



#### **FY 2021**

## Small Business Innovation Research (SBIR) Program Phase II

**Notice of Funding Opportunity (NOFO)** 

#### **ANNOUNCEMENT**

#### **FUNDING OPPORTUNITY NUMBER: 2021-NIST-SBIR-02**

Catalog of Federal Domestic Assistance (CFDA) Number: 11.620, Science, Technology, Business and/or Education Outreach

## U.S. DEPARTMENT OF COMMERCE National Institute of Standards and Technology

Opening Date of NOFO: April 7, 2021

Closing Date: June 7, 2021

http://www.nist.gov/sbir

#### **TABLE OF CONTENTS**

L.O PROGRAM DESCRIPTION AND FEDERAL AWARD INFORMATION	5
L.01 Introduction	5
1.02 Three-Phase Program	6
L.03 SBIR Applicant Eligibility and Limitations	8
1.04 Contact with NIST	
1.05 Definitions	10
1.06 Fraud, Waste and Abuse	16
1.07 Other Information	18
2.0 CERTIFICATIONS	19
2.01 Funding Agreement Certification	19
2.02 Research Activities Involving Human Subjects, Human Tissue, Data or Recordings Ir Human Subjects Including Software Testing	_
2.03 Research Applications Involving Live Vertebrate Animals or Pre-Existing Cell Lines/Trom Vertebrate Animals	
3.0 APPLICATION PREPARATION INSTRUCTIONS AND REQUIREMENTS	29
3.01 Phase II Application Requirements	29
3.02 Phase II Application	30
4.0 METHOD OF SELECTION AND EVALUATION CRITERIA	35
1.01 Introduction	35
4.02 Phase II Screening Criteria	36

2

4.03 Phase II Evaluation Criteria	37
4.04 Phase II Award Selections	38
5.0 CONSIDERATIONS	39
5.01 Awards	39
5.02 Reporting Requirements	40
5.03 Payment Schedule	41
5.04 Innovations, Inventions and Patents	41
5.05 Cost Sharing	50
5.06 Profit or Fee	50
5.07 Joint Ventures or Limited Partnerships	50
5.08 Research and Analytical Work	50
5.09 Awardee Commitments	50
5.10 Summary Statements	51
5.11 Additional Information	52
5.12 Technical and Business Information (TABA)	53
5.13 Technical Assistance for Application Preparation and Project Conduct	53
6.0 SUBMISSION OF APPLICATIONS	54
6.01 Deadline for Applications	54
6.02 Address to Request Application Package	55
6.03 Application Submission	55

7.0 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES	57
8.0 SUBMISSION FORMS AND CERTIFICATIONS	58
8.01 Required Forms and Documents	58
8.02 Attachment of Required Application Documents	65
8.03 Verifying the Submission and Tracking the Application	66
8.04 Unique Entity Identifier and System for Award Management (SAM)	66
9.0 RESEARCH AREAS	67
Appendix A. COVER SHEET	70
Appendix B. CERTIFICATIONS	72

# US DEPARTMENT OF COMMERCE NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY FY 2021 SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM PHASE II NOTICE OF FUNDING OPPORTUNITY (NOFO)

#### 1.0 PROGRAM DESCRIPTION AND FEDERAL AWARD INFORMATION

#### 1.01 Introduction

The National Institute of Standards and Technology (NIST) invites FY 2020 NIST SBIR Phase I awardees to submit Phase II research applications under this Notice of Funding Opportunity (NOFO). Only FY 2020 NIST SBIR Phase I awardees are eligible to submit applications in response to this NOFO for Phase II of their projects.

The Small Business Innovation Research (SBIR) program was originally established in 1982 by the Small Business Innovation Development Act (P.L. 97-219), codified at 15 U.S.C. § 638. It was then expanded and extended by the Small Business Research and Development (R&D) Enhancement Act of 1992 (P.L. 102-564), and received subsequent reauthorization and extensions, the most recent of which extends the SBIR program through 2022. (P.L. 114-328).

Eleven Federal agencies implement SBIR by setting aside a portion of their extramural research and development budget each year to fund research applications from small science and technology-based firms. The statutory purpose of the SBIR Program is to strengthen the role of innovative small business concerns (SBCs) in Federally-funded research or research and development (R/R&D). Specific program goals 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 small businesses and by women-owned small businesses in technological innovation; and (4) increase private sector commercialization of innovations derived from Federal R/R&D, thereby increasing competition, productivity, and economic growth.

The NIST FY 2021 SBIR program identifies and solicits applications in topics that fall within NIST's mission and allow collaboration between NIST scientists and the SBIR awardees whenever possible.

When reviewing applications, NIST gives high priority to SBCs that participate in or conduct energy efficiency or renewable energy system R&D projects, consistent with Executive

Order (EO) 13329 (<a href="http://www.gpo.gov/fdsys/pkg/FR-2004-02-26/pdf/04-4436.pdf">http://www.gpo.gov/fdsys/pkg/FR-2004-02-26/pdf/04-4436.pdf</a>)
"Encouraging Innovation in Manufacturing," the Energy Independence and Security Act of 2007 (P.L. 110-140 § 1203(e), codified at 15 U.S.C. § 638(z)), and the <a href="mailto:Small Business Administration">Small Business Administration (SBA) Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Policy Directive, § 9.

For any SBIR award that requires a license to use a NIST-owned invention covered by a patent or patent application, the SBIR awardee will need to contact NIST's Technology Partnerships Office for a license to use the NIST-owned invention. Such awardees will be granted a non-exclusive research license and will be given the opportunity to negotiate a non-exclusive or an exclusive commercialization license to the NIST-owned invention, in accordance with the Federal patent licensing regulations, set forth in 37 C.F.R. Part 404, and to the extent that such NIST-owned invention is available for licensing and has not otherwise been exclusively licensed to another party. It is the goal of this program to position the SBIR awardee to use and build upon such licensed NIST-owned invention with the awardee's own innovation to develop a commercially viable product based on the NIST-owned invention.

#### 1.02 Three-Phase Program

The SBIR statute (15 U.S.C. § 638) requires the Department of Commerce to establish a three-phase SBIR program by reserving a percentage of its extramural R&D budget to be awarded to SBCs for innovation research. SBIR policy is provided by the SBA through the SBIR/STTR Policy Directive.

The funding vehicles for NIST's SBIR program in both Phase I and Phase II are cooperative agreements. NIST's authority to implement its SBIR program through cooperative agreements is 15 U.S.C. § 272(b)(4). NIST programmatic authorities for the research areas listed in this NOFO are found at 15 U.S.C. § 272(b) and (c). The nature of NIST's "substantial involvement" will generally be collaboration with the awardees in carrying out the projects' approved scope of work. Grants and agreements administrative requirements set forth at 2 C.F.R. Part 200 will apply to NIST SBIR awards.

#### 1.02.01 Phase I - Feasibility Research

The purpose of Phase I is for NIST to determine the technical feasibility of the research, preliminary commercialization merit of the proposed effort, and the quality of the awardee's performance. The application should concentrate on describing research that

will significantly contribute to proving the feasibility of the proposed Phase II research and commercialization potential, prerequisites to receiving further support in Phase II. Each Phase I award is for up to \$100,000 and up to a six (6) month period of performance. Up to an additional \$6,500 may be requested for Technical and Business Assistance (TABA); see Section 5.12 for more information about TABA.

#### This NOFO is not soliciting applications for Phase I research.

#### 1.02.02 Phase II - Research and Development

This NOFO provides an opportunity to all NIST FY 2020 SBIR I awardees to submit a Phase II application following the completion of Phase I. This NOFO provides instructions for FY 2021 NIST SBIR Phase II application preparation and submission requirements.

In Phase II, work from Phase I that exhibits potential for commercial application is further developed. Phase II is the R&D or prototype development phase. To apply for a Phase II award, each Phase I awardee will be required to submit a comprehensive application outlining the proposed research and a detailed plan to commercialize the final product. Each NIST Phase II award is for up to \$400,000 and up to a 24-month period of performance. One year after completing the Phase II R&D activity, the awardee shall be required to report on its commercialization activities.

#### 1.02.03 Phase III - Commercialization

Phase III refers to work that derives from, extends, or completes an effort made under prior SBIR funding agreements, but is funded by sources other than the SBIR Program. Phase III work is typically oriented towards commercialization of SBIR research or technology and may be for products, production, services, R/R&D or a combination thereof.

#### 1.02.04 Commercialization Readiness Pilot Program

As allowed in Section 5123 of the SBIR/STTR Reauthorization Act of 2011, Division E of Pub. L. 112-81, codified in 15 U.S.C. § 638(gg), NIST has received authorization to establish a Commercialization Readiness Pilot Program (CRPP). NIST may provide follow-on funding (up to an additional \$100,000) to selected awardees after completion of Phase II. The funding would be used to further develop Phase II technologies, to support advancement toward Phase III, and to increase the likelihood of commercialization. NIST is under no obligation to make any CRPP awards.

#### 1.03 SBIR Applicant Eligibility and Limitations

#### 1.03.01 Applicant Qualifications

Under this NOFO, only FY 2020 NIST SBIR Phase I awardees are eligible to submit applications. Applications received from entities other than FY 2020 NIST SBIR Phase I awardees will not be reviewed or considered for award. Each applicant must qualify as an SBC for R/R&D purposes, as defined in Section 1.05 of this NOFO, at the time of award. In addition, the primary employment of the principal investigator must be with the small business at the time of the award and during the conduct of the proposed research. Primary employment means that more than one-half of the principal investigator's time is spent working with the small business. Primary employment with a small business precludes full-time employment with another organization. Occasionally, deviations from this requirement may occur, which must be approved in writing by the NIST Grants Officer after consultation with the SBIR Program Manager. Further, a small business may only replace the principal investigator on an SBIR Phase II award if the NIST Grants Officer provides prior written approval. Personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee.

The R/R&D work must be performed in the United States. Requests for an exemption must be submitted in writing at the time of application submission. Only rare and unique circumstances will be considered for an exemption. The NIST Grants Officer must approve each exemption and its terms in writing.

NIST has elected to not use the authority that would allow venture capital operating companies (VCOCs), hedge funds or private equity firms to participate in the SBIR Program. Therefore, applications in which work would be performed by VCOCs will not be considered for award.

For Phase II, a minimum of one-half of the research and/or analytical effort must be performed by the awardee. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements, excluding funds requested for TABA (see Section 5.12), may not exceed one-half of the total award.

Each applicant will be required to provide certain information via <a href="www.sbir.gov">www.sbir.gov</a> as well as other information required by the SBIR/STTR Policy Directive (see Appendices V-VI), found at <a href="Small Business Innovation Research (SBIR) Program Policy Directive Appendices.">Small Business Innovation Research (SBIR) Program Policy Directive Appendices</a>. Each SBC applying for an award is required to update the appropriate information in the SBA database on SBIR.gov for any of its existing and prior Phase II awards.

Applicants may not participate in the review of applications.

The statement of work of an SBIR award awarded under this NOFO cannot overlap with the statement of work of an existing NIST Cooperative Research and Development Agreement (CRADA) with the awardee. NIST will consider the issue of any potential overlap on a case-by-case basis.

#### 1.03.02 Company Registry Requirements

#### 1.04 Contact with NIST

For general programmatic, electronic submission, or grants questions, please contact the appropriate individual:

Subject Area	Point of Contact
Programmatic Questions	Mary Clague Phone: (301) 975-4188 E-mail: mary.clague@nist.gov or
	J'aime Maynard Phone: (301) 975-8408 E-mail: <u>imaynard@nist.gov</u>

Electronic Application Submission through Grants.gov	Grants.gov (800) 518-4726 E-mail: support@grants.gov
Grant Rules and Regulations	Dean Iwasaki Phone: (301) 975-8449 E-mail: dean.iwasaki@nist.gov

Applicants may also contact the NIST Hollings Manufacturing Extension Partnership (MEP) for technical assistance with application preparation. More information on obtaining technical assistance from MEP Centers for application preparation can be found in Section 5.13 of this NOFO.

#### 1.05 Definitions

#### (a) General Definitions

Except as specifically noted by citation or reference, all definitions below are excerpted from the <u>SBA SBIR/STTR Policy Directive</u>.

<u>Applicant</u> – 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.

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

<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.

<u>Contract</u>, 2 CFR §200.22 - A legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term as used in this part does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward (see §200.92 Subaward).

<u>Cooperative Agreement</u>, 2 CFR §200.24 - A legal instrument of financial assistance between a Federal awarding agency or pass-through entity and a non-Federal entity that, consistent with 31 U.S.C. 6302-6305:

- (a) Is used to enter into a relationship the principal purpose of which is to transfer anything of value from the Federal awarding agency or pass-through entity to the non-Federal entity to carry out a public purpose authorized by a law of the United States (see 31 U.S.C. 6101(3)); and not to acquire property or services for the Federal Government or pass-through entity's direct benefit or use;
- (b) Is distinguished from a grant in that it provides for substantial involvement between the Federal awarding agency or pass-through entity and the non-Federal entity in carrying out the activity contemplated by the Federal award.

<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.

<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.

Joint Venture – See 13 C.F.R. § 121.103(h).

Research or Research and Development (R/R&D) - 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.

<u>Small Business Concern (SBC)</u> – A concern that meets the SBIR/STTR program eligibility requirements set forth in 13 C.F.R. 121.702, "What size and eligibility standards are applicable to the SBIR and STTR programs?" (available at <a href="https://www.ecfr.gov/cgi-bin/text-idx?SID=3ccaf429aac93292cdf7afdc1689514e&mc=true&node=se13.1.121">https://www.ecfr.gov/cgi-bin/text-idx?SID=3ccaf429aac93292cdf7afdc1689514e&mc=true&node=se13.1.121</a> 1702&rgn=div8.

Socially and Economically Disadvantaged SBC (SDB) - See 13 C.F.R. Part 124, Subpart B.

Socially and Economically Disadvantaged Individual - See 13 C.F.R. §§ 124.103 and 124.104.

<u>Subaward</u>, 2 CFR §200.92 - An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract.

<u>Women-Owned Small Business (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.

(b)Definitions related to rights in data developed under the SBIR program. These definitions are also included in Section 5.04.02 of this NOFO.

All definitions below are excerpted from the <u>SBA SBIR/STTR Policy Directive</u>.

<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.

<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.

<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.

<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.

<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.

<u>Form, Fit, and Function Data</u> - 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.

<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.

<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).

<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 Government. The Federal Government may exercise SBIR/STTR Computer Software Rights within the Government for:

- (i) Use in Federal 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 § 3(ee) of the SBIR/STTR Policy Directive 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 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.
- (2) 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—
  - (A) 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
  - (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.

SBIR/STTR Data - 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.

SBIR/STTR Data Rights - 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 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. The Federal Government receives Unlimited Rights in Form Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.

SBIR/STTR Protection Period - 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).

<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.

- (1) 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.
- (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 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.

<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.

<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.

#### 1.06 Fraud, Waste and Abuse

As defined in the SBIR/STTR Policy Directive section 9(f), 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 Principal Investigator (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 prevents 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.

Report any allegations of fraud, waste and abuse using the online Department of Commerce Office of Inspector General Complaint Form, available at

https://www.oig.doc.gov/Pages/Hotline.aspx#complainthotline. Contact information for the Office of Inspector General is available at: <a href="https://www.oig.doc.gov/pages/Contact-Us.aspx">https://www.oig.doc.gov/pages/Contact-Us.aspx</a>. Please do not include Personally Identifiable Information (PII) through the website. PII is considered to be items containing Social Security numbers, dates of birth, credit card and passport numbers, or other personally identifying information that could adversely affect an individual. Should you desire to provide this information, it is strongly recommended that you contact the Hotline by telephone at the number listed below.

#### Phone:

Toll Free 800-424-5197

#### Mail:

Office of Inspector General Hotline HCHB 7709 1401 Constitution Avenue, N.W. Washington, DC 20230

#### 1.07 Other Information

#### 1.07.01 Personal and Business Information

The applicant acknowledges and understands that information and data contained in applications for financial assistance, as well as information and data contained in financial, performance and other reports submitted by applicants, may be used by the Department of Commerce in conducting reviews and evaluations of its financial assistance programs. For this purpose, applicant information and data may be accessed, reviewed and evaluated by Department of Commerce employees, other Federal employees, and also by Federal agents and contractors, and/or by non-Federal personnel, all of whom enter into appropriate conflict of interest and confidentiality agreements covering the use of such information. As may be provided in the terms and conditions of a specific financial assistance award, applicants are expected to support program reviews and evaluations by submitting required financial and performance information and data in an accurate and timely manner, and by cooperating with Department of Commerce and external program evaluators. In accordance with 2 C.F.R. § 200.303(e), applicants are reminded that they must take reasonable measures to safeguard protected personally identifiable information and other confidential or sensitive personal or business information created or obtained in connection with a Department of Commerce financial assistance award.

In addition, Department of Commerce regulations implementing the Freedom of Information Act (FOIA), 5 U.S.C. § 552, are found at 15 C.F.R. Part 4, Public Information. These regulations set forth rules for the Department regarding making requested materials, information, and records publicly available under the FOIA. Applications submitted in response to this Notice of Funding Opportunity may be subject to requests for release under the Act. In the event that an application contains information or data that the applicant deems to be confidential commercial information that should be exempt from disclosure under FOIA, that information should be identified, bracketed, and marked as Privileged, Confidential, Commercial or Financial Information. In accordance with 15 CFR § 4.9, the Department of Commerce will protect from disclosure confidential business information contained in financial assistance applications and other documentation provided by applicants to the extent permitted by law.

#### 2.0 CERTIFICATIONS

#### 2.01 Funding Agreement Certification

Awardees will be required to certify size, ownership and other SBIR Program requirements at the time of award and during the funding agreement life cycle using the SBIR Funding Agreement Certification and the SBIR Funding Agreement Certification – Life-Cycle Certification, which are provided in Appendix B of this NOFO.

### 2.02 Research Activities Involving Human Subjects, Human Tissue, Data or Recordings Involving Human Subjects Including Software Testing

Any application that includes research activities involving human subjects, human tissue/cells, or data or recordings from or about human subjects, must satisfy the requirements of the Common Rule for the Protection of Human Subjects ("Common Rule"), codified for the Department of Commerce at 15 C.F.R. Part 27. Research activities involving human subjects that fall within one or more of the classes of vulnerable subjects found in 45 C.F.R. Part 46, Subparts B, C and D must satisfy the requirements of the applicable subpart(s). In addition, any such application that includes research activities on these subjects must be in compliance with all applicable statutory requirements imposed upon the Department of Health and Human Services (DHHS) and other Federal agencies, all regulations, policies and guidance adopted by DHHS, the Food and Drug Administration (FDA), and other Federal agencies on these topics, and all Executive Orders and Presidential statements of policy on applicable topics. (Regulatory Resources:

http://www.hhs.gov/ohrp/humansubjects/index.html which includes links to FDA regulations, but may not include all applicable regulations and policies).

NIST uses the following Common Rule definitions for research and human subjects research:

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- (1) *Intervention* includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
- (2) *Interaction* includes communication or interpersonal contact between investigator and subject.
- (3) Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator associated with the information) in order for obtaining the information to constitute research involving human subjects.
- (4) *Identifiable biospecimen* includes a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

See 15 C.F.R. § 27.102 (Definitions).

1) Requirement for Federalwide Assurance. If the application is accepted for [or awarded] funding, organizations that have an Institutional Review Board (IRB) are required to follow the procedures of their organization for approval of exempt and

non-exempt research activities that involve human subjects. Both domestic and foreign organizations performing exempt research requiring limited IRB review or non-exempt research activities involving human subjects will be required to have protocols approved by a cognizant, active IRB currently registered with the Office for Human Research Protections (OHRP) within the DHHS that is linked to the engaged organizations. All engaged organizations must possess a currently valid Federalwide Assurance (FWA) on file from OHRP. Information regarding how to apply for an FWA and register an IRB with OHRP can be found at <a href="http://www.hhs.gov/ohrp/assurances/index.html">http://www.hhs.gov/ohrp/assurances/index.html</a>. See 15 C.F.R. § 27.103. NIST relies only on OHRP-issued FWAs and IRB Registrations for both domestic and foreign organizations for NIST supported research involving human subjects. NIST will not issue its own FWAs or IRB Registrations for domestic or foreign organizations.

- 2) Administrative Review. The NIST Research Protections Office (RPO) reserves the right to conduct an administrative review<sup>1</sup> of all applications that potentially include research involving human subjects and were approved by an authorized non-NIST institutional entity (an IRB or entity analogous to the NIST RPO) under 15 C.F.R. § 27.112 (Review by Institution). If the NIST RPO determines that an application includes research activities that potentially involve human subjects, the applicant will be required to provide additional information to NIST for review and approval. The documents required for funded proposals are listed in each section below. Most documents will need to be produced during the proposal review process; however, the Grants Officer may allow final versions of certain required documents to be produced at an appropriate designated time post-award. Research involving human subjects may not start until the NIST Grants Officer issues an award explicitly authorizing such research. In addition, all amendments, modifications, or changes to approved research and requests for continuing review and closure will be reviewed by the NIST RPO. Please note that the NIST IRB is unable to serve as the IRB for financial assistance recipients.
- 3) Required documents for proposal review. All applications involving human subjects research must clearly indicate, by separable task, all research activities believed to

21

<sup>&</sup>lt;sup>1</sup> Conducting an "administrative review" means that the NIST RPO will review and verify the performing institution's determination for research not involving human subjects or exempt human subjects research. In addition, for exempt research requiring limited IRB review and non-exempt human subjects research, the NIST RPO will review and confirm that the research and performing institution(s) are in compliance with 15 C.F.R. Part 27, which means RPO will 1) confirm the engaged institution(s) possess, or are covered under a Federalwide Assurance, 2) review the research study documentation submitted to the IRB and verify the IRB's determination of level of risk and approval of the study for compliance with 15 C.F.R. Part 27, 3) review and verify IRB-approved substantive changes to an approved research study before the changes are implemented, and 4) review and verify that the IRB conducts a continuing review at least annually, as appropriate.

be exempt or non-exempt research involving human subjects, the expected institution(s) where the research activities involving human subjects may be conducted, and the institution(s) expected to be engaged in the research activities.

- a. **Not research determination.** If an activity/task involves human subjects as defined in the Common Rule, but the applicant participant(s) indicates to NIST that the activity/task is not research as defined in the Common Rule, the following information may be requested for that activity/task:
  - (1) Justification, including the rationale for the determination and such additional documentation as may be deemed necessary by NIST to review and/or support a determination that the activity/task in the application is not research as defined in the Common Rule.
  - (2) If the applicant participant(s) used a cognizant IRB that provided a determination that the activity/task is not research, a copy of that determination documentation must be provided to NIST. The applicant participant(s) is not required to establish a relationship with a cognizant IRB if they do not have one.

NIST will review the information submitted and may coordinate further with the applicant before determining whether the activity/task will be defined as research under the Common Rule in the applicable NIST financial assistance program or project.

- b. **Research not involving human subjects**. If an activity/task is determined to be research and involves human subjects, but is determined to be *not human subjects research* (or *research not involving human subjects*) under the Common Rule, the following information may be requested for that activity/task:
  - (1) Justification, including the rationale for the determination and such additional documentation as may be deemed necessary by NIST to review and/or support a determination that the activity/task in the application is not research as defined in the Common Rule.
  - (2) If the applicant participant(s) used a cognizant IRB that provided a determination that the activity/task is research not involving human subjects, a copy of that determination documentation must be provided to NIST. The applicant participant(s) is not required to establish a relationship with a cognizant IRB if they do not have one.
- c. **Exempt research determination with no IRB**. If the application appears to NIST to include exempt research activities that do not meet the criteria for requiring a limited IRB review, and the performer of the activity or the supplier and/or the receiver of the information or

biospecimens from human subjects <u>does not</u> have a cognizant IRB to provide an exemption determination, the following information may be requested during the review process so that NIST can evaluate whether an exemption under the Common Rule applies (*see* 15 C.F.R. § 27.104(b) and (d)):

- (1) The name(s) of the institution(s) where the exempt research will be conducted.
- (2) The name(s) of the institution(s) providing the biospecimens or information from human subjects.
- (3) A copy of the protocol for the research to be conducted; and/or the biospecimens or information from human subjects to be collected/provided, not pre-existing samples (i.e., will proposed research collect only information without personal identifiable information, will biospecimens or information be de-identified and when and by whom was the de-identification performed, how were the materials or data originally collected).
- (4) For pre-existing biospecimens or information from human subjects, provide copies of the consent forms used for collection and a description of how the biospecimens or information were originally collected and stripped of personal identifiers. If copies of consent forms are not available, explain.
- (5) Any additional clarifying documentation that NIST may deem necessary in order to make a determination whether the activity/task or use of biospecimens or information from human subjects is exempt under the Common Rule.
- d. **Research review with an IRB.** If the application appears to NIST to include research activities (exempt or non-exempt) involving human subjects, the proposed performer of the activity must have a relationship with a cognizant IRB registered with OHRP, and linked to their Federalwide Assurance. The following information may be requested during the review process:
  - (1) The name(s) of the institution(s) where the research will be conducted.
  - (2) The name(s) and institution(s) of the cognizant IRB(s), and the IRB registration number(s).
  - (3) The FWA number of the applicant linked to the cognizant IRB(s).
  - (4) The FWAs associated with all organizations engaged in the planned research activity/task, linked to the cognizant IRB.
  - (5) If the IRB review(s) is pending, the estimated start date for research involving human subjects.
  - (6) The IRB approval date (if currently approved for exempt or non-exempt research).
  - (7) If any of the engaged organizations has applied for or will apply for an FWA or IRB registration, those details should be clearly provided for each engaged organization.

If the application includes research activities involving human subjects to be performed in the first year of an award, additional documentation may be requested by NIST during pre-award review for those performers, and may include the following for those research activities:

- (1) A copy of each applicable final IRB-approved protocol.
- (2) A signed and dated approval letter from the cognizant IRB(s) that includes the name of the institution housing each applicable IRB, provides the start and end dates for the approval of the research activities, and any IRB-required interim reporting or continuing review requirements.
- (3) A copy of any IRB-required application information, such as documentation of approval of special clearances (*i.e.*, biohazard, HIPAA, etc.) conflict-of-interest letters, or special training requirements.
- (4) A brief description of which portions of the IRB submitted protocol are specifically included in the application submitted to NIST, if the protocol includes tasks not included in the application, or if the protocol is supported by multiple funding sources. For protocols with multiple funding sources, NIST will not approve the study without a non-duplication-of-funding letter indicating that no other federal funds will be used to support the tasks proposed under the proposed research or ongoing project.
- (5) If a new protocol will only be submitted to an IRB if an award from NIST is issued, a draft of the proposed protocol.
- (6) Any additional clarifying documentation that NIST may request during the review process to perform the NIST administrative review of research involving human subjects. (See 15 C.F.R. § 27.112 (Review by Institution)).

This clause reflects the existing NIST policy and requirements for Research Involving Human Subjects. Should the policy be revised prior to award, a clause reflecting the policy current at time of award may be incorporated into the award.

If the policy is revised after award, a clause reflecting the updated policy may be incorporated into the award.

For more information regarding research projects involving human subjects, contact Anne Andrews, Director, NIST Research Protections Office (e-mail: <a href="mailto:anne.andrews@nist.gov">anne.andrews@nist.gov</a>; phone: (301) 975-5445).

2.03 Research Activities Involving Live Vertebrate Animals or Pre-Existing Cell Lines/Tissues From Vertebrate Animals

Any application that proposes research activities involving live vertebrate animals that are to be cared for, euthanized, or used by award recipients to accomplish research goals, teaching, or testing must meet the requirements of the Animal Welfare Act (AWA) (7 U.S.C. § 2131 et seq.), and the AWA final rules (9 C.F.R. Parts 1, 2, and 3), and if appropriate, the Good Laboratory Practice for Nonclinical Laboratory Studies (21 C.F.R. Part 58). In addition, such research activities should be in compliance with the "U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" (Principles). The Principles and guidance on these Principles are available in the National Research Council's "Guide for the Care and Use of Laboratory Animals," which can be obtained from National Academy Press, 500 5<sup>th</sup> Street, N.W., Department 285, Washington, DC 20055, or as a free PDF online at <a href="http://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth">http://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth</a>.

- applications that potentially include research activities that involve live vertebrate animals, or custom samples from, or field studies with live vertebrate animals. If the application includes research activities, field studies, or custom samples involving live vertebrate animals, the applicant will be required to provide additional information for review and approval. In addition, NIST will verify the applicant's determination(s) of excluded samples from vertebrate animals. The documents required for funded proposals are listed in each section below. Some may be requested for a pre-review during the proposal review process; however, the Grants Officer may allow final versions of certain required documents to be produced at an appropriate designated time post-award. If an award is issued, no research activities involving live vertebrate animals shall be initiated or costs incurred for those activities under the award until the NIST Grants Officer issues written approval. In addition, all re-approvals, amendments, modifications, changes, annual reports and closure will be reviewed by NIST.
- 2) Required documents for NIST proposal review. The applicant should clearly indicate in the application, by separable task, all research activities believed to include research involving

25

<sup>&</sup>lt;sup>2</sup> Conducting an "administrative review" means that the NIST RPO will review and verify the performing institution's IACUC's approval of research with live vertebrate animals, and confirm that the research and performing institution(s) have an appropriate assurance and are in compliance with applicable regulations. RPO will 1) confirm the engaged institution(s) possess, or are covered under an applicable assurance, 2) review the research study documentation submitted to the IACUC and verify the IACUC's determination of level of risk and approval of the study for compliance with applicable regulations,

<sup>3)</sup> review and verify IACUC-approved substantive changes to an approved research study before the changes are implemented, and 4) review and verify that the IACUC receives an annual report for the study and conducts an appropriate continuing review at least every three years.

live vertebrate animals and the institution(s) where the research activities involving live vertebrate animals may be conducted. In addition, the applicant should indicate any activity/task that involves an excluded or custom collection from vertebrate animals, or a field study with animals.

a) **Excluded Collections from Vertebrate Animals:** The requirements for review and approval by an Institutional Animal Care and Use Committee (IACUC) do not apply to proposed research using preexisting images of animals or to research plans that do not include live animals. These regulations also do not apply to obtaining stock or preexisting items from animal material suppliers (*e.g.*, tissue banks), such as pre-existing cell lines and tissue samples, or from commercial food processors, where the vertebrate animal was euthanized for food purposes and not for the purpose of sample collection.

For pre-existing cell lines and tissue samples originating from vertebrate animals, NIST requires that the proposer provide documentation or the rationale for the determination that the cell line or tissue is pre-existing and not a custom collection from live vertebrate animals for an activity/task within the proposal. NIST may require additional documentation to review and/or support the determination that the cells and/or tissues from vertebrate animals are excluded from IACUC review.

- b) **Custom Collections Harvested from Live Vertebrate Animals:** NIST requires documentation for obtaining custom samples from live vertebrate animals from animal material suppliers and other organizations (*i.e.*, universities, companies, and government laboratories, etc.). Custom samples includes samples from animal material suppliers, such as when a catalog item indicates that the researcher is to specify the characteristics of the live vertebrate animal to be used, or how a sample is to be collected from the live vertebrate animal.
- c) Field Studies of Animals: Some field studies of animals may be exempt under the Animal Welfare Act from full review and approval by an animal care and use committee, as determined by each institution. Field study is defined as "... a study conducted on free-living wild animals in their natural habitat...". 9 C.F.R. § 1.1. However, this term excludes any study that involves an invasive procedure or that harms or materially alters the behavior of an animal under study. Field studies, with or without invasive procedures, may also require obtaining appropriate federal or local government permits (marine mammals, endangered species, etc.). If the applicant's institution requires review and approval by an animal care and use committee, NIST will require that documentation to be provided as described below.

- d) For custom collections or studies with live vertebrate animals that require review and approval by an animal care and use committee the following documentation is required:
  - (1) Requirement for Assurance. An applicable assurance for the care and use of the live vertebrate animal(s) to be used in the proposed research is required. NIST may request documentation to confirm an assurance, if adequate confirmation is not available through an assuring organization's website. The cognizant IACUC where the research activity is located may hold one or more assurances applicable to the research activity that are acceptable to NIST. These four assurances are:
    - i. Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) indicated by the OLAW assurance number, *i.e.*, A-1234;
    - ii. USDA Animal Welfare Act certification indicated by the certification number, *i.e.*, 12-R-3456;
    - iii. Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) indicated by providing the organization name accredited by AAALAC as listed in the AAALAC Directory of Accredited Organizations; and
    - iv. Letter of Assurance of compliance with the Animal Welfare Act, the U.S. Government Principles, and National Marine Fisheries Service (NFMS) IACUC policy that is valid for five years and provided by a NMFS Regional IACUC for activities with marine mammals or sea turtles (NMFS Policy Directive 04-112).
  - (2) Documentation of Research Review by an IACUC: If the applicant's application appears to include research activities, field studies, or custom sample collections involving live vertebrate animals the following information regarding review by an applicable IACUC may be requested during the application review process:
    - 1. The name(s) of the institution(s) where the research involving live vertebrate animals will be conducted and/or custom samples collected.
    - 2. The assurance type and number, as applicable, for the cognizant Institutional Animal Care and Use Committee (IACUC) where the research activity is located. [For example: Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) should be indicated by the OLAW assurance number, i.e. A-1234; an USDA Animal Welfare Act certification should be indicated by the certification number i.e. 12-R-3456; and an Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) should be indicated by

AAALAC.]

- 3. The IACUC approval date for the Animal Study Protocol (ASP) (if currently approved).
- 4. If the review by the cognizant IACUC is pending, the estimated start date for research involving vertebrate animals.
- 5. If any assurances or IACUCs need to be obtained or established, that should be clearly stated.
- 6. If any special permits are required for field studies, those details should be clearly provided for each instance, or indicated as pending.

If the application includes research activities involving vertebrate animals to be performed in the first year of an award, additional documentation may be requested by NIST during pre-award review for those performers, and may include the following for those research activities, which may also include field studies, custom sample collections involving live vertebrate animals:

- 1. A copy of the IACUC approved ASP.
- 2. Documentation of the IACUC approval indicating the approval and expiration dates of the ASP.
- 3. If applicable, a non-duplication-of-funding letter if the ASP is funded from several sources.
- 4. If a new ASP will only be submitted to an IACUC if an award from NIST is issued, a draft of the proposed ASP may be requested.
- Any additional clarifying documentation that NIST may request during review of applications to perform the NIST administrative review of research involving live vertebrate animals.

This clause reflects the existing NIST policy for Research Involving Live Vertebrate Animals. Should the policy be revised prior to award, a clause reflecting the policy current at time of award may be incorporated into the award.

If the policy is revised after award, a clause reflecting the updated policy may be incorporated into the award.

For more information regarding research projects involving live vertebrate animals, contact Linda Beth Schilling, Senior Analyst (e-mail: <a href="mailto:linda.schilling@nist.gov">linda.schilling@nist.gov</a>; phone: 301-975-2887).

#### 3.0 APPLICATION PREPARATION INSTRUCTIONS AND REQUIREMENTS

#### **3.01 Phase II Application Requirements**

Only FY 2020 NIST SBIR Phase I awardees are eligible to submit FY 2021 Phase II applications in response to this NOFO. Phase I applications are not being accepted at this time.

The application must provide sufficient information to demonstrate that the proposed work represents a sound approach to the investigation of an important scientific or engineering innovation worthy of support. The application must sufficiently identify and address a specific NIST technical program area that falls within one of the research areas described in Section 9.0 or a NIST-patented technology available for licensing. The research area or NIST-patented technology must be the same as identified in Phase I. The research must be directed towards development of a commercial product or service in the NIST program area. The application must be self-contained and written with all the care and thoroughness of a scientific paper submitted for publication. It should indicate a thorough knowledge of the current status of research area addressed by the application. Each application should be checked carefully by the applicant to ensure inclusion of all essential material needed for a complete evaluation (see Sections 4.02 and 8.01).

The application must serve as the basis for technological innovation and lead to a new commercial product, process, or service that benefits the public.

NIST reserves the right to not submit an application for merit review if NIST determines the application has insufficient scientific and technical information, fails to comply with the administrative procedures as outlined in the applicable Screening Criteria in Section 4.02, or is missing any of the required forms and documents listed in Section 8.01.

All applicants are 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:

- Any business concern or subsidiary established for the commercial application of a product or service for which an SBIR award is made.
- Revenue from the sale of new products or services resulting from the research conducted under each Phase II award.
- 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.
- Updated information in the SBA Tech-Net database on sbir.gov for any prior 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.

Each Phase II awardee is required to update appropriate information on the award in the database upon completion of the last program objective under the funding agreement and is requested to voluntarily update the information in the database annually thereafter for a minimum period of 5 years.

#### 3.02 Phase II Application

A complete application must include a Technical Proposal (described below) and all other forms and documents listed in Section 8.01.

The Cover Sheet (a) and Technical Content (b) of the Technical Proposal is **limited to 15 pages**. Additional pages beyond the 15-page limit will not be considered in the evaluation process. The Commercialization Plan (c) and Phase I Final Report (d) are not included in the page count. Pages should be of standard size (8 1/2" x 11"; 21.6 cm x 27.9 cm) with margins of 2.5 cm and type at least 10-point font. All units of measurement should be presented in metric units.

The Technical Proposal portion of the application requires the following:

- (a) Cover Sheet (3.02.01) pages 1 and 2,
- (b) Technical Content (3.02.02) pages 3 through 15,
- (c) Commercialization Plan (3.02.03), and
- (d) Phase I Final Report (3.02.04).

The listing of all forms and documents needed to complete the application is given in Section 8.01 of this NOFO. The additional required forms and documents in Section 8.01 are not included in the 15-page count.

See Section 6.0 for information on the submission of applications in response to this NOFO.

#### 3.02.01 Cover Sheet

A completed Cover Sheet (see Appendix A of this NOFO) is a required part of the Technical Proposal. The Cover Sheet is counted as pages 1 and 2 of the Technical Proposal.

If an applicant checks 'Yes' on #11, the applicant's contact information will be provided to the NIST Hollings Manufacturing Extension Partnership (MEP). Such applicants may be contacted by your local MEP Center to explore a wide range of services and initiatives to help identify potential opportunities to accelerate and strengthen growth and competitiveness in the global marketplace for small and medium-sized manufacturers, including business-related support services that could potentially benefit the applicant's proposed project.

The applicant must provide in the space available on the Cover Sheet an abstract (limited to 200 words) and summary of potential commercial application of the research results (limited to 100 words). Each applicant's abstract and summary of potential commercial applications will be provided to the SBA and should not contain proprietary information. Each awardee's abstract and summary of potential commercial applications will be published on the NIST SBIR website (<a href="www.nist.gov/tpo/small-business-innovation-research-program">www.sbir.gov</a>.

#### 3.02.02 Technical Content

Beginning on page 3 of the Technical Proposal, include the following items with headings as shown:

- (1) Identification and Significance of the Problem or Opportunity. Make a clear statement of the specific research problem or opportunity addressed, its innovativeness, commercial potential, and why the research is important. Explain how it applies to the specific research area in Section 9 that was utilized in Phase I.
- **(2) Phase II Technical Objectives.** State the specific objectives of the Phase II effort, including the technical questions it will try to answer, to determine the feasibility of the proposed approach.
- (3) Phase II Work Plan. Include a detailed description of the Phase II research plan. The plan

should indicate what will be done, where it will be done, and how the research will be carried out. The method(s) planned to achieve each objective or task should be discussed in detail.

- **(4) Related R/R&D.** Describe significant R/R&D that is directly related to the application, including any conducted by the principal investigator or by the proposing SBC. Describe how it relates to the proposed effort and describe any planned coordination with outside sources. The applicant must persuade evaluators of his or her awareness of key, recent R/R&D conducted by others in the specific topic area.
- **(5) Key Individuals and Bibliography of Related Work.** Identify key individuals involved in Phase II, including their related education, experience, and publications. Where vitae are extensive, summaries that focus on the most relevant experience and publications are desired and may be necessary to meet application size limitations.
- **(6) Relationship with Future R/R&D.** Discuss the significance of the Phase II effort in providing a foundation for the Phase III R/R&D effort. Also state the anticipated commercial results of the proposed approach.
- (7) Facilities and Equipment. A description, availability, and location of instrumentation and physical facilities proposed for Phase II should be provided.
- **(8) Consultants, Contracts, and Subawards.** The purpose of this section is to show that any third-party research assistance would materially benefit the proposed effort and that arrangements for such assistance are in place at time of application submission.

For Phase II, a minimum of one-half of the research and/or analytical effort must be performed by the awardee. Outside involvement in the project is encouraged where it strengthens the conduct of the research. Outside involvement is not a requirement of this program and is limited to no more than one-half of the research and/or analytical effort in Phase II. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements, excluding funds requested for TABA – see Section 5.12 – may not exceed one-half of the total award.

No individual or entity may serve as consultant, contractor, or subrecipient if they have been the recipient of any NIST information related to the research area that is not generally available to the public.

The applicant must also include Letters of Commitment from any participating consultants, subrecipients, or subcontractors. The Letters of Commitment do not count against the page limit. See Section 8.01.16.

- **(9)** Cooperative Research and Development Agreements (CRADA). State if the applicant is a former or current CRADA partner with NIST, or with any other Federal agency, naming the agency, title of the CRADA, and any relationship with the proposed work. The statement of work of an SBIR award awarded under this NOFO cannot overlap with the statement of work of an applicant's existing CRADA with any federal agency, including NIST. NIST will consider whether there is any overlap on a case by case basis.
- (10) Guest Researcher. State if any of the applicant's employees, consultants, contractors, or subrecipients or their employees is a domestic or foreign guest researcher at NIST (see <a href="http://www.nist.gov/tpo/collaborations/guestresearchers.cfm">http://www.nist.gov/tpo/collaborations/guestresearchers.cfm</a>), naming the sponsoring laboratory.
- (11) Cost Sharing. Cost sharing is not required and is not considered during the evaluation process for Phase II applications.
- (12) Similar Applications or Awards. WARNING -- While it is permissible to submit identical applications or applications containing a significant amount of essentially equivalent work for consideration under numerous Federal program funding announcements, it is unlawful to enter into a funding agreement requiring essentially equivalent work to an SBIR award (see 15 U.S.C. § 638(bb)(3)). If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award.

If an application submitted in response to this NOFO is substantially the same as another application that has been funded, is now being funded, or is pending with another Federal Agency, the applicant must provide the following information:

- (a) Names and addresses of agencies to which an application was submitted or from which an award was received.
- (b) Date of application submission or date of award.
- (c) Title, number, and date of NOFO(s) under which an application was submitted or award received.

- (d) Specific applicable research topic(s) for each application submitted or award received.
- (e) Title of research projects for each application submitted or award received.
- (f) Name and title of principal investigator or project manager for each application submitted or award received.

If no equivalent application is under consideration or award for equivalent work received, a statement to that effect **must** be included in this section of the technical content area of the application.

**3.02.03 Commercialization Plan** Attach a copy of your commercialization plan that follows the guidelines below.

An important criterion for selection of NIST Phase II awards is the potential for commercial applications of the research, as evidenced by one or more of the following:

- The SBC's record of commercializing SBIR and other research;
- The existence of Phase III follow-on funding commitments from the private sector or non-SBIR Government funding sources; and
- Other indicators of the concept's commercial potential.

There are no page limits (upper or lower) for the commercialization plan because each project is distinct and each company's vision for deploying its technology into the marketplace is unique.

The commercialization plan should provide information directly related to bringing the anticipated research results to market. For more information on preparing a commercialization plan, please visit the Small Business Administration website, Writing a Business Plan: <a href="http://www.sba.gov/category/navigation-structure/starting-managing-business/starting-business/how-write-business-plan">http://www.sba.gov/category/navigation-structure/starting-managing-business/starting-business/how-write-business-plan</a>. The commercialization plan should indicate how the Phase II research results are to be carried out in Phase III and should address the following areas:

**Company Information** – Focused objectives/core competencies; specialization area(s); products with significant sales, and history of previous Federal and nonfederal funding, regulatory experience, and subsequent commercialization.

**Commercial Applications** - A clear description of the product/service/process you plan on providing as a result of your Phase II research and the potential commercial application or use.

**Customers and Competition** – Clear description of key technology objectives, current competition, and advantages compared to competing products or services; description of hurdles to acceptance of the innovation.

**Market** – 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.

**Intellectual Property** – Patent status, technology lead, trade secrets, or other demonstration of a plan to achieve sufficient protection to realize the commercialization state and attain at least a temporal competitive advantage.

Financing – Plans for securing necessary funding in Phase III.

**Assistance and Mentoring** - Plans for securing needed technical or business assistance through mentoring, partnering, or through arrangements with state assistance programs, Small Business Development Centers (SBDCs), Hollings Manufacturing Extension Partnership Centers, or other assistance providers.

Each SBC applying for a Phase II award is required to update its Commercialization information on <a href="https://www.SBIR.gov">www.SBIR.gov</a> for all of its prior Phase II awards.

#### 3.02.04 Phase I Final Report

Attach a copy of your Phase I Final Report. The Phase I Final Report does not count toward the Technical Proposal's 15 page limit.

#### 4.0 METHOD OF SELECTION AND EVALUATION CRITERIA

#### 4.01 Introduction

All applications will be evaluated and judged on a competitive basis. Applications will be initially screened to determine eligibility, completeness, and responsiveness to this NOFO (see Sections 4.02 and 8.01). Applications passing the initial screening will be evaluated in accordance with the evaluation criteria (see Section 4.03). Each application will be judged on its own merit.

NIST is under no obligation to fund any application or any specific number of applications in a given topic. NIST may elect to fund several or none of the applications for the same research area. If an application is submitted that requires a license to use a NIST-owned invention covered by a patent or patent application and such NIST-owned invention has

become unavailable for licensing prior to the close of this NOFO in the field of use relevant to the application, NIST has the sole discretion to deem the application ineligible.

#### 4.02 Phase II Screening Criteria

Please carefully read the entire NOFO and review the following Phase II Screening Criteria to ensure that your application meets NIST requirements. Phase II applications that do not clearly satisfy all seven (7) of the screening criteria will be eliminated from the review and selection process and not receive further consideration. However, NIST, in its sole discretion, may continue the review process for an application that is missing minor non-substantive information, the absence of which may easily be rectified.

The screening criteria are:

- (1) The application must be received by NIST before the deadline specified in Section 6.01.
- (2) The proposing firm must qualify as eligible according to the criteria provided in Section 1.03.
- (3) The Phase II application must include all required forms and documents listed in Section 8.01:
  - i) SF-424 (R&R), Application for Federal Assistance
  - ii) Research and Related Budget (Total Fed + Non-Fed)
  - iii) CD-511, Certification Regarding Lobbying
  - iv) Research and Related Other Project Information
  - v) SF-LLL Disclosure of Lobbying Activities (if applicable)
  - vi) Technical Content see Section 3.02
    - a. Cover Sheet see Section 3.02.01
    - b. Technical Proposal see Section 3.02.02
    - c. Commercialization Plan see Section 3.02.03
    - d. Phase I Final Report see Section 3.02.04
  - vii) Budget Narrative and Justification see Section 8.01.7
  - viii) Indirect Cost Rate Agreement see Section 8.01.8
  - ix) SBA Company Registry Form see Section 8.01.9
  - x) Data Management Plan -see Section 8.01.10
  - xi) Subaward Budget Form see Section 8.01.11
  - xii) Research and Related Personal Data see Section 8.01.12
  - xiii) Current and Pending Support Form see Section 8.01.13

- xiv) Compliance with SBIR Program Requirements, Applicant Fraud Awareness Training Certificate of Training Completion see Section 8.01.14
- xv) Letters of Commitment see Section 8.01.15
- (4) The Technical Content must not exceed 15 pages.
- (5) The Phase II total proposed project budget must not exceed \$400,000. Up to \$50,000 of the award may be requested for TABA. For Phase II, a minimum of one-half of the research and/or analytical effort must be performed by the awardee. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements, excluding funds requested for TABA see Section 5.12 may not exceed one-half of the total award (Section 1.03).
- (6) The duration of R/R&D for the Phase II project must not exceed 24 months.
- (7) If an application is submitted that requires a license to use a NIST-owned invention covered by a patent or patent application, the relevant NIST-owned invention must be available for licensing prior to the close of this NOFO in the field of use relevant to the application.

#### 4.03 Phase II Evaluation Criteria

Phase II applications that satisfy the screening criteria in Section 4.02 will proceed to a scored merit review process.

**Merit Review.** The applications will be evaluated by at least three (3) reviewers composed of NIST staff or non-federal personnel in accordance with the following equally-weighted criteria for a maximum of 100 points. Reviewers may discuss the applications with each other, but scores will be determined on an individual basis. The reviewers will evaluate:

- (1) The soundness of the technical approach to the proposed research.
- (2) The likelihood the proposed effort will yield significant results leading to a product within the technical area as described in the commercialization plan.
- (3) The likelihood the proposed approach will contribute to the field of study in the technical area.
- (4) Qualifications of the proposed principal/key investigators, supporting staff, and consultants as they relate to accomplishing the proposed research effort.

Applicants should be specific and clear when writing their applications and not assume information not clearly spelled out can be inferred by the reviewer. No technical clarifications may be made after application submission.

#### 4.04 Phase II Award Selections

Final selection decisions will be made by the Selecting Official, the Director of the NIST Technology Partnerships Office, or designee, considering the following selection factors:

- (1) Scores and comments provided by the Merit reviewers;
- (2) Diversity across NIST program areas;
- (3) Proposed projects that include SBIR high priority areas of manufacturing and energy efficiency research;
- (4) Proposed projects that include participation by women and socially and economically disadvantaged SBCs, and SBCs from HUBZones or underserved-states;
- (5) Possible duplication of other federally-funded research; and
- (6) Availability of funding.

NIST may select some, all, or none of the applications, or part(s) of any particular application. Prior to issuing an award, NIST may ask for supplemental information and may negotiate the scope and amount of the award. The final approval of selected applications and issuance of awards will be by the NIST Grants Officer. The award decisions of the NIST Grants Officer are final.

# 4.04.01 Federal Awarding Agency Review of Risk Posed by Applicants

After applications are proposed for funding by the Selecting Official, the NIST Grants Management Division (GMD) performs pre-award risk assessments in accordance with 2 C.F.R. § 200.206 which may include a review of the financial stability of an applicant, the quality of the applicant's management systems, the history of performance, and/or the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

In addition, prior to making an award where the total Federal share is expected to exceed the simplified acquisition threshold (currently \$250,000), NIST GMD will review and consider the publicly available information about that applicant in the Federal Awardee Performance and Integrity Information System (FAPIIS). An applicant may, at its discretion, review and comment on information about itself previously entered into FAPIIS by a Federal awarding

agency. As part of its review of risk posed by applicants, NIST GMD will consider any comments made by the applicant in FAPIIS in making its determination about the applicant's integrity, business ethics, and record of performance under Federal awards.

Upon completion of the pre-award risk assessment, the Grants Officer will make a responsibility determination concerning whether the applicant is qualified to receive the subject award and, if so, whether appropriate specific conditions that correspond to the degree of risk posed by the applicant should be applied to an award.

# 4.04.02 Release of Proposal Review Information

After final award decisions have been announced, the merit evaluations of applications that passed the screening criteria will be provided to the applicant with written notification of award/non-award. The identity of the reviewers will not be disclosed.

### **5.0 CONSIDERATIONS**

#### 5.01 Awards

Review of applications, selection of successful applicants, and award processing is expected to be completed by September 2021. The earliest start date for awards under this NOFO is expected to be September 2021.

Through 2 C.F.R. § 1327.101, the Department of Commerce adopted **Uniform** Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 C.F.R. Part 200, which apply to awards in this program. Refer to http://go.usa.gov/SBYh and http://go.usa.gov/SBg4.

The Department of Commerce will apply to all awards made under this NOFO the **Financial Assistance Standard Terms and Conditions** in effect on the date of award. The current version, dated November 12, 2020, is accessible at Department of Commerce Financial Assistance Standard Terms and Conditions.

The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements, 79 FR 78390 (December 30, 2014), are applicable to this NOFO and are available at <a href="http://go.usa.gov/hKkR">http://go.usa.gov/hKkR</a>.

Contingent upon availability of funds, NIST anticipates making a total number of approximately eight (8) Phase II awards with a project budget of no more than

\$400,000 each. Of this amount, up to \$50,000 be included in each application for TABA. The total performance period shall be no more than 24 months beginning on the agreement start date. A period of one (1) month is allotted after the 24-month R&D duration for the awardee to prepare and submit a final report. One year after completing the R&D activity, the awardee shall be required to report on its commercialization activities.

The funding vehicles for NIST's SBIR program in both Phase I and Phase II are cooperative agreements.

To provide for an in-depth review of the Phase I final report and the Phase II application, Phase II awards will be made approximately 6 months after the completion of Phase I, contingent upon availability of funds.

In no event will NIST or the Department of Commerce be responsible for application preparation costs. This NOFO does not obligate NIST or the Department of Commerce to make any awards under either Phase I or Phase II. Furthermore, NIST will not fund any costs incurred by the applicants before awards are made. Publication of this NOFO does not oblige NIST or the Department of Commerce to award any specific project or to obligate any available funds.

## **5.02** Reporting Requirements

Phase II awardees will be required to submit Research Performance Progress Reports (RPPR) including a final report. RPPRs are generally due 30 days after the end of the 6<sup>th</sup>, 12<sup>th</sup>, 18<sup>th</sup>, and 24<sup>th</sup> month of the period of performance. Publication citation information as well as links to publicly available data or revised Data Management Plans (DMPs) shall be submitted as soon as they become available.

The RPPR should include a response to each of the metric questions that address the technical details regarding the research conducted up to that point in the project, detailed plans for the next stages of the project, results obtained, estimates of technical feasibility, a description of TABA services provided, and the benefits and results of TABA services provided for those awardees who requested and were approved for TABA services. Consideration will be given to changes from the solicited and proposed milestones if results from experimentation warrant a deviation from the plan. Inclusion of proprietary information within the RPPRs may be necessary in order to effectively communicate progress and gain appropriate consultation from NIST experts regarding next steps. All such

proprietary information must be marked by the awardee according to instructions provided in Section 5.04.02.

A commercialization report is due 12 months after the end of the period of performance. The commercialization report must include an abstract appropriate for posting on the NIST SBIR website. To help assess the effectiveness of our program in meeting programmatic and SBIR objectives, NIST may periodically request information from small businesses about progress taken towards commercialization of the technology after the completion of Phase I and II awards.

### 5.03 Payment Schedule

Cooperative agreements will include an award term with electronic payment system information. Pursuant to 2 C.F.R. § 200.305 awardees are to be paid in advance, provided they maintain or demonstrate the willingness to maintain: written procedures that minimize the time elapsing between the transfer of funds and disbursement by the recipient, and financial management systems that meet the standards for fund control and accountability as established in 2 C.F.R. § 200.302. Advances of funds to a recipient organization shall be limited to the minimum amounts needed and be timed to be in accordance with the actual, immediate cash requirements of the recipient organization in carrying out the purpose of the approved program or project.

The Department of Commerce policy requires that in the usual case, non-Federal entities time advance payment requests so that Federal funds are on hand for a maximum of three calendar days before being disbursed by the non-Federal entity for eligible award costs. In no case should advances exceed the amount of cash required for a 30-day period.

#### **5.04** Innovations, Inventions and Patents

# **5.04.01 Proprietary Information Contained in Proposals**

Information contained in unsuccessful applications will remain the property of the applicant. Unsuccessful applications will be retained in accordance with the <u>General Record Schedule 1.2/021</u>. The Federal Government may, however, retain copies of all applications. Public release of information in any application submitted will be subject to existing statutory and regulatory requirements. Applicants are discouraged from submitting proprietary information unless the information is deemed essential for proper evaluation of the application. If proprietary information provided by an applicant in a proposal, which constitutes a trade secret, proprietary commercial or financial information, confidential

personal information, or data affecting national security, 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 award 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 number 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.

The use of any other legend is unacceptable to the Government and may constitute grounds for removing the application from further consideration without assuming any liability for inadvertent disclosure.

### 5.04.02 Rights in Data Developed Under SBIR Funding Agreements

In lieu of the <u>Department of Commerce Financial Assistance Standard Terms and Conditions</u>, Section C.03, Intellectual Property Rights, the following terms and conditions will apply to and be included in all SBIR awards issued under this NOFO:

- (a) Definitions. All definitions below are excerpted from the <u>SBA SBIR/STTR Policy</u> <u>Directive</u>.
- (1) Computer Database. A collection of data recorded in a form capable of being processed by a computer. The term does not include Computer Software.

- (2) Computer Programs. 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.
- (3) Computer Software. 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.
- (4) Computer Software Documentation. 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.
- (5) Data. 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.
- (6) 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.
- (7) Government Purpose. 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.
- (8) Operations, Maintenance, Installation, or Training Purposes (OMIT) Data. Data that is necessary for operation, maintenance, installation, or training purposes (but not including detailed manufacturing or process data).
- (9) SBIR/STTR Computer Software Rights. 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 Government. The Federal Government may exercise SBIR/STTR Computer Software Rights within the Government for:
  - (i) Use in Federal 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 § 3(ee) of the SBIR/STTR Policy Directive 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 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.
  - (2) 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—
    - (A) 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
- (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.
- (10) SBIR/STTR Data. 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.
- (11) SBIR/STTR Data Rights. 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 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. The Federal Government receives Unlimited Rights in Form Fit, and Function Data, OMIT Data, and all unmarked SBIR/STTR Data.
- (12) SBIR/STTR Protection Period. 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).
- (13) 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 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.

- (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 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.
- (14) Technical Data. 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.
- (15) Unlimited Rights. 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 Function Data, OMIT Data, and all unmarked SBIR/STTR Data.
  - (c) Identification and Delivery of SBIR/STTR Data. 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 (e.g., 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:

# "SBIR/STTR DATA RIGHTS

Funding Agreement No.	
Award Date	
SBIR/STTR Protection Period	
SBIR/STTR Awardee	
SBIR/STTR Awardee Address	

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.
- (e) Copyright.
- (1) Data first produced in the performance of this award.
  - (i) Except as otherwise specifically provided in this award, the Awardee may assert copyright subsisting in any data first produced in the performance of this award.
  - (ii) When asserting copyright, the Awardee shall affix the applicable copyright notice of 17 U.S.C. § 401 or § 402 and an acknowledgment of Government sponsorship (including award number).
  - (iii) For data other than computer software, the Awardee grants to the Government, and others acting on its behalf, a paid-up nonexclusive, irrevocable, worldwide

license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Awardee grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly, by or on behalf of the Government.

- (2) Data not first produced in the performance of this award. The Awardee shall not, without prior written permission of the Grants Officer, incorporate in data delivered under this award any data that are not first produced in the performance of this award unless the Awardee: (i) identifies such data; and (ii) grants to the Government, or acquires on its behalf, a license of the same scope as set forth in subparagraph (c)(1) of this clause.
- (3) Removal of copyright notices. The Government will not remove any copyright notices placed on data pursuant to this paragraph (c)) and will include such notices on all reproductions of the data.

(End of Clause)

#### 5.04.03 NIST-Owned Inventions

Awardees will not have any automatic rights to make, use, or sell products or services incorporating NIST-owned inventions. For any SBIR award that requires a license to use a NIST-owned invention covered by a patent or patent application, the SBIR awardee will be required to contact NIST's Technology Partnerships Office for a patent license for research or for commercial use.

To the extent that such NIST-owned invention is available for licensing and has not otherwise been exclusively licensed to another party, the SBIR awardee will be granted a non-exclusive research license and will be given the opportunity to negotiate a non-exclusive or an exclusive commercialization license to the NIST-owned invention, in accordance with the Federal patent licensing regulations, set forth in 37 C.F.R. Part 404.

### 5.04.04 Patent Rights

Normally, SBCs may retain worldwide patent rights to any invention developed with Federal support. The specific requirements governing the development, reporting, and disposition of rights to inventions and patents resulting from Federal awards are described in more detail in 37 C.F.R. Part 401, which implements 35 U.S.C. § 202 through 204 and

includes standard patent rights clauses in 37 C.F.R. § 401.14, which are incorporated by reference into all awards.

#### 5.04.05 Invention Reporting

SBIR awardees must report inventions to the NIST SBIR Program Office within 2 months of the inventor's report to the awardee. Inventions must also be reported through the iEdison Invention Reporting System at <a href="https://www.iedison.gov">www.iedison.gov</a>.

#### 5.05 Cost Sharing

Cost sharing is permitted for applications under this program NOFO; however, cost sharing is not required and will not be considered in evaluation of applications.

#### **5.06 Profit or Fee**

A reasonable profit or fee not to exceed 7% of the sum of the direct and indirect costs is allowed.

#### **5.07 Joint Ventures or Limited Partnerships**

Joint ventures and limited partnerships are eligible provided the entity created qualifies as an SBC as defined in this NOFO.

#### 5.08 Research and Analytical Work

For Phase II, a minimum of one-half of the research and/or analytical effort, per Section 1.03, must be performed by the proposing SBC. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements, excluding funds requested for TABA – see Section 5.12 – may not exceed one-half of the total award.

#### **5.09 Awardee Commitments**

Upon award of a funding agreement, the awardee will be required to make certain legal commitments through acceptance of numerous Specific Award Conditions (SAC) in the funding agreement. Awards also will be governed by the Department of Commerce Financial Assistance Standard Terms and Conditions (November 12, 2020 or successor version); the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 C.F.R. Part 200, adopted by the Commerce

Department through 2 C.F.R. § 1327.101; and the Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements, 79 FR 78390 (December 30, 2014).

Section 5.10 describes the types of terms and conditions to which the awardee would commit. This list is not a complete list of terms and conditions to be included in Phase I and Phase II funding agreements and is not the specific wording of such terms and conditions.

### 5.10 Summary Statements

The following statements apply to Phase I and Phase II awards and are examples of some of the topic areas that will be addressed in the award terms and conditions.

- (1) Access to Records. Government officials have the right of timely and unrestricted access to records of awardees, including access to personnel for discussion related to the records. See 2 C.F.R. § 200.337.
- (2) Termination. Awards may be terminated (a) by the NIST Grants Officer, if an awardee materially fails to comply with the terms and conditions of an award, or for cause; (b) by the NIST Grants Officer with the consent of the awardee, in which case the two parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; (c) by the awardee upon sending to the NIST Grants Officer written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. See 2 C.F.R. §§ 200.339-343.
- (3) <u>Non-Discrimination</u>. The awardee will be required to comply with statutory and other non-discrimination requirements. No person in the United States shall, on the ground of race, color, national origin, handicap, age, religion, or sex, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance. *See* Section G.02 of the <u>Department of Commerce</u> Financial Assistance Standard Terms and Conditions (November 12, 2020).
- (4) Audit Requirements. Government officials may conduct an audit of an award at any time. Unless otherwise specified in the award, for-profit organizations that expend \$750,000 or more in Department of Commerce funds during their fiscal year must have an audit conducted for that year in accordance with Section D.01.c of the Department of Commerce Financial Assistance Standard Terms and Conditions (November 12, 2020).

- (5) Codes of Conduct. Pursuant to Section F.01 of the Department of Commerce Financial Assistance Standard Terms and Conditions (November 12, 2020), the awardee must maintain written standards of conduct to establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain in the administration of the award.
- (6) Officials Not To Benefit. No Federal Government official may benefit personally, to include financial and/or profession gain, from the SBIR/STTR Funding Agreement.
- (7) <u>Duplication of Effort</u>. The funding agreement shall not support the duplication of other federally-funded research.
- (8) <u>Scheduling and Use of Federal Agency Facilities and Equipment</u>. The Awardee must schedule, reserve, and complete usage within the period of performance of the Funding Agreement.

#### **5.11 Additional Information**

This NOFO reflects current planning. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR funding agreement, the terms of the funding agreement are controlling.

Before award of a SBIR funding agreement, the Government may request the applicant to submit certain organizational, management, personnel, and financial information to assure responsibility of the applicant.

The Government is not responsible for any funds expended by the applicant before award of any funding agreement.

This program NOFO is not an offer by the Government and does not obligate the Government to make any specific number of awards. Also, awards under the SBIR Program are contingent upon the availability of funds.

The SBIR Program is not a substitute for existing unsolicited application mechanisms. Unsolicited applications will not be accepted under the SBIR Program in either Phase I or Phase II.

If an award is made pursuant to an application submitted under this SBIR Program NOFO, a representative of the awardee 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.

The responsibility for the performance of the principal investigator, and other employees or consultants who carry out the proposed work, including those of subrecipients or contractors, lies with the management of the organization receiving an award.

Safety is a top priority at NIST. Employees and affiliates of award recipients who conduct project work at NIST will be expected to be safety-conscious, to attend NIST safety training, and to comply with all NIST safety policies and procedures, and with all applicable terms of their guest research agreement.

## **5.12 Technical and Business Assistance (TABA)**

NIST is committed to the goal of commercialization of the results of SBIR projects and will provide funding for Technical and Business Assistance (TABA) to Phase I and Phase II awardees as authorized by 15 U.S.C. § 638(q). The NIST TABA program assists in the successful commercialization of products, services, or technologies developed in association with the NIST SBIR Program. The NIST TABA program provides guidance and mentoring in topics such as assessing small business commercialization needs; planning, developing, and assisting in the preparation of a commercialization plan; and identifying markets and developing entry strategies. Allowable services include 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.

Applicants may propose up to \$50,000 of Phase II funding for TABA services. Funding for TABA counts toward the maximum \$400,000 award limit. To include TABA services as part of a Phase II award, provide amount and vendor information in the budget justification that demonstrates the provider can provide the services needed and include a letter of commitment from the provider (see Section 8.01 for additional information). NIST may disapprove a proposed TABA provider. TABA requests must be part of the application submission and may not be requested subsequent to award. Reimbursement is limited to services received that comply with 15 U.S.C. § 638(q). Requested TABA funds should be clearly labeled in the Budget Narrative (see Section 8.01.8).

### 5.13 Technical Assistance for Application Preparation and Project Conduct

Applicants may wish to contact the NIST Hollings Manufacturing Extension Partnership (MEP), a nationwide network of locally managed extension centers whose sole purpose is to provide small- and medium-sized manufacturers with the help they need to succeed. The centers provide guidance to high-technology companies seeking resources and teaming relationships. To be referred to an MEP center for technical assistance, call 1-800-MEP-4-MFG (1-800-637-4634) or visit MEP's website at <a href="http://www.nist.gov/mep">http://www.nist.gov/mep</a>.

MEP Centers are also prepared to provide referrals to state and local organizations offering resources and technical assistance to all NIST SBIR applicants after awards have been announced. If you would like your local MEP Center to contact you, please respond affirmatively to the statement (#11) about MEP on the Cover Sheet.

# **6.0 SUBMISSION OF APPLICATIONS**

#### **6.01 Deadline for Applications**

Phase II applications must be received no later than 11:59 p.m. Eastern Time, Monday, June 7, 2021. Only electronic applications submitted via Grants.gov will be accepted.

Applicants should be aware, and factor in their application submission planning, that the Grants.gov system closes periodically for routine maintenance. Applicants should visit Grants.gov for information about any scheduled closures.

Applicants are cautioned to be careful of unforeseen delays that can cause late arrival of applications, with the result that they **will not** be forwarded for evaluation.

Applications not received by the specified due date and time, as recorded by Grants.gov, or that do not adhere to the other requirements of this NOFO (*see* Section 4.02 Screening Criteria and Section 8.01 Required Forms and Documents) will not be considered.

NIST strongly recommends that applicants do not wait until the last minute to submit an application. NIST will not make allowance for any late submissions. To avoid any potential processing backlogs due to last minute Grants.gov registrations, applicants are highly encouraged to begin their Grants.gov registration process early. No extensions will be granted.

When developing your submission timeline, please keep in mind that (1) all applicants are

required to have current registrations in the System for Award Management (SAM.gov) and Grants.gov; (2) the free annual registration process in the electronic System for Award Management (SAM.gov) (see Section 6.03.(1.).b) of this NOFO) generally takes between three and five business days but can take more than three weeks; and (3) applicants will receive a series of e-mail messages from Grants.gov over a period of up to two business days before learning whether a Federal agency's electronic system has received its application. Please note that a federal assistance award cannot be issued if the designated recipient's registration in the System for Award Management (SAM.gov) is not current at the time of the award.

Applicants will find instructions on registering with SAM.gov as part of the Grants.gov process at: <a href="http://www.grants.gov/web/grants/applicants/organization-registration.html">http://www.grants.gov/web/grants/applicants/organization-registration.html</a>.

## **6.02 Standard Application Package**

The standard application package, consisting of the standard forms, i.e., SF-424 (R&R), CD-511, Research and Related Other Project Information, SF-LLL (if applicable), and Research & Related Subaward Budget is available at <a href="https://www.grants.gov">www.grants.gov</a>.

Please see Section 8.01 for a complete list of required forms and documents.

# **6.03 Application Submission**

Applications must be submitted electronically through Grants.gov at <a href="www.grants.gov">www.grants.gov</a>. Paper applications or applications submitted by other electronic means will not be accepted. Supplementary material, revisions, substitutions, audio or video tapes, or computer storage media or devices will **not** be accepted. While applicants may not submit replacement pages or missing documents once an application has been submitted, an applicant may submit a complete, new application including such information by the required deadline. Applications are limited to one proposal per SBC. The last application received in Grants.gov will be used for evaluation.

- (1) Applications must be submitted via Grants.gov at <a href="www.grants.gov">www.grants.gov</a>, under announcement 2021-NIST-SBIR-02.
- a) Applicants should carefully follow specific Grants.gov instructions to ensure the attachments will be accepted by the Grants.gov system. A receipt from Grants.gov indicating an application is received does not provide information about whether attachments have been received. Attachment files names should be kept as short as

possible due to potential file corruption after the addition of extensions by Grants.gov. For further information or questions regarding the electronic application process for the 2021-NIST-SBIR-02 announcement, e-mail at grants@nist.gov.

b) Applicants are strongly encouraged to start early and not wait until the approaching due date before logging on and reviewing the instructions for submitting an application through Grants.gov. The Grants.gov registration process must be completed before a new registrant can apply. If all goes well, the registration process takes three (3) to five (5) business days. If problems are encountered, the registration process can take three (3) weeks or more. Applicants must have a valid unique entity identifier number and must maintain a current registration in the Federal government's primary registrant database, the System for Award Management (<a href="https://www.sam.gov/SAM/">https://www.sam.gov/SAM/</a>), as explained on the Grants.gov website. See also Section 8.04 of this NOFO. After registering, it may take several days or longer from the initial log-on before a new Grants.gov system user can submit an application. Only authorized individuals(s) will be able to submit an application, and the system may need time to process a submitted application. Applicants should save and print the proof of submission they receive from Grants.gov. If problems occur while using Grants.gov, the applicant is advised to (a) print any error message received and (b) call Grants.gov directly for immediate assistance. If calling from within the United States or from a U.S. territory, please call 800-518-4726. If calling from a place other than the United States or a U.S. territory, please call 606-545-5035. Assistance from the Grants.gov Help Desk will be available around the clock every day, with the exception of Federal holidays. Help Desk assistance will resume at 7:00 a.m. Eastern Time the day after Federal holidays. For assistance using Grants.gov, you may also contact <a href="mailto:support@grants.gov">support@grants.gov</a>.

c) To find instructions on submitting an application on Grants.gov, Applicants should refer to the "Applicants" tab in the banner just below the top of the <a href="http://www.grants.gov">http://www.grants.gov</a> home page. Clicking on the "Applicants" tab produces two exceptionally useful sources of information, Grant Applications and Applicant Resources, which applicants are advised to review.

Applicants will receive a series of e-mail messages over a period of up to two business days before learning whether a Federal agency's electronic system has received its application. Closely following the detailed information in these subcategories will increase the likelihood of acceptance of the application by the Federal agency's electronic system.

Applicants should pay close attention to the guidance under "Applicant FAQs," as it contains information important to successful submission on Grants.gov, including essential details on the naming conventions for attachments to Grants.gov applications.

The <u>Grants.gov Online Help</u> site provides vital information on checking the status of applications. See especially the "Check Application Status" option, found by clicking first on Applicants, and then by clicking on Grant Applications.

The application must be both received and validated by Grants.gov. The application is "received" when Grants.gov provides the applicant a confirmation of receipt and an application tracking number. If an applicant does not see this confirmation and tracking number, the application has not been received. After the application has been received, it must still be validated. During this process, it may be "validated" or "rejected with errors." To know whether the application was rejected with errors and the reasons why, the applicant must log in to Grants.gov, select "Applicants" from the top navigation, and select "Track my application" from the drop-down list. If the status is "rejected with errors," the applicant may still seek to correct the errors and resubmit your application before the deadline. If the applicant does not correct the errors, the application will not be forwarded to NIST by Grants.gov.

NIST uses the Tracking Numbers assigned by Grants.gov and does not issue Agency Tracking Numbers.

Applicants should be aware that adequate time must be factored into applicants' schedules for delivery of their application. Submitters are advised that volume on Grants.gov may be extremely heavy leading up to the deadline date.

Refer to important information in Section 6.01 Deadline for Applications, to help ensure your application is received on time.

Any amendments to this NOFO will be announced through Grants.gov. Applicants can sign up for Grants.gov NOFO amendments or may request copies from J'aime Maynard by telephone at 301- 975-8408, or by e-mail to jmaynard@nist.gov.

# 7.0 SCIENTIFIC AND TECHNICAL INFORMATION SOURCES

Background information related to the NIST research programs referenced within the research areas may be found within the NIST website at: <a href="www.nist.gov">www.nist.gov</a>. The NIST Research Library, <a href="https://www.nist.gov/nist-research-library">https://www.nist.gov/nist-research-library</a>, may also provide valuable scientific and technical information resources. A listing of NIST-developed technologies is available on the Federal Laboratory Consortium's (FLC) website

#### 8.0 SUBMISSION FORMS AND CERTIFICATIONS

#### 8.01 Required Forms and Documents

Applicants should review the following list carefully to ensure the proposal includes all required forms and documents. Failure to include any of the applicable listed forms and/or documents will result in rejection of the proposal without consideration. All required forms and documents must be complete. Please also review Section 4.02 Phase II Screening Criteria. Guidelines provided below are based on frequently asked questions and are not intended to be comprehensive – all forms must be fully completed. A complete application contains the following forms and documents:

**1. SF-424 (R&R), Application for Federal Assistance.** The SF-424 (R&R) must be signed by an authorized representative of the applicant organization.

For SF-424 (R&R), items 5, 14, and 19, use the Zip Code +4 format (##### - ####) when addresses are called for.

For SF-424 (R&R), item 16, the NIST SBIR Program is not covered by that Executive Order.

For SF-424 (R&R), item 17, the list of certifications and assurances is contained in the Federal Financial Assistance Certifications and Representations (Certs and Reps) as part of the SAM.gov entity registration.

For SF-424 (R&R), item 18, if the SF-LLL, Disclosure of Lobbying Activities form (item 6. below) is applicable, attach it to field 18.

Instructions for filling in the SF-424 (R&R) can be found on Grants.gov, as well as in the NIST Grants Management Division SF-424 Research and Related (R&R) Application Package Guidance.

**2.** Research & Related Budget (Total Fed + Non-Fed). The budget should reflect anticipated expenses for the full term of the project, considering all potential cost increases, including cost of living adjustments.

The budget should be detailed in these categories:

- A. Senior/Key Person;
- B. Other Personnel;

- C. Equipment Description;
- D. Travel;
- E. Participant/Trainee Support Costs (not relevant to this competition);
- F. Other Direct Costs;
- G. Direct Costs (automatically generated);
- H. Indirect Costs;
- I. Total Direct and Indirect Costs (automatically generated);
- J. Fee;
- K. Total Costs and Fee (automatically generated);
- L. Budget Narrative and Justification document (item 8. below) should be attached to field L.

Instructions for completing the Research & Related Budget (Total Fed + Non-Fed) form can be found on Grants.gov, as well as in the NIST Grants Management Division <a href="SF-424">SF-424</a> Research and Related (R&R) Application Package Guidance.

- **3. CD-511, Certification Regarding Lobbying.** Enter "2021-NIST-SBIR-02" in the Award Number Field. Enter the title of the application used in field 11 of the SF-424 (R&R), or an abbreviation of that title, in the Project Name field.
- **4. Research and Related Other Project Information.** Answer the highlighted questions and use this form to attach the Cover Sheet, Technical Proposal, Commercialization Plan and Phase I Final Report (item (6) below); the Indirect Cost Rate Agreement (item (8) below); the SBA Company Registry Form (item (9) below); the Data Management Plan (item (10) below); the Research & Related Personal Data form(s) (item (12) below); the Current and Pending Support Form (item (13) below); the Compliance with SBIR Program Requirements, Applicant Fraud Awareness Training (item (14) below); and Letters of Commitment (item (15) below). Instructions for completing the Research and Related Other Project Information can be found on Grants.gov, as well as in the NIST Grants Management Division SF-424 Research and Related (R&R) Application Package Guidance.

Please note that the Project Summary/Abstract is not relevant to this competition. However, Grants.gov requires an attachment to field 7 of the Research and Related Other Project Information form to successfully pass through Grants.gov. Please attach a document to field 7 stating, "A Project Summary/Abstract is not relevant to this competition".

There are no separate documents required for field 9, "Bibliography & References Cited';

or for field 10, "Facilities & Other Resources;" or for field 11, "Equipment". Any details relating to these topics should be included in other documents and forms, if and as specified in this NOFO.

- 5. SF-LLL, Disclosure of Lobbying Activities (if applicable).
- 6. Cover Sheet (Appendix A) and Technical Proposal. Read Section 3.02 of this NOFO very carefully, and in its entirety, for directions on completing this section of the application. The Technical Content is limited to 15 pages, see Section 3.02. The Commercialization Plan and Phase I Final Report portions of the Technical Proposal do not count against the page limit see Sections 3.02.03 and 3.02.04.
- **7. Budget Narrative and Justification.** There is no set format for the Budget Narrative and Justification; however, the written justification should include the necessity and the basis for the cost, as described below. Proposed funding levels must be consistent with the project scope, and only allowable costs should be included in the budget. Information on cost allowability is available in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 C.F.R. Part 200 (<a href="http://go.usa.gov/SBYh">http://go.usa.gov/SBYh</a>), which apply to awards in this program. If requested, include TABA funds (see Section 5.12) in the Budget Narrative and Justification.

The Budget Narrative and Justification must be attached to the Research & Related Budget (Total Fed + Non-Fed) and it does not count against the 15-page limit of the Technical Proposal.

Information needed for each budget category is as follows (categories not listed are automatically generated by the form or are not relevant to this competition):

(a) **Senior/Key Person** – At a minimum, the budget justification should include the following: name, job title, commitment of effort on the proposed project in terms of average number of hours per week or percentage of time, salary rate, total direct charges on the proposed project, description of the role of the individual on the proposed project, and the work to be performed.

Fringe benefits should be identified separately from salaries and wages and based on rates determined by organizational policy. The items included in the fringe benefit rate (e.g., insurance, parking, etc.) should not be charged under another cost category.

(b) Other Personnel – Data is requested at the project role level, and not at the individual level for Other Personnel. The budget justification should include the following: job title, commitment of effort on the proposed project in terms of average number of hours per week or percentage of time, salary rate, total direct charges on the proposed project, description of the role of the position on the proposed project and the work to be performed.

Fringe benefits should be identified separately from salaries and wages and based on rates determined by organizational policy. The items included in the fringe benefit rate (e.g., health insurance, parking, etc.) should not be charged under another cost category.

(c) Equipment Description – Equipment is defined as an item of property that has an acquisition cost of \$5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. The budget justification should list each piece of equipment, the cost, and a description of how it will be used and why it is necessary to the successful completion of the proposed project. Please note that any general use equipment (computers, etc.) charged directly to the award should be allocated to the award according to expected usage on the project (i.e. prorated cost). Applicants should provide at least two (2) quotes, if available, for equipment costing \$25,000 or more. If two (2) quotes are not available.

Any items that do not meet the threshold for equipment can be included under the Materials and Supplies line item in Section F, Other Direct Costs.

(d) Travel — For all travel costs, required by the recipient to complete the project, including attendance at any relevant conferences, the budget justification for travel should include the following: destination; names or number of people traveling; dates and/or duration; mode of transportation, lodging and subsistence rates; and description of how the travel is directly related to the proposed project. For travel that is yet to be determined, please provide best estimates based on prior experience. If a destination is not known, an approximate amount may be used with the assumptions given for the location of the meeting.

- (f) Other Direct Costs For costs that do not easily fit into the other cost categories, please list the cost, and the breakdown of the total costs by quantity or unit of cost. Include the necessity of the cost for the completion of the proposed project. Only allowable costs can be charged to the award.
  - Each subaward or contractual cost should be treated as a separate item in the Other Direct Costs category. Describe the services to be provided and the necessity of the subaward or contract to the successful performance of the proposed project. Contracts are for obtaining goods and services. Subawardees perform part of the project scope of work. For each subaward, applicants must provide budget detail justifying the cost of the work performed on the project.
- (h) Indirect Costs Commonly referred to as Facilities & Administrative Costs, Indirect Costs are defined as costs incurred by the applicant organization that cannot otherwise be directly assigned or attributed to a specific project. For more details, see Section 8.01(9) of this NOFO.
- (j) **Fee** Profit or fee not to exceed 7% of the sum of the direct and indirect costs must be listed in this cost category if included in the proposed budget.
- 8. Indirect Cost Rate Agreement. If indirect costs are included in the proposed budget, provide a copy of the approved negotiated agreement if this rate was negotiated with a cognizant Federal audit agency. If a rate has not been established, provide a statement to this effect and a computation for the cost in the budget narrative. Applicants without an established rate may propose estimated indirect costs at a rate not to exceed 40 percent of the total direct costs and will not be required to provide further justification if selected for an award. Applicants without an established rate who propose a rate exceeding 40% may request negotiation of an indirect cost rate agreement. Any profit or fee requested is not considered a direct cost for the purpose of the indirect cost base calculation.
- 9. SBA Company Registry Form. SBA maintains and manages a Company Registry at <a href="http://www.sbir.gov/registration">http://www.sbir.gov/registration</a> to track ownership and affiliation requirements for all companies applying to the SBIR Program. The SBIR/STTR Policy Directive requires each Phase II applicant to register in the Company Registry prior to submitting an application. The applicant must save its information from the registration in a .pdf document. Attach this document to the Research and Related Other Project Information form as described in Section 8.02.

**10. Data Management Plan.** Consistent with NIST Policy 5700.00<sup>3</sup>, *Managing Public Access to Results of Federally Funded Research*, and NIST Order 5701.00<sup>4</sup>, *Managing Public Access to Results of Federally Funded Research*", applicants proposing projects that include the conduct of research must include a Data Management Plan (DMP).

All applications for activities that will generate scientific data using NIST funding are required to adhere to a DMP or explain why data sharing and/or preservation are not within the scope of the project. For the purposes of the DMP, NIST adopted the definition of "research data" at 2 C.F.R. § 200.315(e)(3).

The DMP must include, at a minimum, a summary of proposed activities that are expected to generate data; a summary of the types of data expected to be generated by the identified activities; a plan for storage and maintenance of the data expected to be generated by the identified activities, including after the end of the award's period of performance; and a plan describing whether and how data generated by the identified activities will be reviewed and made available to the public.

A template for the DMP, an example DMP, and the rubric against which the DMP will be evaluated for sufficiency is available at <a href="https://www.nist.gov/open/information-awardees">https://www.nist.gov/open/information-awardees</a>. An applicant is not required to use the template as long as the DMP contains the required information.

If an application stands a reasonable chance of being funded and the DMP is determined during the review process to be insufficient, the program office may reach out to the applicant to resolve deficiencies in the DMP. If an award is issued prior to the deficiencies being fully rectified, the award will include a Specific Award Condition (SAC) stating that no research activities shall be initiated or costs incurred for those activities under the award until the NIST Grants Officer amends the award to indicate the SAC has been satisfied.

Reasonable costs for data preservation and access may be included in the application.

**11. Subaward Budget Form.** The Research & Related Subaward Budget Attachment Form is required if sub-recipients and contractors are included in the application budget.

Instructions for completing and attaching subaward budget forms are available by

<sup>&</sup>lt;sup>3</sup> https://www.nist.gov/system/files/documents/2018/06/19/final p 5700.pdf

<sup>&</sup>lt;sup>4</sup> https://www.nist.gov/system/files/documents/2019/11/08/final\_o\_5701\_ver\_2.pdf

visiting the R & R Family section of the Grants.gov Forms Repository and scrolling down to the R & R Subaward Budget Attachment(s) Form and selecting "Instructions."

- **12. Research & Related Personal Data**. Answer the highlighted questions. Complete and print the form available at <a href="https://www.grants.gov/forms/r-r-family.html">https://www.grants.gov/forms/r-r-family.html</a>. Attach this document to the Research and Related Other Project Information form as described in Section 8.02.
- 13. Current and Pending Support Form. Any application that includes investigators, researchers, and key personnel must identify all sources of current and potential funding, including this proposal. Any current project support (e.g., Federal, state, local, public or private foundations, etc.) must be listed on this form. The proposed project and all other projects or activities requiring a portion of time of the Principal Investigator (PI), co-PI, and key personnel must be included, even if no salary support is received. The total award amount for the entire award period covered, including indirect costs, must be shown as well as the number of person-months per year to be devoted to the project, regardless of the source of support. Similar information must be provided for all proposals already submitted or that are being submitted concurrently to other potential funders.

Applicants must complete the Current and Pending Support Form, using multiple forms as necessary to account for all activity for each individual identified in the PI, co-PI and key personnel roles. A separate form should be used for each identified individual.

Applicants must download the Current and Pending Support Form from the NIST website at <a href="https://www.nist.gov/oaam/grants-management-division/current-and-pending-support">https://www.nist.gov/oaam/grants-management-division/current-and-pending-support</a> and reference the guidance provided as it contains information to assist with accurately completing the form.

- **14. Compliance with SBIR Program Requirements, Applicant Fraud Awareness Training Certificate of Training Completion**. Complete the training at: <a href="https://www.nist.gov/file/384881">https://www.nist.gov/file/384881</a>. After completion, print and fill out the last page of the training presentation. Attach this document to the Research and Related Other Project Information form as described in Section 8.02.
- 15. Letters of Commitment. Letters must be submitted by all funded and unfunded

entities, including TABA providers, that will have an active role in executing the activities outlined in the Project Narrative. Letters of Commitment must address the level of participation, qualifications of the personnel who will be actively involved, and how successful completion of this project would positively impact their profession or community. Letters of Commitment must also specify any voluntary committed cost-share, including the specific services and/or products to be used in the project. Letters of Commitment must be signed by an individual with authority to legally bind the organization to its commitment. Letters of commitment do not count against the specified page limits.

# 8.02 Attachment of Required Application Documents

Items 8.01.1 through 8.01.4 above are part of the standard application package in Grants.gov and can be completed through the download application process.

Item 8.01.5, the SF-LLL, Disclosure of Lobbying Activities form, is an optional application form which is part of the standard application package in Grants.gov. If item 8.01.5, the SF-LLL, Disclosure of Lobbying Activities form is applicable to this proposal, attach it to field 18 of the SF-424 (R&R), Application for Federal Assistance.

Item 8.01.6, the Cover Sheet, Technical Proposal, Commercialization Plan and Phase I Final Report, should be attached to field 8 (Project Narrative) of the Research and Related Other Project Information form by clicking on "Add Attachment".

Item 8.01.7, the Budget Narrative and Justification, should be attached to field L (Budget Justification) of the Research and Related Budget (Total Fed + Non-Fed) form by clicking on "Add Attachment".

Items 8.01.8, the Indirect Cost Rate Agreement; 8.01.9, the SBA Company Registry Form; 8.01.10, the Data Management Plan; 8.01.12, the Research & Related Personal Data; 8.01.13, the Current and Pending Support Form; 8.01.14, the SBIR Applicant Fraud Awareness Training Certificate of Training Completion; and 8.01.15 Letters of Commitment, must be attached by clicking on "Add Attachments" found in item 12 (Other Attachments) of the Research and Related Other Project Information form.

Item 8.01.11, the Subaward Budget Form(s), if applicable to the submission, should be attached to the Research & Related Subaward Budget (Total Fed + Non-Fed)
Attachment(s) Form in the application package.

Following these directions will create zip files which permit transmittal of the documents electronically via Grants.gov.

# 8.03 Verifying the Submission and Tracking the Application

Applicants should carefully follow specific Grants.gov instructions at <a href="www.Grants.gov">www.Grants.gov</a> to ensure the attachments will be accepted by the Grants.gov system. A receipt from Grants.gov indicates only that an application was transferred to a system. It does not provide details concerning whether all attachments (or how many attachments) transferred successfully. Attachment file names should be kept as short as possible due to potential file corruption after the addition of extensions by Grants.gov. Applicants will receive a series of e-mail messages over a period of up to two business days before learning whether a Federal agency's electronic system has received its application.

Applicants are strongly advised to use Grants.gov's "Download Submitted Forms and Applications" option to check that their application's required attachments were contained in their submission.

After submitting the application, check the status of your application here: <a href="CHECK"><u>CHECK</u></a>
<a href="APPLICATION STATUS">APPLICATION STATUS</a>. If any, or all, of the required attachments are absent from the submission, follow the attachment directions found above, resubmit the application, and check again for the presence of the required attachments.

## If the directions found at

https://www.grants.gov/help/html/help/index.htm#t=GetStarted%2FGetStarted.htm are not effective, please contact the Grants.gov Help Desk immediately. If calling from within the United States or from a U.S. territory, please call 800-518-4726. If calling from a place outside the United States or a U.S. territory, please call 606-545-5035. E-mails should be addressed to <a href="mailto:support@grants.gov">support@grants.gov</a>. Assistance from the Grants.gov Help Desk will be available around the clock every day, with the exception of Federal holidays. Help Desk service will resume at 7:00 a.m. Eastern Time the day after Federal holidays.

Applicants can track their submission in the Grants.gov system by following the procedures at the Grants.gov site (<a href="http://go.usa.gov/cjamz">http://go.usa.gov/cjamz</a>). It can take up to two business days for an application to fully move through the Grants.gov system to NIST. NIST uses the Tracking Numbers assigned by Grants.gov, and does not issue Agency Tracking Numbers.

8.04 Unique Entity Identifier and System for Award Management (SAM)

Pursuant to 2 C.F.R. Part 25, applicants and recipients (as the case may be) are required to: (i) be registered in SAM before submitting its application; (ii) provide a valid unique entity identifier in its application; and (iii) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency, unless otherwise excepted from these requirements pursuant to 2 C.F.R. § 25.110. NIST will not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time that NIST is ready to make a Federal award pursuant to this NOFO, NIST may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

#### 9.0 RESEARCH AREAS

The NIST research programs work at the frontiers of measurement science to ensure that the U.S. system of measurements is firmly grounded in sound scientific and technical principles. Today, the NIST laboratories address increasingly complex measurement challenges, ranging from the very small (nanoscale devices for advanced computing) to the very large (vehicles and buildings), and from the physical (resilient infrastructure) to the virtual (cybersecurity and data science). As new technologies develop and evolve, NIST's measurement research and services remain central to national defense, homeland security, trade and innovation.

NIST's research activities provide industry, academia and other federal agencies with worldclass research capabilities in measurement science that form the foundation of the global system of weights and measures and enable innovation. NIST provides measurement tools and standards to strengthen U.S. competitiveness and security in the following areas:

## **Advanced Communications, Networks and Scientific Data Systems**

NIST's Advanced Communications, Networks and Scientific Data Systems activities enable secure, reliable, high-speed wireless and wireline communications critical to U.S. economic competitiveness, safety and security. NIST measurement science research and support for the development of standards accelerates the deployment of next-generation communication technologies needed for commercial- scale use of connected vehicles, "internet of things" (IoT) applications, drones and future artificial intelligence/machine learning-based systems. NIST is committed to helping solve the measurement and validation challenges of these fast-moving fields to help the U.S. achieve and maintain global leadership in these areas.

# **Advanced Manufacturing and Material Measurements**

NIST has partnered with the U.S. manufacturing sector for more than a century and has a proven track record of delivering useful tools and technical assistance to existing manufacturers and aspiring start-ups. NIST's Advanced Manufacturing and Material Measurements activities provide industry with precision measurement technologies, tests, protocols and world-class scientific and engineering knowledge through targeted research across a broad portfolio, including advanced materials development, advanced sensing, biomanufacturing and smart manufacturing systems. NIST's efforts in advanced manufacturing and material measurements rely on three major mechanisms: partnerships with manufacturers, development of physical and information standards, and development of new measurement capabilities.

## **Cybersecurity and Privacy**

NIST's Cybersecurity and Privacy activities strengthen the security of the digital environment through a portfolio bridging foundational and applied cybersecurity research, and through the development of publicly available standards and technical guidance. NIST's sustained outreach efforts support the effective application of standards and best practices enabling the adoption of practical cybersecurity and privacy. Through internal research and collaboration with the private sector, academia, standards development organizations, other government agencies and national and international stakeholders, NIST addresses the nation's current and future measurement science needs and is responsive to Congressional mandates and Executive Orders.

#### Fundamental Measurement, Quantum Science and Measurement Dissemination

At the heart of NIST's mission is the dissemination of the fundamental units of measurement (the International System of Units, or SI). NIST determines the definitive methods for nearly every kind of measurement employed in commerce and research, provides NIST-traceable calibrations, and disseminates standards and best practices throughout the nation. Staying ahead of the increasingly challenging demands of U.S. industry requires that NIST push the frontiers of measurement science by devising new tools and techniques—especially at the quantum scale where the rules of classical physics do not apply. Through balanced and coordinated programs, NIST leads the world in disseminating the fundamental units of measurement. This leadership in metrology advancement directly impacts NIST's relevance and leadership in measurement services.

### **Health and Biological Systems Measurements**

NIST provides a solid foundation of measurement assurance enabling reproducibility of biomedical research results and confidence in clinical decision-making and ensuring the efficacy and safety of treatments. As a nonregulatory agency, NIST's research plays an essential role in health and bioscience innovations, including in precision medicine, engineering biology, medical imaging, regenerative medicine and our understanding of the microbiome and how it affects health. New and improved measurement capabilities advance our understanding of biology and provide the basis for industries to harness this information for future medical technologies.

# **Physical Infrastructure and Resilience**

NIST's Physical Infrastructure and Resilience activities support the safety, interoperability and resilience of the nation's infrastructure at the component, structure and system levels. NIST's research supports the development of building codes making the built environment healthier for occupants, more resilient against hazards, and safer for both residents and first responders. In collaboration with policymakers, building officials and planning groups, NIST produces guides to help communities integrate resilience into their economic development, zoning, mitigation and other local planning activities impacting buildings, public utilities and infrastructure systems.

## **Exploratory Measurement Science**

NIST's mission requires deep expertise in a broad range of disciplines. To best position NIST to support U.S. technological interests well into the future, it is essential that NIST maintain a portfolio of exploratory measurement science research programs. NIST invests in higher-risk and potentially transformative measurement science research to stay on the cutting edge of technology trends.

# **Appendix A. COVER SHEET**

(A fillable version of the Cover Sheet is available at <a href="http://www.nist.gov/sbir">http://www.nist.gov/sbir</a>)

# Application to National Institute of Standards and Technology (NIST) Small Business Innovation Research (SBIR) Program Phase II 2021-NIST-SBIR-02 (June 7, 2021)

Cover Sheet						
Name & Address of Submitting Firm:						
Project Title						
Principal PI Title Investigator (PI) Name						
PI Phon	ne#		PI E-mail			
	NIST may verify	the following responses with	information prov	ided elsewhere in your application or by i	ndependent sources	i.
THE AP	PPLICANT CER	TIFIES THAT:				
1.		It is a small business concern (SBC) and meets the definition as stated in this Notice of Funding				
2.	The primary emp		vith the SBC at th	ne time of award and during the	☐ Yes	□ No
3.	3. A minimum of either two-thirds for Phase I or one-half for Phase II of the research will be performed by the SBC as determined by data provided in the Budget Narrative. See NOFO Section 1.03.01 for details on funding determination.			□ No		
4. The applicant and/or PI ☐ has / ☐ has not submitted applications for essentially equivalent work under other Federal program FFOs and ☐ has / ☐ has not received other Federal awards for essentially equivalent work. If "has", what agency? Click here to enter text. See NOFO Section 3.02.02(14) for additional details that must be provided.						
5.						
6.	The applicant qu	applicant qualifies as a woman-owned SBC and meets the definition as stated in this NOFO.			□ No	
7.		applicant qualifies as a HUBZone-owned SBC and meets the SBA's definition (see o://www.sba.gov/hubzone).		☐ Yes	□ No	
8.	Year SBC founde	SBC founded:		Click here to enter text.		
9.	Number of Empl	oyees:			Click here to	enter text.
STATEME	NTS:					
10. 7	number of the co	orporate official of your co	ncern, if your ap economic devel	name, address, and telephone plication does not result in an opment organizations that may	☐ Yes	□ No
11.	Manufacturing E contact informat	xtension Partnership (MEP ion will be provided to NIS ousiness-related support se	r) after awards h T MEP. If so, you	e to be provided to the NIST ave been announced. If 'Yes' your u will be contacted by your local d benefit the potential of the	□ Yes	□ No

Signature of Company Official and typed name, title, address, telephone number, and date		
Signature of Principal Investigator		
and typed name, title, address, telephone number, and date		
TECHNICAL ABSTRACT (limit to 200 words):		
POTENTIAL COMMERCIAL APPLICATION OF THE RESEARCH: (limit to 100 words)		
OTHER INFORMATION:		

Information contained in unsuccessful applications will remain the property of the applicant. The Federal Government may, however, retain copies of all applications. Public release of information in any application submitted will be subject to existing statutory and regulatory requirements Applicants are discouraged from submitting proprietary information unless the information is deemed essential for proper evaluation of the application. If proprietary information provided by an applicant in a proposal constitutes trade secret, proprietary commercial or financial information, confidential personal information, or data affecting national security, 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 award 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 number 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.

The use of any other legend is unacceptable to the Government and may constitute grounds for removing the application from further consideration without assuming any liability for inadvertent disclosure.

This collection of information contains Paperwork Reduction Act (PRA) requirements approved by the Office of Management and Budget (OMB). Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA unless that collection of information displays a currently valid OMB control number. Public reporting burden for this collection is estimated to be 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any aspect of this collection of information, including suggestions for reducing this burden, to the National Institute of Standards and Technology, Attn: Mary Clague, 100 Bureau Dr., MS 2200, Gaithersburg, MD 20899.

OMB Control No. 0693-0072 Expiration Date: 1/31/2024

# **Appendix B. CERTIFICATIONS**

# SBIR Funding Agreement Certification (at time of award)

All small businesses that are selected for award of an SBIR 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 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 C.F.R. 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), who 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 questions must be responded to</u> by checking the appropriate box):

The Awardee business concern meets the ownership and control requirements set forth in 13
C.F.R. § 121.702.
□Yes □No

(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 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 include evidence that the corporation meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.
(3) If a partnership, the partnership agreement evidences that it meets the ownership and control requirements set forth in 13 C.F.R. § 121.702.  ☐ Yes ☐ No ☐ 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 C.F.R. § 121.702.  □Yes □No □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.  Yes □No □N/A Explain why N/A:
(6) The Awardee business concern has no more than 500 employees, including the employees of its affiliates.  □Yes □No
(7) SBA has not issued a size determination currently in effect finding that this business concern exceeds the 500 employee size standard. $\Box$ Yes $\Box$ No
(8) During the performance of the award, the principal investigator will spend more than one half of his/her time (based on a 40 hour workweek) as an employee of the awardee or

has requested and received a written deviation from this requirement from the funding agreement officer.
☐ Yes ☐ No ☐ Deviation approved in writing by funding agreement officer:%
<ul> <li>(9) All, essentially equivalent work, or a portion of the work proposed under this project (check the applicable line):</li> <li>☐ Has not been submitted for funding to this agency or another Federal agency.</li> <li>☐ 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.</li> <li>☐ A portion has been funded by another grant, contract, or subcontract as described in detail in the application and approved in writing by the funding agreement officer.</li> </ul>
<ul> <li>(10) During the 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 the applicable line and fill in if needed):</li> <li>□SBIR Phase I: at least two-thirds (66 2/3%) of the research.</li> <li>□SBIR Phase II: at least half (50%) of the research.</li> <li>□Deviation approved in writing by the funding agreement officer:%</li> </ul>
<ul> <li>(11) During performance of award, the research/research and development will be performed in the United States unless a deviation is approved in writing by the funding agreement officer.</li> <li>□Yes</li> <li>□No</li> <li>□Waiver has been granted</li> </ul>
(12) During performance of award, the research/research and development will be performed at the Awardee's facilities with the Awardee's employees, except as otherwise indicated in the SBIR application and approved in the funding agreement. $\Box$ Yes $\Box$ No
(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.  ☐ Yes ☐ No ☐ N/A Explain why N/A:
(14)The SBIR Awardee is a Covered Small Business Concern (a small business concern 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 vent companies, hedge funds, or private equity firms). $\Box$ Yes $\Box$ No	ure capital operating
(15) The SBIR Awardee will notify this agency immediately if all or authorized and funded under this award is subsequently funded by $\Box$ Yes $\Box$ No	•
(16) I understand that the information submitted may be given to F local agencies for determining violations of law and other purposes $\square$ Yes $\square$ No	
(17) I am an officer of the business concern authorized to represent certification on its behalf. By signing this certification, I am represe and on behalf of the business concern that the information provide application, and all other information submitted in connection with and correct as of the date of submission. I acknowledge that any interpresentation of the information contained in this certification or administrative sanctions, including but not limited to: (1) fines, reimprisonment under 18 U.S.C. § 1001; (2) treble damages and civil procure (31 U.S.C.§ 3729 et seq.); (3) double damages and civil procure (31 U.S.C.§ 3801 et seq.); (4) civil recover suspension and/or debarment from all Federal procurement and not transactions (FAR Subpart 9.4 or 2 C.F.R. Part 180); and (6) other addincluding termination of SBIR/STTR awards.	enting on my own behalf, d in this certification, the this application, is true tentional or negligent may result in criminal, civil estitution and/or penalties under the False enalties under the Program y of award funds, (5) conprocurement
Signature	Date//
Print Name (First, Middle, Last)	
Title	
Business Name	

# SBIR Funding Agreement Certification (Life-Cycle Certification)

All SBIR 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 (<u>all questions must be responded to by checking the appropriate box</u>):

(1) The principal investigator spent more than one half of his/her time (based on a 40 hour workweek) as an employee of the awardee or the awardee has requested and received a written deviation from this requirement from the funding officer.	
☐ Yes ☐ No ☐ Deviation approved in writing by funding agreement officer:%	1
(2) All, essentially equivalent work, or a portion of the work performed 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 i the proposal and approved in writing by the funding agreement officer.	n

(3) Upon completion of the award the awardee will have performed the applicable percentage or 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):  □ SBIR Phase I: at least two-thirds (66 2/3%) of the research.  □ SBIR Phase II: at least half (50%) of the research.  □ Deviation approved in writing by the funding agreement officer:%
(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):  □ SBIR Phase I: at least two-thirds (66 2/3%) of the research.  □ SBIR Phase II: at least half (50%) of the research.  □ Deviation approved in writing by the funding agreement officer:%  □ N/A because work is not completed.
<ul> <li>(5) The research/research and development is performed in the United States unless a deviation is approved in writing by the funding agreement officer.</li> <li>□ Yes</li> <li>□ No</li> <li>□ Waiver has been granted</li> </ul>
(6) The research/research and development is performed at the awardee's facilities by the awardee's employees, except as otherwise indicated in the SBIR application and approved in the funding agreement. $\Box$ Yes $\Box$ No
(7) I will notify the Federal agency immediately if all or a portion of the work authorized and funded under this award is subsequently funded by another Federal agency. $\Box$ Yes $\Box$ No
(8) I understand that the information submitted may be given to Federal, State and local agencies for determining violations of law and other purposes. $\Box$ Yes $\Box$ No
(9) 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 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, restit	ution and,	or/	
imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil pena	lties unde	r the F	alse
Claims Act (31 U.S.C. § 3729 et seq.); (3) double damages and civil penal	ties unde	r the	
Program Fraud Civil Remedies Act (31 U.S.C. § 3801 et seq.); (4) civil rec	overy of a	ward f	unds,
(5) suspension and/or debarment from all Federal procurement and no	nprocuren	nent	
transactions (FAR Subpart 9.4 or 2 C.F.R. Part 180); and (6) other admini	strative p	enaltie	:S
including termination of SBIR/STTR awards.			
□ Yes □No			
Signature	Date	_/_	_/
Print Name (First, Middle, Last)			
Title			
Business Name			