



FY 2019

**Small Business Innovation Research
(SBIR) Program Phase I**

Notice of Funding Opportunity (NOFO)

ANNOUNCEMENT

FUNDING OPPORTUNITY NUMBER: 2019-NIST-SBIR-01

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: February 19, 2019

Closing Date: April 19, 2019

<http://www.nist.gov/sbir>

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**US DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
FY 2019 SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM
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 small businesses to submit Phase I research applications under this Notice of Funding Opportunity (NOFO). Science and technology-based firms with strong research capabilities in any of the areas listed in Section 9 of this NOFO are encouraged to participate. Applications must sufficiently identify and clearly address a specific NIST technical program area that falls within one of the research areas described in Section 9 (see Section 3.02.02(1)) or a NIST-patented technology available for licensing.

Only FY 2019 Phase I applications may be submitted in response to this NOFO. Phase II applications are not being accepted at this time. NIST publishes a Phase II NOFO approximately 30 days prior to the end of the previous year's Phase I period of performance to request Phase II applications. That NOFO provides instructions for Phase I awardees to prepare a Phase II application and the closing date for submission of applications; only the previous year's Phase I awardees are eligible to submit a Phase II application.

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 2019 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 small business concerns that participate in or conduct energy efficiency or renewable energy system R&D projects, consistent with Executive Order (EO) 13329 (<http://www.gpo.gov/fdsys/pkg/FR-2004-02-26/pdf/04-4436.pdf>) "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 Small Business Administration (SBA) SBIR Policy Directive, § 9, found at http://www.sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf.

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 small business concerns for innovation research. SBIR policy is provided by the SBA through the SBIR Policy Directive found at http://www.sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf.

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 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 (TABAs); see Section 5.11 for more information about TABAs.

1.02.02 Phase II - Research and Development

All Phase I awardees under this NOFO will be given the opportunity to submit a Phase II application following completion of Phase I. Instructions for Phase II application preparation and submission requirements will be published in an NOFO approximately 30 days prior to the end of the FY 2019 Phase I performance period to request FY 2020 Phase II applications.

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

Each applicant must qualify as a small business concern 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 I 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 (VCOs), hedge funds or private equity firms to participate in the SBIR Program. Therefore, applications in which work would be performed by VCOs will not be considered for award.

For Phase I, a minimum of two-thirds 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 may not exceed one-third of the total 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 may not exceed one-half of the total award.

Each applicant will be required to provide certain information via www.sbir.gov as well

as other information required by the SBIR Policy Directive (*see* Appendices V-VI), found at https://www.sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf. Each SBC applying for an award is required to update the appropriate information in the SBA Tech-Net 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

SBA maintains and manages a Company Registry at <http://www.sbir.gov/registration> to track ownership and affiliation requirements for all companies applying to the SBIR Program. **Each Phase I applicant must register in the Company Registry prior to submitting an application. The applicant must save its information from the registration in a .pdf document and append this document to the SF-424 form as described at the end of Section 8.01. of this NOFO.** All applicants are required to report and/or update their registration information in the SBA Company Registry prior to each SBIR application submission or if any information changes prior to an award.

1.03.03 Performance Benchmark Ratings Requirements

All Phase I applicants with a current SBA assessment of their *Phase I to Phase II Transition Rate* must at the time of the award have satisfied the requirements of that Performance Benchmark to be eligible for a new Phase I award. NIST will not consider proposals from firms that are currently ineligible for Phase I awards as a result of failing to meet the benchmark rate at the last assessment.

The *Phase I to Phase II Transition Rate* requirement applies only to SBIR Phase I applicants that have received more than 20 (21 or more) Phase I awards over the past 5 fiscal years (excluding the most recent year). For these applicants, the ratio of the number of Phase II awards (awarded during the past 5 fiscal years) to the number of Phase I awards (awarded during the past 5 years excluding the most recent year) must be at least 0.25. For the purposes of this NOFO, the applicable five fiscal year period is fiscal year 2013 to fiscal year 2017. On June 1st of each year, the SBA assesses the Performance Benchmark rates for all applicable SBIR and Small Business Technology Transfer (STTR) awardees in the Company Registry. STTR is another program that expands funding opportunities in the federal

innovation research and development arena. See <https://www.sbir.gov/about/about-sttr>. Performance Benchmark rates are based on a company's total SBIR/STTR awards, across all the participating agencies. Companies that fail to meet the Performance Benchmark requirements are not eligible to receive a Phase I award for a period of one year from the assessment: from June 1st through May 31st. Note that this does not affect a company's eligibility for Phase II or Phase III awards.

The **Commercialization Rate** is not applicable for FY 2019. When in effect, the **Commercialization Rate** requirement applies to SBIR and STTR Phase I applicants that have received more than 15 (16 or more) Phase II awards over the past 10 fiscal years, excluding the last two years. These companies must have realized, to date, an average of at least \$100,000 of sales and/or investments per Phase II award (awarded during this period) or have received a number of patents resulting from the SBIR work equal to or greater than 15% of the number of Phase II awards.

SBA sends three notifications each year to companies affected by the benchmark performance requirements:

- **February 1st** – SBA identifies and notifies via email all companies that, on that date, have won enough past awards to be subject to the benchmark requirements.
- **April 1st** – SBA runs a preliminary assessment to determine which companies appear to be failing a benchmark given the data in the system on that date. SBA sends a Warning Notice to these companies so that they can review the award in the Company Registry (SBIR.gov) and update as needed.
- **June 1st** – SBA identifies companies that fail a benchmark and notifies them that they may not be eligible to receive a new Phase I award for a period of one year.

NOTE: Before responding to this NOFO, all applicants should verify their *Transition Rate* eligibility for Phase I awards. When logged in to the Company Registry at <https://www.sbir.gov/registration>, awardees can view their last assessed *Transition Rate* by clicking on the “Performance Benchmark” side-bar. These company-specific rates appear under the heading “At Last Assessment.” A thumbs-up/thumbs-down indicator shows whether or not the company passed the benchmark rates at the last assessment. If at any time, a company believes the award information on SBIR.gov is not correct, it should notify SBA using the *dispute* link provided. If a company's dispute of the data used for the rates is under review, it will see “TBD” under the “At Last Assessment” heading. Companies with less than the threshold number of awards (21 Phase I awards for the Transition Rate) will see “N/A” displayed because the requirement did not apply to them.

Under the heading “Current (On-Going)”, the page displays a running calculation of the benchmark rates using the next years' time periods (each period moved up by one year) and current data in the system. Companies should monitor these rates to anticipate their

standing for each upcoming June 1 Assessment. Prior to proposal preparation, all applicants to this NOFO that have received more than 20 Phase I awards across all federal SBIR/STTR agencies over the past five (5) years should verify that their company will not have a failing status on the *Transition Rate* Benchmark at the time of award.

Performance Benchmarks: (General information on the Performance Benchmark requirements is available at <https://www.sbir.gov/performance-benchmarks>.)

1.04 Contact with NIST

Administrative questions may be submitted at the public Question and Answer site (<https://tsapps.nist.gov/sbir/default.aspx>).

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 5.12 of this NOFO.

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 Fax: (301) 975-3482 E-mail: mary.clague@nist.gov or J'aime Maynard Phone: (301) 975-8408 E-mail: jmaynard@nist.gov
Electronic Application Submission through Grants.gov	Leon Sampson Phone: (301) 975-3086 Fax: (301) 975-6368 E-mail: grants@nist.gov or Grants.gov

Subject Area	Point of Contact
	Phone: 800-518-4726 E-mail: support@grants.gov
Grant Rules and Regulations	Nuria Martinez Phone: (301) 975-6215 Fax: (301) 975-6368 E-mail: nuria.martinez@nist.gov

1.05 Definitions

Except as specifically noted by citation or reference, all definitions below are excerpted from the SBA SBIR Policy Directive, available at http://sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf.

Applicant – The organizational entity that qualifies as a Small Business Concern (SBC) at all pertinent times and that submits a contract proposal or a grant application for a funding agreement under the SBIR Program.

Awardee – The organizational entity that receives an SBIR Phase I, Phase II or Phase III award.

Commercialization - 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.

Cooperative Agreement - A financial assistance mechanism used when substantial Federal programmatic involvement with the awardee during performance is anticipated by the issuing agency. The Cooperative Agreement contains the responsibilities and respective obligations of the parties.

Contract – A mutually binding legal relationship obligating the seller to furnish equipment, goods or services and the buyer to pay for them.

Essentially Equivalent Work - 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.

Feasibility - The practical extent to which a project can be performed successfully.

Funding Agreement - 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, intensive study directed toward greater knowledge or understanding of the subject studied;
- (2) a systematic study directed specifically toward applying new knowledge to meet a recognized need; or
- (3) a systematic application of knowledge toward the production of useful materials, devices, services, or methods, and includes design, development, and improvement of prototypes and new processes to meet specific requirements.

SBIR Technical Data - All data generated during the performance of an SBIR award.

SBIR Technical Data Rights - The rights an SBIR awardee obtains in data generated during the performance of any SBIR Phase I, Phase II, or Phase III award that an awardee delivers to the Government during or upon completion of a Federally-funded project, and to which the Government receives a license.

Small Business Concern (SBC) – A concern that meets the requirements set forth in 13 C.F.R. § 121.702 (available at <http://www.gpo.gov/fdsys/granule/CFR-2011-title13-vol1.CFR-2011-title13-vol1-sec121-702>).

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.

Subaward – See 2 C.F.R. § 200.92.

Women-Owned Small Business (WOSB) - 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.

1.06 Fraud, Waste and Abuse

As defined in the SBIR 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 Program include, but are not limited to:

- (i) misrepresentations or material, factual omissions to obtain, or otherwise receive funding under, an SBIR award;
- (ii) misrepresentations of the use of funds expended, work done, results achieved, or compliance with program requirements under an SBIR award;
- (iii) misuse or conversion of SBIR award funds, including any use of award funds while not in full compliance with SBIR Program requirements, or failure to pay taxes due on misused or converted SBIR award funds;
- (iv) fabrication, falsification, or plagiarism in applying for, carrying out, or reporting results from an SBIR 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/online-hotline-complaint-form.aspx> send an e-mail to: Hotline@oig.doc.gov. **Note:** Because the Internet is not secure, it is possible, though unlikely, that e-mail complaints may be read by persons other than your intended source. If you are concerned about this, you may choose to call or mail. Contact information for the Office of Inspector General is available at: <https://www.oig.doc.gov/pages/Contact-U.s.aspx>. Please do not include Personally Identifiable Information (PII) through the website or via e-mail. 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. Web submissions and e-mails containing such information will be blocked by our system administrator and will not be processed by our Complaint Department. Should you desire to provide this information, please contact the Hotline by telephone at the numbers listed below.

Phone:

Toll Free 800-424-5197
In the DC metro area 202-482-2495
TTD Toll Free 855-860-6950
TTD in the DC metro area 202-482-5923

Mail:

Office of Inspector General
Complaint Intake Unit, Mail Stop 7886
1401 Constitution Avenue, N.W.
Washington, DC 20230

Fax:

855-569-9235

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).

On January 19, 2017, a final rule was published in the *Federal Register* that made significant amendments to the Common Rule: <https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects>. These amendments, known as the “2018 Requirements,” took effect on January 21, 2019. Any new award made by NIST after January 21, 2019 will be subject to the 2018 Requirements.

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

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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 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 <http://www.hhs.gov/ohrp/assurances/index.html>. 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 Human Subjects Protection Office (HSPO) reserves the right to conduct an administrative review¹ 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 HSPO) under 15 C.F.R. § 27.112 (Review by Institution). If the NIST HSPO determines that an

¹ Conducting an “administrative review” means that the NIST HSPO will review and verify the performing institution’s determination for research not involving human subjects or exempt human subjects research. In addition, for non-exempt human subjects research, the NIST HSPO will review and confirm that the research and performing institution(s) are in compliance with 15 C.F.R. Part 27, which means HSPO 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.

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 HSPO.

3) Required documents for proposal review. All applications involving human subjects research must clearly indicate, by separable task, all research activities believed to 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, and the performer of the activity or the supplier and/or the receiver of the information or biospecimens from human subjects **does not** 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, and the proposed performer of the activity has 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 signed (by the study principal investigator) 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 Human Subjects Protection Office (e-mail: anne.andrews@nist.gov; phone: (301) 975-5445).

2.03 Research Applications 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 5th Street, N.W., Department 285, Washington, DC 20055, or as a free PDF online at <http://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth>.

- 1) Administrative Review.** NIST reserves the right to conduct an administrative review² of all 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

² Conducting an “administrative review” means that the NIST HSPO 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. HSPO 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, 3) 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.

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 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 pre-existing 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.). A custom sample 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 (NMFS) 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 signed (by the Principal Investigator) 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.
5. 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: linda.schilling@nist.gov; phone: 301-975-2887).

2.04 Certifications Regarding Federal Felony and Federal Criminal Tax Convictions, Unpaid Federal Tax Assessments and Delinquent Federal Tax Returns

In accordance with Federal appropriations law, an authorized representative of the selected applicant(s) may be required to provide certain pre-award certifications regarding federal felony and federal criminal tax convictions, unpaid federal tax assessments, and delinquent federal tax returns.

3.0 APPLICATION PREPARATION INSTRUCTIONS AND REQUIREMENTS

3.01 Phase I Application Requirements

Only FY 2019 Phase I applications may be submitted in response to this NOFO. Phase II applications are not being accepted at this time. NIST publishes a Phase II NOFO approximately 30 days prior to the end of the previous year's Phase I period of performance to request Phase II applications. That NOFO provides instructions for Phase I awardees to prepare a Phase II application and the closing date for submission of applications. To reiterate, only the previous year's Phase I awardees are eligible to submit a Phase II application.

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 or a NIST-patented technology available for licensing. 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 (www.sbir.gov). 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 I Application

A complete application must include a Technical Proposal (described below) and all other forms and documents listed in Section 8.01. An applicant may submit multiple applications but each application must be clearly differentiated.

The Technical Proposal, both the Cover Sheet and Technical Content, is limited to 25 pages. The only exception to the 25-page limit is for applicants covered by the provision for Prior SBIR Phase II Awards (Section 3.02.02 (14)). Additional pages beyond the 25-page limit will not be considered in the evaluation process. 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, and**
- (b) Technical Content (3.02.02) pages 3 through 25.**

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 25-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 (www.nist.gov/tpo/small-business-innovation-research-program) and www.sbir.gov.

3.02.02 Technical Content

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

(1) NIST Program Area or NIST-Patented Technology Available for Licensing. The first paragraph of the proposal must describe a research project that addresses a current NIST technical program area falling within one of the research areas identified in Section 9.0 or utilizes a NIST-patented technology available for licensing; this paragraph must include the full URL of the NIST or Federal Laboratory Consortium (FLC) website that provides the source of the information for the program area or NIST-patented technology. A listing of NIST-patented technologies is available on the Federal Laboratory Consortium's (FLC) website (<https://www.federallabs.org/labs/national-institute-of-standards-and-technology-nist-0>).

(2) 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.

(3) Phase I Technical Objectives. State the specific objectives of the Phase I effort, including

the technical questions it will try to answer, to determine the feasibility of the proposed approach.

(4) Phase I Work Plan. Include a detailed description of the Phase I feasibility 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.

(5) 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.

(6) Key Individuals and Bibliography of Related Work. Identify key individuals involved in Phase I, 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.

(7) Relationship with Future R/R&D. Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort. Also state the anticipated commercial results of the proposed approach.

(8) Facilities and Equipment. A detailed description, availability, and location of instrumentation and physical facilities proposed for Phase I should be provided.

(9) 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 I, a minimum of two-thirds 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-third of the research and/or analytical effort in Phase I. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements may not exceed one-third 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 following definitions apply to this NOFO:

1. Consultant - A person outside the firm, named in the application as contributing to the research, must provide a signed statement confirming his/her availability, role in the project, and agreed consulting rate for participation in the project.
2. Contract - Similarly, where a contract is involved in the research, the contractor institution must furnish a letter signed by an appropriate official describing the programmatic arrangements and confirming its agreed participation in the research, with its proposed budget for this participation.
3. Subawards - As the funding instrument used in this program is financial assistance, an awardee might pass through funds to another organization to carry out part of the Federally-supported project. A “subaward” relationship fits the circumstances more appropriately than a contract when used to carry out part of the Federally-supported project. See 2 CFR §§ 200.92 (subaward), 200.93 (subrecipient), and 200.330 (Subrecipient and contractor determinations), respectively.

The subrecipient institution must furnish a letter signed by an appropriate official describing the programmatic arrangements and confirming its agreed participation in the research, with its proposed budget for this participation.

(10) Potential Commercial Application. A primary program goal is to provide opportunities for small businesses to convert research into technological innovation in the private sector. All proposed research should have a commercial outcome. Describe in detail the commercial potential of the proposed research, how commercialization would be pursued and potentially used by the private sector and/or the Federal Government. Include any optional letters of support and relevant supporting material such as references to journal articles, literature, or government publications. Provide any indicators of commercial potential and address the following:

- (a) Market opportunity – Describe the current and anticipated target market, the size of the market, and include a brief profile of the potential customer(s).
- (b) Technology and competition – Describe the competitive landscape, the value proposition and competitive advantage of the product or service enabled by the proposed innovation. Also include the critical milestones and pathway for commercial deployment of the proposed product or service.
- (c) Finances – Describe your strategy for financing the innovation beyond the SBIR award. Describe the existence of any outside, non-SBIR funding or partnering commitments

including any Phase II funding commitments from private sector or non-SBIR funding sources and/or the existence of Phase III follow-on commitments for the subject research.

(d) Benefits - Describe the anticipated commercial benefits of the resulting product or service.

(e) Experience -- Describe your record of commercializing SBIR or other research. Include any additional indicators of the commercial potential of the idea.

(11) 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 existing CRADA with any federal agency, including NIST, with the awardee. NIST will consider whether there is any overlap on a case by case basis.

(12) Guest Researcher. State if the applicant or any of its consultants, contractors, or subrecipients or their employees is a domestic or foreign guest researcher at NIST (see <http://www.nist.gov/tpo/collaborations/guestresearchers.cfm>), naming the sponsoring laboratory.

(13) Cost Sharing. Cost sharing is not required and is not considered during the evaluation process for Phase I applications.

(14) 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.

(15) Prior SBIR Phase II Awards. If the SBC has received more than 15 Phase II awards in the prior 5 fiscal years, the SBC must submit the following information in its Phase I application: name of the awarding agency; date of award; funding agreement number; amount of award; topic, subtopic, or research area title; follow-on agreement amount; source and date of commitment; and current commercialization status for each Phase II award. This required information will not be counted toward the 25-page Technical Proposal limitation.

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, and 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 I Screening Criteria

Please carefully read the entire NOFO and review the following Phase I Screening Criteria to

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assure that your application meets NIST requirements. Phase I applications that do not clearly satisfy all eight (8) 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 I application must include all required forms and documents listed in Section 8.01:

- i) SF-424, Application for Federal Assistance
- ii) SF424A, Budget Information – Non-Construction Programs
- iii) SF-424B, Assurances – Non-Construction Programs
- iv) CD-511, Certification Regarding Lobbying
- 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
- vii) Budget Narrative – 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) Research and Related Personal Data – see Section 8.01.11
- xii) Compliance with SBIR Program Requirements, Applicant Fraud Awareness Training – Certificate of Training Completion – see Section 8.01.12

(4) The Phase I total proposed project budget must not exceed \$100,000. Up to an additional \$6,500 may be requested for TABA. For Phase I, a minimum of two-thirds 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 may not exceed one-third of the total award (Section 1.03).

(5) The feasibility research duration for the Phase I project must not exceed 6 months.

(6) 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.

(7) The Phase I application must be submitted only under one of the research areas in Section 9 and must clearly address NIST research priorities as shown by identification of a NIST or FLC website. (Section 3.02.02 (1))

(8) The Phase I application must include a commercialization plan. (Section 3.02.02.(10))

4.03 Phase I Evaluation Criteria

Phase I 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 in accordance with the following weighted criteria for a maximum of 100 points. Reviewers will evaluate:

(1) The degree to which the proposed technical approach is comprehensive, feasible, and demonstrates a clear understanding of the research area. (20 points)

(2) The appropriateness of the qualifications and extent of the experience of the proposed principal/key investigators, supporting staff, and consultants as they relate to accomplishing the proposed research effort. In addition, reviewers will evaluate, as applicable, the extent to which the applicant has access to the facilities and equipment necessary to complete the proposed research. (5 points)

(3) The likelihood that the proposed research program will lead to a successful product or service with a viable pathway for commercial deployment as described in the commercialization plan. (30 points)

(4) The magnitude of the anticipated commercial benefits of the resulting product or service. (20 points)

(5) The extent to which the proposed commercial product or service relates to the goals of a NIST technical program and the NIST mission. (20 points)

(6) SBIR Programmatic priorities (5 points):

a) The extent to which the proposed project includes SBIR high priority areas of manufacturing-related and energy-efficiency research.

b) The extent of participation by women and socially and economically disadvantaged

SBCs, and SBCs from HUBZones or under-served states in the proposed project.

4.04 Phase I 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 participants and NIST program areas;
- (3) Applicants that have received fewer than 20 SBIR awards in the past;
- (4) Possible duplication of other federally-funded research; and
- (5) 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 administrative reviews, 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. Upon review of these factors, if appropriate, specific conditions that correspond to the degree of risk may be applied to an award.

In addition, prior to making an award where the total Federal share is expected to exceed the simplified acquisition threshold (currently \$150,000), 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 option, 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 special 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

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 October 9, 2018, is accessible at http://www.osec.doc.gov/oam/grants_management/policy/default.htm.

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 <http://go.usa.gov/hKkR>.

Contingent upon availability of funds, NIST anticipates making a total number of approximately twelve (12) Phase I awards with a project budget of no more than \$100,000 each. Up to an additional \$6,500 may be included in each award for TABA. The total performance period shall be no more than seven (7) months beginning on the agreement start date. A period of one (1) month is allotted after the six (6) month R&D duration for the awardee to prepare and submit a final report.

Phase II awards shall be for no more than \$400,000. The R&D activity period of performance in Phase II will depend upon the scope of the research, but should not exceed 24 months. One year after completing the R&D activity, the awardee shall be required to report on its commercialization activities. The total period of performance for Phase II is 36 months.

It is anticipated that approximately half of the Phase I awardees will receive Phase II awards,

depending upon the availability of funds. 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 4 months after the completion of Phase I, contingent upon availability of funds.

Funding for the program listed in this NOFO is contingent upon the availability of appropriations. NIST issues this notice subject to the appropriations made available under the current continuing resolution funding the Department of Commerce: Section 101 of the Further Additional Continuing Appropriations Act, 2019, Public Law 116-5, January 25, 2019. NIST anticipates making awards for the program listed in this notice provided that funding for Fiscal Year 2019 is continued beyond February 15, 2019, the expiration of the current continuing resolution.

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 I awardees will be required to submit a performance (technical) report covering the award's first three months during the fourth month of the period of performance, and a final report seven months after the start of the award.

Performance (technical) reports should include technical details regarding the research conducted up to that point in the project and provide detailed plans for the next stages of the project. 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 performance (technical) reports and final report 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.(d)(1).

Final reports shall include a single-page project summary as the first page. The remainder of the report should indicate the research objectives, research work carried out, results obtained, and estimates of technical feasibility.

All final reports must carry an acknowledgment on the cover page such as: "This material is based upon work supported by the National Institute of Standards and Technology (NIST) under cooperative agreement _____. Any opinions, findings, conclusions or

recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of NIST."

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 Proposals

Applicants are discouraged from submitting proprietary information unless the information is deemed essential for proper evaluation of the application. If proprietary information is provided by an applicant in a proposal, which constitutes a trade secret, proprietary commercial or financial information, confidential personal information or data affecting the national security, it will be treated in confidence, to the extent permitted by law. This information must be clearly marked by the applicant with the term "confidential proprietary information" and the following legend must appear on the title page of the proposal:

"These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data,

the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages_____of this proposal.”

Any other legend may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration, without assuming any liability for inadvertent disclosure. The Government will limit dissemination of such information to within official channels. Information contained in unsuccessful proposals will remain the property of the applicant. The Government may, however, retain copies of all proposals. Public release of information in any proposal submitted will be subject to existing statutory and regulatory requirements. These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this agreement and are controlling.

5.04.02 Rights in Data Developed Under SBIR Funding Agreements

In lieu of [the Department of Commerce Financial Assistance Standard Terms and Conditions](#), Section C.03, Intellectual Property Rights, the following terms and conditions will apply to and be included in all SBIR awards issues under this NOFO:

(a) Definitions. As used in regards this NOFO and awards made pursuant to this NOFO:

“Computer database” or **“database”** means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

“Computer software” (1) means: (i) computer programs that comprise a series of instructions, rules routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and (ii) recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be

produced, created, or compiled; and (2) does not include computer databases or computer software documentation.

“Computer software documentation” means 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.

“Data” means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing or management information.

“Form, fit, and function data” means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability as well as 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. **“Limited rights data”** means data (other than computer software) developed at private expense that embody trade secrets or are commercial or financial and confidential or privileged.

“Restricted computer software” means computer software developed at private expense and that is a trade secret; is commercial or financial and confidential or privileged; or is copyrighted computer software; including modifications of the computer software.

“SBIR data” means data first produced by an Awardee that is a small business concern in performance of a small business innovation research award issued under the authority of 15 U.S.C. § 638, which data are not generally known, and which data without obligation as to its confidentiality have not been made available to others by the Awardee or are not already available to the Government.

“SBIR rights” means the rights in SBIR data set forth in the SBIR Rights Notice of paragraph (d) of this clause.

“Technical data” means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. (See 41 U.S.C. § 403(8)).

“Unlimited rights” means the right of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose whatsoever, and to have or permit others to do so.

(b) Allocation of rights.

(1) Except as provided in paragraph (c) section regarding copyright, the Government shall have unlimited rights in—

- (i) Data specifically identified in this award as data to be delivered without restriction;
- (ii) Form, fit, and function data delivered under this award;
- (iii) Data delivered under this award (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this award; and
- (iv) All other data delivered under this award unless provided otherwise for SBIR data in accordance with paragraph (d) of this clause or for limited rights data or restricted computer software in accordance with paragraph (f) of this clause.

(2) The Awardee shall have the right to—

- (i) Assert copyright in data first produced in the performance of this award to the extent provided in paragraph (c)(1) of this clause;
- (ii) Protect SBIR rights in SBIR data delivered under this award in the manner and to the extent provided in paragraph (d) of this clause;
- (iii) Substantiate use of, add, or correct SBIR rights or copyright notices and to take other appropriate action, in accordance with paragraph (e) of this clause; and
- (iv) Withhold from delivery those data which are limited rights data or restricted computer software to the extent provided in paragraph (f) of this clause.

(c) 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.

(d) Rights to SBIR data.

(1) The Awardee is authorized to affix the following “SBIR Rights Notice” to SBIR data delivered under this award and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with such Notice:

SBIR Rights Notice

These SBIR data are furnished with SBIR rights under Award No. _____ (and contract or subaward _____, if appropriate). For a period of 4 years, unless extended, after acceptance of all items to be delivered under this award, the Government will use these data for Government purposes only, and they shall not be disclosed outside the Government (including disclosure for procurement purposes) during such period without permission of the Awardee, except that, subject to the foregoing use and disclosure prohibitions, these data may be disclosed for use by support contractors and/or subrecipients. After the protection period, the Government has a paid-up license to use, and to authorize others to use on its behalf, these data for Government purposes, but is relieved of all disclosure prohibitions and assumes no liability for unauthorized use of these data by third parties, except that any such data that is also protected and referenced under a subsequent SBIR award shall remain protected through the protection period of that subsequent SBIR award. This Notice shall be affixed to any reproductions of these data, in whole or in part.

(End of notice)

(2) The Government’s sole obligation with respect to any SBIR data shall be as set forth in this paragraph (d).

(e) Omitted or incorrect markings.

(1) Data delivered to the Government without any notice authorized by paragraph (d) of this clause shall be deemed to have been furnished with unlimited rights. The Government assumes no liability for the disclosure, use, or reproduction of such data.

(2) If the unmarked data has not been disclosed without restriction outside the Government, the Awardee may request, within six months (or a longer time approved by the Grants Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on data at the Awardees expense, and the Grants Officer may agree to do so if the Awardee—

- (i) Identifies the data to which the omitted notice is to be applied;
- (ii) Demonstrates that the omission of the notice was inadvertent;
- (iii) Establishes that the use of the proposed notice is authorized; and
- (iv) Acknowledges that the Government has no liability with respect to the disclosure or use of any such data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If the data has been marked with an incorrect notice the Grants Officer may—

- (i) Permit correction, at the Awardee's expense, if the Awardee identifies the data and demonstrates that the correct notice is authorized, or
- (ii) Correct any incorrect notices.

(f) Protection of limited rights data and restricted computer software. The Awardee may withhold from delivery qualifying limited rights data and restricted computer software that are not identified in paragraphs (b)(1)(i), (ii), and (iii) of this clause. As a condition to this withholding the Awardee shall identify the data being withheld and furnish form, fit, and function data instead.

(g) Contracting and Subawards. The Awardee shall obtain from its contractors and subawardees all data and rights therein necessary to fulfill the Awardee's obligations to the Government under this award. If a contractor or subawardee refuses to accept terms affording the Government those rights, the Awardee shall promptly notify the Grants Officer of the refusal and not proceed with the contract or subaward without further authorization in writing from the Grants Officer.

(h) Relationship to patents. Nothing contained in this subsection shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

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, small business concerns 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 www.iedison.gov.

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

See [13 C.F.R. § 121.103\(h\)](http://www.iedison.gov). Joint ventures and limited partnerships are eligible, provided the entity created qualifies as a small business as defined in this NOFO. The awardee may enter

into contracts, subawards, or other agreements with universities or other non-profit organizations.

5.08 Research and Analytical Work

For Phase I, a minimum of two-thirds 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 may not exceed one-third of the total award. For Phase II, a minimum of one-half of the research and/or analytical effort, per Section 1.03, must be performed by the applicant. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements 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 (October 9, 2018), 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; when applicable, 48 C.F.R. Subpart 31.2, Contracts with Commercial Organizations; 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. § 200.336, available at www.gpo.gov/fdsys/pkg/CFR-2017-title2-vol1/pdf/CFR-2017-title2-vol1-sec200-336.pdf.

(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. §§ 200.338-342 available at www.gpo.gov/fdsys/granule/CFR-2014-title2-vol1/CFR-2014-title2-vol1-sec200-338.

(3) Non-Discrimination. 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 [Department of Commerce Financial Assistance Standard Terms and Conditions](#).

(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 the requirements of Subpart F of 2 C.F.R. Part 200. See Section D.01 of the Department of Commerce Financial Assistance Standard Terms and Conditions.

(5) Codes of Conduct. Codes of Conduct. Pursuant to the certification in Form SF-424B, paragraph 3, 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. See Section F.01 of the Department of Commerce Financial Assistance Standard Terms and Conditions.

5.11 Additional Information

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.

NIST is committed to the goal of commercialization of the results of SBIR projects and will provide 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. You may request up to an additional \$6,500 for TABA during Phase I. If you wish to utilize your own vendor, you must include vendor information in your budget and provide details in the budget narrative, see Section 8.01 for additional information. Reimbursement is limited to services received that comply with 15 U.S.C. § 638(q).

5.12 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 <http://www.nist.gov/mep>.

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 I applications must be received no later than 11:59 p.m. Eastern Time, Friday, April 19, 2019. Only electronic applications submitted via Grants.gov will be accepted.

Applicants should be aware that, and factor in their application submission planning, that the Grants.gov system is expected to be closed for routine maintenance at these times:

From 12:01 A.M. Eastern Time	To 6:00 A.M. Eastern Time
Saturday	Monday
February 16, 2019	February 18, 2019
March 16, 2019	March 18, 2019

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 a current registration in the System for Award Management (SAM.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) may take between three and five business days or as long as more than two weeks; and (3) applicants are required to have a current registration in Grants.gov; and (4) 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: <http://www.grants.gov/web/grants/applicants/organization-registration.html>.

6.02 Address to Request Application Package

The standard application package, consisting of the standard forms, i.e., SF-424, SF-424A, SF-424B, SF-LLL, and the CD-511, is available at www.grants.gov. The standard application package may be requested by contacting the NIST personnel listed below:

J'aime Maynard by phone: (301) 975-8408 or by e-mail: jmaynard@nist.gov.

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 www.grants.gov. 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. The last application received in Grants.gov will be used for evaluation. Applications to multiple research areas or multiple applications to the same research area must be clearly differentiated.

(1) Applications must be submitted via Grants.gov at www.grants.gov, under announcement 2019-NIST-SBIR-01.

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. For further information or questions regarding the electronic application process for the 2019-NIST-SBIR-01 announcement, contact Leon Sampson by phone at 301-975-3086 or by 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 up to two (2) 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 (<https://www.sam.gov/SAM/>), as explained on the Grants.gov Web site. See *also* Section 8.03 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 support@grants.gov.

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 <http://www.grants.gov> home page. Clicking on the "Applicants" tab produces two exceptionally useful sources of information, Applicant Actions 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 [Grants.gov Online Help](#) 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: www.nist.gov. The NIST Research Library, <https://www.nist.gov/nist-research-library>, 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 (<https://www.federallabs.org/labs/national-institute-of-standards-and-technology-nist-0>).

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 I 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, Application for Federal Assistance. Item 12 should list the NOFO number 2019-NIST-SBIR-01. The response to #19 should be ‘no’ – the NIST SBIR Program is not covered by that Executive Order. For SF-424, Item 21, the list of certifications and assurances is contained in the SF-424B, which is item 3 in this list of Required Forms and Documents.

2. SF-424A, Budget Information – Non-Construction Programs. The budget should reflect all anticipated expenses for the project.

In Section A, the Grant Program Function or Activity on Line 1 under Column (a) should be entered as “Science, Tech., Business and/or Educ. Outreach”. The Catalog of Federal Domestic Assistance Number on Line 1 under Column (b) should be entered as “11.620”.

In Section B, Acceptable fees (see Section 5.06 of this NOFO) should be included in “Other (h)”.

These sections of the SF-424A should reflect funds for the entirety of the award: Section A; Section B; Section C; and Section D. Section E is not relevant to the 2019-NIST-SBIR-01 program.

3. SF-424B, Assurances - Non-Construction Programs.

4. CD-511, Certification Regarding Lobbying. Enter “2019-NIST-SBIR-01” in the Award Number Field. Enter the title of the application used in field 15 of the SF-424, or an abbreviation of that title, in the Project Name field.

5. SF-LLL, Disclosure of Lobbying Activities (if applicable).

6. Cover Sheet 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. Attach this document to the SF-424 as described at the end of Section 8.01.

7. Budget Narrative. In addition to other mandatory budget information, a separate Budget Narrative is required. There is no set format for the budget narrative; however, it should provide a detailed breakdown of costs under each applicable object class

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category as reflected on the SF-424A (personnel, fringe benefits, equipment, travel, supplies, other direct costs and indirect costs), and written justification that includes the necessity and the basis for the cost. Proposed funding levels must be consistent with the project scope, and only allowable costs that fall within the spending limitations specified in Section 1.03.01 of this NOFO should be included in the budget. The proposed budget should reflect planned costs, but the awardee must charge actual costs to the award consistent with cost principles applicable to the type of awardee in accordance with the 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. More information is available at <http://go.usa.gov/SBYh> and <http://go.usa.gov/SBg4>. Information needed for each category in the budget narrative is as follows. Attach this document to the SF-424 as described at the end of Section 8.01.

- (a) **Personnel** – At a minimum, the budget justification for all personnel 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. For Phase I, a minimum of two-thirds of the research and/or analytical effort must be performed by the awardee.
- (b) **Fringe Benefits** – 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, workers’ compensation, etc.) should not be charged under another cost category.
- (c) **Travel** – For all travel costs, 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.
- (d) **Equipment** – 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. Any items that do not meet the threshold for equipment can be included under the supplies line item. 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).

- (e) **Supplies** — Supplies are defined as all tangible personal property other than that described as equipment. Provide a list of each supply, 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.
- (f) **Contractual (i.e. Contracts/Subawards)** – Each contract or subaward should be treated as a separate item. Identify the cost and 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 normal goods and services. Subawardees perform part of the project scope of work. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements may not exceed one-third of the total award. Any funds requested for TABA should be included in this section; see Section 5.11.
- (g) **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. 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 applicant’s budget.

8. Indirect Cost Rate Agreement. NIST will not negotiate indirect cost rates for Phase I awards. If indirect costs are included in the proposed budget, include the cost computation in the budget narrative, and provide a copy of the current, approved negotiated agreement if this rate was negotiated with a cognizant Federal audit agency. Attach this document to the SF-424 as described at the end of Section 8.01. 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. 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 <http://www.sbir.gov/registration> to track ownership and affiliation requirements for all companies applying to the SBIR Program. The SBIR Policy Directive requires each Phase I 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 SF-424 as described at the end of Section 8.01.

10. Data Management Plan. In accordance with NIST Policy 5700.00³, *Managing Public Access to Results of Federally Funded Research*, and NIST Order 5701.00⁴, *Managing Public Access to Results of Federally Funded Research*, applicants must include a Data Management Plan (DMP).

The DMP is a supplementary document of not more than two pages that 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, and a plan describing whether and how data generated by the identified activities will be reviewed and made available to the public. As long as the DMP meets these NIST requirements, it may take the form specified by the applicant's institution or some other entity (e.g., the National Science Foundation⁵ or the National Institutes of Health⁶).

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) (available at <http://go.usa.gov/3sZvQ>).

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

The sufficiency of the DMP will be considered as part of the administrative review (see Section 4.02. of this NOFO); however, the DMP will not be evaluated against any evaluation criteria. Attach this document to the SF-424 as described at the end of Section 8.01.

11. Research & Related Personal Data. Complete and print the form available at <https://www.grants.gov/web/grants/forms/r-r-family.html#sortBy=1>. Attach this document to the SF-424 as described at the end of Section 8.01.

³ <http://www.nist.gov/data/upload/Final-P-5700.pdf>

⁴ http://www.nist.gov/data/upload/Final-O-5701_0.pdf

⁵ <http://www.nsf.gov/bfa/dias/policy/dmp.jsp>

⁶ https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

12. Compliance with SBIR Program Requirements, Applicant Fraud Awareness Training - Certificate of Training Completion. Complete the training at: <https://www.nist.gov/file/384881>. After completion, print and fill out the last page of the training presentation. Attach this document to the SF-424 as described at the end of Section 8.01.

Items (1) through (5) above are part of the standard application package in Grants.gov and are completed through the download application process. **Items (6) through (12) must be completed and attached by clicking on “Add Attachments” found in item 15 of the SF-424, Application for Federal Assistance. This will create a zip file that allows for transmittal of the documents electronically via Grants.gov.** Applicants should carefully follow specific Grants.gov instructions at www.grants.gov 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.**

8.02 Verifying the Submission and Tracking the Application

Applicants are urged to use Grants.gov’s Download Submitted Applications feature to check that all required attachments were contained in their submission. Go to the [Grants.gov Online Help](#) site for more information.

See especially the “Check Application Status” option, found by clicking first on Applicants, and then by clicking on Grant Applications.

Applicants can track their submission in the Grants.gov system by following the procedures at the Grants.gov site (<https://www.grants.gov/>). It can take up to two business days for an application to fully move through the Grants.gov system to NIST.

8.03 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 world-class 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 existing manufacturers and aspiring start-ups need. 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 <http://www.nist.gov/sbir>)

Application to National Institute of Standards and Technology (NIST) Small Business Innovation Research (SBIR) Program Phase I 2019-NIST-SBIR-01 Cover Sheet			
Name of Submitting Firm:			
Project Title	Click here to enter text.		
Principal Investigator (PI) Name		PI Title	
PI Phone #		PI E-mail	
NIST may verify the following responses with information provided elsewhere in your application or by independent sources.			
THE APPLICANT CERTIFIES THAT:			
1.	It is a small business concern (SBC) and meets the definition as stated in this Notice of Funding Opportunity (NOFO).	<input type="checkbox"/>	Yes <input type="checkbox"/> No
2.	The primary employment of the PI will be with the SBC at the time of award and during the conduct of research.	<input type="checkbox"/>	Yes <input type="checkbox"/> No
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.	<input type="checkbox"/>	Yes <input type="checkbox"/> No
4.	The applicant and/or PI <input type="checkbox"/> has / <input type="checkbox"/> has not submitted applications for essentially equivalent work under other Federal program FFOs and <input type="checkbox"/> has / <input type="checkbox"/> 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 (j) 14) for additional details that must be provided.		
5.	The applicant qualifies as a socially and economically disadvantaged SBC and meets the definition as stated in this NOFO.	<input type="checkbox"/>	Yes <input type="checkbox"/> No

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6. The applicant qualifies as a woman-owned SBC and meets the definition as stated in this NOFO.	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. The applicant qualifies as a HUBZone-owned SBC and meets the SBA's definition (see http://www.sba.gov/hubzone).	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Year SBC founded:	Click here to enter text.
9. Number of Employees:	Click here to enter text.
STATEMENTS:	
10. The applicant will permit the Government to disclose contact information if this application does not result in an award, to appropriate local and State-level economic development organizations that may be interested in contacting you for further information.	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. The applicant authorizes contact information and project title to be provided to the NIST Manufacturing Extension Partnership (MEP) after awards have been announced. If 'Yes' your contact information will be provided to NIST MEP. If so, you will be contacted by your local MEP to explore business-related support services that could benefit the potential of the project you proposed.	<input type="checkbox"/> Yes <input type="checkbox"/> No
TECHNICAL ABSTRACT (limit to 200 words):	
POTENTIAL COMMERCIAL APPLICATION OF THE RESEARCH: (limit to 100 words)	
OTHER INFORMATION:	
<p>Information contained in unsuccessful applications will remain the property of the applicant. The 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.</p> <p>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 an application 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. This information must be clearly marked by the applicant with the term 'confidential proprietary information' and the following legend must appear in this section of the application.</p> <p style="text-align: center;">PROPRIETARY NOTICE</p> <p>"These data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part for any purpose other than evaluation of this proposal. If a funding agreement is awarded to this applicant as a result of or in connection with the submission of these data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the funding agreement and pursuant to applicable law. This restriction does not limit the Government's right to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction are contained on pages _____ of this proposal."</p> <p>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.</p>	

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

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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: 12/31/2020

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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 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 (all questions must be responded to by checking the appropriate box):

(1) The 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 (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) 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:

(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) It 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.

Yes No

(8) During the performance of the award, the principal investigator will spend more than one half of his/her time 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: _____ %

(9) All, essentially equivalent work, or a portion of the work proposed under this project (check the applicable line):

Has not been submitted for funding by another Federal agency.

Has been submitted for funding by another Federal agency but has not been funded under

any other Federal grant, contract, subcontract or other transaction.

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.

(10) During the performance of award, it 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):

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: _____ %

(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.

Yes No Waiver has been granted

(12) During performance of award, the research/research and development will be performed at my facilities with my employees, except as otherwise indicated in the SBIR application and approved in the funding agreement.

Yes No

(13) It 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) It 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 NOFO; and (b) on the date of the SBIR award, which is made more than 9 months after the closing date of the NOFO, is majority-owned by multiple venture capital operating companies, hedge funds, or private equity firms).

Yes No

It will notify the Federal agency immediately if all or a portion of the work proposed is subsequently funded by another Federal agency.

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

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of

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the business concern that the information provided in this certification, the application, and all other information submitted in connection with this application, is true and correct as of the date of submission. I acknowledge that any intentional or negligent misrepresentation of the information contained in this certification may result in criminal, civil or administrative sanctions, including but not limited to: (1) fines, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C.

§ 3729 *et seq.*); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. § 3801 *et seq.*); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. Part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

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(h) of the SBIR Policy Directive). 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 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 Policy Directive, and also any statutory and regulatory provisions referenced in those authorities.

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

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

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

(1) The principal investigator spent more than one half of his/her time 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: _____ %

(2) All, essentially equivalent work, or a portion of the work performed under this project (check applicable line):

Has not been submitted for funding by another Federal agency.

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

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.

(3) Upon completion of the award it 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 it 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.

(5) The research/research and development is performed in the United States unless a deviation is approved in writing by the funding agreement officer.

- Yes
- No
- Waiver has been granted

(6) The research/research and development is performed at my facilities with my employees, except as otherwise indicated in the SBIR application and approved in the funding agreement.

- Yes
- No

It 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.

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

I am an officer of the business concern authorized to represent it and sign this certification on its behalf. By signing this certification, I am representing on my own behalf, and on behalf of the business concern, that the information provided in this certification, the application, and all other information submitted in connection with 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, restitution and/or imprisonment under 18 U.S.C. § 1001; (2) treble damages and civil penalties under the False Claims Act (31 U.S.C. § 3729 *et seq.*); (3) double damages and civil penalties under the Program Fraud Civil Remedies Act (31 U.S.C. § 3801 *et seq.*); (4) civil recovery of award funds, (5) suspension and/or debarment from all Federal procurement and nonprocurement transactions (FAR Subpart 9.4 or 2 C.F.R. Part 180); and (6) other administrative penalties including termination of SBIR/STTR awards.

Signature _____ **Date** ___ / ___ / ___

Print Name (First, Middle, Last)

Title

Business Name
