report data. <u>See</u> § 10 of this Policy Directive for further information about reporting and data collection requirements.

(d) <u>Monitoring implementation of the program and annually reporting to Congress</u>. SBA is responsible for providing oversight and monitoring the implementation of the SBIR/STTR programs at the agency level. This monitoring includes:

(1) <u>SBIR/STTR Funding Allocations.</u> The Act establishes the source of the funds for the SBIR/STTR programs (extramural R/R&D), the percentage of such funds to be obligated through the SBIR and STTR programs, and it requires that SBA monitor these annual allocations. Participating Agencies may include in their annual report to SBA an explanation of the specific budgeting process used to allocate funds to the SBIR/STTR programs and describe any issues observed with the compliance determination process.

(2) <u>SBIR/STTR Program Solicitation and Award Status.</u> The accomplishment of scheduled SBIR/STTR events, such as SBIR/STTR Program Solicitation releases and the issuance of Funding Agreements is critical to meeting statutory mandates and to operating an effective, useful program. SBA monitors these and other operational features of the SBIR/STTR programs and publishes information relating to notice of and application for awards under the SBIR/STTR programs for each SBIR/STTR Participating Agency at <u>www.SBIR.gov</u>. SBA does not plan to monitor administration of the awards except in instances where SBA assistance is requested and is related to a specific SBIR/STTR project or Funding Agreement.
(3) <u>Follow-on Funding Commitments.</u> SBA will monitor whether follow-on non-Federal funding commitments obtained by Phase II Awardees for Phase III were considered in the evaluation of Phase II proposals as required by the Act.
(4) <u>Fraud, Waste, and Abuse (FWA).</u> SBA will ensure that each SBIR/STTR Participating Agency has taken steps to maintain a FWA prevention system to

minimize its impact on the programs.

(5) <u>Performance Areas, Metrics, and Goals.</u> SBA is responsible for defining performance areas consistent with statute (<u>e.g.</u>, reducing timelines for awards, simplification) against which agencies will set goals. SBA will work with the Participating Agencies to set metrics, in order to measure an agency's accomplishments of its goals against the defined performance areas. The purpose of these metrics and goals is to assist SBA in evaluating and reporting on the progress achieved by the agencies in improving the SBIR/STTR programs. For further

information on Performance Areas, Metrics and Goals see § 10(h) of this Policy Directive.

(e) <u>Additional efforts to improve the performance of the program</u>. SBA, in its continuing effort to improve the program, will make recommendations for improvement within the framework of the SBIR/STTR program managers/coordinators' meetings. This may include recommending a "best practice" currently being utilized by an agency or business, or open discussion and feedback on a potential "best practice" for agency adoption. This may also involve program-wide initiatives.

(f) <u>Federal and State Technology (FAST) Partnership Program</u>. SBA coordinates and administers the FAST program. SBA develops the solicitation, reviews proposals, and oversees grant awards. FAST provides grantees with funding to assist in outreach, proposal preparation, and other technical assistance to developing innovation-oriented SBCs.

12. Supporting Programs and Initiatives

(a) <u>Federal and State Technology (FAST) Partnership Program.</u> The purpose of the FAST program is to strengthen the technological competitiveness of SBCs in the United States. Congress found that programs that foster economic development among small high-technology firms vary widely among the states. Thus, the purpose of the FAST program is to improve the participation of small technology firms in the innovation and Commercialization of new technologies, thereby ensuring that the United States remains on the cutting-edge of research and development in the highly competitive arena of science and technology. Additional and detailed information regarding this program is available at <u>www.SBIR.gov</u>.

(b) <u>Commercialization Readiness Program (CRP) - DoD</u>

(1) <u>General</u>. The Secretary of Defense and the Secretary of each military department is authorized to create and administer the Commercialization Readiness Program (CRP) to accelerate the transition of technologies, products, and services developed under the SBIR program to Phase III, including the acquisition process. The authority for CRP does not eliminate or replace any other SBIR or STTR program that enhances the insertion or transition of SBIR or STTR technologies. This includes any program in effect as of December 31, 2011.

(2) Identification of research programs for accelerated transition to acquisition

process. The Secretary of each military department must identify research programs of the SBIR or STTR program that have the potential for rapid transitioning to Phase III and into the acquisition process and certify in writing that the successful transition of the program to Phase III and into the acquisition process is expected to meet high priority military requirements of such military department.

(3) <u>Limitation</u>. The Secretary of Defense shall identify research programs of the SBIR or STTR program that have the potential for rapid transitioning to Phase III and into the acquisition process after receiving this certification from each military department.

(4) <u>Funding</u>.

(i) The Secretary of Defense and each Secretary of a military department is authorized to use its SBIR funds for administration of CRP in accordance with the procedures and policies set forth in § 9(e)(3) of this Policy Directive.
(ii) In addition, the Secretary of Defense and Secretary of each military

department is authorized to use not more than an amount equal to 1% of its SBIR funds available to DoD or the military departments for payment of expenses incurred to administer the CRP. Such funds--

(A) shall not be subject to the limitations on the use of funds in 9(e)(2) or

9(e)(3) of this Policy Directive; and

(B) shall not be used to make Phase III awards.

(5) <u>Contracts Valued at not less than \$100,000,000</u>. For any contract awarded by DoD valued at not less than \$100,000,000, the Secretary of Defense may:

(i) establish goals for the transition of Phase III technologies in subcontracting plans; and

(ii) require a prime contractor on such a contract to report the number and dollar amount of the contracts entered into by the prime contractor for Phase III projects.

(6) The Secretary of Defense shall:

(i) set a goal to increase the number of SBIR/STTR Phase II contracts that lead to technology transition into programs of record of fielded systems;

(ii) use incentives in effect as of December 31, 2011 or create new incentives to encourage agency SBIR/STTR program managers/coordinators and prime contractors to meet the goal set forth in paragraph (6)(i) above; and

(iii) submit the following to SBA, as part of the annual report:(A) the number and percentage of Phase II SBIR/STTR contracts awarded by DoD that led to technology transition into programs of record or fielded systems;

(B) information on the status of each project that received funding through the CRP and the efforts to transition these projects into programs of record or fielded systems; and

(C) a description of each incentive that has been used by DoD, the effectiveness of the incentive with respect to meeting DoD's goal to increase the number of SBIR/STTR Phase II contracts that lead to technology transition into programs of record or fielded systems, and measures taken to ensure that such incentives do not act to shift the focus of Phase II awards away from relatively high-risk innovation projects.

(c) <u>Commercialization Readiness Pilot Program for Civilian Agencies.</u>

(1) <u>General</u>. The Commercialization Readiness Pilot Program permits the head of any Federal Agency participating in the SBIR program (except DoD) to allocate not more than 10% of its funds allocated to the SBIR program--

 (i) for follow-on awards to small businesses for technology development, testing, evaluation, and Commercialization assistance for SBIR or STTR Phase II technologies; or

(ii) for awards to small businesses to support the progress of research, research and development, and Commercialization conducted under the SBIR or STTR programs to Phase III.

(2) <u>Application to SBA</u>. Before establishing this pilot program, the agency must submit a written application to SBA not later than 90 days before the first day of the fiscal year in which the pilot program is to be established. The written application must set forth a compelling reason that additional investment in SBIR or STTR

technologies is necessary, including unusually high regulatory, systems integration, or other costs relating to development or manufacturing of identifiable, highly promising small business technologies or a class of such technologies expected to substantially advance the mission of the agency.

(3) <u>SBA's Determination</u>. SBA must make its determination regarding an application submitted under paragraph (c)(2) above not later than 30 days before the first day of the fiscal year for which the application is submitted. SBA must also publish its determination in the <u>Federal Register</u> and make a copy of the determination and any related materials available to the Committee on Small Business and Entrepreneurship of the Senate and the Committee on Small Business and the Committee on Science, Space, and Technology of the House of Representatives.

(4) <u>Maximum Amount of Award</u>. The SBIR agency may not make an award to an SBC under this pilot program in excess of 3 times the dollar amounts generally established for Phase II awards under § 7(i)(1) of this Policy Directive.

(5) <u>Registration</u>. Any SBC that receives an award under this pilot program shall register with SBA in the Company Registry Database.

(6) <u>Award Criteria or Consideration</u>. When making an award under this pilot program, the agency is required to consider whether the technology to be supported by the award is likely to be manufactured in the United States.

(7) <u>Termination of Authority</u>. The authority to establish a pilot program under this section expires on September 30, 2022, unless otherwise extended.

(d) <u>Technology Development Program</u>. The Act permits an agency that has established a Technology Development Program to review for funding under that program, in each

fiscal year:

(1) any proposal to provide outreach and assistance to 1 or more SBCs interested in participating in the SBIR program, including any proposal to make a grant or loan to a company to pay a portion or all of the cost of developing an SBIR proposal, from an entity, organization, or individual located in—

(i) a State that is eligible to participate in that Technology Development Program; or

(ii) an Additionally Eligible State.

(2) any meritorious proposal for an SBIR Phase I award that is not funded through the SBIR program for that fiscal year due to funding constraints, from an SBC located in a State identified in (i) or (ii) immediately above.

(e) [STTR only] <u>Phase 0 Proof of Concept Partnership Pilot Program.</u>

(1) <u>General.</u> The Director of NIH may use \$5,000,000 of the funds allocated for the STTR program set forth in § 2(b) of this Policy Directive for a Proof of Concept Partnership Pilot Program to accelerate the creation of small businesses and the Commercialization of research innovations from qualifying institutions. A qualifying institution is a university or other Research Institution that participates in the NIH's STTR program. The Director shall award, through a competitive, merit-based process, grants to qualifying institutions in order to implement this program. These grants shall only be used to administer Proof of Concept Partnership awards.

(2) <u>Awards to Qualifying Institutions.</u>

(i) The Director may make awards to a qualifying institution for up to \$1,000,000 per year for up to 4 years.

(ii) In determining which qualifying institutions will receive pilot program grants, the Director of NIH shall consider, in addition to any other criteria the Director determines necessary, the extent to which qualifying institutions--

(A) have an established and proven technology transfer or commercialization office and have a plan for engaging that office in the program's implementation;

(B) have demonstrated a commitment to local and regional economic development;

(C) are located in diverse geographies and are of diverse sizes;

(D) can assemble project management boards comprised of industry, start-up, venture capital, technical, financial, and business experts;

(E) have an Intellectual Property rights strategy or office; and

(F) demonstrate a plan for sustainability beyond the duration of the funding award.

(3) <u>Proof of Concept Partnerships.</u> A qualifying institution selected by NIH shall establish a Proof of Concept Partnership with NIH to award grants to individual researchers. These grants should provide researchers with the initial investment and the resources to support the proof of concept work and Commercialization mentoring needed to translate promising research projects and technologies into a viable company. This work may include technical validations, market research, clarifying Intellectual Property rights position and strategy, and investigating commercial or business opportunities.

(4) <u>Award Guidelines</u>. The administrator of a Proof of Concept Partnership program shall award grants in accordance with the following guidelines:

(i) The Proof of Concept Partnership shall use a market-focused project management oversight process, including--

(A) a rigorous, diverse review board comprised of local experts in translational and proof of concept research, including industry, start-up, venture capital, technical, financial, and business experts and university technology transfer officials;

(B) technology validation milestones focused on market feasibility;

(C) simple reporting effective at redirecting projects; and

(D) the willingness to reallocate funding from failing projects to those with more potential.

(ii) The Proof of Concept Partnership shall not award more than \$100,000 towards an individual proposal.

(5) <u>Educational Resources and Guidance</u>. The administrator of a Proof of Concept Partnership program shall make educational resources and guidance available to researchers attempting to commercialize their innovations.

(6) Limitations.

(i) The funds for the pilot program shall not be used for basic research or to fund the acquisition of research equipment or supplies unrelated to Commercialization activities.

(ii) The funds for the pilot program can be used to evaluate the commercialpotential of existing discoveries, including proof of concept research or Prototype

development; and activities that contribute to determining a project's Commercialization path, to include technical validations, market research, clarifying Intellectual Property rights, and investigating commercial and business opportunities.

(7) <u>Termination of Authority</u>. The pilot program under this subsection shall terminate on September 30, 2022, unless otherwise extended.

<u>Appendix I: Instructions for SBIR and STTR Program Solicitation</u> <u>Preparation</u>

a. <u>General</u>. Subsections 9(j) and 9(p) of the Act (15 U.S.C. 638(j)) require simplified, standardized and timely SBIR/STTR solicitations and for SBIR/STTR Participating Agencies to utilize a "uniform process" minimizing the regulatory burden of participation. Therefore, the following instructions purposely depart from normal Government solicitation formats and requirements. SBIR/STTR solicitations must be prepared and issued as Program Solicitations in accordance with the following instructions.

b. <u>Limitation in Size of Solicitation</u>. In the interest of meeting the requirement for simplified and standardized solicitations, while also recognizing that the Internet has become the main vehicle for distribution, each agency should structure its entire SBIR/STTR solicitation to produce the least number of pages (electronic and printed), consistent with the procurement/assistance standard operating procedures and statutory requirements of the Participating Agencies.

c. Format. SBIR/STTR Program Solicitations must be prepared in a simple,

standardized, easy-to-read, and easy-to-understand format. It must include a cover sheet,

a table of contents, and the following sections in the order listed.

- 1. Program Description
- 2. Certifications
- 3. Proposal Preparation Instructions and Requirements
- 4. Method of Selection and Evaluation Criteria
- 5. Considerations
- 6. Submission of Proposals
- 7. Scientific and Technical Information Sources
- 8. Submission Forms
- 9. Research Topics

d. <u>Cover Sheet</u>. The cover sheet of an SBIR/STTR Program Solicitation must clearly identify the solicitation as an SBIR/STTR solicitation, identify the agency releasing the solicitation, specify date(s) on which contract proposals or grant applications are due under the solicitation, and state the solicitation number or year.

e. Instructions for Preparation of SBIR or STTR Program Solicitation - Sections 1-9

§ 1. Program Description.

(a) Summarize in narrative form the request for proposals and the objectives of the SBIR or STTR program.

(b) Describe in narrative form the agency's SBIR or STTR program including a description of the three phases. Note in your description whether the solicitation is for Phase I or Phase II proposals. Also note in each solicitation for Phase I that all

Awardees may apply for a Phase II award and provide guidance on the procedure for doing so.

(c) Describe program eligibility.

(d) List the name, address and telephone number of agency contacts for general information on the SBIR or STTR Program Solicitation.

(e) Whenever terms are used that are unique to the SBIR or STTR program, a specific SBIR or STTR solicitation or a portion of a solicitation, define them or refer potential offerors/Applicants to a source for the definition. At a minimum, the definitions of "Funding Agreement," "R/R&D," "SBC," "SBIR/STTR Data," and "SBIR/STTR Data Rights" must be included.

(f) Include information explaining how an individual can report fraud, waste and abuse (e.g. include the fraud hotline for the agency's Office of Inspector General);

§ 2. Certifications.

(a) This section must include certifying forms required by legislation, regulation or standard operating procedures, to be submitted by the Applicant to the contracting or granting agency. This would include certifying forms such as those for the protection of human and animal subjects.

(b) This section must include any certifications required concerning size, ownership and other SBIR or STTR program requirements.

(i) The agency may request the SBIR/STTR Applicant to submit a certification at the time of submission of the application or offer. The certification may require the Applicant to state that it intends to meet the size, ownership and other requirements of the SBIR or STTR program at the time of award of the Funding Agreement, if selected for award. (ii) The agency must request the Applicant to submit a certification at the time of award and at any other time set forth in SBA's regulations at 13 CFR 121.701-121.705. The certification will require the Applicant to state that it meets the size, ownership and other requirements of the SBIR or STTR program at the time of award of the Funding Agreement. (iii) The agency must request the Awardee to submit certifications during the Funding Agreement life cycle. A Phase I Funding Agreement must state that the Awardee shall submit a new certification that it is in compliance with specific SBIR or STTR program requirements at the time of final payment or disbursement. A Phase II Funding Agreement must state that the Awardee shall submit a new certification that it is in compliance with specific SBIR or STTR program requirements prior to receiving more than 50% of the total award amount and prior to final payment or disbursement.

(iv) Agencies may require additional certifications at other points in time during the life cycle of the Funding Agreement, such as at the time of each payment or disbursement.

(c) The agency must use the following certification at the time of award and upon notification by SBA, must check <u>www.SBIR.gov</u> for updated certifications prepared by SBA:

SBIR/STTR Funding Agreement Certification

All small businesses that are selected for award of an SBIR/STTR Funding Agreement must complete this certification at the time of award and any other time set forth in the Funding Agreement that is prior to performance of work under this award. This includes checking all of the boxes and having an authorized officer of the Awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal Government relies on the information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) program or Small Business Technology Transfer (STTR) program award. A similar certification will be used to ensure continued compliance with specific program requirements during the life of the Funding Agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 CFR part 121), the SBIR/STTR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the Funding Agreement officer believes that the business may not meet certain eligibility requirements at the time of award, they are required to file a size protest with the U.S. Small Business Administration (SBA), which will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Funding Agreement officer believes, after award, that the business is not meeting certain Funding Agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal Government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (<u>all boxes must be checked</u> <u>unless otherwise directed</u>):

(1) \Box The Awardee business concern meets the ownership and control requirements set forth in 13 CFR 121.702.

(2) If a corporation – all corporate documents(namely: articles of incorporation and any amendments, articles of conversion, by-laws and amendments, shareholder meeting minutes showing director elections, shareholder meeting minutes showing officer elections, organizational meeting minutes, all issued stock certificates, stock ledger, buy-sell agreements, stock transfer agreements, voting agreements, and documents relating to stock options, including the right to convert non-voting stock or debentures into voting stock) must evidence that the corporation meets the ownership and control requirements set forth in 13 CFR 121.702. (Check one box).

 \Box Yes \Box N/A Explain why N/A:

(3) If a partnership -- the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 CFR 121.702. (Check one box).

 \Box Yes \Box N/A Explain why N/A:

(4) If a limited liability company – the articles of organization and any amendments, and operating agreement and amendments, evidence that it meets the ownership and control requirements set forth in 13 CFR 121.702. (Check one box).

 \Box Yes \Box N/A Explain why N/A:

(5) The birth certificates, naturalization papers, or passports show that any individuals it relies upon to meet the eligibility requirements are U.S. citizens or permanent resident aliens in the United States. (Check one box).

 \Box Yes \Box N/A Explain why N/A:

(6) \Box The Awardee business concern has no more than 500 employees, including the employees of its Affiliates.

(7) \Box SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard.

(8) During the performance of the award, the Principal Investigator/Project Manager will spend more than one half of his/her time (based on a 40 hour workweek) as an employee of the Awardee (or Research Institution – STTR only) or has requested and received a written deviation from this requirement from the Funding Agreement officer. (Check one box).

 \Box Yes \Box Deviation approved in writing by Funding Agreement officer: _%

(9) All Essentially Equivalent Work, or a portion of the work, proposed under this project (check applicable line):

□ **Has not** been submitted for funding to this Agency or another Federal agency.

□ Has been submitted for funding to this Agency or another Federal agency but has not been funded under any other grant, contract, subcontract or other transaction.

☐ A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Funding Agreement officer.

(10) During performance of award, the Awardee will perform the applicable percentage of work unless a deviation from this requirement is approved in writing by the Funding Agreement officer (check applicable line and fill in if needed):

 \Box SBIR Phase I: at least two-thirds (66 2/3%) of the research.

 \Box SBIR Phase II: at least half (50%) of the research.

 \Box STTR Phase I or Phase II: at least forty percent (40%) of the research.

□ Deviation approved in writing by the Funding Agreement officer (SBIR only):

__%

(11) During performance of award, the R/R&D will be performed in the United States unless a deviation is approved in writing by the Funding Agreement officer (check one box).

 \Box Yes \Box Waiver has been granted

(12) \Box During performance of award, the R/R&D will be performed at the Awardee's facilities by the Awardee's employees, except as otherwise indicated in the SBIR/STTR application and approved in the Funding Agreement.

(13) The SBIR Awardee has registered itself on SBA's database as majority-owned by venture capital operating companies, hedge funds or private equity firms (check one box).

 \Box Yes \Box No \Box N/A Explain why N/A:

(14) The SBIR Awardee is a Covered Small Business Concern (a Small BusinessConcern that: (a) was not majority-owned by multiple venture capital operating

companies (VCOCs), hedge funds, or private equity firms on the date on which it submitted an application in response to an SBIR solicitation; and (b) on the date of the SBIR award, which is made more than 9 months after the closing date of the solicitation, is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms). (Check one box).

 \Box Yes \Box No

 $(15) \square$ I will notify this Agency immediately if all or a portion of the work authorized and funded under this award is subsequently funded by another Federal Agency.

(16) [*For STTR only*] The Small Business Concern, and not a partnering Research Institution, is exercising management direction and control of the performance of the STTR Funding Agreement.

□Yes □No

 $(17) \square$ I understand that the information submitted may be given to Federal, State, and local agencies for determining violations of law and other purposes.

 $(18) \square$ I am an <u>officer</u> of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. 3729 et seq.); (3)

double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 <u>et seq</u>.); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR subpart 9.4 or 2 CFR part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Signature	Date_/_/
Print Name (First, Middle, Last)	
Title	
Business Name	

(d) The agency must use the following certification during the life cycle of the Funding Agreement in accordance with subsection 8(j) of the SBIR/STTR Policy Directive and paragraph 2(b)(iii) of this Appendix and upon notification by SBA, must check <u>www.SBIR.gov</u> for updated certifications prepared by SBA:

SBIR/STTR Funding Agreement Certification – Life Cycle Certification

All SBIR/STTR Phase I and Phase II Awardees must complete this certification at all times set forth in the Funding Agreement (see § 8(j) of the SBIR/STTR Policy Directive). This includes checking all of the boxes (unless otherwise directed) and having an authorized officer of the Awardee sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal Government relies on the information to ensure compliance with specific program requirements during the life of the Funding Agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, the SBIR/STTR Policy Directive, and also any statutory and regulatory provisions referenced in those authorities.

If the Funding Agreement officer believes that the business is not meeting certain Funding Agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal Government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (all boxes must be checked except where otherwise directed):

(1) The Principal Investigator/Project Manager spent more than one half of his/her time (based on a 40 hour workweek) as an employee of the Awardee (or Research Institution – STTR only) or the Awardee has requested and received a written deviation from this requirement from the Funding Agreement officer.

 \Box Yes \Box No \Box Deviation approved in writing by Funding Agreement officer: _%

(2) All Essentially Equivalent Work, or a portion of the work, performed under this project (check the applicable line):

□ **Has not** been submitted for funding to this Agency or another Federal Agency.

□ Has been submitted for funding to this Agency or another Federal agency but has not been funded under any other grant, contract, subcontract or other transaction. □ A portion has been funded by another grant, contract, or subcontract as described in detail in the proposal and approved in writing by the Funding Agreement officer.

(3) Upon completion of the award, the Awardee will have performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Funding Agreement officer (check the applicable line and fill in if needed):

 \Box SBIR Phase I: at least two-thirds (66 2/3%) of the research.

 \Box SBIR Phase II: at least half (50%) of the research.

 \Box STTR Phase I or Phase II: at least forty percent (40%) of the research.

□ Deviation approved in writing by the Funding Agreement officer (SBIR only):

__%

(4) The work is completed and the small business Awardee has performed the applicable percentage of work, unless a deviation from this requirement is approved in writing by the Funding Agreement officer (check the applicable line and fill in if needed):

 \Box SBIR Phase I: at least two-thirds (66 2/3%) of the research.

 \Box SBIR Phase II: at least half (50%) of the research.

 \Box STTR Phase I or Phase II: at least forty percent (40%) of the research.

 \Box Deviation approved in writing by the Funding Agreement officer: ____%

 \Box N/A because work is not completed

(5) [*For STTR only*] The Small Business Concern, and not a partnering Research Institution, is exercising management direction and control of the performance of the STTR Funding Agreement.

 \Box Yes \Box No

(6) The R/R&D is performed in the United States unless a deviation is approved in writing by the Funding Agreement officer.

 \Box Yes \Box No \Box Waiver has been granted

(7) The R/R&D is performed at the Awardee's facilities by the Awardee's employees, except as otherwise indicated in the SBIR/STTR application and approved in the Funding Agreement.

□Yes □No

(8) \Box I will notify this Agency immediately if all or a portion of the work authorized and funded under this award is subsequently funded by another Federal Agency.

(9) \Box I understand that the information submitted may be given to Federal, State, and local agencies for determining violations of law and other purposes.

 $(10) \square$ I am an officer of the Awardee business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern, that the information provided in this certification, the application, and all other information submitted in connection with the award, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. 3729 <u>et seq</u>.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 <u>et seq</u>.); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR subpart 9.4 or 2 CFR part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Signature	Date_/_/_
Print Name (First, Middle, Last)	
Title	
Business Name	

(e) [SBIR only] The agency must require any SBC that is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms to submit the following certification with its SBIR application:

Certification for SBIR Applicants that are Majority-Owned by Multiple Venture

Capital Operating Companies, Hedge Fund or Private Equity Firms

Any small business that is majority-owned by multiple venture operating companies (VCOCs), hedge funds, or private equity firms and is submitting an application for an SBIR Funding Agreement must complete this certification prior to submitting an application. This includes checking all of the boxes and having an authorized officer of the Applicant sign and date the certification each time it is requested.

Please read carefully the following certification statements. The Federal Government relies on the information to determine whether the business is eligible for a Small Business Innovation Research (SBIR) program award and meets the specific program requirements during the life of the Funding Agreement. The definitions for the terms used in this certification are set forth in the Small Business Act, SBA regulations (13 CFR part 121), the SBIR/STTR Policy Directive and also any statutory and regulatory provisions referenced in those authorities.

If the Funding Agreement officer believes that the business may not meet certain eligibility requirements at the time of award, he/she is required to file a size protest with the U.S. Small Business Administration (SBA), which will determine eligibility. At that time, SBA will request further clarification and supporting documentation in order to assist in the verification of any of the information provided as part of a protest. If the Funding Agreement officer believes, after award, that the business is not meeting certain Funding Agreement requirements, the agency may request further clarification and supporting documentation in order to assist in the verification of any of the information provided.

Even if correct information has been included in other materials submitted to the Federal Government, any action taken with respect to this certification does not affect the Government's right to pursue criminal, civil or administrative remedies for incorrect or incomplete information given in the certification. Each person signing this certification may be prosecuted if they have provided false information.

The undersigned has reviewed, verified and certifies that (<u>all boxes must be</u> <u>checked</u>):

(1) \Box The Applicant is NOT more than 50% owned by a single VCOC, hedge

fund, or private equity firm.

(2) \Box The Applicant is more than 50% owned by multiple domestic business concerns that are VCOCs, hedge funds, or private equity firms.

(3) \Box I have registered with SBA at <u>www.SBIR.gov</u> as a business that is majority-owned by multiple VCOCs, hedge funds or private equity firms.

(4) \Box I understand that the information submitted may be given to Federal, State, and local agencies for determining violations of law and other purposes.

(5) \Box All the statements and information provided in this form and any documents submitted are true, accurate, and complete. If assistance was obtained in completing this form and the supporting documentation, I have personally reviewed the information and it is true and accurate. I understand that, in general, these statements are made for the purpose of determining eligibility for an SBIR Funding Agreement and continuing eligibility.

(6) \Box I understand that the certifications in this document are continuing in nature. Each SBIR Funding Agreement for which the small business submits an offer or application or receives an award constitutes a restatement and reaffirmation of these certifications.

(7) \Box I understand that I may not misrepresent status as small business to: 1) obtain a contract under the Act; or 2) obtain any benefit under a provision of Federal law that references the SBIR program.

(8) \Box I am an <u>officer</u> of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the SBIR Applicant or Awardee,

that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. 3729 <u>et seq</u>.); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. 3801 <u>et seq</u>.); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR subpart 9.4 or 2 CFR part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Signature	Date_/_/
Print Name (First, Middle, Last)	
Title	
Business Name	

§ 3. <u>Proposal Preparation Instructions and Requirements</u>. The purpose of this section is to inform the Applicant on what to include in the proposal and to set forth limits on what may be included. It should also provide guidance to assist Applicants, particularly those that may not have previous Government experience, in improving the quality and acceptance of proposals. (a) <u>Limitations on Length of Proposal. Include at least the following information:</u>

(1) SBIR/STTR Phase I proposals must not exceed a total of 25 pages, including cover page, budget, and all enclosures or attachments, unless stated otherwise in the agency solicitation. Pages should be of standard size (8 1/2" x 11"; 21.6 cm x 27.9 cm) and should conform to the standard formatting instructions. Margins should be 2.5 cm and type at least 10 point font.

(2) A notice that no additional attachments, appendices, or references beyond the 25-page limitation shall be considered in proposal evaluation (unless specifically solicited by an agency) and that proposals in excess of the page limitation shall not be considered for review or award.

(b) <u>Proposal Cover Sheet</u>. Every Applicant is required to provide a copy of its registration information printed from the Company Registry unless the information can be transmitted automatically to SBIR/STTR Participating Agencies. Every Applicant must also include at least the following information on the first page of proposals. Items 8 and 9 are for statistical purposes only.

(1) Agency and Program Solicitation Number or Year.

(2) Topic Number or Letter.

- (3) Subtopic Number or Letter.
- (4) Topic Area.
- (5) Project Title.

(6) Name and Complete Address of SBC.

(7) Disclosure permission (by statement or checkbox), such as follows, must be included at the discretion of the funding agency:

"Will you permit the Federal Government to disclose the name, address, and telephone number of the corporate official of your concern, if your proposal does not result in an award, to appropriate local and State-level economic development organizations that may be interested in contacting you for further information? \Box Yes \Box No"

(8) Signature of a company official of the proposing Small Business Concern and that individual's typed name, title, address, telephone number, and date of signature.

(9) Signature of Principal Investigator or Project Manager within the proposing Small Business Concern and that individual's typed name, title, address, telephone number, and date of signature.

(10) Legend for proprietary information as described in the "Considerations" section of this Program Solicitation if appropriate. This may also be noted by asterisks in the margins on proposal pages.

(c) <u>Data Collection Requirement</u>

(1) Each Phase I and Phase II Applicant is required to provide information for SBA's database (<u>www.SBIR.gov</u>). The following are examples of the data to be entered by Applicants into the database:

(i) Any business concern or subsidiary established for the commercial application of a product or service for which an SBIR or STTR award is made.

(ii) Revenue from the sale of new products or services resulting from the research conducted under each Phase II award;

(iii) Additional investment from any source, other than Phase I or Phase II

awards, to further the research and development conducted under each Phase II award.

(iv) Update the information in the database for any prior Phase II award received by the SBC. The SBC may apportion sales or additional investment information relating to more than one Phase II award among those awards, if it notes the apportionment for each award.

(2) Each Phase II Awardee is required to update the appropriate information on the award in the database upon completion of the last deliverable under the Funding Agreement and is requested to voluntarily update the information in the database annually thereafter for a minimum period of 5 years.

(d) <u>Abstract or Summary</u>. Applicants will be required to include a one-page project summary of the proposed R/R&D including at least the following:

(1) Name and complete address of SBC.

- (2) Name and title of Principal Investigator/Project Manager.
- (3) Participating Agency name, Program Solicitation number, and Program Solicitation topic and subtopic.

(4) Title of project.

- (5) Technical abstract limited to two hundred words.
- (6) Summary of the anticipated results and implications of the approach (both PhasesI and II) and the potential commercial applications of the research.

(e) <u>Technical Content</u>. SBIR or STTR Program Solicitations must require, as a minimum, the following to be included in proposals submitted thereunder:

(1) Identification and Significance of the Problem or Opportunity. A clear statement

of the specific technical problem or opportunity addressed.

(2) <u>Phase I Technical Objectives</u>. State the specific objectives of the Phase I research and development effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

(3) <u>Phase I Work Plan</u>. Include a detailed description of the Phase I R/R&D plan. The plan should indicate what will be done, where it will be done, and how the R/R&D will be carried out. Phase I R/R&D should address the objectives and the questions cited in (e)(2) immediately above. The methods planned to achieve each objective or task should be discussed in detail.

(4) <u>Related R/R&D</u>. Describe significant R/R&D that is directly related to the proposal, including any conducted by the Principal Investigator/Project Manager or by the proposing SBC. Describe how it relates to the proposed effort, and any planned coordination with outside sources. The Applicant must persuade reviewers of his or her awareness of key, recent R/R&D conducted by others in the specific topic area.

(5) <u>Key Individuals and Bibliography of Directly Related Work</u>. Identify Key Individuals involved in Phase I 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 and may be necessary to meet proposal size limitation.

(6) <u>Relationship with Future R/R&D</u>.

(i) State the anticipated results of the proposed approach if the project is successful (Phase I and II).

(ii) Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort.

(7) <u>Facilities</u>. A detailed description, availability and location of instrumentation and physical facilities proposed for Phase I should be provided.

(8) <u>Consultants</u>. Involvement of consultants in the planning and research stages of the project is permitted. If such involvement is intended, it should be described in detail.

(9) Potential Post Applications. Briefly describe:

(i) Whether and by what means the proposed project appears to have potential commercial application.

(ii) Whether and by what means the proposed project appears to have potential use by the Federal Government.

(10) <u>Similar Proposals or Awards</u>. WARNING—While it is permissible with proposal notification to submit identical proposals or proposals containing a significant amount of Essentially Equivalent Work for consideration under numerous Federal Agency Program Solicitations, it is unlawful to enter into Funding Agreements requiring Essentially Equivalent Work. If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award. If an Applicant elects to submit identical proposals or proposals containing a significant amount of Essentially Equivalent Work under other Federal Agency Program Solicitations, a statement must be included in each such proposal indicating:

(i) The name and address of the Federal Agencies to which proposals were submitted or from which awards were received.

(ii) Date of proposal submission or date of award.

(iii) Title, number, and date of Program Solicitations under which proposals were submitted or awards received.

(iv) The specific applicable research topics for each proposal submitted or award received.

(v) Titles of research projects.

(vi) Name and title of Principal Investigator/Project Manager for each proposal submitted or award received.

(11) <u>Prior SBIR Phase II Awards</u>. If the SBC has received more than 15 Phase II awards in the prior 5 fiscal years, the SBC must submit in its Phase I proposal: name of the awarding agency; date of award; Funding Agreement number; amount of award; topic or subtopic title; follow-on agreement amount; source and date of commitment; and current Commercialization status for each Phase II award. (This required proposal information will not be counted toward the proposal pages limitation.)

(f) <u>Cost Breakdown/Proposed Budget</u>. The solicitation will require the submission of simplified cost or budget data.

§ 4. Method of Selection and Evaluation Criteria.

(a) <u>Standard Statement</u>. Essentially, the following statement must be included in all SBIR or STTR Program Solicitations:

"All Phase I and II proposals will be evaluated and judged on a competitive basis. Proposals will be initially screened to determine responsiveness. Proposals passing this initial screening will be technically evaluated by engineers or scientists to determine the most promising technical and scientific approaches. Each proposal will be judged on its own merit. The Federal Agency is under no obligation to fund any proposal or any specific number of proposals in a given topic. It also may elect to fund several or none of the proposed approaches to the same topic or subtopic."

(b) Evaluation Criteria.

(1) The SBIR/STTR Participating Agency must develop a standardized method in its evaluation process that will consider, at a minimum, the following factors:

(i) The technical approach and the anticipated agency and commercial benefits that may be derived from the research.

(ii) The adequacy of the proposed effort, and its relationship to the fulfillment of requirements of the research topic or subtopics.

(iii) The soundness and technical merit of the proposed approach and its incremental progress toward topic or subtopic solution.

(iv) Qualifications of the proposed Principal Investigators/Project Managers, supporting staff, and consultants.

(v) Evaluations of proposals require, among other things, consideration of a proposal's commercial potential as evidenced by:

(A) the SBC's record of commercializing SBIR or other research,

(B) the existence of Phase II funding commitments from private sector or non-SBIR funding sources,

(C) the existence of Phase III follow-on commitments for the subject of the research, and,

(D) the presence of other indicators of the commercial potential of the

idea.

(2) The factors in (b)(1) above and other appropriate evaluation criteria, if any, mustbe specified in the "Method of Selection" section of SBIR Program Solicitations.

(c) <u>Peer Review</u>. The Program Solicitation must indicate if the SBIR/STTR Participating Agency contemplates that as a part of the SBIR/STTR proposal evaluation, it will use external peer review.

(d) <u>Release of Proposal Review Information</u>. After final award decisions have been announced, the technical evaluations of the Applicant's proposal may be provided to the Applicant. The identity of the reviewer must not be disclosed.

§ 5. <u>Considerations</u>. This section must include, as a minimum, the following information:

(a) <u>Awards.</u> Indicate the estimated number and type of awards anticipated under the particular SBIR/STTR Program Solicitation in question, including:

(1) Approximate number of Phase I awards expected to be made.

(2) Type of Funding Agreement, that is, contract, grant, or cooperative agreement.

(3) Whether fee or profit will be allowed.

(4) Cost basis of Funding Agreement, for example, fixed-price, cost reimbursement, or cost-plus-fixed fee.

(5) Information on the approximate average dollar value of awards for Phase I and Phase II.

(b) <u>Reports</u>. Describe the frequency and nature of reports that will be required under Phase I Funding Agreements. Interim reports should be brief letter reports.

(c) Payment Schedule. Specify the method and frequency of progress and final payment

under Phase I and II Funding Agreements.

(d) Innovations, SBIR/STTR Data Rights, Inventions and Patents.

(1) <u>Proprietary Information in Proposals</u>. The following statement must be included in all SBIR/STTR Program Solicitations:

"Information contained in unsuccessful proposals will remain the property of the

Applicant. The Federal Government may, however, retain copies of all proposals.

Public release of information in any proposal submitted will be subject to existing

statutory and regulatory requirements. If proprietary information is provided by an

Applicant in a proposal, which constitutes a trade secret, commercial or financial

information, , it will be treated in confidence, to the extent permitted by law, provided

that the proposal is clearly marked by the Applicant as follows:

(A) The following legend must appear on the title page of the proposal:

This proposal contains information that shall not be disclosed outside the Federal Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal, unless authorized by law The Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract if award is made as a result of the submission of this proposal. . . The information subject to these restrictions are contained on all pages of the proposal except for pages [*insert page numbers or other identification of pages that contain no restricted information.*]

(End of Legend); and

(B) The following legend must appear on each page of the proposal that contains information the Applicant wishes to protect:

Use or disclosure of information contained on this sheet is subject to the

restriction on the title page of this proposal.

(2) <u>Alternative To Minimize Proprietary Information</u>. Agencies may elect to instruct

Applicants to limit proprietary information to only that absolutely essential to their proposal.

(3) <u>SBIR/STTR Data Rights Clause</u>. Participating Agencies must include a clause in their SBIR and STTR Program Solicitations and resulting Funding Agreements that reflects the following necessary elements:

SBIR/STTR Data Rights Clause

(a) <u>Definitions</u>.

(1) <u>Computer Software</u>. Computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae, and related material that would enable the software to be reproduced, recreated, or recompiled. Computer Software does not include Computer Databases or Computer Software Documentation.

(2) <u>Data</u>. All recorded information, regardless of the form or method of recording or the media on which it may be recorded. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(3) Form, Fit, and Function Data. Data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For Computer Software it means data identifying source, functional characteristics, and performance requirements, but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

(4) <u>Government Purpose</u>. Any activity in which the United States Government is a party, including cooperative agreements with international or multi-national defense organizations or sales or transfers by the United States Government to foreign governments or international organizations. Government Purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Technical Data or Computer Software for commercial purposes or authorize others to do so.

(5) <u>Operations, Maintenance, Installation, or Training Purposes (OMIT) Data</u>. Data that is necessary for operation, maintenance, installation, or training purposes (but not including detailed manufacturing or process data).

(6) <u>SBIR/STTR Computer Software Rights</u>. The Federal Government's rights during the SBIR/STTR Protection Period in specific types of SBIR/STTR Data that are Computer Software.

(A) The Federal Government may use, modify, reproduce, release, perform, display, or disclose SBIR/STTR Data that are Computer Software within the Government. The Federal Government may exercise SBIR/STTR Computer Software Rights within the Government for:

(1) Use in Federal Government computers;

(2) Modification, adaptation, or combination with other Computer
Software, provided that the Data incorporated into any derivative software are subject to the rights in § 3(ee) of the SBIR/STTR Policy Directive and that the derivative software is marked as containing SBIR/STTR Data;
(3) Archive or backup; or

(4) Distribution of a computer program to another Federal agency, without further permission of the Awardee, if the Awardee is notified of the distribution and the identity of the recipient prior to the distribution, and a copy of the SBIR/STTR Computer Software Rights included in the Funding Agreement is provided to the recipient.

(B) The Federal Government shall not release, disclose, or permit access to SBIR/STTR Data that is Computer Software for commercial, manufacturing, or procurement purposes without the written permission of the Awardee. The Federal Government shall not release, disclose, or permit access to SBIR/STTR Data outside the Government without the written permission of the Awardee unless:

(i) The non-Governmental entity has entered into a non-disclosure agreement with the Government that complies with the terms for such agreements outlined in § 8 of the SBIR/STTR Policy Directive; and
(ii) The release or disclosure is—

(I) To a Federal Government support service contractor or their subcontractor for purposes of supporting Government internal use or activities, including evaluation, diagnosis and correction of deficiencies, and adaptation, combination, or integration with other Computer Software provided that SBIR/STTR Data incorporated into any derivative software are subject to the rights in § 3(ee) of the SBIR/STTR Policy Directive; or

(II) Necessary to support certain narrowly-tailored essential

Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul.

(7) <u>SBIR/STTR Data</u>. All Data developed or generated in the performance of an SBIR or STTR award, including Technical Data and Computer Software developed or generated in the performance of an SBIR or STTR award. The term does not include information incidental to contract or grant administration, such as financial, administrative, cost or pricing or management information.

(8) <u>SBIR/STTR Data Rights.</u> The Federal Government's license rights in properly marked SBIR/STTR Data during the SBIR/STTR Protection Period are as follows: SBIR/STTR Technical Data Rights in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software; and SBIR/STTR Computer Software Rights in SBIR/STTR Data that is Computer Software. Upon expiration of the protection period for SBIR/STTR Data, the Federal Government has a royaltyfree license to use, and to authorize others to use on its behalf, these data for Government Purposes, and is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties, except that any such data that is also protected under a subsequent SBIR/STTR award shall remain protected through the protection period of that subsequent award. The Federal Government receives Unlimited Rights in Form Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.

(9) <u>SBIR/STTR Protection Period</u>. The period of time during which the Federal

Government is obligated to protect SBIR/STTR Data against unauthorized use and disclosure in accordance with SBIR/STTR Data Rights. The SBIR/STTR Protection Period begins at award of an SBIR/STTR Funding Agreement and ends not less than twenty years from that date (See § 8(b)(4) of the SBIR/STTR Policy Directive). (10) <u>SBIR/STTR Technical Data Rights.</u> The Federal Government's rights during the SBIR/STTR Protection Period in SBIR/STTR Data that are Technical Data or any other type of Data other than Computer Software.

(A) The Federal Government may, use, modify, reproduce, perform, display, release, or disclose SBIR/STTR Data that are Technical Data within the Government; however, the Government shall not use, release, or disclose the data for procurement, manufacturing, or commercial purposes; or release or disclose the SBIR/STTR Data outside the Government except as permitted by paragraph
(B) below or by written permission of the Awardee.

(B) SBIR/STTR Data that are Technical Data may be released outside the Federal Government without any additional written permission of the Awardee only if the non-Governmental entity or foreign government has entered into a non-disclosure agreement with the Federal Government that complies with the terms for such agreements outlined in § 8 of the SBIR/STTR Policy Directive and the release is:

(i) Necessary to support certain narrowly-tailored essential Government activities for which law or regulation permits access of a non-Government entity to a contractors' data developed exclusively at private expense, non-SBIR/STTR Data, such as for emergency repair and overhaul;
(ii) To a Government support services contractor in the performance of a

Government support services contract for internal Government use or activities, including evaluation, diagnosis or modification, provided that SBIR/STTR Technical Data incorporated into any derivative Data are subject to the rights in § 3(ii) of the SBIR/STTR Policy Directive, and the release is not for commercial purposes or manufacture;

(iii) To a foreign government for purposes of information and evaluation if required to serve the interests of the U.S. Government; or

(iv) To non-Government entities or individuals for purposes of evaluation.

(11) <u>Technical Data</u>. Recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including Computer Software Documentation and Computer Databases). The term does not include Computer Software or financial, administrative, cost or pricing, or management information, or other data incidental to contract or grant administration. The term includes recorded Data of a scientific or technical nature that is included in Computer Databases.
(12) <u>Unlimited Rights.</u> The Government's rights to access, use, modify, prepare derivative works, reproduce, release, perform, display, disclose, or distribute Data in whole or in part, in any manner and for any purpose whatsoever, and to have or authorize others to do so.

(b) Allocation of SBIR/STTR Data Rights.

(1) An SBC retains ownership of all SBIR/STTR Data it develops or generates in the performance of an SBIR/STTR award. The SBC retains all rights in SBIR/STTR Data that are not granted to the Federal Government in accordance with the SBIR/STTR Policy Directive. These rights of the SBC do not expire.

(2) During the SBIR/STTR Protection Period, the Federal Government receives SBIR/STTR Technical Data Rights in appropriately marked SBIR/STTR Data that is Technical Data or any other type of Data other than Computer Software; and SBIR/STTR Computer Software Rights in appropriately marked SBIR/STTR Data that is Computer Software.

(3) After the protection period, the Federal Government may use, and authorize others to use on its behalf, for Government Purposes, SBIR/STTR Data that was protected during the SBIR/STTR Protection Period. Awards issued by the U.S. Department of Energy are subject to Unlimited Rights after the expiration of the SBIR/STTR Protection Period.

(4) The Federal Government receives Unlimited Rights in Form Fit, and FunctionData, OMIT Data, and all unmarked SBIR/STTR Data

(c) <u>Identification and Delivery of SBIR/STTR Data</u>. Any SBIR/STTR Data delivered by the Awardee, and in which the Awardee intends to limit the Federal Government's rights to SBIR/STTR Data Rights, must be delivered with restrictive markings. The Federal Government assumes no liability for the access, use, modification, reproduction, release, performance, display, disclosure, or distribution of SBIR/STTR Data without markings. The Awardee or its subcontractors or suppliers shall conspicuously and legibly mark all such SBIR/STTR Data with the appropriate legend.

(1) The authorized legend shall be placed on each page of the SBIR/STTR Data. If only portions of a page are subject to the asserted restrictions, the SBIR/STTR Awardee shall identify the restricted portions (<u>e.g.</u>, by circling or underscoring with a note or other appropriate identifier). With respect to SBIR/STTR Data embodied in

Computer Software, the legend shall be placed on: (1) the printed material or media

containing the Computer Software; or (2) the transmittal document or storage

container. The legend shall read as follows:

Funding Agreement No.	
Award Date	
SBIR/STTR Protection Period	
SBIR/STTR Awardee	
SBIR/STTR Awardee Address	

"SBIR/STTR DATA RIGHTS

This is SBIR/STTR Data (or is Computer Software or a Prototype that embodies or includes SBIR/STTR Data) to which the SBIR/STTR Awardee has SBIR/STTR Data Rights and to which the Federal Government has received SBIR/STTR Technical Data Rights (or SBIR/STTR Computer Software Rights) during the SBIR/STTR Protection Period and rights of use for Government Purposes after the SBIR/STTR Protection Period, as those terms are defined in the SBIR/STTR Funding Agreement. Awards issued by the U.S. Department of Energy are subject to Unlimited Rights after the SBIR/STTR Protection Period, as that term is defined in the SBIR/STTR Funding Agreement. Any reproduction of SBIR/STTR Data or portions of such data marked with this legend must also reproduce the markings." (End of Legend)

(2) Data submitted without correct or appropriate markings may be corrected within 6

months from the date the data is delivered.

(d) Relation to patents. Nothing regarding SBIR/STTR Data Rights in this clause shall

imply a license to or imply a requirement to license to the Federal Government any patent

to a Subject Invention (as defined under the Bayh-Dole Act implemented at 37 CFR 401)

made under an SBIR/STTR award.

(End of Clause)

(4) Copyrights. Include an appropriate statement concerning copyrights and

publications addressing national security considerations, if any, and the appropriate acknowledgement and disclaimer statement.

(5) <u>Invention Reporting</u>. Include requirements for reporting inventions. Include appropriate information concerning the reporting of inventions, for example:

"SBIR/STTR Awardees must report inventions to the awarding agency within 2 months of the inventor's report to the Awardee."

Note: Many federal agencies require electronic reporting of inventions and patents made with Federal funds through the Interagency Invention Reporting System (iEdison) that is maintained and managed by NIH. The iEdison System is used to satisfy all invention reporting requirements mandated by an SBIR/STTR award. Access to iEdison is through a secure interactive Internet site, <u>http://www.iedison.gov</u>. All Federal Agencies are encouraged to use the iEdison System. In addition to fulfilling reporting requirements, iEdison notifies the user of future time sensitive deadlines with enough lead-time to avoid the possibility of loss of invention or patent ownership or rights.

(e) <u>Cost Sharing</u>. Include a statement essentially as follows:

"Cost sharing is permitted for proposals under this Program Solicitation; however, cost sharing is not required. Cost sharing will not be an evaluation factor in consideration of your Phase I proposal."

(f) <u>Profit or Fee</u>. Include a statement on the payment of profit or fee on awards made under the SBIR/STTR Program Solicitation.

(g) Joint Ventures or Limited Partnerships. Include essentially the following language:

"Joint Ventures and limited partnerships are eligible provided the entity created qualifies as a Small Business Concern as defined in this Program Solicitation."

(h) <u>Research and Analytical Work</u>. Include essentially the following statement: SBIR: (1) "For Phase I a minimum of two-thirds of the research and/or analytical effort must be performed by the proposing Small Business Concern unless otherwise approved in writing by the Funding Agreement officer after consultation with the agency SBIR program manager/coordinator.
 (2) For Phase II a minimum of one-half of the research and/or analytical effort must be performed by the proposing Small Business Concern unless otherwise approved in writing by the Funding Agreement officer after consultation with the agency SBIR program manager/coordinator.

STTR:

"For both Phase I and Phase II, not less than 40 percent of the R/R&D work must be performed by the Small Business Concern, and not less than 30 percent of the R/R&D work must be performed by a partnering Research Institution, as defined in this Program Solicitation."

(i) Awardee Commitments. To meet the legislative requirement that SBIR/STTR

Program Solicitations be simplified, standardized and uniform, clauses expected to be in

or required to be included in SBIR/STTR Funding Agreements must not be included in

full or by reference in SBIR/STTR Program Solicitations. Rather, Applicants must be

advised that they will be required to make certain legal commitments at the time of

execution of Funding Agreements resulting from SBIR/STTR Program Solicitations.

Essentially, the following statement must be included in the "Considerations" section of

SBIR/STTR Program Solicitations:

"Upon award of a Funding Agreement, the Awardee will be required to make certain legal commitments through acceptance of numerous clauses in Phase I Funding Agreements. The outline 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 Funding Agreements, and is not the specific wording of such clauses. Copies of complete terms and conditions are available upon request."

(j) <u>Summary Statements</u>. The following are illustrative of the type of summary statements to be included immediately following the statement in subparagraph (i). These statements are examples only and may vary depending upon the type of Funding Agreement used. (1) <u>Standards of Work</u>. Work performed under the Funding Agreement must conform to high professional standards.

(2) <u>Inspection</u>. Work performed under the Funding Agreement is subject to Government inspection and evaluation at all times.

(3) <u>Examination of Records</u>. The Comptroller General (or a duly authorized representative) must have the right to examine any pertinent records of the Awardee involving transactions related to this Funding Agreement.

(4) <u>Default</u>. The Federal Government may terminate the Funding Agreement if the contractor fails to perform the work contracted.

(5) <u>Termination for Convenience</u>. The Funding Agreement may be terminated at any time by the Federal Government if it deems termination to be in its best interest, in which case the Awardee will be compensated for work performed and for reasonable termination costs.

(6) <u>Disputes</u>. Any dispute concerning the Funding Agreement that cannot be resolved by agreement must be decided by the contracting officer with right of appeal.

(7) <u>Contract Work Hours</u>. The Awardee may not require an employee to work more than 8 hours a day or 40 hours a week unless the employee is compensated accordingly (for example, overtime pay).

(8) <u>Equal Opportunity</u>. The Awardee will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

(9) <u>Equal Opportunity for Veterans</u>. The Awardee will not discriminate against any employee or application for employment because he or she is a disabled veteran or veteran of the Vietnam era.

(10) Equal Opportunity for People with Disabilities. The Awardee will not discriminate against any employee or applicant for employment because he or she is physically or intellectually disabled.

(11) <u>Officials Not To Benefit</u>. No Federal Government official may benefit personally from the SBIR/STTR Funding Agreement.

(12) <u>Covenant Against Contingent Fees</u>. No person or agency has been employed to solicit or secure the Funding Agreement upon an understanding for compensation except bona fide employees or commercial agencies maintained by the Awardee for the purpose of securing business.

(13) <u>Gratuities.</u> The Funding Agreement may be terminated by the Federal Government if any gratuities have been offered to any representative of the Government to secure the award.

(14) <u>Patent Infringement</u>. The Awardee must report each notice or claim of patent infringement based on the performance of the Funding Agreement.

(15) <u>American Made Equipment and Products</u>. When purchasing equipment or a product under the SBIR/STTR Funding Agreement, purchase only American-made items whenever possible.

(k) <u>Additional Information</u>. Information pertinent to an understanding of the administration requirements of SBIR/STTR proposals and Funding Agreements not included elsewhere must be included in this section. As a minimum, statements essentially as follows must be included under "Additional Information" in SBIR/STTR Program Solicitations:

(1) This Program 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/STTR Funding Agreement, the terms of the Funding Agreement are controlling.

(2) Before award of an SBIR/STTR Funding Agreement, the Federal Government may request the Applicant to submit certain organizational, management, personnel, and financial information to assure responsibility of the Applicant.

(3) The Federal Government is not responsible for any monies expended by the Applicant before award of any Funding Agreement.

(4) This Program Solicitation is not an offer by the Federal Government and does not obligate the Government to make any specific number of awards. Also, awards under the SBIR/STTR program are contingent upon the availability of funds.

(5) The SBIR/STTR program is not a substitute for existing unsolicited proposal mechanisms. Unsolicited proposals must not be accepted under the SBIR/STTR program in either Phase I or Phase II.

(6) If an award is made pursuant to a proposal submitted under this SBIR/STTR Program Solicitation, a representative of the contractor or grantee or party to a cooperative agreement will be required to certify that the concern has not previously been, nor is currently being, paid for Essentially Equivalent Work by any Federal Agency.

§ 6. <u>Submission of Proposals</u>.

(a) This section must clearly specify the closing date on which all proposals are due to be received.

(b) This section must specify the number of copies of the proposal that are to be

submitted.

(c) This section must clearly set forth the complete mailing and/or delivery address(es) where proposals are to be submitted.

(d) This section may include other instructions such as the following:

(1) <u>Bindings</u>. Please do not use special bindings or covers. Staple the pages in the upper left corner of the cover sheet of each proposal.

(2) <u>Packaging</u>. All copies of a proposal should be sent in the same package.

§ 7. <u>Scientific and Technical Information Sources</u>. Wherever descriptions of research topics or subtopics include reference to publications, information on where such publications will normally be available must be included in a separate section of the solicitation entitled "Scientific and Technical Information Sources."

§ 8. <u>Submission Forms</u>. Multiple copies of proposal preparation forms necessary to the contracting and granting process may be required. This section may include Proposal Summary, Proposal Cover, Budget, Checklist, and other forms the sole purpose of which is to meet the mandate of law or regulation and simplify the submission of proposals.

§ 9. <u>Research Topics</u>. Describe sufficiently the R/R&D topics and subtopics for which proposals are being solicited to inform the Applicant of technical details of what is desired. Allow flexibility in order to obtain the greatest degree of creativity and innovation consistent with the overall objectives of the SBIR/STTR program.