July 10, 2018

NOTICE OF FUNDING OPPORTUNITY (NOFO)
Economic Impact Research and Assessment of Federal Laboratory Contributions to Standards Development

EXECUTIVE SUMMARY

- **Federal Agency Name:** National Institute of Standards and Technology (NIST), United States Department of Commerce (DoC)

- **Funding Opportunity Title:** Economic Impact Research and Assessment of Federal Laboratory Contributions to Standards Development

- **Announcement Type:** Initial

- **Funding Opportunity Number:** 2018-NIST-TPO-01

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

- **Dates:** Electronic applications must be received at Grants.gov no later than 11:59 p.m. Eastern Time, Thursday August 23, 2018. Applications received after this deadline will not be reviewed or considered. Paper applications will not 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 12:01 a.m. Eastern Time, Saturday, July 21, 2018 until Monday, July 23, 2018 at 6:00 a.m. Eastern Time; and again from 12:01 a.m. Eastern Time, Saturday, August 18, 2018 until 6:00 a.m. Eastern Time Monday, August 20, 2018.

  Applications cannot be submitted when Grants.gov is closed. NIST expects to complete its review, selection of successful applicants, and award processing by September 2018. NIST expects the earliest start date for awards under this NOFO to be October 1, 2018.

  Applicants are strongly urged to read Section IV.2.b. Attachment of Required Documents of this NOFO with great attention. Applicants should carefully follow the instructions and recommendations regarding attachments and use the Download Submitted Forms and Applications feature on www.grants.gov to check that all required attachments were contained in their submission. Applications submitted without the required documents will not pass the Initial Administrative Review, described in Section V.3.a. of this NOFO.

  When developing the submission timeline, please keep in mind that: (1) all applicants are required to have a current registration in both the System for Award

Management (SAM.gov) and Grants.gov; (2) the free annual registration process in the SAM.gov (*see* Section IV.3. and Section IV.7.a.(1)(b) of this NOFO) often takes between three and five business days and may take as long as two weeks; and (4) applicants will receive e-mail notifications over a period of up to two business days as the application moves through intermediate systems before the applicant learns via a validation or rejection notification whether NIST has received the application. (See grants.gov for full information on application and notification through Grants.gov). 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.

- **Application Submission Address:** Applications must be submitted using Grants.gov.

  Funding Opportunity Description: NIST invites applications from eligible applicants to research and assess the economic impact of NIST's and other federal laboratories' contributions to a selected technology field through the development and transfer of relevant documentary or other standards. Specifically, the awardee will select a single, appropriate technology area to which NIST and other federal laboratories have contributed to standards development and propose three relevant programs in this selected technology area for analysis (final program determinations will be made in consultation with NIST). The awardee will produce a case study analysis of each of the three programs and, where appropriate, a quantitative assessment of the retrospective economic impacts of these three standards research programs. The awardee will also conduct a literature review to determine the portion of the national economic impact of the standards in the selected technology area that is attributable to contributions from all federal labs, and from NIST individually.

- **Anticipated Amounts:** NIST anticipates funding one project with a budget and performance period of two (2) years for approximately $800,000.

- **Funding Instrument:** Cooperative Agreement

- **Eligibility:** Eligibility for the program listed in this NOFO is open to all non-Federal entities. Eligible applicants include institutions of higher education, non-profit organizations incorporated in the United States, for-profit organizations incorporated in the United States, state and local governments, territorial and Indian tribal governments, hospitals, foreign public entities, and foreign governments. An eligible organization may propose to work individually or to include proposed sub-awardees, contractors or other collaborators. Please note that, for the purposes of this NOFO, individuals and unincorporated sole proprietors are not considered "non-Federal entities" and are not eligible to apply.

- **Cost Sharing Requirements:** This program does not require cost sharing.

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FULL ANNOUNCEMENT TEXT

I. Program Description

The statutory authority for Economic Impact Research and Assessment of Federal Laboratory Contributions to Standards Development is 15 U.S.C. § 272(b)(4) and (c)(27).

1) Background Information

In FY17, the Federal Government invested over $140 billion in federally-funded research and development (R&D). Over $50 billion of this research was conducted at nearly 300 government-owned, government-operated (GOGO) and government-owned, contractor-operated (GOCO) laboratories across the country.[1] Some of this work will yield extraordinary long-term economic impacts through the generation of new knowledge and job-creating technological breakthroughs that support U.S. competitiveness in the global economy. To ensure that the benefits of this research are fully realized by the taxpayer, its results must be transferred to the private sector. Traditional forms of technology transfer include licensing intellectual property and entering into cooperative research and development agreements; however, other forms of technology transfer also convey research results and know-how to the private sector and produce economic benefits. These can include publications, postdoctoral research programs, and participation in standards development organizations (SDOs). Maximizing the utilization of the results of federally funded research, including research related to the development of standards, is in the best interest of taxpayers.

Recognizing the importance of focused agency efforts to improve federal technology transfer, the Lab-to-Market initiative was established in 2014[2]. These agency strategic efforts are ongoing through designation as a Cross Agency Priority (CAP) goal in the FY19 President's Management Agenda[3]. In addition, the National Science and Technology Council (NSTC)'s Committee on Science and Technology Enterprise

[1] https://ncsesdata.nsf.gov/fedfunds/2015/html/FFS2015_DST_010.html
[2] https://www.nist.gov/tpo/lab-market
[3] https://www.whitehouse.gov/wp-content/uploads/2018/03/Presidents-Management-Agenda.pdf, page 47. "CAP Goal 14: Improve the transfer of federally-funded technologies from Lab-to-Market".

chartered a new subcommittee to oversee CAP goal efforts in five areas: Improve Federal Technology Transfer Practices and Policies, Increase Private Sector Engagement, Build a More Entrepreneurial R&D Workforce, Support Innovative Technology Transfer Tools, and Understand Trends and Benchmarks. NIST currently leads these efforts, with participation from 11 R&D agencies in total. Within the Understand Trends and Benchmarks strategy, specific efforts have focused on ways to demonstrate the economic benefits of technology transfer efforts by federal agencies.

2) Overview

Approximately 35%, or $50.6 billion, of the Federal government's total R&D investment is funded through research at GOGO and GOCO labs. This investment in fundamental research expands the frontiers of human understanding, and yields extraordinary long-term economic impact through the creation of new knowledge and ultimately new industries. NIST has a leadership role within a large group of public and private stakeholders and aids this group in establishing goals, measuring performance, establishing standards, streamlining administrative processes, and facilitating partnerships that encourage commercialization of these federally funded research and development efforts.

To support this role, NIST receives funding to evaluate the impact of federal technology transfer programs and conduct economic research studies to estimate the importance of federal technologies and supporting technical infrastructure. While university technology transfer systems and outcomes have been extensively studied by the academic community focused on the economics of tech transfer, there has been far less research completed on the technology transfer systems and outcomes of the federal laboratories. NIST uses its leadership role to help facilitate the economic assessment of federal laboratories and their technology transfer efforts. For instance, NIST gathers the data for the annual *Technology Transfer Summary Report to the President and Congress*, which summarizes the technology transfer activities and transfer vehicles used by 11 Federal agencies that have significant Federal laboratory operations.

3) Standards Development in the United States

Unlike the European Union and many countries that utilize government-driven standards systems, standards[4] setting in the United States is primarily a private-sector led effort, with a majority of standards setting efforts coming from the work of non-government organizations dedicated to specific technology areas. These organizations rely on research from federal labs, universities, and the private sector to develop voluntary consensus standards. The Federal government does not generally issue

[4] As provided in the National Technology Transfer and Advancement Act of 1995 (NTTA): "(5) DEFINITION OF TECHNICAL STANDARDS--As used in this subsection, the term 'technical standards' means performance-based or design-specific technical specifications and related management systems practices." https://www.nist.gov/standardsgov/national-technology-transfer-and-advancement-act-1995.

voluntary consensus standards, but participates actively in the development process and contributes significant technical expertise.

The National Technology Transfer and Advancement Act of 1995[5] requires federal agencies to use voluntary consensus standards in their regulatory, procurement, and program activities in lieu of government-mandated standards, unless use of voluntary consensus standards would be inconsistent with applicable law or otherwise impractical. Within the United States, there are hundreds of SDOs that provide the infrastructure for the development of these voluntary consensus standards in various technical fields. In the standards development process, government personnel participate in SDO activities alongside representatives from industry, academia, and other organizations and consumers.

U.S. SDOs typically operate through an established consensus process that is characterized by openness, transparency, balance, and due-process mechanisms for ensuring adherence to organizational procedures, including provisions for appeals. These SDOs often form technical working groups to develop their standards. Final SDO approval of such standards is typically based upon evidence of consensus among the membership of the designated voting committee. Standards produced by these SDOs may be termed voluntary consensus standards, or voluntary standards. Compliance is voluntary except in cases where these standards are adopted as technical regulations or incorporated by reference into the Code of Federal Regulations or state or local laws and codes and thus become mandatory.

NIST and other federal laboratory staff participate in the development of standards in two primary ways: first, through the development of measurement science and research; and second, in the development of the actual standards themselves, typically through participation on a standards committee or working group of an SDO. For NIST, these efforts support the agency's mission to "…promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life."[6] In order to have a quantifiable economic impact on the U.S. economy, the research that NIST and other federal laboratories conduct to support the development of these standards as well as the scientific knowledge in the form of participation by federal researchers in SDOs must be transferred to the private sector. Federal researcher participation in standards development can therefore be considered a form of technology transfer.

4) Program analysis and quantification of the impact of federal laboratory contributions to relevant standards development

The goals of this study are to:
(1) Identify a broad, appropriate technology area towards which both NIST and/or other federal labs have contributed towards standards development research and/or participation in SDOs, and analyze three federal laboratory research programs that are

[5] https://www.nist.gov/standardsgov/national-technology-transfer-and-advancement-act-1995.
[6] See https://www.nist.gov/director/pao/nist-general-information.

relevant to the proposed technology area (historical program, established ongoing program, and newly established cutting edge program);
(2) conduct a qualitative assessment of the impacts of the relevant standards research programs through three separate case study analyses (one for each program selected) and where appropriate, a quantitative retrospective economic analysis of the impact of the transferred research on standards development in the selected technology area;
(3) conduct a quantitative empirical assessment of the portion of the national economic impact of the relevant documentary or other standards that is attributable to all federal lab contributions and NIST-only contributions through research and subsequent technology transfer efforts in the selected technology area; and
(4) contribute to the development of the next generation of researchers focused on science, R&D, and technology transfer impact analysis.

Specifically, applicants' proposals will identify a broad, appropriate technology area to which both NIST and/or other federal labs have contributed towards standards development research and/or participation in SDOs. The applicant will also propose for study three federal laboratory standards research programs that are relevant to the proposed technology area. The three federal laboratory programs, which the awardee will finalize in collaboration with NIST, must include one historical program that has completed its research and technology transfer to the relevant documentary or other standards, one program that is established but still ongoing in its standards development efforts, and one newly established 'cutting edge' research program in which most of the benefits have yet to be transferred or realized. These three programs, in total, are intended to demonstrate the length of time and process it takes to realize economic impacts to the nation resulting from this research.

The awardee will produce a case study analysis of each of the three programs and, where appropriate, a quantitative assessment of the retrospective economic impacts of these three standards research programs. The analysis will focus on each stage separately (historical, established and ongoing, and newly established) to demonstrate the impact of standards development over time. Given that the time from research and development of a standard to the time the standard has measurable impacts on the economy can vary and, in some cases, be lengthy, it is expected that the bulk of these retrospective economic impacts will result from the historical program, with marginal impacts (if relevant and appropriate) from the established and ongoing program. Projections of future economic benefits of the standards research programs are not relevant to this funding opportunity.

To help illustrate the types of programs that include technology transfer from federal laboratory programs, one example of an appropriate technology area would be DNA Diagnostics.[7] Examples of relevant programs falling under that technology area across the standards development time horizon include the following:

[7] These examples are offered purely for the sake of illustration and to help potential applicants prepare their proposals. NIST is not suggesting that DNA Diagnostics is a better choice than other technology areas, or that applications proposing DNA Diagnostics will be reviewed more favorably than other applications.

- A historical program: Human Mitochondrial DNA sequencing and Mitochrondrial Proteomics (particularly as it relates to the Human Genome Project);
- An established, ongoing program: - Precision Medicine for Cancer Diagnostics. NIST has developed cancer biomarker reference material SCRM 2373 which can be used to improve the assurance of assays used in basic research and in clinical measurements.
- A newly established program: - the collaborative research efforts to support the Biomarker Reference Library (e.g. Measurement of Low Frequency Mutations in Circulating Tumor DNA (ctDNA)). To improve the confidence in the measurement of ctDNA, NIST is developing reference samples and coordinating interlaboratory testing using ctDNA. NIST is working with the National Cancer Institute (NCI) Early Detection Research Network (EDRN) to plan an interlaboratory testing program with the cancer biomarker discovery labs, to determine the requirements for useful reference materials to support quality assurance for ctDNA measurements in discovery and clinical laboratories. NIST is working with the EDRN and additional stakeholders from the Foundation for the NIH, professional societies for cancer researchers and clinicians, to develop reference materials for ctDNA measurements.

Additionally, the awardee will conduct a literature review of existing economic impact research (including international sources) that is relevant to standards development in the selected technology area. Using economic modeling techniques, the awardee will quantify the portion of the economic impact identified in the literature produced by academic researchers, standards development organizations, and other organizations that is directly attributable to technology transfer efforts from a) federal laboratory research and/or participation in the standards development process by all federal researchers, and b) NIST research and/or participation in the standards development process by NIST researchers.

The awardee is expected to disseminate the results of their work to the public through publications and white papers in appropriate scientific or technical literature, and through presentations at public meetings or technical events. It is expected that awardees will fulfill their obligations consistent with Section C.03 Intellectual Property Rights of the Department of Commerce Financial Assistance Standard Terms and Conditions. *See* Section VI.2.b) of this NOFO.

II. Federal Award Information

1. **Funding Instrument.** The funding instrument that will be used is a cooperative agreement. The nature of NIST's "substantial involvement" will generally include collaboration with the recipient organization in developing and implementing the approved scope of work.

2. **Funding Availability.** NIST anticipates funding one project with a budget and performance period of two (2) years for approximately $800,000.

III. Eligibility Information

1. Eligible Applicants. Eligibility for the program listed in this NOFO is open to all non-Federal entities. Eligible applicants include institutions of higher education, non-profit organizations incorporated in the United States, for-profit organizations incorporated in the United States, state and local governments, territorial and Indian tribal governments, hospitals, foreign public entities, and foreign governments. An eligible organization may propose to work individually or to include proposed sub-awardees, contractors or other collaborators. Please note that, for the purposes of this NOFO, individuals and unincorporated sole proprietors are not considered "non-Federal entities" and are not eligible to apply.

2. Cost Sharing or Matching. This program does not require cost sharing.

IV. Application and Submission Information

1. Address to Request Application Package

The application package is available at **www.grants.gov** under Funding Opportunity Number 2018-NIST-TPO-01.

2. Content and Form of Application Submission

a. Required Forms and Documents

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

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

For SF-424 (R&R), Item 17, the list of certifications and assurances is contained in the SF-424B (item 3 below).

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

Instructions for filling in the SF-424 (R&R) can be found in the 2018-NIST-TPO-01 Application Instructions document found on Grants.gov, as well as at Instructions SF-424 (R&R), Application for Federal Assistance.

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

The budget should be detailed in these categories:

A. Senior/Key Person;

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

Instructions for completing the Research & Related Budget (Total Fed + Non-Fed) form can be found in the 2018-NIST-TPO-01 Application Instructions document on Grants.gov, as well as at Instructions Research & Related Budget (Total Fed + Non-Fed) – Budget.

(3) SF-424B, Assurances – Non-Construction Programs

(4) CD-511, Certification Regarding Lobbying. Enter "2018-NIST-TPO-01" in the Award Number field. Enter the title of the application, or an abbreviation of that title, in the Project Name field.

(5) Research and Related Other Project Information. Answer the highlighted questions and use this form to attach the Project Narrative (item (7) below), the Indirect Cost Rate Agreement (item (9) below), and the Data Management Plan (item (10) below). Instructions for completing the Research and Related Other Project Information can be found in the 2018-NIST-TPO-01 Application Instructions document on Grants.gov, as well as at Instructions Research and Related Other Project Information. Please note that the Project Summary/Abstract field, which has a place to attach an optional Project Summary/Abstract, is not relevant to this competition.

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

(7) Project Narrative. The Project Narrative is a word-processed document of no more than twenty (20) pages responsive to the program description (*see* Section I. of this NOFO) and the evaluation criteria (*see* Section V.1. of this NOFO). The Project Narrative should contain the following information:

(a) Executive Summary. An executive summary of the proposed approach, consistent with the evaluation criteria (*see* Section V.1. of this NOFO). The executive summary should include information indicating how each evaluation criterion and its sub-factors are

addressed. A table can be helpful in providing this information. The executive summary should not exceed two (2) pages.

- The executive summary must also clearly identify a broad, appropriate technology area towards which both NIST and/or other federal labs have contributed towards standards development research and/or participation in SDOs, and propose three federal laboratory research programs that are relevant to the proposed technology area (historical program, established ongoing program, and newly established cutting-edge program).

(b) Project Approach. A description of the applicant's approach to clearly address the program goals (*see* Section I. of this NOFO) and the methodology that will be used to:

- conduct a qualitative assessment of the impacts of the relevant standards research programs through three separate case study analyses (one for each program proposed);
- conduct a quantitative retrospective economic analysis, where appropriate, of the impact of the transferred research from the selected research programs on standards development in the selected technology area;
- conduct a quantitative empirical assessment of the portion of the national economic impact of the relevant documentary or other standard that is attributable to all federal lab contributions and NIST-only contributions through research and subsequent technology transfer efforts in the selected technology area;
- contribute to the development of the next generation of researchers focused on science, R&D, and technology transfer impact analysis; and
- broadly disseminate the results of the research to the public.

This section should address the *Project Approach and Development of the Scientific Field* evaluation criterion (*see* Sections V.1.a. and V.1.c. of this NOFO).

(c) Statement of Work. A complete statement of work covering all aspects of the project, including a schedule of measurable events and milestones as well as measurable performance objectives that can be used to determine the success of the project. In particular, the following should be described:

- the methodologies that will be used to manage the project;
- the milestones for project tasks and how the milestones will permit the applicant to assess incremental progress of the project and fit into the overall schedule for the project;
- the tasks and activities to implement the proposed project objectives; and

- the key project risks and the risk response strategies to address these risks.

This section should address the *Statement of Work* evaluation criterion (*see* Section V.1.b. of this NOFO).

(d) Qualifications. A description of the qualifications of the key personnel, the time commitments of the key personnel, and how the project staff qualifications will enable them to conduct the project work. In particular, the following should be described, as applicable, for key personnel:

- any past experience with evaluating the economic impact of the technology infrastructure and documentary or other standards;
- any past experience with conducting retrospective economic impact studies;
- any past experience with or knowledge of standardization and the U.S. standards system;
- any past experience in the following disciplines: technology assessment, high-tech industry behavioral and structural analyses, microeconomic modeling of complex technology development and commercialization patterns, high-tech industry survey and data collection techniques, and quantitative and qualitative analyses of technology, including documentary or other standards (if an applicant as an organization cannot demonstrate expertise in these disciplines, the applicant should include a plan showing how the applicant will obtain such expertise to meet the objectives of this NOFO); and
- any previously demonstrated ability to achieve positive outcomes in endeavors with program objectives that are similar to those described in Section I. of this NOFO.

This section should address the *Qualifications* evaluation criterion (*see* Section V.1.d. of this NOFO).

(e) Resumes of key personnel must be included. Resumes are not included in the page count of the Project Narrative. Resumes included as part of the application must be a maximum of two pages each. Additional pages beyond the two pages per resume will not be considered during the evaluation of the application.

(8) Budget Narrative and Justification. There is no set format for the Budget Narrative and Justification; however, further explanation must be provided for the specific cost categories and line items identified in the Instructions Research & Related Budget (Total Fed + Non-Fed) – Budget, as well as any other information you deem necessary for NIST's consideration.

The written justification should include the necessity and the basis for the cost. Proposed funding levels must be consistent with the project scope, and only allowable costs should be included in the budget. Information on cost allowability is available in the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 C.F.R. Part 200 (http://go.usa.gov/SBYh), which apply to awards in this program.

The Budget Narrative should also address the Match of Budget to Proposed Work evaluation criterion (see Section V.1.e. of this NOFO).

Information needed for each category is as follows:

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

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

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

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

C. Equipment Description – Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. 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. Applicants should provide at least two (2) quotes, if available, for equipment costing $25,000 or more. If two (2) quotes are not available, please provide a statement as to why two (2) quotes are not available.

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

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

F. Other Direct Costs – For costs that do not easily fit into the other cost categories, please list the cost, and the breakdown of the total costs by quantity or unit of cost. Include the necessity of the cost for the completion of the proposed project. Only allowable costs can be charged to the award.

Each subaward or contractual cost or should be treated as a separate item in the Other Direct Costs category. Describe the services to be provided and the necessity of the subaward or contract to the successful performance of the proposed project. Contracts are for obtaining goods and services. Subawardees perform part of the project scope of work. For each subaward, applicants must provide budget detail justifying the cost of the work performed on the project.

H. Indirect Costs - Commonly referred to as Facilities & Administrative Costs, Indirect Costs are defined as costs incurred by the applicant organization that cannot otherwise be directly assigned or attributed to a specific project. For more details, *see* Section IV.2.a.(9) of this NOFO).

(9) Indirect Cost Rate Agreement. If indirect costs are included in the proposed budget, provide a copy of the approved negotiated agreement if this rate was negotiated with a cognizant Federal audit agency. If the rate was not established by a cognizant Federal audit agency, provide a statement to this effect. If the successful applicant includes indirect costs in the budget and has not established an indirect cost rate with a cognizant Federal audit agency, the applicant will be required to obtain such a rate in accordance with the Department of Commerce Financial Assistance Standard Terms and Conditions dated March 31, 2017, accessible at https://go.usa.gov/xXRxK.

Alternatively, in accordance with 2 C.F.R. § 200.414(f), applicants that have never received a negotiated indirect cost rate may elect to charge indirect costs to an award pursuant to a de minimis rate of 10 percent of modified total direct costs (MTDC), in which case a negotiated indirect cost rate agreement is not required. Applicants proposing a 10 percent de minimis rate pursuant to 2 C.F.R. § 200.414(f) should note this election as part of the budget portion of the

application.

(10) Data Management Plan. Consistent with NIST Policy 5700.00[8], *Managing Public Access to Results of Federally Funded Research,* and NIST Order 5701.00[9], *Managing Public Access to Results of Federally Funded Research*", applicants should 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[10] or the National Institutes of Health[11]).

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 inclusion of the DMP will be considered as part of the administrative review (*see* Section V.3.a. of this NOFO); however, the DMP will not be evaluated against any evaluation criteria.

(11) Subaward Budget Form. The Research & Related Subaward Budget Attachment Form is required if sub-recipients and contractors are included in the application budget.
Instructions for completing subaward budget forms are found at: https://www.grants.gov/help/html/help/ManageWorkspaces/Manage_Subforms.htm.

Select the checkbox for the Research & Related Subaward Budget (Total Fed + Non-Fed) Attachment(s) Form from the optional forms in the application template, and attach the subaward budget form or forms to it.

[8] https://www.nist.gov/sites/default/files/documents/2017/05/09/Final-P-5700.pdf
[9] https://www.nist.gov/sites/default/files/documents/2017/05/09/Final-O-5701_0.pdf
[10] http://www.nsf.gov/bfa/dias/policy/dmp.jsp
[11] http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

b. Attachment of Required Documents

Items IV.2.a.(1) through IV.2.a.(5) above are part of the standard application package in Grants.gov and can be completed through the download application process.

Item IV.2.a.(6), the SF-LLL, Disclosure of Lobbying Activities form, is an optional application form which is part of the standard application package in Grants.gov. If item IV.2.a.(6), the SF-LLL, Disclosure of Lobbying Activities form is applicable to this proposal, attach it to field 18 of the SF-424 (R&R), Application for Federal Assistance.

Item IV.2.a.(7), the Project Narrative, should be attached to field 8 (Project Narrative) of the Research and Related Other Project Information form by clicking on "Add Attachment".

Item IV.2.a.(8), the Budget Narrative and Justification, should be attached to field L (Budget Justification) of the Research and Related Budget (Total Fed + Total Non-Fed) form by clicking on "Add Attachment".

Items IV.2.a.(9), the Indirect Cost Rate Agreement, and IV.2.a.(10), the Data Management Plan, must be completed and attached by clicking on "Add Attachments" found in item 12 (Other Attachments) of the Research and Related Other Project Information form.

Item IV.2.a.(11), the Subaward Budget Form(s), if applicable to the submission, should be attached to the Research & Related Subaward Budget (Total Fed + Non-Fed) Attachment(s) Form in the application package.

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

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 indicates only that an application was transferred to a system. It does not provide details concerning whether all attachments (or how many attachments) transferred successfully. Applicants using Grants.gov will receive a series of e-mail messages over a period of up to two business days before learning whether a Federal agency's electronic system has received its application.

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

After submitting the application, follow the directions found at this link, https://go.usa.gov/xQqeh in the Grants.gov Online Users Guide.
If any, or all, of the required attachments are absent from the submission, follow the attachment directions found above, resubmit the application, and check again for the presence of the required attachments.

If the directions found at https://go.usa.gov/xQqeh are not effective, please contact the Grants.gov Help Desk immediately. If calling from within the United States or from a U.S. territory, please call 800-518-4726. If calling from a place outside the United States or a U.S. territory, please call 606-545-5035. E-mails should be addressed to support@grants.gov. Assistance from the Grants.gov Help Desk will be available around the clock every day, with the exception of Federal holidays. Help Desk service will resume at 7:00 a.m. Eastern Time the day after Federal holidays.

Applicants can track their submission in the Grants.gov system by following the procedures at the Grants.gov site (http://go.usa.gov/cjamz). It can take up to two business days for an application to fully move through the Grants.gov system to NIST.

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

c. Application Format

(1) Paper, E-mail and Facsimile (fax) Submissions. Will not be accepted.

(2) Figures, Graphs, Images, and Pictures. Should be of a size that is easily readable or viewable and may be landscape orientation.

(3) Font. Easy to read font (12-point minimum). Smaller type may be used in figures and tables but must be clearly legible**.**

(4) Page Limit. Twenty (20) pages for the Project Narrative, noting the limit of two (2) pages for the Executive Summary. Resumes are not included in the page count of the Project Narrative. However, if resumes are included, resumes must be a maximum of two (2) pages each.

(5) Page Limit Excludes: SF-424 (R&R), Application for Federal Assistance; Research & Related Budget (Total Fed + Non-Fed); SF-424B, Assurances – Non-Construction Programs; CD-511, Certification Regarding Lobbying; SF-LLL, Disclosure of Lobbying Activities; Research and Related Other Project Information; Budget Narrative and Justification; Indirect Cost Rate Agreement; the Data Management Plan; and the Subaward Budget Form.

(6) Page size. 21.6 centimeters by 27.9 centimeters (8 ½ inches by 11 inches).

(7) Application language. English.

d. Application Replacement Pages. Applicants may not submit replacement pages and/or missing documents once an application has been submitted. Revisions can only be made by submitting a complete new application that is received by NIST before the submission deadline.

e. Pre-Applications. Pre-applications will not be accepted under this NOFO.

f. 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. 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.

4. Submission Dates and Times

Electronic applications must be received at Grants.gov no later than 11:59 p.m. Eastern Time, Thursday, August 23, 2018. NIST will consider the date and time recorded by Grants.gov as the official submission time. Applications received after this deadline will not be reviewed or considered. Paper applications will not 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 from 12:01 a.m. Eastern Time, Saturday, July 21, 2018 until Monday, July 23, 2018 at 6:00 a.m. Eastern Time; and again from 12:01 a.m. Eastern Time, Saturday, August 18, 2018 until 6:00 a.m. Eastern Time Monday, August 20, 2018.

Applications cannot be submitted when Grants.gov is closed. NIST expects to complete its review, selection of successful applicants, and award processing by September 2018. NIST expects the earliest start date for awards under this NOFO to be October 1, 2018.

When developing the submission timeline, please keep in mind that: (1) all applicants are required to have a current registration in the electronic System for Award Management (SAM.gov); (2) the free annual registration process in the SAM.gov (*see* Sections IV.3. and IV.7.a.(1).(b). of this NOFO) often takes between three and five business days and may take as long as two weeks; (3) applicants are required to have a current registration in Grants.gov; and (4) applicants using Grants.gov will receive e-mail notifications over a period of up to two business days as the application moves

through intermediate systems before the applicant learns via a validation or rejection notification whether NIST has received the application. (See http://www.grants.gov for full information on application and notification through Grants.gov.). 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.

5. Intergovernmental Review
Applications under this Program are not subject to Executive Order 12372.

6. Funding Restrictions
Applications for product development and/or commercialization are not considered responsive to this NOFO. Profit or fee is not an allowable cost.

7. Other Submission Requirements

a. Applications must be submitted electronically.

(1) Applications must be submitted via Grants.gov at www.grants.gov.

(a) Applicants should carefully follow specific Grants.gov instructions to ensure that all 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 applying electronically for the 2018-NIST-TPO-01 announcement, contact Christopher Hunton by phone at 301-975-5718 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 electronically. If all goes well, the registration process takes three to five business days. If problems are encountered, the registration process can take up to two 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/), as explained on the Grants.gov Web site (also *see* Section IV.4. 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 individuals authorized as organization representatives will be able to submit the 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, except for Federal holidays. Help Desk service will resume at 7:00 a.m. Eastern Time the day after Federal holidays. For assistance using Grants.gov, the applicant may also contact support@grants.gov.

(c) To find instructions for submitting an application on Grants.gov, Applicants should refer to the "Applicants" tab in the banner just below the top of the www.grants.gov home page. Clicking on the "Applicants" tab produces two exceptionally useful sources of information, Applicant Actions and Applicant Resources, which applicants are advised to review.

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

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

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

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 the application before the deadline. If the applicant does not correct the errors, the application will not be forwarded to NIST by Grants.gov.

Refer to important information in Section IV.4. Submission Dates and Times, to help ensure the application is received on time.

b. Amendments. Any amendments to this NOFO will be announced through Grants.gov. Applicants may sign up on Grants.gov to receive NOFO amendments, or may request copies from Kathleen McTigue by telephone at (301) 975-8530, or by e-mail: kathleen.mctigue@nist.gov.

V. Application Review Information

1. Evaluation Criteria. The evaluation criteria that will be used in evaluating applications are as follows:

a. Project Approach. (0 – 45 points, sub-criteria below receive equal weight) Reviewers will evaluate the extent to which the applicant's proposed approach clearly addresses the program goals (*see* Section I. of this NOFO) and the likelihood and extent to which the proposed methodologies will result in efficiently and effectively conducting the following activities:

- qualitative assessment of the impacts of the relevant standards research programs through three separate case study analyses (one for each program selected in collaboration with NIST);
- quantitative retrospective economic analysis of the impact of the transferred research from the selected research programs on standards development in the selected technology area; and
- quantitative empirical assessment of the portion of the national economic impact of relevant documentary or other standards that is attributable to all federal lab contributions and NIST-only contributions through research and subsequent technology transfer efforts in the selected technology area.

b. Statement of Work. (0 – 20 points, sub-criteria below receive equal weight) Reviewers will assess the extent to which the applicant's schedule of measurable events and milestones as well as the measurable performance objectives are likely to contribute to the successful management of the project. In particular, reviewers will evaluate the extent to which the following aspects of the statement of work are appropriate and likely to contribute to the overall successful management of the project:

- the methodologies used to manage the project;
- the proposed milestones and how well the proposed milestones will permit the applicant to assess incremental progress of the project and fit into the overall schedule for the project;
- the tasks and activities implementing the proposed project objectives; and
- the key project risks and how well the risk response strategies will allow the applicant to address these risks.

c. Development of the Scientific Field. (0 – 10 points, sub-criteria below receive equal weight) Reviewers will evaluate the extent to which the fields of science, R&D, and technology transfer impact analysis are likely to be positively impacted by applicant's plan for:

- disseminating project data and results broadly to the public through publication in the appropriate scientific and technical literature and white papers and presentations at public meetings or other technical events, and
- contributing to the development of the next generation of researchers focused on science, R&D, and technology transfer impact analysis.

d. Qualifications. (0 - 10 points) Reviewers will evaluate the extent to which the qualifications and time commitments of the key personnel, and the project staff's qualifications, will enable the applicant to effectively conduct the project work and address the program goals. In particular, for key personnel, the following will be evaluated for their adequacy and the extent to which they are likely to contribute to the overall success of the project:

- any past experience with evaluating the economic impact of the technology infrastructure and documentary or other standards;
- any past experience with conducting retrospective economic impact studies;
- any past experience with or knowledge of standardization and the U.S. standards system;
- any past experience in the following disciplines: technology assessment, high-tech industry behavioral and structural analyses, microeconomic modeling of complex technology development and commercialization patterns, high-tech industry survey and data collection techniques, and quantitative and qualitative analyses of technology, including documentary or other standards (if an applicant as an organization cannot demonstrate expertise in these disciplines, the reviewers will evaluate the feasibility and likelihood of success of the applicant's plan to obtain such expertise to meet the objectives of this NOFO); and
- any previously demonstrated ability to achieve positive outcomes in endeavors with program objectives that are similar to those described in Section I. of this NOFO.

e. Match of Budget to Proposed Work. (0 - 10 points) Reviewers will evaluate the budget compared to the proposed work to ascertain the reasonableness of the request.

f. Appropriateness of Proposed Technology Area. (0-5 points) Reviewers will evaluate the relevance and appropriateness of the technology area proposed by the applicant to both NIST and other federal laboratory standards research programs.

2. Selection Factors. The Selecting Official, who is the Director of the Technology Partnerships Office, or designee, will make a final award recommendation to the NIST Grants Officer. The Selecting Official shall generally select an application for award based on the rank order of the applications (*see* Section V.3. of this NOFO); however, the Selecting Official has discretion to select an application out of rank order based on one or more of the following selection factors:

a. The results of the reviewers' evaluations.

b. The objectives as set forth in the Funding Opportunity Description (*see* Section I. of this NOFO).

c. Whether the project duplicates other projects funded by NIST, DoC, or by other

Federal agencies.

d. The availability of Federal funds.

3. Review and Selection Process

Proposals, reports, documents and other information related to applications submitted to NIST and/or relating to financial assistance awards issued by NIST will be reviewed and considered by Federal employees, Federal agents and contractors, and/or by non-Federal personnel who have entered into conflict of interest and confidentiality agreements covering such information, when applicable.

a. Initial Administrative Review of Applications. Applications received by the deadline will be reviewed to determine eligibility, completeness, and responsiveness to this NOFO and the scope of the stated program objectives (*see* Section I. of this NOFO). Applications determined to be ineligible, incomplete, and/or non-responsive may be eliminated from further review. However, NIST, in its sole discretion, may continue the review process for an application that is missing non-substantive information, the absence of which may easily be rectified during the review process.

b. Review of Eligible, Complete, and Responsive Applications. Applications that are determined to be eligible, complete, and responsive will proceed for full reviews in accordance with the review and selection process below:

At least three (3) objective reviewers knowledgeable about the scientific areas described in the application will conduct a technical review of each application, based on the evaluation criteria (*see* Section V.1. of this NOFO). The reviewers may discuss the applications with each other, but scores and narrative comments will be determined on an individual basis, not as a consensus. Based on the numerical average of the reviewers' scores, a rank order will be prepared and provided to the Selecting Official for further consideration. The Selecting Official will then recommend a funding recipient based upon the rank order and the selection factors (*see* Section V.2. of this NOFO).

NIST reserves the right to negotiate the budget costs with the selected applicant. Negotiations may include requesting that the applicant remove certain costs. Additionally, NIST may request that the applicant modify objectives or work plans and provide supplemental information required by the agency prior to award. NIST also reserves the right to reject an application where information is uncovered that raises a reasonable doubt as to the responsibility of the applicant. NIST may select some, all, or none of the applications, or part(s) of any particular application. 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.

c. Federal Awarding Agency Review of Risk Posed by Applicants. After applications are proposed for funding by the Selecting Official, the NIST Grants Management Division (GMD) performs pre-award risk assessments in accordance

with 2 C.F.R. § 200.205, which may include a review of the financial stability of an applicant, the quality of the applicant's management systems, the history of performance, reports and finding from financial assistance audits, and/or the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

In addition, prior to making an award where the total Federal share is expected to exceed the simplified acquisition threshold (currently $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 conditions that correspond to the degree of risk posed by the applicant should be applied to an award.

4. **Anticipated Announcement and Award Dates.** The earliest anticipated start date for awards made under this NOFO is expected to be October 2018.

5. **Additional Information**

a. **Notification to Unsuccessful Applicants.** Unsuccessful applicants will be notified in writing.

b. **Retention of Unsuccessful Applications.** Unsuccessful applications will be retained in accordance with the General Record Schedule 1.2/021.

VI. Federal Award Administration Information

1. **Federal Award Notices**
Successful applicants will receive an award package from the NIST Grants Officer.

2. **Administrative and National Policy Requirements**

a. **Uniform Administrative Requirements, Cost Principles and Audit Requirements.** 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.

b. **Department of Commerce Financial Assistance Standard Terms and Conditions.** The Department of Commerce will apply to each award in this program, the Financial Assistance Standard Terms and Conditions in effect on the date of

award. The current version, dated March 31, 2017, is accessible at http://go.usa.gov/xXRxK. Refer to Section VII. of this NOFO, Federal Awarding Agency Contacts, Grant Rules and Regulations, if you need more information.

c. **Pre-Award Notification Requirements.** The Department of Commerce will apply the Pre-Award Notification Requirements for Grants and Cooperative Agreements dated December 30, 2014 (79 FR 78390), accessible at http://go.usa.gov/hKkR. Refer to Section VII. of this NOFO, Federal Awarding Agency Contacts, Grant Rules and Regulations, if you need more information.

d. **Funding Availability and Limitation of Liability.** Funding for the program listed in this NOFO is contingent upon the availability of appropriations.

   In no event will NIST or the Department of Commerce be responsible for application preparation costs if this program fails to receive funding or is cancelled because of agency priorities. Publication of this NOFO does not oblige NIST or the Department of Commerce to award any specific project or to obligate any available funds.

e. **Collaborations with NIST Employees.** If an applicant proposes collaboration with NIST, the statement of work should include a statement of this intention, a description of the collaboration, and prominently identify the NIST employee(s) involved, if known. Any collaboration by a NIST employee must be approved by appropriate NIST management and is at the sole discretion of NIST. Prior to beginning the merit review process, NIST will verify the approval of the proposed collaboration. Any unapproved collaboration will be stricken from the application prior to the merit review. Any collaboration with an identified NIST employee that is approved by appropriate NIST management will not make an application more or less favorable in the competitive process.

f. **Use of NIST Intellectual Property.** If the applicant anticipates using any NIST-owned intellectual property to carry out the work proposed, the applicant should identify such intellectual property. This information will be used to ensure that no NIST employee involved in the development of the intellectual property will participate in the review process for that competition. In addition, if the applicant intends to use NIST-owned intellectual property, the applicant must comply with all statutes and regulations governing the licensing of Federal government patents and inventions, described in 35 U.S.C. §§ 200-212, 37 C.F.R. Part 401, 2 C.F.R. §200.315, and in Section D.03 of the Department of Commerce Financial Assistance Terms and Conditions dated March 31, 2017, accessible at http://go.usa.gov/xXRxK.

   Any use of NIST-owned intellectual property by a recipient of an award under this announcement is at the sole discretion of NIST and will be negotiated on a case-by-case basis if a project is deemed meritorious. The applicant should indicate within the statement of work whether it already has a license to use such intellectual property or whether it intends to seek one.

If any inventions made in whole or in part by a NIST employee arise in the course of an award made pursuant to this NOFO, the United States government may retain its ownership rights in any such invention. Licensing or other disposition of NIST's rights in such inventions will be determined solely by NIST, and include the possibility of NIST putting the intellectual property into the public domain.

g. Research Activities Involving Human Subjects, Human Tissue, Data or Recordings Involving Human Subjects Including Software Testing. Any application that includes research activities involving human subjects, human tissue/cells, or data or recordings from or about human subjects, must satisfy the requirements of the Common Rule for the Protection of Human Subjects ("Common Rule"), codified for the Department of Commerce at 15 C.F.R. Part 27. Research activities involving human subjects that fall within one or more of the classes of vulnerable subjects found in 45 C.F.R. Part 46, Subparts B, C and D must satisfy the requirements of the applicable subpart(s). In addition, any such application that includes research activities on these subjects must be in compliance with all applicable statutory requirements imposed upon the Department of Health and Human Services (DHHS) and other Federal agencies, all regulations, policies and guidance adopted by DHHS, the Food and Drug Administration (FDA), and other Federal agencies on these topics, and all Executive Orders and Presidential statements of policy on applicable topics. (Regulatory Resources: http://www.hhs.gov/ohrp/humansubjects/index.html which includes links to FDA regulations, but may not include all applicable regulations and policies).

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

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

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information.

(1) *Intervention* includes both physical procedures by which data 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 which 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.

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. 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[12] 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

[12] 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 an appropriate continuing review at least annually.

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 subject research must clearly indicate, by separable task, all research activities believed to be exempt or non-exempt research involving human subjects, the expected institution(s) where the research activities involving human subjects may be conducted, and the institution(s) expected to be engaged in the research activities.

   a. **Not research determination.** If an activity/task involves human subjects as defined in the Common Rule, but the applicant participant(s) indicates to NIST that the activity/task is not research as defined in the Common Rule, the following information may be requested for that activity/task:

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

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

   b. **Research not involving human subjects**. If an activity/task is determined to be research and involves human subjects, but is determined to be *not human subjects research* (or *research not involving human subjects*) under the Common Rule, the following information may be requested for that activity/task:

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

c. **Exempt research determination with no IRB.** If the application appears to NIST to include exempt research activities, and the performer of the activity or the supplier and/or the receiver of the biological materials or data 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. § 27.101(b), (c) 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 biological materials or data from human subjects.
(3) A copy of the protocol for the research to be conducted; and/or the biological materials or data from human subjects to be collected/provided, not pre-existing samples (i.e., will proposed research collect only information without personal identifiable information, will biological materials or data 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 biological materials or data from human subjects, provide copies of the consent forms used for collection and a description of how the materials or data 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 biological materials or data 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 what 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).

h. Collaborations Making Use of Federal Facilities. All applications should include a description of any work proposed to be performed using Federal facilities.

If an applicant proposes use of NIST facilities, the statement of work should include a

statement of this intention and a description of the facilities. Any use of NIST facilities must be approved by appropriate NIST management and is at the sole discretion of NIST. Prior to beginning the merit review process, NIST will verify the availability of the facilities and approval of the proposed usage. Any unapproved facility use will be stricken from the application prior to the merit review. Examples of some facilities that may be available for collaborations are listed on the following NIST Web site: https://www.nist.gov/labs-major-programs/user-facilities.

3. Reporting

a. Reporting Requirements. The following reporting requirements described in Sections A.01, Reporting Requirements, of the Department of Commerce Financial Assistance Standard Terms and Conditions dated March 31, 2017, accessible at http://go.usa.gov/xXRxK, apply to awards in this program:

(1) Financial Reports. Each award recipient will be required to submit an SF-425, Federal Financial Report on a semi-annual basis for the periods ending March 31, and September 30 of each year. Reports will be due within 30 days after the end of the reporting period to the NIST Grants Officer and Grants Specialist named in the award documents. A final financial report is due within 90 days after the end of the project period.

(2) Performance (Technical) Reports. Each award recipient will be required to submit a technical progress report to the NIST Grants Officer and the NIST Federal Program Officer on a semi-annual basis for the periods ending March 31 and September 30 of each year. Technical progress reports shall contain information as prescribed in 2 C.F.R. § 200.328 (http://go.usa.gov/xkVgP) and Department of Commerce Standard Terms and Conditions, Section A.01 (https://go.usa.gov/xXRxK). Reports will be due within 30 days after the end of the reporting period. A final technical report shall be submitted within 90 days after the expiration date of the award, and publication citation information as well as links to publicly available data shall be submitted as soon as they become available. If a recipient's Data Management Plan (DMP) has changed since their last submission of a technical progress report, the recipient must include their revised DMP in the next technical progress report following the revision to the DMP. The revised DMP must include all the requirements described in Section IV.2.a.(10) of this NOFO.

(3) Patent and Property Reports. From time to time, and in accordance with the Uniform Administrative Requirements (*see* Section VI.2. of this NOFO) and other terms and conditions governing the award, the recipient may need to submit property and patent reports.

(4) Recipient Integrity and Performance Matters. In accordance with section 872 of Public Law 110-417 (as amended; see 41 U.S.C. 2313), if the total value of a recipient's currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any

period of time during the period of performance of an award made under this NOFO, then the recipient shall be subject to the requirements specified in Appendix XII to 2 C.F.R. Part 200, http://go.usa.gov/cTBwC, for maintaining the currency of information reported to SAM that is made available in FAPIIS about certain civil, criminal, or administrative proceedings involving the recipient.

b. **Audit Requirements.** The Department of Commerce Financial Assistance Standard Terms and Conditions, Section D.01.b.1., and 2 C.F.R. Part 200 Subpart F, adopted by the Department of Commerce through 2 C.F.R. § 1327.101, require any non-Federal entity (e.g., including non-profit institutions of higher education and non-profit organizations) that expends Federal awards of $750,000 or more in the recipient's fiscal year to conduct a single or program-specific audit in accordance with the requirements set out in the Subpart. Additionally, unless otherwise specified in the terms and conditions of the award, entities that are not subject to Subpart F of 2 C.F.R. Part 200 (e.g., for-profit commercial entities) that expend $750,000 or more in DOC funds during their fiscal year must have an audit conducted for that year in accordance with program guidance. 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.

c. **Federal Funding Accountability and Transparency Act of 2006.** In accordance with 2 C.F.R. Part 170, all recipients of a Federal award made on or after October 1, 2010, are required to comply with reporting requirements under the Federal Funding Accountability and Transparency Act of 2006 (Public Law No. 109-282). In general, all recipients are responsible for reporting sub-awards of $25,000 or more. In addition, recipients that meet certain criteria are responsible for reporting executive compensation. Applicants must ensure they have the necessary processes and systems in place to comply with the reporting requirements should they receive funding. Also see the Federal Register notice published September 14, 2010, at 75 FR 55663 available here http://go.usa.gov/hKnQ.

VII. Federal Awarding Agency Contacts

Questions should be directed to the following:

Subject Area	Point of Contact
Programmatic and Technical Questions	Kathleen McTigue Phone 301-975-8530 E-mail: kathleen.mctigue@nist.gov
Grant Rules and Regulations	Dean Iwasaki Phone: (301) 975-8449 Fax: 301-975-6368 E-mail dean.iwasaki@nist.gov

Technical Assistance with Grants.gov Submissions	Christopher Hunton Phone: 301-975-5718 Fax: 301-975-6368 E-mail: grants@nist.gov Or www.grants.gov Phone: 800-518-4726 E-mail: support@grants.gov

VIII. Other Information

1. 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. Sec. 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 Federal Funding Opportunity may be subject to requests for release under the Act. If 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.