FY 2019

Small Business Innovation Research (SBIR) Program Phase II

Notice of Funding Opportunity (NOFO)

ANNOUNCEMENT

FUNDING OPPORTUNITY NUMBER: 2019-NIST-SBIR-02

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11.620, Science, Technology, Business and/or Education Outreach

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

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http://www.nist.gov/sbir

US DEPARTMENT OF COMMERCE
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
FY 2019 SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM PHASE II
NOTICE OF FUNDING OPPORTUNITY (NOFO)

1.0 PROGRAM DESCRIPTION AND FEDERAL AWARD INFORMATION

1.01 Introduction

The National Institute of Standards and Technology (NIST) invites FY 2018 NIST SBIR Phase I awardees to submit Phase II research applications under this Notice of Funding Opportunity (NOFO). Only FY 2018 NIST SBIR Phase I awardees are eligible to submit applications in response to this NOFO for Phase II of their projects.

The Small Business Innovation Research (SBIR) program was originally established in 1982 by the Small Business Innovation Development Act (P.L. 97-219), codified at 15 U.S.C. § 638. It was then expanded and extended by the Small Business Research and Development (R&D) Enhancement Act of 1992 (P.L. 102-564), and received subsequent reauthorization and extensions, the most recent of which extends the SBIR program through 2022. (P.L. 115-232).

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. Subtopics set forth in Section 9 of this NOFO are intended to cultivate private sector innovation.

In developing topics and subtopics and 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 for a subtopic 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 (TABA); see Section 5.11 for more information about TABA.

This NOFO is not soliciting applications for Phase I research.

1.02.02 Phase II - Research and Development

This NOFO provides an opportunity to all FY 2018 NIST SBIR Phase I awardees to submit a Phase II application following completion of Phase I. This NOFO provides instructions for FY 2019 NIST SBIR Phase II application preparation and submission requirements.

In Phase II, work from Phase I that exhibits potential for commercial application is further developed. Phase II is the R&D or prototype development phase. To apply for a Phase II award, each Phase I awardee will be required to submit a comprehensive application outlining the proposed research and a detailed plan to commercialize the final product. Each NIST Phase II award is for up to $400,000 and up to a 24-month period of performance. One year after completing the Phase II R&D activity, the awardee shall be required to report on its commercialization activities. Up to an additional $6,500 may be requested for Technical and Business Assistance (TABA); see Section 5.11 for more information about TABA.

1.02.03 Phase III - Commercialization

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

1.02.04 Commercialization Readiness Pilot Program

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

CRPP awards.

1.03 SBIR Applicant Eligibility and Limitations

1.03.01 Applicant Qualifications

Under this NOFO, only FY 2018 NIST SBIR Phase I awardees are eligible to submit applications. 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 II award if the NIST Grants Officer provides prior written approval. Personnel obtained through a Professional Employer Organization or other similar personnel leasing company may be considered employees of the awardee.

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

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

For Phase II, a minimum of one-half of the research and/or analytical effort must be performed by the awardee. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements 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. **Phase II applicants 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.

1.04 Contact with NIST

In the interest of competitive fairness, all oral or written communication with NIST regarding Section 9.0 Research Topics is prohibited during the Phase II open NOFO period. Questions and answers will not be accepted through, nor posted on, Grants.gov.

Applicants may 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

Subject Area	Point of Contact
	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 Phone: 800-518-4726 E-mail: support@grants.gov
Grant Rules and Regulations	Dean Iwasaki Phone: (301) 975-8449 Fax: (301) 975-6368 E-mail: dean.iwasaki@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-Us.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 award made by NIST in this competition 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 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 review[1] 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 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.**

[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.

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 review[2] 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 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.***

[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.

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 (NFMS) IACUC policy that is valid for five years and provided by a NMFS Regional IACUC for activities with marine mammals or sea turtles (NMFS Policy Directive 04-112).

(2) **Documentation of Research Review by an IACUC:** If the applicant's application appears to include research activities, field studies, or custom sample collections involving live vertebrate animals the following information regarding review by an applicable IACUC may be requested during the application review process:

1. The name(s) of the institution(s) where the research involving live vertebrate animals will be conducted and/or custom samples collected.
2. The assurance type and number, as applicable, for the cognizant Institutional Animal Care and Use Committee (IACUC) where the research activity is located. [For example: Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) should be indicated by the OLAW assurance number, i.e. A-1234; an USDA Animal Welfare Act certification should be indicated by the certification number i.e. 12-R-3456; and an Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) should be indicated by AAALAC.]
3. The IACUC approval date for the Animal Study Protocol (ASP) (if currently approved).
4. If the review by the cognizant IACUC is pending, the estimated start date for research involving vertebrate animals.

5. If any assurances or IACUCs need to be obtained or established, that should be clearly stated.
6. If any special permits are required for field studies, those details should be clearly provided for each instance, or indicated as pending.

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

1. A 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 II Application Requirements

Only FY 2019 Phase II applications may be submitted in response to this NOFO. **Only FY 2018 Phase I awardees are eligible to submit FY 2019 Phase II applications.**

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 address the applicable subtopic in Section 9. 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 not only be responsive to the specific NIST program interests described in Section 9 of the NOFO, but also must serve as the basis for technological innovation leading to new commercial products, processes, or services that benefit the public.

NIST reserves the right to not submit an application for technical 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 II Application

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

The Cover Sheet and Technical Content portion of the Technical Proposal is limited to 25 pages. 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,
(b) Technical Content (3.02.02) pages 3 through 25,
(c) Commercialization Plan (3.02.03), and
(d) Phase I Final Report (3.02.04).

The listing of all forms and documents needed to complete the application is given in Section 8.01 of this NOFO. The additional required forms and documents in Section 8.01 are not included in the 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). These applicants may be contacted

by their 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 published on the NIST SBIR website (www.nist.gov/tpo/small-business-innovation-research-program) and therefore should not contain proprietary information.

3.02.02 Technical Content

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

(1) Identification and Significance of the Problem or Opportunity. Make a clear statement of the specific research problem or opportunity addressed, its innovativeness, commercial potential, and why it is important. Explain how it applies to a specific subtopic in Section 9 that was utilized in Phase I.

(2) Phase II Technical Objectives. State the specific objectives of the Phase II effort.

(3) Phase II Work Plan. Include a detailed description of the Phase II R&D plan. The plan should indicate what will be done, where it will be done, and how the research will be carried out. The method(s) planned to achieve each objective or task should be discussed in detail.

(4) Related R/R&D. Describe significant R/R&D that is directly related to the application, including any conducted by the principal investigator or by the proposing SBC. Describe how it relates to the proposed effort and describe any planned coordination with outside sources. The applicant must persuade evaluators of his or her awareness of key, recent R/R&D conducted by others in the specific topic area.

(5) Key Individuals and Bibliography of Related Work. Identify key individuals involved in Phase II, including their related education, experience, and publications. Where vitae are extensive, summaries that focus on the most relevant experience and publications are desired and may be necessary to meet application size limitations.

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

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

(8) Consultants, Contracts, and Subawards. The purpose of this section is to show that any third-party research assistance would materially benefit the proposed effort and that arrangements for such assistance are in place at time of application submission.

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

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

The 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.

(9) Cooperative Research and Development Agreements (CRADA). State if the applicant is a former or current CRADA partner with NIST, or with any other Federal agency, naming the agency, title of the CRADA, and any relationship with the proposed work. The statement of work of an SBIR award awarded under this NOFO cannot overlap with the statement of work of an 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.

(10) 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.

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

(12) Similar Applications or Awards. WARNING -- While it is permissible to submit identical applications or applications containing a significant amount of essentially equivalent work for consideration under numerous Federal program funding announcements, **it is unlawful to enter into a funding agreement requiring essentially equivalent work to an SBIR award (*see* 15 U.S.C. § 638(bb)(3)).** If there is any question concerning this, it must be disclosed to the soliciting agency or agencies before award.

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

(a) Names and addresses of agencies to which an application was submitted or from which an award was received.

(b) Date of application submission or date of award.

(c) Title, number, and date of NOFO(s) under which an application was submitted or award received.

(d) Specific applicable research topic(s) for each application submitted or award received.

(e) Title of research projects for each application submitted or award received.

(f) Name and title of principal investigator or project manager for each application submitted or award received.

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

3.02.03 Commercialization Plan

Attach a copy of your commercialization plan that follows the guidelines below.

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

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

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

The commercialization plan should provide information directly related to bringing the anticipated research results to market. For more information on preparing a commercialization plan, please visit the Small Business Administration website, Writing a Business Plan: http://www.sba.gov/category/navigation-structure/starting-managing-business/starting-business/how-write-business-plan.

The commercialization plan should indicate how the Phase II research results are to be carried out in Phase III and should address the following areas:

Company - A brief description of your company, the nature of your business and field(s) of interest including core competencies, present size (number of employees and annual sales level), any current products that have had significant sales, history of previous Federal and non-Federal funding, and any growth in the company that can be attributed to the SBIR program.

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

Potential Markets and Customers - Who will be your customers? What market(s) have you identified for this technology? What are your estimates of the size, growth potential, and monetary value of the market(s)? What is your estimated market share 5 years after the first sale?

Competition - Who are the major competitors in these markets, present or anticipated? What significant advantages do you anticipate your technology will have over the competition? What is innovative about your anticipated technology or products? How do you intend to compete with competitors?

Past Intellectual Property Success - Have you filed one or more patents as a result of this SBIR project or taken other steps to protect intellectual property, such as registering copyrights?

Path to Commercialization - A description of the approach you will take to convert your Phase II research results into a viable product/service/process for the marketplace. Include the following to the extent possible:

a) Time Frame to Market. Include a timeline, with milestones, for bringing the invention to a point of practical application and to the marketplace. What is the estimated date of the first commercial sale?
b) What are the hurdles or barriers to entry to overcome?
c) A description of your available resources including manufacturing, marketing, technical, and how they will be employed to fulfill the development of the commercialization plan.
d) Describe in some level of detail your strategy and the steps you will take to bring this technology to market and sell your product/process/service.
e) Describe the nature and status of any third party relationships crucial to commercialization including, but not limited to other licenses required, sublicenses of the licensed NIST Invention (for “Lab to Market” projects), financing, research, marketing, distribution and manufacturing.
f) Describe the existence of Phase III follow-on funding commitments from the private sector

or non-SBIR Government funding sources, if any; and

g) Provide any details for future plans to file one or more patents resulting from this project.

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

3.02.04 Phase I Final Report

Attach a copy of your Phase I Final Report.

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 II Screening Criteria

Please carefully read the entire NOFO and review the following Phase II Screening Criteria to assure that your application meets NIST requirements. Phase II applications that do not clearly satisfy all six (6) of the screening criteria will be eliminated from the review and selection process and not receive further consideration. However, NIST, in its sole discretion, may continue the review process for an application that is missing minor non-substantive information, the absence of which may easily be rectified.

The screening criteria are:

(1) The application must be received by NIST before the deadline specified in Section 6.01.

(2) The proposing firm must qualify as eligible according to the criteria provided in Section 1.03.

(3) The Phase II application must include all required forms and documents listed in Section 8.01:

i) SF-424, 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
    c. Commercialization Plan – see Section 3.02.03
    d. Phase I Final Report – see Section 3.02.04
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
xiii) Current and Pending Support Form – see Section 8.01.13

(4) The Phase II total proposed project budget must not exceed $400,000. Up to an additional $6,500 may be requested for TABA. For Phase II, a minimum of one-half of the research and/or analytical effort must be performed by the awardee. The total cost for all consultant fees, facility leases, usage fees, and other subcontract/subaward or purchase agreements may not exceed one-half of the total award (Section 1.03).

(5) The duration for the Phase II project must not exceed 24 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.

4.03 Phase II Evaluation Criteria

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

Technical Review. The applications will be evaluated by three reviewers in accordance with the following equally weighted criteria, on a scale of 1 to 5, for a maximum of 20 points:

(1) The soundness of the technical approach to the proposed research.

(2) The likelihood the proposed effort will yield significant results leading to a product within the subtopic as described in the commercialization plan.

(3) The likelihood the proposed approach will contribute to the field of study of the subtopic.

(4) Qualifications of the proposed principal/key investigators, supporting staff, and consultants as they relate to accomplishing the proposed research effort.

Applicants should be specific and clear when writing their applications and not assume information not clearly spelled out can be inferred by the reviewer. No technical clarifications may be made after application submission. The Selecting Official will determine the average score above which applications will be considered "technically superior." Applications not rated as technically superior will not be considered further.

4.04 Phase II Award Selections

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

(1) Scores and comments provided by the Merit reviewers;
(2) Diversity across participants and NIST program areas;
(3) Possible duplication of other federally-funded research; and
(4) Availability of funding.

In the event of a "tie" between applications, manufacturing-related projects and those regarding energy efficiency and renewable energy system will receive priority in the award selection process. 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 specific award 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 technical 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 six (6) Phase II awards with a project budget of no more than $400,000 each. Up to an additional $6,500 may be included in each award for TABA. The total performance period shall be no more than 24 months beginning on the agreement start date. A period of one (1) month is allotted after the 24 month R&D duration for the awardee to prepare and submit a final report.

One year after completing the R&D activity, the awardee is expected to report on its commercialization activities.

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

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

5.02 Reporting Requirements

Phase II awardees will be required to submit three interim progress reports, a final report, and a commercialization report. Generally, Phase II reports are due at 6, 12, 18, 24, and 36 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). 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 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 (SACs) 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. 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 submit to the Grants Officer either: (i) a financial related audit of each DOC award or subaward in accordance with Generally Accepted Government Auditing Standards; or (ii) a project specific audit for each award or subaward in accordance with the requirements contained in 2 C.F.R. § 200.507. Applicants are reminded that NIST, the Department of Commerce Office of Inspector General, or another authorized Federal agency may conduct an audit of an award at any time..

(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 II. 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 II applications must be received no later than 11:59 p.m. Eastern Time, Wednesday, June 12, 2019. Only electronic applications submitted via Grants.gov will be accepted.

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

From 12:01 A.M. Eastern Time Saturday	To 6:00 A.M. Eastern Time Monday
April 20, 2019	April 22, 2019
May 18, 2019	May 20, 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 current registrations in the System for Award Management (SAM.gov) and Grants.gov; (2) the free annual registration process in the electronic System for Award Management (SAM.gov) (*see* Section 6.03.1.b) of this NOFO) may take between three and five business days or as long as more than two weeks; and (3) applicants will receive a series of e-mail messages from Grants.gov over a period of up to two business days before learning whether a Federal agency's electronic system has received its application. **Please note that a federal assistance award cannot be issued if the designated recipient's registration in the System for Award Management (SAM.gov) is not current at the time of the award.**

Applicants will find instructions on registering with SAM.gov as part of the Grants.gov process at: 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-02.

a) Applicants should carefully follow specific Grants.gov instructions to ensure the attachments will be accepted by the Grants.gov system. A receipt from Grants.gov indicating an application is received does not provide information about whether attachments have been received. For further information or questions regarding the electronic application process for the 2019-NIST-SBIR-02 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.

Applicants should pay close attention to the guidance under Grants.gov's "Applicant FAQs," as it contains information important to successful submission, including essential details on the naming conventions for attachments to 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 II Screening Criteria. Guidelines provided below are based on frequently asked questions and are not intended to be comprehensive – all forms must be fully completed.

A complete application contains the following forms and documents:

1. SF-424, Application for Federal Assistance. Item 12 should list the NOFO number 2019-NIST-SBIR-02. 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-02 program.

3. SF-424B, Assurances - Non-Construction Programs. The SF-424B is required for all applicants that have not updated their System for Award Management (SAM.gov) entity registration since February 2, 2019 to include the Federal financial assistance certifications and representations. If an applicant has updated their SAM.gov entity registration since February 2, 2019 to include the certifications and representations, then the SF-424B is not required.

4. CD-511, Certification Regarding Lobbying. Enter "2019-NIST-SBIR-02" 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. Technical Proposal (Cover Sheet, Technical Proposal, Commercialization Plan, and Phase I Final Report). 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 category as reflected on the SF-424A (personnel, fringe benefits, equipment, travel, supplies, contractual, 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 II, a minimum of one-half 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-half 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. 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. 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. Attach the 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.

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 II applicant to register in the Company Registry prior to submitting an application. The

applicant must save its information from the registration in a .pdf document. Attach this document to the SF-424 as described at the end of Section 8.01.

10. Data Management Plan. In accordance with NIST Policy 5700.00[3], *Managing Public Access to Results of Federally Funded Research,* and NIST Order 5701.00[4], *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 Foundation[5] or the National Institutes of Health[6]).

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.

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[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.

13. Current and Pending Support Form. Any application that includes investigators, researchers, and key personnel must identify all sources of current and potential funding, including this proposal. Any current project support (e.g. Federal, state, local, public or private foundations, etc.) must be listed on this form. The proposed project and all other projects or activities requiring a portion of time of the Principal Investigator (PI), co-PI, and key personnel must be included, even if no salary support is received. The total award amount for the entire award period covered, including indirect costs, must be shown as well as the number of person-months per year to be devoted to the project, regardless of the source of support. Similar information must be provided for all proposals already submitted or that are being submitted concurrently to other potential funders.

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

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

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 (13) 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

9.01 Advanced Communications, Networks, and Scientific Data Systems

9.01.01.77 SDN Enabled Secure Inter-Domain Routing

There are numerous efforts in the industry and research communities to leverage software defined networking (SDN) in support of the Border Gateway Protocol (BGP). Internet service providers (ISPs) and Internet Exchange Point (IXP) Operators are exploring this integration of BGP and SDN to enable: (a) rich, application specific routing diversity, (b) tight coupling of control and data plane policies, and (c) more efficient deployments of BGP [1,2,3,4,5].

Recent standardization efforts in the Internet Engineering Task Force (IETF) have developed a series of security extensions for BGP. Specifications for both BGP Origin Validation [6] and Path Validation [7] have reached Request for Comments (RFC) status. The objective of this

topic is to explore, through design and prototyping, the integration of these new BGP security protocols in emerging SDN-enable BGP architectures. The scope shall address both BGP Origin Validation and Path Validation and their incorporation into both SDN-enabled BGP routing within an autonomous system and at Internet exchange points.

The goal of this subtopic is to explore, through design and prototyping, the integration of new BGP protocols in emerging SDN-enable BGP architectures. The scope shall address both BGP Origin Validation and Path Validation and their incorporation into both SDN-enabled BGP routing within an autonomous system and at Internet exchange points. Solutions should explore how these technologies can be integrated to: (a) offer routing policies that allow opt-in preference for validated paths/origins for some users/peers, (b) couple data plane routing policies to those of control plane, and (c) offload the computational cost of BGP security mechanisms from edge routers to centralized SDN controllers. Solution designs should be validated through prototype implementation and evaluation in one or more open source BGP/SDN platforms.

Phase I expected results:
In Phase I, a feasibility study and integration plan of BGPsec into one or more of the selected open source SDN-enabled inter-domain routing platforms is expected. The integration of the selected platform must include RPKI origin validation [6] and BGPsec path validation [7]. The results of this phase shall include a design specification of how BGP security technologies can be incorporated into chosen routing platforms and how the approach addresses the suggested capabilities above. The design should include initial prototype experimentation as a proof of concept.

Phase II expected results:
Phase II consists of a full integration of BGPsec path validation and RPKI origin validation as specified in Phase I, into one or more of the selected open source SDN enabled BGP platforms. Phase II includes development of prototype software, documentation, test suites and an evaluation report of the capabilities, performance, and interoperability of the prototype. It is preferred that the BGPsec path validation and RPKI-based origin validation capabilities be based upon the relevant modules of the NIST BGP-SRx software suite [4].

As appropriate based on the mutual interest of both NIST and the awardee, the NIST-ANTD BGP team [6] may provide limited support as subject matter experts and as well as limited support with the usage of the BGP-SRx Software Suite and its components.

References:
[1] A. Gupta et al. SDX: A Software Defined Internet Exchange, ACM SIGCOMM'14, August

2014. http://gtnoise.net/papers/2014/gupta-sigcomm2014.pdf.

[2] SDN-IP / ONOS Project. https://wiki.onosproject.org/display/ONOS/SDN-IP.

[3] SDX A Software Defined Internet Exchange Point. http://sdx.cs.princeton.edu/.

[4] OpenDaylight Border Gateway Protocol (BGP) plugin. http://docs.opendaylight.org/en/stable-nitrogen/user-guide/bgp-user-guide.html.

[5] SDN WAN BGP GATEWAY. https://www.corsa.com/solutions/sdn-wan-bgp-gateway/.

[6] P. Mohapatra et al. BGP Prefix Origin Validation, RFC 6811, January 2013. https://tools.ietf.org/html/rfc6811.

[7] M. Lepinsky (Ed.) and K. Sriram (Ed.). BGPsec Protocol Specification, RFC 8205, September 2017. https://tools.ietf.org/html/rfc8205.

[8] BGP-SRx Software Suite. https://bgpsrx.antd.nist.gov.

[9] NIST Robust Inter-Domain Routing project. https://www.nist.gov/programs-projects/robust-inter-domain-routing.

9.01.02.77 Secure and Distributed Network Measurement

Interest in network measurement has existed since the early days of the Internet. However, today's networks have very limited measurement capabilities used for diagnostic services (such as the traceroute and ping utilities based on the Internet Control Message Protocol-(ICMP). Consequently, complex and ad-hoc procedures are frequently combined to assess network behavior, often using techniques that rely on inference rather than direct measurement. In [1] authors propose measurability as a goal of protocol design, and argue for measurement as a first-class component of the network architecture, rather than conducting measurements through inference from convoluted techniques.

Any deployed IT infrastructure will benefit from a strong network measurement capability. A first step toward developing a general purpose network measurement framework that supports a variety of use cases with flexibility and extensibility is introduced in [2]. Such a framework would allow for built-in measurement and diagnostic capabilities so that as new applications are developed, they can be instrumented with measurement probes and make use of the framework to meet their measurement needs. The network is thus empowered

with a built-in measurement framework that can be used by different applications that need to produce and/or consume network measurements.

Implementation of the framework can be done for a network stack based on IP or on Information Centric Networking (ICN) paradigm. The latter would be more convenient given its clean-slate nature and the availability of Named Data Networking (NDN) as an ICN instance with associated codebase and nationwide NDN testbed available for experimentation. Moreover, ICN is a promising technology for the Internet of Things (IoT) applications [3] and having a suitable measurement infrastructure will accelerate adoption of IoT applications.

Network measurement tools with well-designed measurement probes can result in commercial products and solutions for network operations and network analytics.

The goal is to develop a rich set of network measurement probes that can be deployed in networks to achieve higher levels of network measurability. It is also desirable to explore solutions for correlating measurements from multiple probes for network forensics, for monitoring overall network health, and to achieve higher degrees of network observability. Security of the measurement infrastructure is important and needs to be addressed, including privacy and access control to measurement data.

Phase I activities and expected results:
Provide input to the measurement framework and its security model, propose network measurement probes and associated features that fit within the framework, explore passive and active measurement probes, develop proof-of-concept software implementation (a simple network of IoT sensors, devices, and applications can be emulated for this purpose), provide a discussion of the security properties/features it addresses and how this fits within the measurement framework, explore use cases that involve cooperation between probes.

Phase II activities and expected results:
Expand and mature the Phase I proof-of-concept, provide design details with practical applications in support of potential commercial product or service, evaluate a working prototype of a commercially viable network measurement solution, assess features of the measurement probes, conduct testbed measurements and testing for a number of use cases.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may be available to work collaboratively on design concepts, discuss potential solutions, and evaluate proposed implementations.

References:

[1] Principles for Measurability in Protocol Design. https://doi.org/10.1145/3089262.3089264.

[2] A Network Measurement Framework for Named Data Networks.

https://conferences.sigcomm.org/acm-icn/2017/proceedings/icn17-1005.pdf.

[3] Design Considerations for Applying ICN to IoT. https://tools.ietf.org/html/draft-zhang-icnrg- icniot-01.

9.01.03.77 Using the DNSSEC and DANE to Improve Web Browser Security

For many users, the Internet is experienced through a web browser. Internet users engage in communication, commerce, exchange heath information, control devices and services, and interact with their government through web based tools. Naturally, attackers have focused on intercepting various forms of web traffic in order to eavesdrop on the data, divert the communications to malicious sites, etc. This is often done by tricking the browser into using unencrypted channels (i.e., a downgrade from HTTPS to HTTP), or spoofing the legitimate server and acting as a Man-in-the-Middle (MITM) and intercepting/decrypting all HTTPS traffic. The latter is often accomplished using fraudulently obtained X.509 certificates [1].

Several protocols and protocol extensions have been proposed to combat these types of attacks against web browser users. Some of these proposed solutions have gained traction but suffer from drawbacks. HTTPS Strict Transport Security (HSTS) [2] can be used to inform browsers to only connect via HTTPS, but suffers from a downgrade attack on the first visit to a given web site. HSTS with preloading can prevent the downgrade attack by having a list of known HSTS domains stored locally in the browser. Preloading suffers from the inability to scale to the size of the entire Internet [3] as the global list of HTTPS protected websites could not be stored or accessed quickly in a web browser. Other applications that use HTTPS for things such as accessing media or other information may also have to download and store the pre-load list in order to insure an initial secure connection to a given service.

Domain-based Authentication of Named Entities (DANE)[4] uses the Domain Name System (DNS) to store publish security information about a given host. DANE allows a domain owner to be very flexible with regards to the type of certificates used (including the use of CAs that are otherwise unknown by clients. DANE does suffer from a perceived

performance impact because of the required use of the DNS Security Extensions (DNSSEC). There have been some proposed solutions to this problem, but they are not yet fully specified. There is also some ambiguity in DANE as to how to handle policy discovery and caching, such as provided by HSTS. To date, there has been little published work on how DANE and HSTS should interact.

Ideally, web browsers should be able to benefit from multiple ways of authenticating an HTTPS protected website. That way, an end user will be further protected against various TLS attacks seeking to compromise their communication. However, DANE support in web browsers is lacking and there are no major versions of browsers that currently use DANE to protect end users.

The primary goal of this project is to develop a prototype web browser that can use DANE resource records stored in the DNS to establish an authenticated, TLS protected connection to a web server. Existing open source components can be used in this effort, including an open source web browser as the candidate code base for the prototype. Possible options include (but are not limited to): Chromium, Firefox, Brave, etc. The DANE component may also leverage pre-existing libraries such as OpenSSL [5].

The secondary goal of the project is to develop and implement extensions to the DANE technologies to provide HSTS-like behavior for policy discovery and caching. Prototype implementations should address how to realize/present different validation results (e.g., PKIX validation vs. DANE validation) to the user.

Phase I activities and expected results:
Phase I consists of identifying possible candidates to use as the base code and designing the algorithms to query the DNS for digital certificates and how to interpret the response. A prototype of a web browser that can use certificate information obtained via the DANE to establish HTTPS connections should be part of the deliverables. A report should also be produced that details the design choices for policy enforcement and any recommendations on new specifications to improve policy discovery for TLS clients.

Phase II activities and expected results:
Phase II consists of further development and improvement of the prototype from Phase I. The prototype web browser for Phase II should be able to handle all DANE certificate scenarios as well as implement the DNSSEC serialized chain extension for TLS [6]. The prototype should also include implementations of proposed policy discovery solutions discussed in the report deliverable from Phase I.

As appropriate based on the mutual interest of both NIST and the awardee and on a case-by-case basis for Phase I and Phase II awards, NIST may provide technical experts to act as subject matter experts in DNS and DNSSEC as needed. NIST may also be available to establish the network and DNS infrastructure that would be needed to conduct testing of the resulting prototype web browser.

References:

[1] G. Fleishman. The Huge Web Security Loophole That Most People Don't Know About, and How It's Being Fixed, FastCompany Feb. 2015. https://www.fastcompany.com/3042030/the-huge-web-security-loophole-that-most-people-dont-know-about-and-how-its-be.

[2] J. Hodges et al. HTTPS Strict Transport Security (HSTS). RFC 6797. Nov 2012. https://tools.ietf.org/html/rfc6797.

[3] ICANN 60 Tech Day. https://schd.ws/hosted_files/icann60abudhabi2017/ab/13%20Broadening%20HSTS%20-%20McIlwain.pdf.

[4] P. Hoffman and J. Schlyter. The DNS-Based Authentication of Named Entities (DANE)Transport Layer Security (TLS) Protocol: TLSA, RFC 6698. Aug 2012. http://datatracker.ietf.org/doc/rfc6698/.

[5] Open SSL 1.1.0 Released. https://www.internetsociety.org/blog/2016/09/openssl-1-1-0-released/.

[6] M. Shore et al. A DANE and DNSSEC Authentication Chain Extension for TLS, Work in Progress. https://datatracker.ietf.org/doc/draft-ietf-tls-dnssec-chain-extension/.

9.02 Advanced Manufacturing and Material Measurements

9.02.01.49 Biomanufacturing

The biopharmaceutical industry is a critical component of the U.S. economy, directly employing nearly 900,000 workers, with a $1 trillion economic footprint. By 2020, it is projected that more than 50% of the all prescription drug sales will be biologically-manufactured therapeutics, including protein therapeutics, and emerging gene and cell therapy products. A key challenge to the domestic competitiveness of the U.S.

biopharmaceutical industry is development of agile and scalable manufacturing processes for these biologic therapies. Technology innovation that enables better process control and more quantitative and real-time product characterization is needed to move the industry meet that challenge.

To this end, NIST seeks the development of new or improved measurement tools and methods to efficiently, accurately, and precisely monitor and characterize both processes and products across the diversity of biologic products. Advances in such measurement technology will:

- Improve risk-analysis of process, equipment and raw material changes on product attributes.
- Aid development of scalable manufacturing platforms for emerging types of biologic therapies.
- Build generalizable knowledge to improve industry understanding of the tolerance for change in relation to product quality.

Of interest in this opportunity are new or improved analytical technologies to evaluate key product attributes to aid in the development and control of bioprocesses.

- Improved and generalizable tools for detection of host cell proteins: The co-purification of host-cell proteins (HCPs) during production of protein therapeutics is a challenge for industry, as HCP contaminants can be immunogenic and may affect the safety and efficacy of the final product. The most common detection methods are based on immunoassays, but industry is increasingly seeking alternatives, such as the use of mass spectrometry. This opportunity seeks the development of more standardized and efficient mass spectrometry approaches, or other orthogonal methods to detect HCP.
- Analytical tools to assess the quality and integrity of single-use bioprocess equipment: As the biopharmaceutical industry moves toward single-use systems, analytical tools and standards that enable efficient and robust detection and characterization of leachables under relevant process conditions are needed. Additionally, improved design of single-use systems to enable rapid confirmation of the integrity of components and connections are desirable.
- Quantitative assessment of filled vs. unfilled viral capsids for manufacturing gene therapies: Development of scalable manufacturing processes for gene therapies is hampered by significant technical challenges. Among these is the need for characterization of filled vs. unfilled capsids in AAV vector generation. The presence of the empty capsids can influence the clinical outcome of these gene therapies, yet

efficient and robust measurement tools to quantify and characterize the filled, partially filled, and unfilled capsids have not been well-established. We seek innovative approaches to this measurement challenge to advance the development of manufacturing platforms for gene therapies.

Phase I expected results:
The awardee will establish proof of concept for new or improved analytical technology to measure desired process or product attributes. The performance characteristics of the new or improved analytical technology should be optimized for sensitivity, resolution, quantitation, speed of measurement (including sample preparation), accuracy, precision, and reproducibility.

Phase II expected results:
The new or improved analytical technology will be directly compared with current state-of-the-art methodology for the relevant bioprocess or biologic product attribute, and will demonstrate a factor of 2X or greater improvement in the performance characteristics listed for Phase I above.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may be available to consult or for potential collaboration, depending on the measurement technology to be developed. NIST may also be willing to provide, where appropriate, reference materials to better compare performance of the proposed new method or technology with that of the current state-of-the-art.

References**:**
[1] Battelle/PhRMA report: The US Biopharmaceutical Industry: Perspectives on Future Growth and the Factors That Will Drive It, 2014.

[2] D.G. Bracewell et al. The Future of Host Cell Protein (HCP) Identification During Process Development and Manufacturing Linked to a Risk-based Management for Their Control, Biotechnology and Bioengineering, 112(9), 1727–1737, 2015.

[3] Deloitte Development LLC. Advancing Biopharmaceutical Manufacturing: An Evolution Underway, 2015.

[4] R. Hernandez. Special Considerations for Extractables and Leachables Testing in Biological Products, Pharmaceutical Technology, 39 (2), 2015.

[5] J.F. Wright, Product-Related Impurities in Clinical-Grade Recombinant AAV Vectors:

Characterization and Risk Assessment, Biomedicines, *2*(1), 80–97, 2014.

9.02.03.73 Compton Scattering Tomography System with Sub-keV Energy Resolution for Gamma Ray Energy at 1-10 MeV Range

Advance materials analyses increasingly demand non-destructiveness with spatial and spectral information. Combining the high penetrability of neutrons and gamma rays, nuclear analytical techniques such as prompt gamma activation analysis (PGAA) has long been a special tool for bulk material analysis that reveals the composition with minimal substrate interference and with multi-elemental sensitivity, due to the characteristic nuclear signature of the emitted gamma rays. However, the high penetrability is accompanied by the inherently low detection efficiency for high energy gamma rays. To date, there is no "off the shelf" commercial detector technology that can be made suitable for spectrally resolved MeV gamma ray tomographic applications, unlike detectors for x rays and lower energy radiations which are routinely performed at micrometer scale. For both spatial and energy sensitivity requirements, traditional detectors have given way to the newer class of materials such Cadmium Zinc Telluride (CZT) which can be miniaturized and with wider band gap which enables room temperature operations. Fast on-board electronics allow near-real time image reconstruction of Compton scattered events which dominate the MeV energy range have seen rapid advances in recent years due to better electronic components and computing power. Recent development for clinical applications of such a system [1] shows promise that innovations in detector technology and reconstruction algorithm [2] can make prompt gamma emission tomography a reality. The NIST Center for Neutron Research is a leader in neutron tomography, which can resolve the physical structure of a bulk component such as a fuel cell element and its liquid flow in-situ. However, it does not provide compositional information that PGAA can. With gamma ray tomography, we can provide a new vision by creating a 3D composition map inside a bulk material/manufactured component at a scale and depth that x-ray and surface analysis techniques cannot reach.

NIST solicits proposals to develop a gamma ray spectrometer and tomographic system based on Compton scattering of MeV gamma rays specifically for the cold neutron beam based prompt gamma activation analysis instrument for composition analysis and spatial distribution of light elements in metal or other solid matrices. The key goal is spatially resolving characteristic energy lines in a bulk material via single-sided tomography that does not require physical collimations.

Phase I of this project would be to construct a suitable prototype of detector and electronics to assess energy resolution, spatial resolution, and elemental sensitivity, with a working reconstruction algorithm that can be off-line, and address the gamma ray

background issues surrounding the facility. The expectation for Phase I is to achieve 5 mm spatial resolution for 5% mass fraction of hydrogen in solid matrices.

For Phase II, the detector hardware is optimized for gamma ray energy peaks of interest and for sample geometry. Mostly importantly, the data acquisition and reconstruction algorithm are fully developed and tested for robustness. The desired goal for the phase II product is 1% hydrogen at 1 mm spatial resolution. The finished product can be deployed to other PGAA facilities as well as possible special applications using portable neutron generators.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may work collaboratively with the awardee, providing access to the PGAA experimental station at NCNR for the testing of the detectors throughout the developmental stages.

References**:**

[1] J. Polf et al. Phys. Med. Biol. 60, 7085–7099, 2015.

[2] D. Mackin et al. Phys. Med Biol. 57, 3537–3553, 2012.

9.02.03.73 Continuous Learning for Additive Manufacturing Processes Through Advanced Data Analytics

Many hurdles continue to hinder the widespread adoption of Additive Manufacturing (AM) technologies for production, including: constrained material choices, low repeatability and quality inconsistency associated with AM processes, and high cost and time in AM qualification[0]. A key step in overcoming each of these hurdles is to understand process–structure-property (PSP) relationships across materials and geometries for a given process.

Data-driven modeling approaches are foundational to a better comprehension of materials behavior [2]. Such approaches can be used to harness experimental data and data analytics techniques, such as data preprocessing, metamodeling, and machine learning, etc., to identify process-structure-property relationships. With almost unprecedented variability for a manufacturing process, AM provides a unique opportunity for data-driven materials characterization. As new data sets begin to emerge, the AM community expects that, with appropriate data driven modeling methods, heterogeneous data sets with a multitude of geometries, material types, and processes can be mined to develop empirical equations that correlate material properties, microstructure, part geometry, and process parameters [3, 4].

Towards advanced data analytics, intensive research has been done in employing metamodeling techniques in design and optimization [5]. AM builds are well suited for such

techniques, especially for metal parts, where costs for conducting large scale sampling over many variables can be prohibitive. Experimental studies often contain only a few measurements and focus on specific sub-processes. The small sets of data captured do not adequately represent the inherently large sets of process variables and material microstructure variances that must be analyzed for establishing AM PSP relationships. It is critical to develop and validate efficient and effective data-driven modeling methods, complemented by physics-based models, capable of undertaking rapid explorations of AM PSP relationship with limited and diverse data sets.

This subtopic addresses gaps in adopting AM processes as production technologies, specifically through deepening the understanding of AM process-structure-property relationships using data science and material informatics. It addresses the need for effective data-driven modeling methods to establish multiscale models that link AM processes to highly complex material structures and link AM microstructure to properties. These methods should be general enough to apply to any material, process, and complex geometry while being effective enough for materials, process, and part qualification.

This subtopic directly relates to NIST's goal of supporting U.S. commerce through measurement science. Successful development of the techniques will enable AM industry developing a comprehensive set of design guidelines, qualification methods, engineering tools, and standardization of best practices.

This project aims to develop and validate novel AM informatics and data analytics that are well suited for the low-volume, high complexity, high cost production requirements in metals AM. Methods to be investigated include: multi-scale microstructure data representation; in-situ process monitoring and NDT data pre-processing for complexity reduction; advanced data mining algorithms to develop geometry/process/structure/property relationships using limited data sets from disparate sources; augmentation of experimental data sets with knowledge and simulation data from AM modeling; and methods to transfer PSP metamodels from one material or process to another material or process.

Methods developed for this subtopic are to include advanced data analysis and mining methods to solve both "small data sets" and "big data" problems in AM modeling. Data mining algorithms are expected to address the formation of AM PSP relationships from multimodal data sets contributed through collaborative efforts. Data analysis and data mining methods are expected to address in-situ monitoring and NDT data. The AM data analytics methods are expected to support the acceleration of AM material characterization, AM manufacturability analysis, AM part quality prediction, and AM design and process

optimization.

This project will develop data driven methods for identifying AM PSP relationships and support process optimization to manufacture high quality parts. Goals include establishing the following methods:

1) AM data-driven modeling methods to establish PSP relationships based on small and diverse data sets from collaborative efforts, without the need for sophisticated design of experiments. Specifically designed data analytics methods are required to support continuous learning (also named generative learning) for model improvement, as new data points are added frequently by the AM community.
2) Adaptive/sequential sampling methods to conduct cost-effective experiments based on existing model characterizations.
3) Methods to integrate and analyze in-situ process monitoring data and NDT data for AM PSP relationship modeling.
4) Methods to transfer PSP metamodels developed for one material or process to another material or process based on transfer learning concepts [6].
5) Multi-objective AM process optimization methods based on data-driven AM models.

Applied in concert, these methods will support AM part failure prediction and AM design and process optimization for part quality (shape and performance) with controlled cost and acceptable throughput.

Phase I expected results:
1. Development of an analytics-driven method to incorporate in-situ process monitoring and NDT data into existing data structures [7].
2. Demonstration of a data analytics method that incorporates adaptive sampling, generative learning, and hybrid modeling techniques (combining physics based modeling with data driven modeling) to establish a single PSP relationship in a metal based PBF process.
3. Demonstration and implementation of a machine learning method to transfer a PSP metamodel developed for one type of AM material to another type of AM material.
4. Prototype software that implements and integrates 1-3 with NIST AMMD (https://ammd.nist.gov) through an open API.

Phase II expected results:
1. Validation of Phase 1-developed methods and algorithms by establishing PSPs for three materials for a single metal AM process.
2. Development of software that customizes the application and implementation of Phase I

algorithms for various AM community stakeholders for material characterization, AM manufacturability analysis, design optimization and feedback process control.
3. Extended validation of methods and algorithms developed in Phase I by establishing 10 PSPs for a second AM process.
4. Demonstration of the software suite in a production process case study. Validation of results with experimental measurements at identified process intervals.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may work collaboratively, provide technical direction, and consultation.

References**:**

[1] NIST. Measurement Science Roadmap for Metal-based Additive Manufacturing, National Institute of Standards and Technology, 2013. https://www.nist.gov/sites/default/files/documents/el/isd/NISTAdd_Mfg_Report_FINAL-2.pdf.

[2] S.R. Kalidindi et al. Vision for Data and Informatics in the Future Materials Innovation Ecosystem, JOM, JOM, Vol. 68, No. 8, 2016.

[3] Zhuo Yang et al. Investigating Predictive Metamodeling for Additive Manufacturing, Volume 1A: 36th Computers and Information in Engineering Conference, Charlotte, North Carolina, USA, August 21–24, 2016.

[4] Z. Yang et al. A Domain Driven Approach to Metamodeling in Additive Manufacturing, CIE 2017, Cleveland, OH, Aug. 6-9, 2017.

[5] Y. Pan and M. Hu. A Data-driven Modeling Approach for Digital Material Additive Manufacturing Process Planning, International Symposium on Flexible Automation (ISFA), Cleveland, OH, 1-3 Aug. 2016.

[6] S.J. Pan and Q. Yang. A Survey on Transfer Learning, IEEE Transactions on Knowledge and Data Engineering, Vol 22, Issue 10, 2009.

[7] Y. Lu et al. A Collaborative Data Management System for Additive Manufacturing, CIE 2017, Aug. 6-9, 2017, Cleveland, Ohio.

9.02.04.63 Design of a High-speed, Multiplexed Infrared Sensor Platform for Dynamic Chemical Analysis

NIST seeks to determine the technical feasibility of a compact (≤1 m^3 physical footprint), long-path (≥ 35 m), broad-band (≥ 1 THz) multiplexed infrared sensor platform (MISP) capable of high frequency resolution (≤ 1 GHz) and high acquisition rates (≥ 1 kHz), achieved via the integration of emerging technology in chip-based lasers, mid-infrared fibers, and dispersive optics. We propose development towards a commercial MISP which utilizes one or more quantum cascade laser (QCL) frequency combs [1] as the active source(s) and a virtually imaged phased array (VIPA) spectrometer and infrared camera as the broad-band detector [2, 3]. The purpose of the sensor platform will be to perform accurate and precise quantitative analysis of trace chemicals using their unique "quantum fingerprints" within the long-wave infrared atmospheric window (λ = 8 μm to λ = 12 μm) [4]. As the relevant optical technologies are only now becoming commercially viable, NIST is interested in this feasibility (Phase I) and prototyping (Phase II) study to promote U.S. leadership in laser sensor development throughout the long-wave infrared atmospheric window.

Proof-of-principle multiplexed spectrometers operating in the mid-wave infrared (λ = 3 μm to λ = 5 μm) have reported novel time-resolved chemical kinetics [5, 6] as well as the open-path detection of CH_4 and H_2O [7]. However, many large molecules of interest to advanced manufacturing, air-quality evaluations, and national security applications have strongly absorbing fundamental vibrations in the long-wave infrared atmospheric window. Therefore, NIST seeks to unite in a synergistic way emerging optics and photonics technologies (QCL frequency combs, long-path sample cells, mid-infrared fibers, VIPA etalons, and compact infrared cameras) by studying the feasibility of a compact and broad-band MISP for the high-resolution, simultaneous interrogation of a variety of chemicals using their unique infrared absorbances.

Using this multiplexed infrared sensor platform, one could potentially perform simultaneous, *in situ* measurements of isoprene (C_5H_8) and ozone (O_3) fluxes, and thus begin to elucidate the impact of biogenic volatile organic compounds (BVOCs) released by the urban ecosystems on air quality and human health [8]. To most efficiently achieve commercialization, the proposer/awardee should ultimately identify additional specific MISP chemical targets and sensing applications. Broadly speaking, the development of a MISP would both leverage and further strengthen the United States industrial expertise in laser sensors for advanced manufacturing and quantum science using emerging optics and photonics technology [9, 10]. Relevant activities include the ruggedization of high-resolution imaging dispersive spectrometers and associated high-fidelity data processing, as well as the integration of mid-infrared fiber optics and compact, low-volume, long-path gas cells with chip-based frequency combs.

Phase I expected results:

Determine the technical feasibility of a multiplexed infrared sensor platform (MISP) using a quantum cascade laser (QCL) frequency comb(s), compact and long-path absorption cell, and virtually imaged phase array (VIPA) spectrometer.

Phase II expected results:
Develop a prototype MISP which operates in the long-wave infrared atmospheric window (λ = 8 μm to λ = 10 μm). Identify and potentially demonstrate active optical sensing of awardee-identified chemical targets that will ultimate drive MISP commercialization.

As appropriate based on the mutual interest of both NIST and the awardee, NIST anticipates working collaboratively by providing technical guidance, discussing design concepts, and aiding in component/prototype evaluation.

References:
[1] Y. Bidaux et al. Opt. Lett. 42, 1604 2017.

[2] L. Nugent-Glandorf et al. Opt. Lett. 37, 3285 2012.

[3] A.J. Fleisher. Frontiers in Optics 2017, OSA Technical Digest (online), paper JTu3A.19.

[4] A. Schliesser et al. Nat. Photonics 6, 440 2012.

[5]A.J. Fleisher et al. J. Phys. Chem. Lett. 5, 2241 2014.

[6] B.J. Bjork et al. Science 354, 444 2016.

[7] L. Nugent-Glandorf et al. Appl. Phys. B 119, 327 2015.

[8] T. Zenone et al. Sci. Rep. 6, 32676 2016.

[9] National Photonics Initiative. Photonics: Enabling American Innovation, Competition and Security, February 1, 2017.

[10] National Photonics Initiative. Call for a National Quantum Initiative: Proposal to Address the Urgent Need to Develop the Information Infrastructure of Tomorrow, June 22, 2017.

9.02.05.63 High Throughput, Fast-temperature Response, Force Sensing Material Extrusion Print Head

Thermoplastic material extrusion additive manufacturing is hampered by low production rates, low-fidelity temperature control, weak or nonexistent performance feedback, and no raw material qualification methods. Creating an integrated system meeting these needs will allow wider adoption of material extrusion technologies in the medical, aerospace, and automotive sectors where throughput and qualification are crucial requirements.

The NIST mission in the soft matter additive manufacturing space is well aligned with the proposed technology in several key areas.

- Promoting technological advances in advanced manufacturing
- Basic research in thermoplastic additive manufacturing
- Standard Reference Material and Research Material development
- Standard test method development (ASTM/ISO)

The goals are three-fold: 1) development of a high-throughput, low-slip printing head to further basic research on the fundamental polymer physics underlying the layer-by-layer welding during higher shear rate extrusion. This goal will speed adoption of material extrusion additive manufacturing by making throughput more competitive with traditional manufacturing methods. 2) Integration of force sensing technology, which will provide a feedback mechanism to assess material quality, measure standard reference materials, and provide a quality assurance signature for a given print. Melt flow indexes are commonly used to assess raw material quality, however, currently there is no equivalent method to assess raw material quality with a filament as the raw material. A print head with integrated force sensing can be used to both assess filament quality and measure reference filaments. 3) Incorporation of a fast temperature response system. Voxel-by-voxel control of material properties is a key feature of additive manufacturing systems, however, the slow equilibration time in current material extrusion print heads limits the fidelity to layer-by-layer control. A system with fast temperature response would be capable of rapidly switching the inter-layer adhesion quality within a given layer, radically changing the design space available to the designer/manufacturer. Incorporation of a fast-thermal response will support standard test method development by improving thermal equilibration in systems which prone to temperature fluctuation due to negligible thermal mass.

Phase I expected results:
Stand-alone thermoplastic material extrusion head integrating the following technologies: counter-rotating nut drive (expanding on nut drive from ref [2]), laser assisted pre-heating zone [2], hyperbolic tapered heating zone [2], and strain-gauge for force sensing [1]. The system shall be capable of ~10-fold increase in throughput and ~10-fold increase

temperature response/equilibration time over current pinch wheel systems while simultaneously reporting a viscosity index value. Assessment of accuracy and precision of force sensing system. The system should accept standard 1.75 mm or 2.88 mm diameter filaments.

Phase II expected results:
Transition from stand-alone system prototype to production system and integration with core-XY motion control system.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may work collaboratively on design and performance measurements and provide Reference Material filaments.

References:
[1] J. Go et al. Rate Limits of Additive Manufacturing by Fused Filament Fabrication and Guidelines for High-Throughput System Design, Additive Manufacturing, 16, 1-11, 2016.

[2] J. Go and A.J. Hart. Fast Desktop-Scale Extrusion Additive Manufacturing, Additive Manufacturing, 2017, in press.

9.02.06.62 Integrated Nanophotonic Probes for Scanning Optical Measurements and Atomic Force Microscopy

Recently, novel chip-scale probes with integrated nanophotonics were invented [5,6] and developed by NIST [1-6] and shown to enhance performance and achieve new functionality in scanning probe microscopy [1,2]. In one example, new capability for optical probing of integrated photonic devices has been demonstrated, which may be of commercial interest in the nanophotonics manufacturing. In another example, higher performance and new capabilities were demonstrated [1] using an atomic force microscopy probe with integrated nanophotonic readout [2,3]. In both cases these novel chip-scale probes were integrated with commercial scanning probe systems, lowering the entry barrier for commercial adoption.

Proposals are sought to improve manufacturability and develop batch fabrication of such probes and simplify their integration with commercial scanning probe microscopes and probe stations. Licensing conditions will be the same as in subtopic 9.07.01.40. Currently such probes are difficult to produce in quantity economically, and are hard to integrate with commercial microscopes.

Further development and commercialization of such probes, together with the development of the associated measurement techniques, will enable large improvements in the state of the art of optical/photonic device testing and AFM metrology, and its dissemination to a broader community. NIST in general, and the Center for Nanoscale Science and Technology in particular, are interested in enabling innovative commercial research to achieve such improvement in optical and AFM metrology, and fulfill its mission to support the U.S. nanotechnology enterprise from discovery to production by providing industry, academia, NIST, and other government agencies with access to nanoscale measurement and fabrication methods and technology.

Probing integrated photonics devices by evanescent optical coupling can play a role similar to the role of electrical probing in electronics manufacturing, facilitating quick in-line testing and determining known good die. Evanescent coupling approach with a nanofabricated probe does not require large and expensive dedicated probing areas, and can be applied at wafer scale, which are not currently possible with other techniques.

Atomic Force Microscopy (AFM) is a nanoscale metrology technique essential for both nanoscience and nanotechnology research as well as nanoscale structure and device manufacturing. Decreasing the mass and size of AFM cantilevers both improves the speed of their response and decreases thermal mechanical noise by decreasing drag when operated in air or fluid environments. In both cases the measurement quality and throughput can be increased. Currently such miniaturization is limited by the difficulty of realizing precision measurement of the motion of such cantilevers. NIST research has demonstrated a way to overcome this difficulty by integrating nanophotonic resonators in close proximity to extremely small cantilevers with masses below 1 pg. These allow motion measurements with a motion noise floor below 1 $fm/Hz^{1/2}$ and a force noise floor of a few $fN/Hz^{1/2}$ in air, and a similarly low force noise in water. High resonance frequencies enable the devices to respond on sub-microsecond time scales.

The general goals of this research are to increase the quality, availability, and throughput of high-precision optical probing and AFM metrology by private sector commercialization of innovative, NIST-developed measurement technologies. In addition, this project should use small business to meet federal research and development needs, and to stimulate small business innovation in technology. The specific goals of this project are to eliminate manufacturing challenges and enables mass production of nanophotonic loop probe and nanoscale AFM probe microchips. Innovative research should address these specific challenges:
1) Mass production of microchips with overhanging photonic loops and/or nanomechanical AFM cantilevers.

2) Mass production of chips that can be efficiently coupled to two or more single mode optical fibers. While low-cost fiber pigtailing of probe chips may be considered initially, development of reusable scanning probe microscopy chip holders with built-in optical connections appears to be a preferred path to commercial adoption.

The probes should be compatible with commercial Scanning Probe Microscope / Atomic Force Microscope systems and should be easy to exchange. They should operate in the optical telecommunication wavelengths range and allow quick and efficient coupling to commercial single-mode optical fiber excitation and detection systems with minimal mechanical alignment.

Commercialization of this technology is expected to result in significant advances in the commercial state of the art in photonics testing and AFM instrumentation, with a further positive impact on U.S. nanomanufacturing and nanotechnology enterprise as a whole.

Phase I expected results:
Demonstration of key elements of proposed probe design and fabrication process. Specifically, demonstration of the feasibility of fabricating all on-chip elements required for
1) single-mode fiberoptic connection (such as single-mode fiber pigtailing or a disconnectable optical connection approach)
2) exposing the probe tip for interaction with a sample (such as, but not necessarily, overhanging over the edge of the chip)
3) batch fabricating probe chips on 100 mm, 150 mm or larger wafers (this may include e-beam lithography).
The demonstrated approach should be in principle suitable for optical probe loops of 10 micrometer diameter and width down to 150 nm or AFM probes with modal mass below 1 pg and stiffness in the sense direction of 1 N/m to 100 N/m and optomechanical readout with a noise floor below 1 fm/Hz^0.5, or both (preferred). We are not looking for detailed optomechanical probe structure design, but seeking to establish a clear path to batch fabrication on a wafer scale. Sufficient feasibility demonstration will require fabricating simplified test structures to demonstrate key fabrication process steps (such as overhanging the probe and/or fiber coupling), and a theoretical study specifying a detailed fabrication process flow.

Phase II expected results:
Implementation and demonstration of batch fabrication of functional optical or AFM probes or both (preferred). Probe functionality will be validated b NIST. Optimization of probe's design for improved performance and manufacturability. The optical probes shall have the

width from 100 nm to 500nm and radius of curvature from 2.5 micrometer to 10 micrometer. AFM probes shall have the modal mass below 2 pg, and optomechanical readout noise below 3 fm/Hz^0.5. Probes shall be available in several different designs covering varying stiffnesses (AFM) and effective indexes (optical loop). We expect to have established a path to commercial fabrication of these probes at the end of the program.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may provide to the awardee full data on current NIST optical and AFM probe design and performance. NIST researchers may be available to consult with the awardee on all aspects such probe designs and their perceived applications. NIST may provide full details of currently used fabrication process and its implementation in the NIST CNST NanoFab, including recipes for all steps. Some of these steps are not currently compatible with batch fabrication, and NIST seeks to remedy this. NIST may provide full details of the current approach to assembly and integration of these probes into commercial instruments. NIST is open to regular discussions/consultations regarding design, as well as all other aspects of fabrication, as well as use of the probes. NIST researchers may be available, and in Phase II will be expecting, to test the early prototype probes and final supplied probes in our fiber-optical sensing and AFM systems. NIST will implement the changes necessary to integrate and test the supplied probes in our systems (such as custom adaptors or fiberoptic couplers, if necessary).

To be considered under two subtopics, a separate application may be submitted to subtopic 9.07.01.40 NIST Technology Transfer.

References:

[1] T. Michels and V.A. Aksyuk. Optical Probe for Nondestructive Wafer-scale Characterization of Photonic Elements, IEEE Photonics Tech. Lett., 29 (8), pp. 643 – 646, 2017. https://www.nist.gov/publications/optical-probe-nondestructive-wafer-scale-characterization-photonic-elements.

[2] , J. Chae et al. Nanophotonic Atomic Force Microscope Transducers Enable Chemical Composition and Thermal Conductivity Measurements at the NanoscaleNano Letters, 17 (9), pp 5587–559, 2017. https://www.nist.gov/publications/nanophotonic-atomic-force-microscope-transducers-enable-chemical-composition-and.

[3] S.M. An et al. Optomechanical Transducer-based Soft and High Frequency Nanoscale Cantilever for Atomic Force Microscopy, Proceedings, Solid State Sensor, Actuator and Microsystems Workshop, June 2016. https://www.nist.gov/publications/optomechanical-transducer-based-soft-and-high-frequency-nanoscale-cantilever-atomic.

[4] T. Michels et al. Fabrication Process for an Optomechanical Transducer Platform with Integrated Actuation, NIST JRES, 121, pp. 507-536, 2016. https://www.nist.gov/publications/fabrication-process-optomechanical-transducer-platform-integrated-actuation.

[5] Patent application NIST 17-015 US1, U.S. Patent Application serial number 15/799,337 "Photonic Probe for Atomic Force Microscopy, filed October 31, 2017.

[6] Patent application NIST 17-012 US1, Microfabricated Optical Probe.

9.02.07.63 Measuring Handedness by Fluorescence

Inorganic nanomaterials possess unique electronic and optical properties that may enable future quantum information technology and biomedical sensing and imaging. There is a growing appreciation that the intrinsic handedness of a nanomaterial, i.e. left- vs right-handed twist of the overall structure, plays a critical role in controlling the physical and chemical properties of the nanomaterial [1]. However, handedness character has been largely ignored in the past due to measurement challenges. Optical absorption based circular dichroism (CD) is a well-developed technique for characterizing small molecule enantiomers. However, this technique suffers from low speed, low sensitivity, and inability to derive stereochemical surface coating effect when applied to colloidal nanoparticles. Fast, sensitive, and accurate determination of handedness of manufactured nanomaterials is thus an unmet measurement need. This subtopic solicits proposals to develop fluorescence based measurement of enantiomeric colloidal nanomaterials. A spectrometer that carries out such measurement is expected to provide fast, sensitive, and quantitative assessment of the enantiomeric content of the colloidal nanomaterial under test, as well as stereochemical effects from the coating layer. It is envisioned that this fluorescence-based CD spectrometer can be eventually adopted in on-line monitoring of manufacturing process, high-throughput screening, and other application development for a wide range of nanomaterials.

The specific goals of the project are the following.

1. Construct a fluorescence spectrometer that uses left- and right- circular polarized excitation light covering the entire visible range (400-700 nm) via the state-of-the-art super continuum light excitation technique, and detect difference emission fluorescence in the (900-1600 nm) near IR range, achieving a signal/noise ratio > 100 for the resulting 2D excitation-emission spectrum in less than 2 min accumulation time.

2. Demonstrate the capability of such instrument for the analysis of enantiomeric enriched nanoparticle colloids, such as different chiral forms of single-wall carbon nanotubes, with sample volume no more than 400 μL and concentration no more than OD 1 (peak absorbance, 10 mm path length).

Phase I expected results:
Demonstrate feasibility of fluorescence based circular dichroism detection that meet specifications given in Project Goals.

Phase II expected results:
Assemble a functional unit of fluorescence based CD and deliver it to NIST for long term testing and further improvement. Develop commercialization plans to streamline production of the instrument assembly and reach out to wider research and industrial community for adopting the new measurement capability.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may be available to work collaboratively with the awardee, providing consultation and input, and answering questions related to details of measurement needs. More importantly, NIST will be able to provide nanostructures of defined handedness for instrument development and testing.

References:
[1] G. Ao et al. J. Am. Chem. Soc. 138, 16677-16685, 2016.

9.02.08.73 Smart Visualization for Smart Manufacturing

Today's manufacturing systems are able to collect vast amounts of data; however, much of that data is never used unless and until there is a known problem with the equipment. Sometimes the problem will not even be detected until the product is being used in the field, implying that the manufacturing problem may have persisted for several generations of the product. Advances in data visualization, which is a fundamental means of observing data and discovering problems, hold the potential of faster detection of issues and more rapid improvements. However, data visualization still requires considerable effort to easily integrate with the systems generating data [1].

Current approaches (drag-and-drop dashboards, tableaus, etc.) to visualizing smart and sustainable manufacturing enterprises are limited and suffer from many drawbacks. Substantial manual effort from experienced practitioners is required. In some cases, skilled programming is necessary. In other cases, significant visualization expertise is necessary.

Understanding large amounts of data, often stored as combinations of relational and non-relational data in a variety of quasi-federated databases or being streamed directly from machines and not well understood by anyone in an enterprise, adds further difficulty. Combining all of these skills in a single person is costly and is likely to remain out of reach, particularly for small manufacturers. (Large manufacturers have similar problems although for different reasons – while visualization teams exist, inordinately larger data sets make visualization harder in other ways.)

Currently, even the best results are inflexible, unable to adapt to in-process schema changes or schema-less databases. This leads to inflexible software that either suffers from "bit rot" as schemas and databases change out from under the visualization software or from the inability to incorporate new data to improve visualizations.

Manufacturing systems pose other unique characteristics for data. For instance, correlations between time and spatial coordinates are one fundamental concept for assessing manufacturing performance. Performance is often plagued by the interaction of variables along multiple dimensions, rather than a two-factor correlation. In response, some solutions focus on prioritizing dimensions or mathematically reducing dimensionality to best fit to practical visualizations. However, such data transformations can lead to a loss in context and information. Other unique characteristics exist. All in all, the manufacturing environment has become *data rich* but *information poor*.

The goal of this subtopic is to make available manufacturing visualization software that is more flexible, powerful, and easy to use than existing tools. The project will study fundamental concepts that are of relevance to manufacturing data, develop procedures for automatically applying visualization techniques to those concepts, and provide a natural language-based user interface to allow manufactures to quickly assemble their own visualizations based on their datasets. The solution is expected to make use of accepted and practical visualization principles, such as the proper mapping of visual variables to its target data [2], and apply these principles to create a manufacturing-focused toolset.

Additional features of the toolset may include a natural language-based front-end, user guidance on types of visualizations to apply to a given dataset, and data crawling capabilities. A natural language-based front-end will be a helpful component and, for some users, a superior interface to traditional drag-and-drop techniques. User guidance may come in the form of proffering certain visualization techniques that are recognizably appropriate for a dataset, dissuading the use of visualization techniques that are inappropriate for given data, and explaining visualizations that are not immediately obvious. The tool should offer and suggest appropriate choices to deal with challenging data such as

high-dimension data. The software should include an expandable library of plugin visualization components allowing for inclusion of new visualization technologies as they become available. A backend data crawler may adapt to new data as it becomes available within the enterprise, with and even without explicit schemas.

Phase I of the project will demonstrate the feasibility of developing software for visualizations using limited natural language and based on a library of visualizations for manufacturing-specific "big data" (large and varied databases).

Phase II will focus on richer natural language interfaces, techniques to recommend visualizations based on data, and automated assistance at understanding novel visualizations.

At the end of the project, non-visualization specialists should be able to interact with the system, producing visualizations that are better than Excel, at least as good as those from R, Wolfram, D3JS, etc., but much more quickly and without the development time or skills required by current visualization software.

As appropriate based on the mutual interest of both NIST and the awardee, NIST expects to work collaboratively with the awardee providing consultation and input on the activities and directions and providing data and scenarios as appropriate.

References**:**

[1] Visualization-related collections described in "visualization zoos" such as https://queue.acm.org/detail.cfm?id=1805128., http://www.idea.org/blog/2012/10/25/great-tools-for-data-visualization/, and http://d3js.org.

[2] M.S.T. Carpendale. Considering Visual Variables as a Basis for Information Visualization. Computer Science TR #2001-693-16. Dept. Computer Science, University of Calgary 2003. http://dspace.ucalgary.ca/handle/1880/45758.

9.02.09.73 Standards Development and Implementation Tools for Smart Manufacturing and Industrial Internet of Things Applications

U.S. manufacturers are using new sensors, data processing, and internet technologies to create "smart" manufacturing systems that can compete more effectively. Making manufacturing smarter is all about connecting and using data using new, advanced data

analytics tools.

Advanced data analytics, needed to achieve the agility and productivity goals in smart manufacturing systems, rely on cost- and time-efficient integration of data and services from various sources including the Industrial Internet of Things (IIoT) devices. Standards necessary for such integration are still too costly and take long time to develop and use/reuse.

There have been several previous efforts to develop a computational method to provide a new standards development method with needed capabilities. None of the efforts to date has resulted in a viable solution.

NIST has performed preliminary research, developed specifications and a software prototype (called Message Standard Semantic Refinement Tool – MSSRT) to address such needs. The prototype has proved to provide benefits to manufacturing companies albeit in a single company environment. To realize the full vision and benefit, the tool needs to be used in a cloud-based, multi-tenant environment with additional functionalities to rapidly share and reuse standards-usage information. Only in this way, integration costs will reduce because new requirements can be met through reuse rather than development of new information. In addition, standards development will be more efficient and higher quality by adapting the standard-usage information from the widespread inputs.

The targeted application is not a typical multi-tenant application. Typical multi-tenant applications do not allow tenants to share data across tenants; and current database technologies support such data compartmentalization out of the box. Therefore, the targeted application requirement is an innovation in software architecture that allows specific data to be shared across tenants while ensuring that data cannot be leaked unintentionally across tenants at the application logic layer.

Such software application should be hosted and serviced by commercial entities such as a supply chain hub, standards development organizations, or a joint venture between these types of organizations. This will allow maximum sharing of standards usage information and maximum propagation of the requirements to the standards development organizations.

The goal of this subtopic is to develop a multi-tenant tool supporting standards development and usage with an architecture that supports security and confidentiality such that data can be securely and reliably shared and unshared across tenants.

Phase I expected results:

A design document that includes assessments of various implementation architectures for developing a multi-tenant capability of the MSSRT and additional functionalities needed to support the sharing and the agile standard development life cycle. The document shall describe the trade-offs among the architectures and provide a justification for the most suitable architecture. The report shall describe security and confidentiality requirements and how different architectures are meeting and the way of their evaluation against these requirements. The document shall group the additional functionalities needed into immediate needs, future needs, and visionary needs.

Phase II expected results:
1. A commercial grade multi-tenant MSSRT cloud-based application software implemented using the recommended architecture based on the Phase I design. It shall demonstrate the standard sharing and development life cycle functionalities and meet the security and confidentiality requirements specified in the Phase I design document.
2. The software shall include an HTML-based online user guide for the application.
3. A verification and validation test suite for the MSSRT implementation and test report for the test suite run against the implementation.

As appropriate based on the mutual interest of both NIST and the awardee, NIST staff may be available to work collaboratively with the awardee.

References:
[1] The Open Applications Group Semantic Refinement Tool Working Group Description. http://www.oagi.org/dnn2/OurCommunity/WorkingGroups.aspx.

[2] Semantic Refinement Tool Requirement Document Version 1.0. http://www.oagi.org/dnn2/LinkClick.aspx?link=https%3a%2f%2fdrive.google.com%2fopen%3fid%3d0B--IONsLNMMRV0hlRWFkc0tyQ0U&tabid=134&portalid=0&mid=494.

[3] Semantic Refinement Tool Technical Design Document. http://www.oagi.org/dnn2/LinkClick.aspx?link=https%3a%2f%2fdrive.google.com%2fopen%3fid%3d0B--IONsLNMMRRjAzckhBcVN0OUk&tabid=134&portalid=0&mid=494 .

[4] Profile BOD Draft Specification. http://www.oagi.org/dnn2/LinkClick.aspx?link=https%3a%2f%2fdrive.google.com%2fopen%3fid%3d0B--IONsLNMMRUnh5YTg3VE45Qkk&tabid=134&portalid=0&mid=494.

[5] Overview of the OAGIS Repository, a Component of the Semantic Refinement Tool. http://www.oagi.org/dnn2/LinkClick.aspx?link=https%3a%2f%2fdrive.google.com%2fopen

%3fid%3d0B--IONsLNMMRTmhzdklOOFRmN1U&tabid=134&portalid=0&mid=494.

[6] The OAGIS Repository Installation Guide. http://www.oagi.org/dnn2/LinkClick.aspx?link=https%3a%2f%2fdrive.google.com%2fopen%3fid%3d0B--IONsLNMMReHAxeVJOUktpdnc&tabid=134&portalid=0&mid=494.

[7] The OAGIS Repository Example Query. http://www.oagi.org/dnn2/LinkClick.aspx?link=https%3a%2f%2fdrive.google.com%2fopen%3fid%3d0B--IONsLNMMReDJoTXBqS3E2Vnc&tabid=134&portalid=0&mid=494.

[8] Semantic Refinement Tool GitHub Public Repository. https://github.com/OAGi/OAGi-NIST/wiki/OAGi-NIST-Semantic-Refinement-Tools-Home.

9.03 Cybersecurity and Privacy

9.03.01.77 Cloud Security Rubik's Cube (CSRC) – Leveraging Cyber Security Framework to Identify the SP 800 53 Security and Privacy Controls for Cloud-based Information Systems

All Federal agencies are charged and entrusted with safeguarding the information that is contained in their systems and with ensuring that these systems operate securely and reliably. To support Federal agencies, NIST develops security and privacy risk management standards and guidelines that assist agencies in implementing integrated, organization-wide programs to manage information security risk as mandated by the Federal Information Systems Management Act (FISMA) of 2014 and the May 2017 Presidential Executive Order, Strengthening the Cybersecurity of Federal Networks and Critical Infrastructure: available at https://www.whitehouse.gov/the-press-office/2017/05/11/presidential-executive-order-strengthening-cybersecurity-federal. Agencies manage many types of risk and develop specific policies to identify, assess, and help mitigate adverse effects across a wide range of risks, with cybersecurity among them. The latest broad adoption of cloud-based solution for the federal information systems has the potential to elevate the systems' security posture when solutions are properly architected and implemented. The complexity of such systems makes though the risk assessment and the design of a proper solution more difficult and much harder to achieve, especially when the IT security professionals' work is done in spreadsheets and documents driving paper-based compliance which is out-of-date the day after it's written, and often leaving critical risks undiscovered or unaddressed. The U.S. Chief Information Officer (CIO) tasked the National Institute of Standards and Technology (NIST), along with other agencies, with specific activities aimed at accelerating the adoption of cloud computing. The tasks include the delivery of a Cloud Computing

Security Reference Architecture (SP 500-299 – recently renumbered to SP 800-200). The document provides a methodology of architecting a cloud-based federal information. Additional guidance referred to as SP 800-174: "Security and Privacy Controls for Cloud-based Federal Information Systems", leverages the methodology in SP 500-299/800-200 to provide exhaustive sets of SP 800-53 R4, security and privacy controls recommended for each functional capability or micro-service a system implements. Providing a user-friendly tool that leverages the NIST's cloud computing security architecture (SP 800-200) and the questionnaire that drives the selection process of functional capabilities and associated security and privacy controls deemed necessary to be implemented for the information system to operate as indented with minimum residual risk (data aggregated in the SP 800-174) would support agencies in meeting the FISMA requirements and the Presidential Order mandates while creating a risk management dialog that facilitates the communication among agency stakeholders through the process of prioritization, implementation and integration of the security and privacy controls deemed necessary. The tool, referred to as Cloud Security Rubik's Cube (CSRC), should also allow system information analysis (e.g. user should be able to select a control and identify all its instances and the capabilities with which the instances are associated document the implementation of the controls, the generation), and visualization of the system's security posture.

The purpose of the project is to enhance and facilitate government agencies' adoption of secure cloud solution through the development of the Cloud Security Rubik's Cube (CSRC) – a tool that would draw on the exhaustive guidance NIST provides for the government agencies on how to secure information systems (cloud-based in particular) while meeting FISMA requirements regarding applying a risk based approach to securing information systems and the OMB mandate of using the NIST Cyber Security Framework for this purpose. CSRC would bring together guidance provide by NIST in: FIPS 199: "Standards for Security Categorization of Federal Information and Information Systems", FISP 200: "Minimum Security Requirements for Federal Information and Information Systems", SP 500-299/800-200: "NIST Cloud Computing Security Reference Architecture", SP 800-53: "Security and Privacy Controls for Federal Information systems and Organizations", SP 800-174: "Security and Privacy Controls for Cloud-based Federal Information Systems" (dataset only) (requires GitHub account and proper permissions), NIST Cybersecurity Framework (v1.1), NISTIR 8170: "The Cybersecurity Framework. Implementation Guidance for Federal Agencies" and NIST's proof of concept: GitHub project: https://github.com/usnistgov/CloudSecurityRubiksCube.

Phase I expected results:
The Cloud Security Rubik's Cube is developed as a standalone, enterprise-level application that can be installed on either Windows or Mac OS systems.

Phase II expected results:
Update CSRC to support SP 800-53 Rev5: "Security and Privacy Controls for Information Systems and Organizations" (currently on draft form), and containerize it in a way that makes the tool deployable in a cloud environment (e.g. Cloud.gov), either by the provider of a SaaS or by any interested cloud Consumer of a IaaS or PaaS

As appropriate based on the mutual interest of both NIST and the awardee, NIST may be available for consultation and input.

References:
[1] FIPS 199: Standards for Security Categorization of Federal Information and Information Systems.

[2] FISP 200: Minimum Security Requirements for Federal Information and Information Systems.

[3] SP 500-299/800-200: NIST Cloud Computing Security Reference Architecture.

[4] SP 800-53: Security and Privacy Controls for Federal Information Systems and Organizations.

[5] SP 800-174 dataset (requires GitHub account and proper permissions).

[6] NIST Cybersecurity Framework. https://www.nist.gov/sites/default/files/documents/draft-cybersecurity-framework-v1.11.pdf.

[7] NISTIR 8170: The Cybersecurity Framework. Implementation Guidance for Federal Agencies.

9.03.02.60 Digital Forensics

Digital forensics is a broad field that covers any investigation of digital systems or media ranging from traditional computers to mobile phone to drones and even medical devices. Digital forensics examines systems and media in order to find evidence of crimes and to determine who did them. This includes tasks such as identifying who created, sent, or viewed data, what types of data are on a system, reconstructing deleted data and so forth.

Digital forensics is used not just by law enforcement, but in civil and corporate investigations.

Since the scope of digital forensics is vast, the community needs many tools to be able to examine both the variety of systems and media that come to the lab but also to be able to perform different types of analysis. To support this need, NIST has created datasets that support digital forensic examinations, especially through the National Software Reference Library (NSRL) program. The NSRL publishes several datasets related to software that are imported into digital forensic tools. The NSRL recently created new datasets for mobile device apps and gaming platform software.

There are currently no tools that use these datasets to increase the efficiency and effectiveness of digital forensic analysis. NIST is interested in having research performed to determine the best ways to use these datasets and then to create software that digital forensics labs, or other forensic tool makers, can use.

Project goals are:
1. Research the potential for using new NSRL datasets in digital forensic examinations. There are multiple ways in which a dataset can be used to help with digital forensic examinations. Research is needed to understand what forensic processes can be improved by having access to this data. Each new system and media type presents new challenges to forensic examination. The goal is not to simply replicate how previous datasets were used, but to develop new approaches to the examination. The new approaches should address not just finding new types of evidence, but also helping address the problem that forensic examinations can be overwhelmed with the amount of data in a case. Efficiency is also an important goal.

2. Develop prototype software that increases the efficiency and effectiveness of digital forensic examinations by using the new NSRL datasets. The software can be either a standalone tool or appropriate for incorporation into existing tool suites.

3. Develop commercial grade software. The software can be either a standalone tool or appropriate for incorporation into existing tool suites.

Phase I expected results:
Prototype software that increases the efficiency and effectiveness of digital forensic examinations by using the new NSRL datasets.

Phase II expected results:

Commercial-level software that increases the efficiency and effectiveness of digital forensic examinations by using the new NSRL datasets.

As appropriate based on the mutual interest of both NIST and the awardee, NIST will provide datasets for mobile apps for both Android and iOS; for Steam/Valve software, and possibly for Blizzard and Origin games; NIST will also provide a research environment in which the awardee can test their software against the NSRL corpus.

Reference:
[1] National Software Reference Library (NSRL). http://www.nsrl.nist.gov.

9.03.03.77 Imposing Fine-grain Next Generation Access Control over Database Queries

Relational Database Management Systems (RDBMSs) do not typically impose fine-grain access control directly on its data. To restrict access to sensitive data that might reside in a RDBMS, controls are typically implemented at the application level or through proprietary RDBMS methods such as views. These controls take on many forms including role-based access to “screens” with parameters that can be characterized and subsequently used to formulate and issue SQL queries. SQL queries comprise four basic types of operations–Select, Insert, Update, and Delete–that respectively read, create, write, and delete data in tables. An important feature of RDBMSs is that they can specify criteria and extract and/or alter data that might reside in one or more tables with great efficiency. For example, “give me all the employees over 50 years old that live in Virginia”. NIST has developed a method for which a patent application has been filed [1] that leverages ANSI/INCITS Next Generation Access Control (NGAC) standard [2] called Next-generation Database Access Control (NDAC) for imposing access control over database queries at the data level, independent of the application and with minimal impact on performance. Licensing conditions will be the same as in subtopic 9.07.01.40. As a result, the same policies can protect multiple databases from queries sent from multiple applications. Furthermore, NDAC not only provides control down to the field level, but to varying fields of select rows. NDAC is unique in achieving this granularity of control without the use and coordination of multiple protection mechanisms. Operationally, users issue wide sweeping queries, and NDAC allows access to the optimal amount of data permissible for the user. The method includes an Access Manager for trapping and enforcing policy over SQL queries issued by applications as well as a Translator for converting SQL statements to NGAC inputs and converting NGAC authorization responses to either an access Deny or a permitted SQL statement that is submitted to the database. [4] provides a comprehensive description of the NDAC method.

In support of the NGAC standardization effort, NIST has developed an NGAC open source reference implementation [5] called the Policy Machine (PM), that includes an administrative tool for expressing policy and an NGAC authorization engine that may serve as a critical component in an NDAC implementation. In addition, NIST has developed a partial NDAC prototype implementation that demonstrates partial functionality for Select and Update SQL statements to demonstrate the viability of NDAC. This prototype implementation can be found on GitHub as open source [6].

This SBIR subtopic seeks development of a commercially viable NDAC product that leverages Policy Machine opensource. This effort includes development of an Access Manger and Translator. The translator should include a SQL parser that may be developed from scratch, purchased, or adapted from an open source parser. The Access Manager must include a SQL proxy. In addition, a commercially viable product should include user, administrator, and application developer documentation. An anticipated challenge is capturing and extracting a user identity from an application that is required along with SQL as input to the Access Manager.

Phase I activities and expected results:
1. Plan, specification and design for an NDAC implementation based on the existing PM open source for future commercial use.
2. Completed development plan, specification, and design including test plan for the proposed capabilities.

Phase II activities and expected results:
1. Code development, documentation, and testing of the Beta version of a commercially viable NDAC product.
2. A robust beta version of NDAC product that contains the proposed capabilities, documentation for the code and user manual, and testing results to verify the completeness of the development.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may provide PM source code [5], NDAC prototype source code [6], consultation, input, and discussion with the awardee to help with the evaluation of the proposed development. Upon request, NIST would conduct a demonstration of the prototype NDAC implementation.

To be considered under two subtopics, a separate application may be submitted to subtopic 9.07.01.40 NIST Technology Transfer.

References:
[1] D. Ferraiolo, S. Gavrila, G. Katwala, J. Roberts. U.S. Patent App. 15/215,556.

[2] American National Standards Institute, Information technology - Next Generation Access Control - Functional Architecture (NGAC-FA), INCITS 499-2013, American National Standard for Information Technology, March 2013.

[3] American National Standards Institute, Information technology – Next Generation Access Control – Generic Operations and Data Structures (GOADS), INCITS 526-2016, American National Standard for Information Technology, January 2016.

[4] D. Ferraiolo et al. Imposing Fine-grain Next Generation Access Control over Database Queries Proceedings of the 2nd ACM Workshop on Attribute-Based Access Control, pp 9-15, 2017.

[5] NIST Policy Machine Versions 1.5 and 1.6 - Harmonia [Website], https://github.com/PM-Master [accessed 9/26/16].

[6] NDAC prototype implementation, https://github.com/PM-Master/NDAC.

9.04 Exploratory Measurement Science

9.04.01.63 In-line Spectral Filtering for Integrated Raman Fiber Optic Probes

Novel designs of Raman spectroscopic probes benefit from the flexibility afforded by the use of optical fibers, yet Raman scattering intrinsic to the fibers is an undesirable spectral background that results in reduced analyte sensitivity. Spectral filters can be deployed to eliminate this background at the cost of increased probe size and complexity. NIST seeks the development of optical fiber assemblies wherein the spectral filtering is engineered into the fibers themselves through the use of fiber Bragg gratings or other similar technology. Development of such fiber technology is expected to benefit wide ranging applications of Raman spectroscopy such as biomedical endoscopy and remote sensing, in addition to the development of integrated Raman/mechanical probes being pursued at NIST.

Raman spectroscopy is a widely used, non-destructive technique for extracting compositional and structural information about a wide variety of materials on micrometer length scales. In recent years, Raman instrumentation has moved beyond the traditional microscope and spectrometer paradigm to include a wide variety of portable form factors in

which the analysis technology can be brought to the specimen, rather than the typical reverse approach. A key element in some of these new designs is the use of optical fibers for both delivery of the excitation light and collection of the Raman scattered photons. The use of fibers provides a great deal of flexibility over free space optics, particularly for analysis in remote (*e.g.*, undersea [1]) or difficult to access locations (*e.g.*, *in vivo* [2]). A complication of the use of silica fibers is the Raman scattering generated by the fibers themselves; this scattering can be of sufficient intensity to mask the detection of analytes in low wavenumber Raman scattering (< 1250 cm^{-1}) [2]. The fiber Raman scattering can be suppressed through the use of narrow bandpass filters (excitation beam) and steep long pass filters (Stokes scattered beam) located between the excitation/collection fibers and the specimen. The use of such filters works well in conventional Raman instruments, but presents significant design challenges for applications with significant space limitations. It is worth noting that these are often the same applications that stand to benefit the most from the flexibility afforded by the use of fiber optics.

Several researchers have explored the idea of engineering the functionality of the Raman filters *directly* into optical fibers, thus eliminating the space constraints imposed by the need for the spectral filters. For example, Popp and co-workers demonstrated the use of Bragg gratings written into several collection fibers to suppress the silica fiber background in the Raman spectroscopy of brain tissue [3]. The further development of this type of technology opens the possibility of greatly simplifying the Raman probe designs for a wide variety of applications, including endoscopy [2] and remote Raman sensing (*e.g.*, mine shafts [4]).

NIST researchers have an interest in coupling an optical fiber or fiber bundle directly to an optically transparent mechanical probe (e.g., ceramic ball lens) to allow simultaneous Raman and mechanical measurements of materials. An optical fiber assembly with integrated spectral filtering of the silica fiber Raman from the excitation beam and rejection of Rayleigh scattered light in the collection fibers would greatly improve on current implementations of integrated Raman/mechanical probes.

Phase I expected results:
NIST expects a design for an optical fiber or fiber bundle with integrated filtering technology sufficient to suppress fiber Raman scattering to a degree comparable to commercial Raman filters (*e.g.*, narrow bandpass/longpass Raman filter combinations). The design should include fiber parameters derived from relevant optical modeling for fiber Bragg gratings (or other appropriate technology) that will yield sufficient filtering performance. Additionally, a plausible methodology for fabrication of fibers or fiber bundles with the integrated filtering technology that will allow coupling to NIST specified mechanical probes should also be

developed.

Phase II expected results:
NIST expects fabrication of a working prototype optical fiber assembly with integrated spectral filtering yielding performance comparable to commercial Raman filter sets. Additionally, the assembly design should accommodate reproducible coupling to ceramic ball lens mechanical probes specified by NIST.

As appropriate based on the mutual interest of both NIST and the awardee, NIST staff may be willing to consult awardees on specific details of planned use of fiber optics at NIST and to provide mechanical probes for testing along with providing general input on requirements for other possible applications.

References:
[1] X. Zhang et al. A Review of Advances in Deep-ocean Raman Spectroscopy, Appl. Spec., 66 (2012) pp. 237 – 249 DOI:10.1366/11-06539.

[2] O. Stevens et al. Developing Fibre Optic Raman Probes for Applications in Clinical Spectroscopy, Chem. Soc. Rev., 45 (2016) pp. 1919-1934 DOI: 10.1039/C5CS00850F.

[3] S. Dochow et al. Multicore Fiber with Integrated Fiber Bragg Gratings for Background-free Raman Sensing," Opt. Express, 20 (2012), pp. 20156-20169 DOI: 10.1016/j.addr.2015.03.009.

[4] J. Pope, and J. Herries. In-situ Detection and Analysis of Methane in Coal Bed Methane Formations with Spectrometers, U.S. Patent 7,821,635, October 26, 2010.

9.04.02.68 Intermediate Frequency Conversion System for High-Bandwidth Multiplexed Sensors Arrays

Arrays of cryogenic sensors below 1 Kelvin provide unique measurement capabilities for both industrial applications, for example materials analysis in a scanning electron microscope, and for fundamental scientific applications, for example x-ray beam-line science and cosmic microwave background research. New application areas are emerging as the arrays become larger and move beyond the domain of specialized cryogenic facilities. These systems use a variety of different cryogenic sensors, including microwave kinetic inductance detectors, magnetic calorimeters, and microcalorimeters and bolometers based on transition-edge sensors (TESs).

In order to read out cryogenic sensor arrays at the scale of tens to hundreds of thousands of sensors, multiplexing with GHz of bandwidth per output channel is necessary. Without this multiplexing, the heat load caused by electrical connections to room temperature would be prohibitive. Cryogenic sensor groups at NIST, as well as other institutions around the world, have been developing microwave multiplexing technologies to meet this need.

All solutions currently being developed rely on the measurement of the system with a superposition of microwave tones at different frequencies, one for each detector. The cryogenic circuit is designed to modulate the microwave tones, each with the signal from its own sensor. If the input tones can be digitally synthesized, and the modulated tones digitally processed, the sensor signals can then be demultiplexed using software-defined radio (SDR). However, room temperature hardware is needed to bridge to frequency gap between the GHz carrier tones and existing digital-to-analog (DAC) and analog-to-digital (ADC) converters.

The microwave carriers are generated using IQ mixing to upconvert baseband tones from a pair of DACs. The modulated signals are similarly mixed down and fed into a pair of ADCs. To read out more bandwidth than the DACs and ADCs provide, we split the signal from the cryostat (combine the signal into the cryostat), mix down (up), and filter to exclude aliasing from tones outside the band of interest. Currently the up-mix and down-mix are accomplished using discrete connectorized components including the mixers and various amplifiers, attenuators, and filters necessary to match the signals to both the sensors and digitizers. In order to read out future large arrays of cryogenic sensors, a more integrated and scalable commercial solution is necessary.

The project goal is to enable multiplexed readout of large scale cryogenic sensor arrays, we seek proposals for a scalable system to perform the frequency conversion between the microwave frequencies and existing DACs and ADCs that meets the following technical goals:

- Capability for up- and down-mix of several adjacent bands in the 4-8 GHz range. As the bandwidth of ADCs and DACs is rapidly evolving, system adaptability is preferred. However, our current system is set up to use 4X 1 GHz bands.
- Ability to match the range of the DACs and ADCs to the amplitude of microwave signals into and out of the cryostat, without degrading signal-to-noise (SNR). For example, with a +/- 0.5 V scale on the digitizers and 2000 tones, the power per tone is -38 dBm on I and Q. The microwave power per generated tone must be at least -45 dBm, preferably -40 dBm. While meeting this goal, the conversions must not degrade either input or

output SNR to worse than 130 dB/Hz.

- Switchable calibration modes to allow the I/Q imbalances to be characterized and compensated for in the digital signal processing. This calibration is necessary to suppress image tones, which can interfere with the signals of other sensors.
- Integrated solution that provides power for the active components and communication for control of the relays, attenuators, microwave sources, etc.
- Scalable manufacture, to satisfy the needs of systems accessing many tens of GHz of bandwidth with low lead time, and without high cost per unit.

Phase I expected results:
A substantially complete mechanical and electrical design that addresses the project goals described above.

Phase II expected results:
Construction of a prototype frequency conversion system that fulfills the project goals above. This prototype will remain the property of the awardee. Demonstration of the frequency conversion system together with NIST staff. Commercialization of frequency conversion system if technically successful.

As appropriate based on the mutual interest of both NIST and the awardee, NIST personnel may be available to assist the awardee in a variety of ways including consultation on instrument design and participation in design reviews.

References:
[1] J.N. Ullom and D.A. Bennett. Review of superconducting transition-edge sensors for x-ray and gamma-ray spectroscopy. Superconductor Science and Technology 28.8, 084003, 2015.

[2] J. Zmuidzinas. Superconducting Microresonators: Physics and applications. Annu. Rev. Condens. Matter Phys. 3.1 (2012): 169-214.

[3] J.A.B. Mates et al. Simultaneous Readout of 128 X-ray and Gamma-ray Transition-edge Microcalorimeters using Microwave SQUID Multiplexing. Applied Physics Letters 111.6, 062601, 2017.

9.04.03.68 Solid-State Dynamic Mode Mixer for Multi-Mode Optical Fiber

Multi-mode optical fiber is a common delivery system for radiant flux, in particular from lasers, and as the input for detection systems such as spectrographs. The output from a

multi-mode optical fiber is non-uniform and sensitive to the input geometry. For example, a common incident flux condition is for quasi-collimated flux introduced into the optical fiber at an angle. In this case, the output distribution will be a ring or doughnut. This type of distribution creates calibration issues with both spectrographs and integrating spheres. For spectrographs, the optical fiber is often coupled directly to the slit, resulting in a non-uniform 'saddle' image on the focal plane. This type of image can lead to partial saturation of the spectrum and measurement errors.

Propagation of radiation through a multi-mode optical fiber does not by itself reduce effects of laser coherence, often referred to as speckle, on the measured signal. Currently, speckle is reduced by placing a length of unjacketed optical fiber into an ultrasonic bath. The bath modulates the optical signal at frequencies of 40 kHz, reducing speckle in the output beam. Over time, however, cracks develop in the optical fiber, increasing the loss in the fiber. The optical fiber in the ultrasonic bath needs to be replaced every 4 weeks to 8 weeks (depending on usage). While some modes are mixed using the ultrasonic bath, the mixing is not sufficient to produce a uniform output beam. Static mode mixers have been developed, but are not suitable because they do not reduce coherence effects. One U.S. company claims to have a mode mixer product (General Photonics, MMS-201). However, it operates over a very limited spectral range, from 500 nm to 1650 nm, and does not adequately mix the spatial modes in the fiber, though it does reduce the coherence of the light propagated through the system.

A Solid-State Dynamic Mode Mixer will mix the spatial modes in the optical fiber at frequencies of 1 kHz or greater, effectively averaging out the non-uniform spatial distribution and shifting coherence effects to higher frequencies. It will impact all research and products that benefit from a uniform output from a multi-mode fiber.
Project goals include the following:

1. Demonstrate dynamic mode mixing in a multi-mode optical fiber covering the spectral range from 360 nm to 1000 nm.
a. Mode mixing should be dynamic, scrambling the spatial modes at 1 kHz or greater.
b. Mode mixing should improve the uniformity of the output beam to either a flat-hat or Gaussian-like spatial distribution.
c. Insensitivity of the output of the multi-mode fiber to input conditions should be demonstrated.
2. Extend the mode mixing to 2.5 um.
3. Extend the spectral range to 3 µm.
4. Extend the spectral range to 300 nm.
5. Extend the spectral range to 200 nm.

Phase I expected results:
It is expected that project goal 1 will be complete by the end of Phase I.

Phase II expected results:
1. Package demonstrated product in a box suitable for rack-mounting. Keep the size within 3U.
2. Project goals 2-5. For all goals 1a, 1b, and 1c shall be demonstrated.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may be available to assist in any way it can be helpful and hopes to work with the awardee to understand the performance of the mode mixer – in particular the degree of homogenization of the light output from the fiber and the temporal behaviors.

9.05 Health and Bioscience

9.05.01.68 Open Source Image Analysis for NIST/RSNA/NCI Validated MRI Phantoms

There is a critical need for National Metrology Institute-validated medical imaging calibration structures (SI-traceable phantoms) as well as validated analysis platforms that can determine the accuracy of advanced quantitative imaging techniques that are coming online. An open analysis package for NIST phantoms was one of the most requested items in a recent MRI Standards workshop held at NIST Boulder in August 2017. Commercial versions of this analysis package were identified as an essential element getting these reference objects used in clinical trials.

The new quantitative imaging techniques, included advanced diffusion mapping and magnetic resonance fingerprinting, can provide more information about tissue properties, which is critical for identifying cancerous lesions, neural trauma, and the onset and progression of neurodegenerative diseases. These new techniques, which are faster and more cost effective, need to be validated using primary reference structures provided by NIST(1-4), with protocols validated by NIST, the National Cancer Institute (NCI), and the Radiological Society of North America (RSNA). An example public-domain best-practice protocol is the diffusion imaging profile recently published by RSNA Quantitative Imaging Biomarker Alliance(5). It is imperative that an open source analysis framework be setup so that different institutions, medical instrument makers, pharmaceutical companies can verify and compare their analysis protocols on the same SI-traceable object.

While the open source component of this subtopic is not a commercial product, it lays the foundation for many commercial packages that rely on their ability to demonstrate that they can successfully implement standard analysis protocols or can provide ones with demonstrated superiority. Once the company can demonstrate the open source framework, it can market application specific versions that are tailored to specific clinical trials.The existence of an open source image analysis package for SI-traceable phantoms will greatly assist the NIST goal of transitioning medical imaging to a precise metrology. Having NIST-validated components in a widely used open source analysis platform will advance precision medicine. A very successful model of an open source image analysis package is ImageJ (and offspring such as FIJI), which was originally developed by NIH.

The goal of the project is to create a new and unique platform to extract quantitative information from MRI phantom data sets. The platform must be open to inspection, modular so users can swap in analysis packages that they wish to compare against current standards, implement advanced physics models for artifact identification and uncertainty analysis, provide a platform where machine learning analysis, such as magnetic resonance fingerprinting and deep learning image reconstruction, can be compared against standards. At present, there is no such common platform to compare and test quantitative image analysis protocols on primary reference standards. Currently, when comparing analysis techniques, a hodgepodge of different packages, both commercial and in-house, are used. This platform would be a ground-breaking critical component connecting medical imaging to the SI.

The Phase I effort should develop a framework of tools to allow processing of data from the NIST system phantom, diffusion phantom, and breast phantom(6-8) using NIST, RSNA, and NCI prescribed protocols(5). The framework should be open to allow swapping in different analysis protocols and allow rapid comparison between protocols. Phase I should provide a demonstration on one phantom of how the analysis framework will work. Phase I should also produce innovative plans for improved analysis of geometric distortion, automated resolution determination, and better methods for dealing with noise and artifacts.

The Phase II effort should develop the complete analysis framework and include innovative components going beyond what has been currently developed by NIST, RSNA, and NCI. These elements may include deep learning based analysis of geometric distortion, RF inhomogeneity analysis, and an automated image resolution analysis. The analysis framework should be completely modular with the ability to import and analyze all existing SI-traceable phantoms.(6-8) The open source component should be published on Github with public accessibility. The company should further demonstrate the ability to use the open source package to provide improved quality assurance tools for clinical trials.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may provide access to all details of phantom construction and access to NIST in house analysis packages. NIST may provide virtual phantoms (digital reference object) providing full numerical description of NIST developed phantoms. NIST will facilitate access to RSNA QIBA and NCI Quantitative Imaging Network imaging protocols. NIST will provide continuous test and feedback on the platform as it is developed using existing NIST datasets.

References**:**

[1] N.M. deSouza et al. Implementing Diffusion-weighted MRI for Body Imaging in Prospective Multicentre Trials: Current Considerations and Future Perspectives. Eur Radiol. 2017. doi: 10.1007/s00330-017-4972-z. PubMed PMID: 28956113.

[2] Y. Jiang et al. Repeatability of Magnetic Resonance Fingerprinting T1 and T2 Estimates Assessed Using the ISMRM/NIST MRI System Phantom. Magnetic Resonance in Medicine: Official Journal of the Society of Magnetic Resonance in Medicine / Society of Magnetic Resonance in Medicine. 2016. doi: 10.1002/mrm.26509. PubMed PMID: 27790751; PMCID: PMC5408299.

[3] D.C. Newitt et al. Multisite Concordance of Apparent Diffusion Coefficient Measurements Across the NCI Quantitative Imaging Network. J Med Imaging (Bellingham). 2018; 5(1):011003. doi: 10.1117/1.JMI.5.1.011003. PubMed PMID: 29021993; PMCID: PMC5633866.

[4] E.M. Palacios et al. Toward Precision and Reproducibility of Diffusion Tensor Imaging: A Multicenter Diffusion Phantom and Traveling Volunteer Study. AJNR American Journal of Neuroradiology. 2017; 38(3):537-45. doi: 10.3174/ajnr.A5025. PubMed PMID: 28007768; PMCID: PMC5352533.

[5] QIBA Profile: Diffusion-Weighted Magnetic Resonance Imaging (DWI). http://qibawiki.rsna.org/index.php/Perfusion, Diffusion and Flow-MRI Biomarker Ctte. 2017.

[6] K.E. Keenan et al. Comparison of T1 Measurement Using ISMRM/NIST Phantom. Proceedings Title: Proceedings of the International Society of Magnetic Resonance in Medicine, #3290 2016.

[7] K.E. Keenan et al. Variability and Bias Assessment in Breast ADC Measurement Across Multiple Systems. Journal of Magnetic Resonance Imaging. 2016;44(4):846-55.

[8] K.E. Keenan et al. Design of a Breast Phantom for Quantitative MRI. Journal of Magnetic Resonance Imaging, 44(3):610-9 2016.

9.05.02.68 Optical Imager for Quantitative Deep Tissue Oximetry

In image-based tumor detection, exposure of the human body to ionizing radiation in x-ray tomography and the use of heavy metal contrast reagents in MRI cause harmful side effects (See "The surprising dangers of CT scans and X-rays"[7], Label-free optical imaging technologies, i.e. without the need for ionizing radiation exposure and exogenous contrast agents will enable safe and complication-free tumor diagnostics. However, optical techniques are fundamentally limited to surface imaging or to low resolution diffuse light scattering applications as the optical wavelengths of light significantly scatter through thick tissue, preventing the backscattered light from refocusing for precise image reconstruction.[8] A new technique has been recently demonstrated that overcomes some of the issues associated with traditional optical imaging. In the new technique, optoacoustic imaging, the absorption of light by existing (endogenous) colored molecules in a sample provides specificity and contrast, but unlike traditional optical techniques, there is no need to collect the scattered light. Rather, the initial absorption of light creates an acoustic wave which is much easier to collect because it is not as susceptible to scattering as optical wavelengths. The goal of this innovative research is to realize an instrument based on label- free optical imaging that is capable of *quantitative and functional* oximetric imaging (i.e. determination of oxy- and deoxyhemoglobin concentration ratios as a map of tissue oxygenation) of deep tissues with depth and lateral resolutions, and tumor-identifying specificity comparable to those of MRI and x-ray computed tomography. Functional evaluation of the tissue oxygen levels has been shown to be a key biomarker to quantitatively diagnose the disease states of tumor tissues.[9]

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[7] https://www.consumerreports.org/cro/magazine/2015/01/the-surprising-dangers-of-ct-sans-and-x-rays/index.htm)

[8] http://www.laserfocusworld.com/articles/print/volume-51/issue-11/newsbreaks/multimode-holographic-waveguides-tackle-in-vivo-biological-imaging.html

[9] https://www.researchgate.net/figure/267657254_fig1_Figure-2-An-illustration-of-the-differences-between-normal-oxygen-level-in-the evaluation of tissue oxygen levels

Recent technological advancements in this area have been research-based (preclinical) and exploratory, mostly taking place in academic laboratories. Commercialization of a technology to make an optical technique readily available and validated will allow a broad range of clinical applications for non-invasive diagnostics of tumors. Label-free deep tissue optical imaging will significantly enhance the safety and lower the health care cost of tumor diagnostics in the clinic. Broad distribution of this technology through commercialization would also provide a valuable tool in evaluation of the efficacy of a variety of cancer treatment approaches. Non-invasive optical imaging will enable prognosis of tumors in response to new drugs as well as image-guided surgeries and treatments, promoting a broad range of industries such as medical device manufacturers to pharmaceutical companies.

This innovative research is well aligned with NIST's mission to improve the quality of people's lives by working with industry to develop and apply technology, measurements, and standards. NIST began a program in Optical Medical Imaging approximately 8 years ago to help with the development of phantoms (i.e. calibration artifacts) for a variety of pre-clinical optical imaging techniques. The Molecular and BioPhotonics Group has received standards development (SD) funds to respond to the needs of the optical medical imaging community, specifically to develop phantoms for optical coherence tomography and photoacoustic imaging. Both Europe and Asia are currently approving clinical use of photoacoustic imaging, but the U.S. is lagging behind because of stricter approvals required by the Food and Drug Administration (FDA). NIST is working to support the FDA to develop phantoms that would enable the FDA to assess and accelerate approval of new optical medical imaging devices and their applications. NIST's participation in this SBIR is expected to encourage small start-ups and businesses to develop a product and begin FDA submission for approval of the device. The success of this SBIR will also provide a benchmark to accelerate clinical applications (i.e. use of the device) of a broad range of label-free tissue optical imaging methods for accurate disease diagnostics to improve the quality of people's lives.

Label-free deep tissue optical imaging with a penetration depth of a few centimeters and with the spatial resolution of about 250 micrometers has been demonstrated by photoacoustic computed tomographic imaging. In tumor imaging applications, this technique uses endogenous molecular contrast originated from hemoglobin molecules highly concentrated in newly formed blood vessels in tumor regions. While demonstration of tumor imaging has the potential for huge clinical impact in the noninvasive diagnostic of

tumors, an accurate measurement of the oxygen level in the tissue is essential to provide a prognostic indicator directly related to the efficacy test of tumor treatments. The project goals are to integrate a quantitative label-free functional imaging capacity capable of mapping oxygen saturation (SO_2) level in tissues (with < ±5% absolute accuracy and < ±1% repeatable precision) into existing photoacoustic computed tomographic imaging technology with the following requirements: spatial resolution of < 300 micrometer, and temporal resolution 10 Hz in 2D frame rate, and < 20 s to acquire a volume tomography of ~4cm deep tissues.

Phase I expected results:
1. Integration of a functional imaging capability to determine tissue oxygen levels into a deep-tissue photoacoustic imaging system.
2. Develop methods for quantitative evaluation of the image quality involving tissue oxygen saturation (SO_2) level, spatial resolution, temporal resolution, and contrast to noise ratio. 3. Demonstration of the resolution, precision and accuracy levels stated in project goals for NIST provided phantoms.

Phase II expected results:
1. Demonstrate quantitative functional oximetry mapping capability in at least 5 human subjects with the oxygen saturation measurement with < ±5% accuracy and < ±1% precision.
2. Demonstrate <350 micrometer spatial and < 20 s for 3D and 0.1 s for 2D temporal resolutions for the tomography of > 4cm deep tissues.
3. Success would ultimately entail submitting an Investigational device exemption (IDE) package to FDA for device approval.

One of the major foci of the NIST's Optical Medical Imaging program is to develop standards to enable quantitative label free imaging of biological tissues. Through the program, the NIST team has successfully developed a series of tissue-mimicking phantoms with well-defined and well-characterized optical properties for a broad range of label free optical imaging technologies, including photoacoustic microscopy and tomography. As appropriate based on the mutual interest of both NIST and the awardee, NIST's phantoms will be available for the calibration of devices and the validation of the optical measurements for this study. The NIST team has also demonstrated a capability to accurately measure the ratio of oxy-hemoglobin to deoxy-hemoglobin at a single cell sensitivity. This knowledge base will be available to help the SBIR researcher(s) to verify their quantitative oximetry measurements.

References:
[1] S. Hunjan et al. Tumor Oximetry: Demonstration of an Enhanced Dynamic Mapping

Procedure Using Fluorine-19 Echo Planar Magnetic Resonance Imaging in the Dunning Prostate R3327-AT1 Art Tumor, Int. J. Radiation Oncology Biol. Phys., 49(4) 1097, 2001.

[2] L.V. Wang and J. Yao, A Practical guide to Photoacoustic Tomography in the Life Sciences, Nature Methods 13, 627, 2016.

[3] J.Y. Lee et al. Absorption-Based Hyperspectral Imaging and Analysis of Single Erythrocytes, IEEE Journal of Selected Topics in Quantum Electronics, Vol. 18, No. 3, 1130-1139, May/June 2013.

[4] B. Chon et al. Digital Phantoms Generated by Spectral Light Modulators, Journal of Biomedical Optics, 20(11), 11215, November 2015.

9.05.03.77 Parallel Algorithms for Processing Huge Sparsely Labeled Datasets on Clusters of Multicore Processors and Many-Core Accelerators for Healthcare Applications

Many healthcare applications are unavoidably spatio-temporal and generate large amounts of data. Expert interaction and measurement costs for these datasets imply that only a very small fraction of the data can be labeled such that models or results are presented in a form that supports human understanding. In general, the underlying spatial and spatio-temporal relationships in these data can be represented as three-dimensional grid or graph structures. Traditional machine learning algorithms are not applicable as they tend to be sample-based, requiring labelling of a significant fraction of the data. Therefore, a pressing need exists for algorithms that can handle very large datasets with only a fraction of data labeled. Additionally, data volume and speed of data acquisition requires that such algorithms effectively exploit networked multicore, GPU, and parallel computing resources. The underlying technology should have broad applicability in spatio-temporal big data applications.

The goal of the proposed research is to develop fast, parallel semi-supervised machine learning (ML) algorithms that address challenges of very large datasets and applications in the domain of healthcare. Such ML algorithms should be effective for datasets having millions to billions of data points, with only a few thousands of data points labelled.

Phase I expected results:
Select a representative sparsely labeled healthcare dataset. Develop novel machine learning algorithms that can work effectively for sparsely labeled datasets. Demonstrate their parallelization capability on hundreds of traditional cores.

Phase II expected results:

Demonstrate the effectiveness of machine learning algorithms developed in Phase I on real world applications in health care domains. Demonstrate scalability of these algorithms on large clusters of GPUs and multicore machines. Phase II results should lead to a commercialization path for the technology applications in specific domains within Healthcare.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may be available to work both in consultative and collaborative capacity in assisting the awardee.

Reference:
[1] O. Chapelle et al. Semi-Supervised Learning, MIT Press, 2010.

9.05.04.77 Process Modeling for IoT Health Services

Two central challenges in contemporary health IT are (i) the rising heterogeneity of elements interacting in health systems and (ii) the unprecedented level of interconnectivity between them [1]. Consequently, it is no longer sufficient to consider medical processes (only) at the level of doctor and patient; we must also consider the interactions between electronic health records, embedded medical devices and web apps as well as other parties like specialists, testing labs and insurance providers. Adding to the problem, these health processes occur at multiple scales, and we may wish to analyze them from many different perspectives, ranging from psychological to biophysical to probabilistic.

Recent work in mathematics has revealed a powerful new approach to open and interconnected systems based on resource-sensitive process representations called string diagrams [2]. Developed to facilitate calculations in quantum computing, these allow for a formal representation of correlations and entanglement between interacting elements in a system. This provides a common context and mathematical structure in which to comprehend both the diversity and the interaction implicit in modern health systems. Moreover, there is a rich semantic theory for string diagrams, allowing us to realize different perspectives on these processes. Best of all, these approaches are generic; while we want to apply them here for health IT, the same methods are directly relevant to other IoT systems including smart manufacturing processes.

The goal of this project is to develop a prototype tool for the representation and modeling of IoT processes based on string diagrams, following the work in [3] and [4]. This should allow for process representation based on string diagrams as well as semantic modeling of the resources and processes there-in. The tool must also allow for the construction of structured mappings (i.e., functors) between these diagrams, in order to support multi-scale

representations.

The project must also demonstrate the application of this tool in healthcare IT, through one or more examples to be developed jointly with NIST.

The results of the Phase I award should include (i) a user interface for constructing string diagrams, (ii) a means of connecting components in the diagram with semantic and/or computational representations and (iii) a toy example demonstrating such a representation and an analysis based on it.

Phase II should result in a polished prototype tool, extending the capabilities above with (i) multi-scale analysis based on structured mappings between diagrams, (ii) the capability for editing both process and semantic representations and (iii) an automated or guided tool for updating analyses after process modification. These capabilities should be validated through a use-case which will involve >3 interacting components, two scales of representation and analyses from two distinct perspectives.

As appropriate based on the mutual interest of both NIST and the awardee, NIST may be available to assist with the design of the tool, including user interaction and underlying data structures. NIST may also be available to assist in modeling and construction of use cases. The work on medical device inter-operability in the division can be used to generate the examples for prototype implementations.

References:

[1] S. Jabbar et al. Semantic Interoperability in Heterogeneous IoT Infrastructure for Healthcare, Wireless Communications and Mobile Computing, vol. 2017, Article ID 9731806, 10 pages, doi:10.1155/2017/9731806, 2017.

[2] B. Fong et al. A Categorical Approach to Open and Interconnected Dynamical Systems. Proceedings of the 31st Annual ACM/IEEE Symposium on Logic in Computer Science. ACM, 2016.

[3] S. Reinert et al. Modeling the Internet of Things: A Foundational Approach. Proceedings of the Seventh International Workshop on the Web of Things. ACM, 2016.

[4] S. Breiner et al. Categorical Foundations for Systems Engineering". 15th Annual Conference on Systems Engineering Research. Redondo Beach, CA. March 23-25, 2017.

9.06 Physical Infrastructure and Resilience

9.06.01.73 Self Configuring Residential Conditioned Air Zoning System for Low Energy Homes

Several years of testing and data analysis at the NIST Net Zero Energy Residential Test Facility (NZERTF) have shown that this low energy home has difficulty with temperature differences between the upstairs and lower levels of the home. Design airflow rates to those rooms have been verified, but the low sensible loads in the home mean that the air-conditioning system does not operate enough to keep the air well-mixed. Temperature differences of as much as 2 °C to 3 °C are prevalent during the warmest days of summer and coolest days of winter. Therefore, the need for more dedicated control of temperature in each room is needed. This observation has already been noted in the literature for other low energy homes; the conclusions were that zoned systems are a way to ensure comfort in all occupied areas (Stecher 2011).

This subtopic proposes the development of an easy-to-install, (hopefully) lower cost, performance-verifiable conditioned air zoning system that will be applicable for both new homes and retro-fit into existing homes. NIST foresees that the leveraging of Internet of Things (IoT) technology such as blue-tooth, zigbee, wifi, etc. can have a huge impact on the heating, ventilating, and air-conditioning systems that residential and commercial contractors install every day. Current building code homes and low energy homes could benefit from multiple temperature and humidity controlled zones. As far as human comfort is concerned, the use of a conditioned air zoning system is a very good way of producing comfortable conditions for all occupants in the various spaces of the home; in some instances, the installation of this zoning system can also save energy by directing conditioned air to the occupied spaces only.

The product of this SBIR project will be the demonstration of a conditioned air zoning system; this zoning system would be designed to deliver the appropriate conditioned air flow rates, as calculated from an ACCA Manual J (2016a) cooling and heating load analysis, to each area of the NZERTF based upon the measurement of each zone's temperature and humidity. The novel idea behind this project would be the merge of Internet of Things (IoT) technology and control of the zoning system's dampers and measurements. Wireless communications protocols would be used to control the zone dampers and communicated to the master zone controller that initiates calls for heating or cooling. The master zone controller should be designed to work with single-speed, multi-speed, and variable-speed equipment. It should be able to operate with heat pumps, air conditioners, hot air furnaces, or combinations of furnaces with air-conditioners or heat pumps.

Ideally the zone control system should have features that speed setup and installation; zoning dampers should quickly be recognized by the master zone controller and a suitable graphic interface should show the relative location of zone sensors and zone dampers on a schematic of the zoning plan for the residence. Plug-and-Play is the ideal for the installer; in an ideal embodiment, a typical zone damper would be installed, recognized by the zone controller software, automatically displayed on the zoning system schematic, and assigned a physical location and zone by the installer. The only hard wiring that would need to occur, would be the application of electrical power to the zone dampers and master zone controller. The master zone controller could also be hard-wired to the control inputs of the HVAC system(s).

The zone dampers and any other optional hardware should be able to accommodate installations within hard sheet metal round duct and flexible duct. Novel duct fittings for takeoffs from the main duct that make the installation very quick and easy are desired. Quick installation of zone dampers using novel installation fittings and/or techniques are also desired. These installation methods should work for “hard” duct and “flex” duct takeoffs from the main supply trunk line. If a particular takeoff or damper installation hardware is suitable for only one kind of duct material, hard or flex, then the demonstration can proceed with that particular duct material. All installations of zoning hardware (takeoffs and dampers) should provide low air pressure drop per design criteria of ACCA Manual D and Zr (ACCA 2016b, 2011) and ease of installation (Abushakra et al. 2002). The ability to add optional equipment such as duct air flow booster fans, smoke detectors, temperature/humidity sensors, indoor air quality monitoring sensors, air volume flow measurement sensors, or other sensors is desirable as well. All optional accessories should be quickly recognized by the master zone controller and displayed to the installer automatically in the graphical interface during setup and installation. The relative locations of the installed options should be easily placed in appropriate locations on the overall zoning system configuration graphical schematic.

The zoning system setup and installation software should have a commissioning mode that allows for verification of appropriate air flow rates (CFM) to each zone according to the awardee performed room load calculations (ACCA Manual J) and CFM requirements.

This project will also allow a broad sampling of technical experts in the fields of consumer electronics, air conditioning, and related fields to offer input toward the development of a practical, simplified installation and self-configuring residential HVAC air distribution zoning system. This input should produce an effective device design at minimal cost.

Phase I activities and expected results:

The awardee will create an acceptable design that performs all the necessary functions described above. A complete working example of a zone thermostat, zone damper, and master zone controller with installer software as described above should be demonstrated on the benchtop. Functionality to control the HVAC equipment listed above should also be demonstrated. If all functions cannot be directly incorporated, the contractor shall work with the NIST technical expert to re-define the criteria to something buildable while meeting most of the previously listed requirements.

Phase II activities and expected results:
In Phase II of the SBIR project, the awardee shall construct a prototype of the Phase I zone system design. The awardee shall demonstrate their takeoff and zone damper or optional accessory installation in hard and flex duct. The duct installation will demonstrate installation of takeoffs and zone dampers plus accessories. Installer graphical interface software that demonstrates the setup, commissioning, and full installation operation shall be provided to NIST. Training to use/install all hardware and software will also be provided to NIST for up to six (6) people. Takeoffs will not be installed at the NZERTF, but the zone system installation will be performed like a retrofit rather than a new construction installation. The zone system will be field deployed in the NZERTF by NIST personnel that have been trained by the awardee on the software and hardware necessary to do a zoned system installation. During the prototype test, the awardee shall work with the NIST technical experts to refine their design, perfect software tools, and refine the design to remove any flaws. The awardee shall provide a complete zoning system for at least three (3) controlled zones at the NZERTF.

As appropriate based on the mutual interest of both NIST and the awardee, NIST technical experts may be available for consultations and discussions to answer design questions and clarify any other technical aspects within their field of expertise. NIST will provide architectural drawings of the existing duct work and structure as required by the zone system designers. The awardee will be allowed supervised inspection visits to the NZERTF to complete their load calculations, prepare a zoned system design, and/or to answer any other design related questions.

References:

[1] B. Abushakra and M. Sherman. A Study of Pressure Losses in Residential Air Distribution Systems. Lawrence Berkley National Laboratory, 2002. Available at http://escholarship.org/uc/item/2db0m8p8.

[2] ACCA Manual D. 2016. ANSI/ACCA Manual D – Residential Duct Systems.

[3] ACCA Manual J. 2016. ANSI/ACCA Manual J – Residential Load Calculation.

[4] ACCA Manual Zr. 2011. ANSI/ACCA Manual Zr – Residential Zoning.

[5] ASHRAE 120-2017. Method of Testing to Determine Flow Resistance of HVAC Ducts and Fittings. ANSI approved. American Society of Heating, Refrigerating, and Air Conditioning Engineers. Available at http://www.techstreet.com.

[6] D. Stecher. Final Expert Meeting Report: Simplified Space Conditioning Strategies for Energy Efficient Houses. U.S. Dept. of Energy, Building Technologies Program, 2011. Available at http://www.osti.gov/bridge.

9.07 Lab to Market

9.07.01.40 NIST Technology Transfer

NIST has numerous technologies that require additional research and innovation to advance them to a commercial product. The goal of this SBIR subtopic is for small businesses to advance NIST technologies to the marketplace. The Technology Partnerships Office at NIST will provide the Awardee with a no-cost research license for the duration of the SBIR award. When the technology is ready for commercialization, a commercialization license will be negotiated with the Awardee. Applications may be submitted for the development of any NIST-owned technology that is covered by a pending U.S. non-provisional patent application or by an issued U.S. patent.

Small businesses can obtain information about available NIST-owned inventions at http://www.nist.gov/tpo. Applicants can also obtain information from the U.S. Patent and Trademark Office site (http://www.uspto.gov) and private search engines.
Applicants will need to confirm that the NIST-owned invention is available for licensing by searching the invention using the link provided on the websites provided above. Alternatively, the applicant can confirm the status of availability by submitting a question to the NIST SBIR website as directed in Section 1.04. Some NIST-owned inventions are described as only available for licensing on a non-exclusive basis, which typically means that at least one non-exclusive commercialization license has been granted by NIST. Any such NIST-owned inventions are still available for licensing on a non-exclusive basis. Any NIST-owned invention that has been exclusively licensed to another party is not available for licensing. If the NIST-owned invention has become unavailable for licensing prior to the close of this NOFO in the field of use relevant to the subtopic, NIST has the sole discretion to

deem such an application as ineligible under the subtopic, as stated in Section 4.02 (Phase I Screening Criteria).

A SBIR awardee for this subtopic will be able to obtain from NIST's Technology Partnership Office a research license to use the NIST-owned invention for the award. Awardees 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. Any research license granted for the purpose of this subtopic will be royalty-free during the award period. More information about licensing NIST inventions is available at http://www.nist.gov/Licensing.

The technical portion of an application should cite the NIST patent or patent application, and include a description of the research that will be undertaken. Included in this technical portion of the application, the applicant should provide a brief description of the proposed plan to develop the commercial product or to develop a commercial service using the NIST invention. The absence of this development plan will result in the application being less competitive.

Phase I expected results:
Develop a feasibility study that examines expectations of the research to produce a commercial product or service.

Phase II expected results:
Provide further R&D that leads to demonstrated practical application and advancement toward a commercial product or service.

As appropriate based on the mutual interest of both NIST and the awardee, NIST staff may be available for consultation and collaboration to the extent that resources are available.

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 II 2019-NIST-SBIR-02 Cover Sheet			
Name of Submitting Firm:	Click here to enter text.		
Project Title	Click here to enter text.		
Principal Investigator (PI) Name		**PI Title**	Click here to enter text.
PI Phone #	Click here to enter text.	**PI E-mail**	Click here to enter text.

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).	☐ Yes ☐ No
2. The primary employment of the PI will be with the SBC at the time of award and during the conduct of research.	☐ Yes ☐ 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.	☐ Yes ☐ No
4. The applicant and/or PI ☐ has / ☐ has not submitted applications for essentially equivalent work under other Federal program FFOs and ☐ has / ☐ has not received other Federal awards for essentially equivalent work. If "has", what agency? **Click here to enter text.** See NOFO Section 3.02.02(12) 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.	☐ Yes ☐ No
6. The applicant qualifies as a woman-owned SBC and meets the definition as stated in this NOFO.	☐ Yes ☐ No
7. The applicant qualifies as a HUBZone-owned SBC and meets the SBA's definition (see http://www.sba.gov/hubzone).	☐ Yes ☐ 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.	☐ Yes ☐ 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.	☐ Yes ☐ No
TECHNICAL ABSTRACT (limit to 200 words):	

Click here to enter text.

POTENTIAL COMMERCIAL APPLICATION OF THE RESEARCH: (limit to 100 words)

Click here to enter text.

OTHER INFORMATION:

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.

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.

PROPRIETARY NOTICE

"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."

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

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

OMB Control No. 0693-0072
Expiration Date: 12/31/2020

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 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

_____