AMENDED NOTICE OF FUNDING OPPORTUNITY FOR MAXIMIZING TECHNOLOGY COMMERCIALIZATION OF FEDERAL RESEARCH INVESTMENTS THROUGH THE BEST PRACTICES AT INNOVATION AND ECONOMIC PROSPERITY UNIVERSITIES AMENDMENT 1 June 23, 2017

The National Institute of Standards and Technology (NIST) is amending its May 11, 2017 Notice of Funding Opportunity (NOFO) number 2017-NIST-TPO-01, posted on Grants.gov and on the NIST Web site

(https://www.nist.gov/sites/default/files/documents/2017/05/12/20170503_tpo_ffo_iep_a nalysis.pdf), that solicits proposals for "Maximizing Technology Commercialization of Federal Research Investments through the Best Practices at Innovation and Economic Prosperity Universities".

NIST is issuing this amendment (Amendment 1) to make two updates to the 2017-NIST-TPO-01 NOFO as described below. This Amendment Package will be in effect through the closing date of the NOFO, 11:59 pm Eastern Time, Monday, July 10, 2017 on Grants.gov.

Update #	Section	What does the revision do?	How does the new text now read?
1	Section IV.2.a.	Provides a new paragraph to Section IV.2.a. as Section IV.2.a.(11). This new paragraph provides information on how an applicant may provide detailed breakdowns of any proposed subawards/consortium costs, if applicable, in an application.	Section IV.2.a.(11). Subaward Budget Form (optional). Subaward budget forms are not required, but may be provided by any applicant who wishes to supplement the subaward budget details set out in the Budget Narrative and Justification (see Section IV.2.a.(8) of this NOFO) and in the Research & Related Budget (Total Fed + Non-Fed) form (see Section IV.2.a.(2) of this NOFO). To access the form, copy the link appearing at the end of this paragraph into the browser, and download the form. On the Budget Type field, found on the

Update #	Section	What does the revision do?	How does the new text now read?
			second line of the form, check the "Subaward/Consortitium" box, fill in the form, save it, and attach it to field 12 (Other Attachments) of the Research and Related Other Project Information form by clicking on "Add Attachments". If the proposal involves more than one subaward, and the applicant wishes to provide similar detail for the additional subaward(s), download one form for each additional subaward, and attach it to the application as described above. The link to create the subaward budget form(s) is: <u>https://apply07.grants.gov/apply/fo</u> <u>rms/sample/RR_FedNonFedBudg</u> <u>et 1_2-V1.2.pdf</u> .
2	Section IV.2.b.	Provides direction on attaching the optional subaward budgets to the application.	Item IV.2.a.(11), the optional form(s) for subaward budget(s), may be attached to field 12 (Other Attachments) of the Research and Related Other Project Information form by clicking on "Add Attachments".

No other revisions are being made by this amendment. The full text of the Amended NOFO, including the revisions being made now, is set forth below.

Announced May 11, 2017; Amended June 23, 2017

NOTICE OF FUNDING OPPORTUNITY (NOFO) Maximizing Technology Commercialization of Federal Research Investments through the Best Practices at Innovation and Economic Prosperity Universities

EXECUTIVE SUMMARY

- Federal Agency Name: National Institute of Standards and Technology (NIST), United States Department of Commerce
- Funding Opportunity Title: Maximizing Technology Commercialization of Federal Research Investments through the Best Practices at Innovation and Economic Prosperity Universities
- Announcement Type: Initial
- Funding Opportunity Number: 2017-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 no later than 11:59 p.m. Eastern Time, Monday, July 10, 2017 on Grants.gov. Applications by mail, e-mail, or fax will not be accepted. Applications received after this deadline will not be reviewed or considered. The earliest anticipated start date for awards under this NOFO is expected to be approximately November 2017.

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 Eastern Time, Saturday, May 20, 2017 until Monday, May 22, 2017 at 6:00 a.m. Eastern Time, and again from 12:01 Eastern Time, June 17, 2017 until Monday, June 19, 2017 at 6:00 a.m. Eastern Time. Applications cannot be submitted when Grants.gov is closed.

Applicants are strongly urged to read Section IV.2.b., Attachment of Required Application Documents, found on pages 13 and 14 of this NOFO, with great attention. Applicants should carefully follow the instructions and recommendations regarding attachments and using Grants.gov's Download Submitted Applications feature 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 your submission timeline, please keep in mind that (1) all applicants are required to have a current registration in the System for Award Management (SAM.gov); (2) the free annual registration process in the electronic System for Award Management (SAM.gov) (see Section IV.3. and Section IV.7.a.(1).b. of this NOFO) may take between three and five business days, or as long as more than two weeks; (3) applicants are required to have a current registration in Grants.gov; and (4) applicants will receive a series of e-mail messages from Grants.gov over a period of up to two business days before learning whether a Federal agency's electronic system has received its application. Please note that a federal assistance award cannot be issued if the designated recipient's registration in the System for Award Management (SAM.gov) is not current at the time of the award.

- Application Submission Address: Applications will only be accepted using Grants.gov.
- Funding Opportunity Description: The federal government invests over \$140 billion annually in research and development, including over \$50 billion annually in extramural research conducted by universities, companies, and non-profit organizations. The Department of Commerce, as delegated to NIST, has responsibility for promoting commercialization of technologies resulting from federally sponsored research across all government agencies under the Bayh-Dole Act of 1980, as amended.

NIST therefore invites proposals from eligible applicants for a one-year study to evaluate universities that have been designated as Innovation and Economic Prosperity Universities (IEPUs), by the Association of Public and Land-Grant Universities (APLU) for their approaches to innovation and technology commercialization and to review and evaluate existing technology-based collaborations between IEPUs and technology development entities, including Federal research laboratories (FRLs). It is expected that the recipient will: (1) research and broadly disseminate a set of best practice recommendations for increased innovation, commercialization, technology transfer, entrepreneurship and regional partnering and development activities based on the specific activities of IEPUs; (2) identify existing collaboration networks or clusters of IEPUs and technology development entities, including FRLs; (3) identify overlaps and gaps in the technology-based collaboration networks between IEPUs and technology development entities; (4) recommend six pilot projects for new or expanded technology development networks or clusters of IEPUs and technology development entities; or clusters of IEPUs and technology development

entities, including FRLs; and (5) develop an analysis of the potential economic impact of the six pilots and a plan for longer term scale-up, to aid in future resource prioritization.

The recipient is expected to disseminate the results of the collaboration networks analysis and the recommendations to the public through publications and white papers in appropriate literature to communicate results to other parties, and through presentations at public meetings or technical events.

- Anticipated Amounts: NIST anticipates funding one project with a budget and performance period of one (1) year for approximately \$300,000.
- Funding Instrument: Cooperative Agreement
- Who is Eligible: 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 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 Maximizing Technology Commercialization of Federal Research Investments through the Best Practices at Innovation and Economic Prosperity Universities is 15 U.S.C. § 272(b) and (c), and 15 U.S.C. § 3710(g).

1. Background Information.

a. Lab-to-Market. The federal government currently invests over \$140 billion each year on federally-funded R&D conducted at universities, FRLs, non-profit organizations, and companies. This work has yielded 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. Maximizing the utilization of the results of federally funded research is in the best interest of all taxpayers.

The federal R&D system was critical for the development of life-changing commercial technologies, including the Internet, global positioning system (GPS), and leading-edge vaccines. Federally-funded R&D historically has led to dramatic economic growth, and there is significant potential to increase the public's return on this investment in terms of innovation, job creation, societal impact, competitiveness, and economic prosperity. However, these economic impacts can only be realized after new knowledge and technologies have left the confines of federally-funded labs and entered the marketplace as new products and services that are available to American citizens.

The Lab-to-Market initiative was established in 2014 to direct cross-agency efforts in five areas: Developing Human Capital, Empowering Effective Collaborations, Opening R&D Assets, Fueling Small Business Innovation, and Evaluating Impact¹. Under the sub-goal of Empowering Effective Collaborations, specific efforts have focused on ways to advance commercialization of federal R&D through partnership and technology transfer best practices.

The Lab-to-Market efforts were further institutionalized in 2016 when the National Science and Technology Council (NSTC) chartered the Lab-to-Market subcommittee under their Committee on Technology. NSTC leadership identified

¹ <u>https://www.nist.gov/tpo/lab-market</u>

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the IEPUs as an underutilized resource in federal research and commercialization efforts, and indicated that the best practices and long-term outcome-based metrics of the IEPUs could help inform FRLs and other collaborative partners in improving their own efforts to increase technology-based economic development. They also identified that, under the Empowering Effective Collaborations sub-goal, more effective collaborations between IEPUs and outside partners, including FRLs, could lead to improved commercialization outcomes of both federal and non-federal technologies due to the programmatic resources and mindsets of the IEPUs.

b. Innovation and Economic Prosperity Designation. APLU is a network of 235 public and land grant universities and affiliated organizations in North America, established in 1887 to focus on strengthening and advancing the work of public institutions through research, policy, and advocacy. Through their Commission on Innovation, Competitiveness & Economic Prosperity (CICEP), APLU created the IEP designation for select member universities in 2013. The designation recognizes universities that meet or exceed benchmarks in innovation and promoting regional economic development. To date, 55 universities have been selected by the CICEP IEP Universities Committee to receive this designation.

In August 2015, APLU and the University Economic Development Association drafted a definition of economic development and engagement for universities and a series of principles of practice. This framework, entitled "Higher Education Engagement: Foundations for Strategy and Practice"², outlined general best practices in two functional areas: Strategic Program Principles and Business and Policy Principles. Member universities use this framework in conjunction with a series of metrics and impact guidelines to undergo a self-assessment and prepare a narrative on how they incorporate the aforementioned principles into their mission-based research and growth plans.

2. Overview.

In FY16, the Federal Government invested over \$140 billion in research and development (R&D). Approximately 35% funded research at FRLs, both Government-Operated and Contractor-Operated; another 21% funded research at universities and colleges in the United States.³ This combined investment in academia and FRLs supports fundamental research that expands the frontiers of

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² <u>http://www.aplu.org/library/higher-education-engagement-in-economic-development-foundations-for-</u> strategy-and-practice/File

³ https://ncsesdata.nsf.gov/fedfunds/2015/html/FFS2015_DST_009.html

human knowledge, 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, streamlining administrative processes, and facilitating partnerships that encourage commercialization of federally funded research and development, including interagency efforts towards the Lab-to-Market initiative. To support these efforts, NIST works to facilitate effective collaborations between FRLs and non-federal partners, with the goal of increasing the economic impact of federally-funded research and development by accelerating and improving the transfer of new technologies from the laboratory to the commercial marketplace.

NIST has identified a need to analyze the best practices for technology-based economic development at IEPUs; these practices could then be implemented by other technology development entities, including FRLs, and recommendations made to the entrepreneurial and R&D communities on opportunities to improve existing collaborative networks to benefit the public through the creation of new businesses dedicated to commercializing federally funded inventions. NIST therefore invites applications from eligible applicants to evaluate the commercialization activities of universities who have received the Association of Public and Land-Grant Universities (APLU) Innovation and Economic Prosperity (IEP) designation, to improve the commercialization of Federally-funded technologies by researching:

- best practices of the universities with IEP designations;
- existing technology-based collaboration networks between IEP Universities (IEPUs) and outside partners, including Federal research laboratories (FRLs); and
- new or expanded collaborative opportunities in technology development.

The goals of this study are to: (1) research and broadly disseminate a set of best practice recommendations for increased innovation, commercialization, technology transfer, entrepreneurship and regional partnering and development activities based on the specific activities of IEPUs; (2) identify existing collaboration networks or clusters of IEPUs and technology development entities, including FRLs; (3) identify overlaps and gaps in the technology-based collaboration networks between IEPUs and technology development entities; (4) recommend six pilot projects for new or expanded technology development networks or clusters of IEPUs and technology development entities, including FRLs; and (5) develop an analysis of the potential economic impact of the six pilots and a plan for longer term scale-up, to aid in future resource prioritization.

Contingent on the availability of funding, NIST may announce a future funding opportunity for the implementation of the six pilot projects developed as part of this award. See Section I.3. of this NOFO below for information on the awardee's requirements for meeting the goals of this NOFO.

3. Evaluation of IEPUs, identification of technology intersections, and pilot project development. The awardee, in collaboration with NIST, will undertake an evaluation of the universities who have received APLU's IEP designation, to determine specific best practices and programs in innovation, commercialization, technology transfer, entrepreneurship, and regional partnering and development activities, with the goal of identifying specific practices and programs that increase an IEPU's economic impact and/or ability to collaborate in ways that enhance technology-based economic development. Analysis should focus on the Strategic Program Principles of Practice and the Business and Policy Principles of Practice as outlined by the IEP designation program.⁴ Using this information, the awardee will identify specific practices and programs in these areas that could be adopted by other technology development entities, including FRLs, and provide an analysis and recommendations of how these practices and programs might be adopted to enhance the economic impact of technology development.

In addition, the awardee will assess and map the technology capabilities of IEPUs and of their collaborators, including FRLs, and identify intersections as potential targets for new technology development clusters or increased collaborative participation in existing technology development clusters. It is anticipated that mapping would be organized by technology sector, with regional clustering indicated where appropriate. The recipient will identify collaboration gaps in the existing technology-based collaborative relationships and propose pilot projects to enable and expand the technology-based economic development capabilities of collaborative research efforts between IEPUs and outside partners, including FRLs. Pilot projects should be directed towards the gaps and opportunities for improving collaborative research as identified in the technology mapping analysis. Examples of pilot projects could include facilitating specific technology-based research collaborations between IEPUs and outside partners, including FRLs, greater utilization of information sharing resources and research consortia, opportunities to utilize personnel exchange authorities for commercialization, or identification of administrative improvements to reduce barriers to collaboration.

The awardee is expected to disseminate the results of the review and evaluation and

⁴ See footnote 2 above.

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the best practice recommendations to the public through appropriate literature sources and presentations at public meetings or technical events. Where appropriate, findings may be disseminated in the form of academic publications.

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 be collaboration between NIST and the recipient organizations. This includes NIST collaboration with a recipient on the scope of work.
- **2. Funding Availability.** NIST anticipates funding one project with a budget and performance period of one (1) year for approximately \$300,000.

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 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 <u>www.grants.gov</u> under NOFO number 2017-NIST-TPO-01.
- 2. Content and Format 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 2017-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 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;
- F. Other Direct Costs;
- G. Direct Costs;
- H. Indirect Costs;
- I. Total Direct and Indirect Costs;
- J. Fee (not relevant to this competition);
- K. Budget Narrative and Justification document (item (8) below) should be attached to field K.

Instructions for filling in the Research& Related Budget (Total Fed + Non-Fed) form can be found in the 2017-NIST-TPO-01 Application Instructions document on Grants.gov, as well as at <u>Instructions Research & Related Budget (Total Fed</u> + <u>Non-Fed</u>) – <u>Budget</u>.

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

- (4) CD-511, Certification Regarding Lobbying. Enter "2017-NIST-TPO-01" in the Award Number field. Enter the title of the application used in field 15 of the SF-424 (R&R), 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 filling in the Research and Related Other Project Information can be found in the 2017-NIST-TPO-01 Application Instructions document on Grants.gov, as well as at Instructions Research and Related Other Project Information.
- (6) SF-LLL, Disclosure of Lobbying Activities (if applicable).
- (7) Project Narrative. The Project Narrative is a word-processed document of no more than fifteen (15) 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.
 - (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:
 - research and develop a set of best practice recommendations for increased innovation, commercialization, technology transfer, entrepreneurship and regional partnering and development activities based on the specific activities of IEPUs;
 - identify existing collaboration networks or clusters of IEPUs and technology development entities, including FRLs;
 - identify overlaps and gaps in the technology-based collaboration networks between IEPUs and technology development entities;
 - recommend six pilot projects for new or expanded technology development networks or clusters of IEPUs and technology development entities, including FRLs;
 - develop an analysis of the potential economic impact of the six

pilots and a plan for longer term scale-up, to aid in future resource prioritization; and

• develop a plan to broadly disseminate the results of the collaboration networks analysis and the best practice recommendations to the public.

This section should address the *Project Approach* evaluation criterion (see Section V.1.a. of this NOFO).

- (c) Statement of Work. A complete statement of work covering all aspects of the project describing 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 or familiarity with the IEPU designation;
 - any past experience in the following disciplines: federal technology transfer, entrepreneurship, technology assessment, evaluation of best practices in research and commercialization, technologybased economic development (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 of this NOFO as described in Section I. of this NOFO.

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

- (e) Resumes of key personnel may be included, but are not required. Resumes are not included in the page count of the Project Narrative. If resumes are included, resumes 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, it should provide a detailed breakdown of each of the categories as reflected on the Research & Related Budget (Total Fed + Non-Fed) form. This section should address the Match of Budget to Proposed Work evaluation criterion (see Section V.1.d. 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 5700.00⁵, Managing Public Access to Results of Federally Funded Research, and NIST Order 5701.00⁶, 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 Foundation⁷ or the National Institutes of Health⁸).

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 <u>http://go.usa.gov/3sZvQ</u>).

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 (optional). Subaward budget forms are not required, but may be provided by any applicant who wishes to supplement the subaward budget details set out in the Budget Narrative and Justification (see Section IV.2.a.(8) of this NOFO) and in the Research & Related Budget (Total Fed + Non-Fed) form (see Section IV.2.a.(2) of this NOFO). To access the form, copy the link appearing at the end of this paragraph into the browser, and download the form. On the Budget Type field, found on the second line of the form, check

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⁵ <u>https://www.nist.gov/sites/default/files/documents/2017/05/09/Final-P-5700.pdf</u>

⁶ <u>https://www.nist.gov/sites/default/files/documents/2017/05/09/Final-O-5701_0.pdf</u>

⁷ http://www.nsf.gov/bfa/dias/policy/dmp.jsp

⁸ <u>http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm</u>

the "Subaward/Consortitium" box, fill in the form, save it, and attach it to field 12 (Other Attachments) of the Research and Related Other Project Information form by clicking on "Add Attachments". If the proposal involves more than one subaward, and the applicant wishes to provide similar detail for the additional subaward(s), download one form for each additional subaward, and attach it to the application as described above. The link to create the subaward budget form(s) is:

https://apply07.grants.gov/apply/forms/sample/RR_FedNonFedBudget_1_2-V1.2.pdf

b. Attachment of Required Application Documents

Items IV.2.a.(1) through IV.2.a.(5) above are mandatory application forms which 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, 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 12 (Other Attachments) of the Research and Related Other Project Information form by clicking on "Add Attachments".

Item IV.2.a.(8), the Budget Narrative and Justification, should be attached to field K (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 of the Research and Related Other Project Information form.

Item IV.2.a.(11), the optional form(s) for subaward budget(s), may be attached to field 12 (Other Attachments) of the Research and Related Other Project Information form by clicking on "Add Attachments".

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 <u>www.grants.gov</u> 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.

The Grants.gov Online Users Guide available at the Grants.gov site (<u>http://go.usa.gov/cjaEh</u>) provides vital information on checking the status of applications. See especially the "Check My Application Status" option, found by clicking first on Applicants, and then by clicking on Applicant Actions.

Applicants can track their submission in the Grants.gov system by following the procedures at the Grants.gov site (<u>http://go.usa.gov/cjamz</u>). It can take up to two business days for an application to fully move through the Grants.gov system to NIST, however, applicants can immediately check that they properly submitted the application in Grants.gov by following the Grants.gov tracking procedures cited above.

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

- c. Application Format
 - (1) Mail, 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 (10-point minimum). Smaller type may be used in figures and tables but must be clearly legible.
 - (4) Line spacing. Applicants may use single spacing or double spacing.
 - (5) Margins. One (1) inch top, bottom, left, and right.
 - (6) **Page layout.** Portrait orientation except for figures, graphs, images, and pictures. Paragraphs are to be clearly separated from each other by double spacing, paragraph formatting or equivalent.

- (7) Page limit. The Project Narrative is limited to fifteen (15) pages.
 - (a) Page limit includes: Table of contents (if included), Project Narrative with all suggested information, including figures, graphs, tables, images, and pictures.
 - (b) Page limit excludes: SF-424 (R&R), Application for Federal Assistance; Research and Related Budget (Total Fed + Total Non-Fed); SF-424B, Assurances – Non-Construction Programs; CD-511, Certification Regarding Lobbying; Research and Related Other Project Information form; SF-LLL, Disclosure of Lobbying Activities; Resumes (if included); Budget Narrative and Justification; Indirect Cost Rate Agreement; and the Data Management Plan.
- (8) Page numbering. Number pages sequentially.
- (9) Page size. 21.6 centimeters by 27.9 centimeters (8 ½ inches by 11 inches).
- (10) Application Language. English.
- **d. Application Replacement Pages.** Applicants may not submit replacement pages and/or missing documents once an application has been submitted. Any revisions must be made by submission of a new application that must be received by NIST by the submission deadline.
- e. Pre-Applications. NIST is not accepting pre-applications or white papers 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. Applications must be received by NIST electronically through Grants.gov no later than 11:59 p.m. Eastern Time, Monday, July 10, 2017. Applications received after this deadline will not be reviewed or considered. NIST will consider the date and time stamped on the validation generated by www.grants.gov as the official submission time.

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 Eastern Time, Saturday, May 20, 2017 until Monday, May 22, 2017 at 6:00 a.m. Eastern Time, and again from 12:01 Eastern Time, June 17, 2017 until Monday, June 19, 2017 at 6:00 a.m. Eastern Time.

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.

When developing your submission timeline, please keep in mind that (1) all applicants are required to have a current registration in the System for Award Management (SAM.gov); (2) the free annual registration process in the electronic System for Award Management (SAM.gov) (see Section IV.3. and Section IV.7.a.(1).b. of this NOFO) may take between three and five business days, or as long as more than two weeks; (3) electronic applicants are required to have a current registration in Grants.gov; and (4) applicants will receive a series of e-mail messages from Grants.gov over a period of up to two business days before learning whether a Federal agency's electronic system has received its application. Please note that a federal assistance award cannot be issued if the designated recipient's registration in the System for Award Management (SAM.gov) is not current at the time of the award.

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

- **5. Intergovernmental Review.** Applications under this Program are not subject to Executive Order 12372.
- 6. Funding Restrictions. Profit or fee is not an allowable cost.
- 7. Other Submission Requirements
- a. Applications must be submitted electronically through <u>www.grants.gov</u>. NIST will not accept applications submitted by mail, facsimile, or e-mail.
 - (1) Electronic applications must be submitted via Grants.gov at <u>www.grants.gov</u> under announcement 2017-NIST-TPO-01.
 - 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 <u>does not provide</u> <u>information about whether attachments have been received</u>. For further information or questions regarding applying electronically for the 2017-NIST-TPO-01 announcement, contact Christopher Hunton by phone at 301-975-5718 or by e-mail at <u>grants@nist.gov</u>.
 - 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 (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/), as explained on the Grants.gov Web site. See also Section IV.3. 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, with the exception of Federal holidays. Help Desk service 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 <u>www.grants.gov</u> home page. Clicking on the "Applicants" tab produces two exceptionally useful sources of information, Applicant Actions and Applicant Resources, which applicants are advised to review.

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

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

The 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.

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 on the deadline date.

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

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

V. Application Review Information

- **1. Evaluation Criteria.** The evaluation criteria that will be used in evaluating applications are as follows:
 - a. Project Approach. (0 50 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 extent to which the proposed methodologies will efficiently and effectively accomplish the following:
 - research and develop a set of best practice recommendations for increased innovation, commercialization, technology transfer, entrepreneurship and regional partnering and development activities based on the specific activities of IEPUs;
 - identify existing collaboration networks or clusters of IEPUs and technology development entities, including FRLs;
 - identify overlaps and gaps in the technology-based collaboration networks between IEPUs and technology development entities;
 - create recommendations for six pilot projects for new or expanded technology development networks or clusters of IEPUs and technology development entities, including FRLs;
 - develop an analysis of the potential economic impact of the six pilots and a plan for longer term scale-up, to aid in future resource prioritization; and
 - develop a plan to broadly disseminate the results of the collaboration networks analysis and the best practice recommendations to the public.
 - 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 contribute to the evaluation of the success of the project. In particular, reviewers will evaluate the extent to which the following aspects of the statement of work are reasonable and likely to contribute to the overall management of the project by the applicant:

- the methodologies used to manage the project;
- the milestones and how well 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 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.** Qualifications. (0 15 points) Reviewers will evaluate the extent to which the qualifications of the key personnel, the time commitments of the key personnel, and the project staff's qualifications will enable them to conduct the project work. In particular, the following aspects for key personnel will be assessed and evaluated for their adequacy and the extent to which they are likely to contribute to success of the project:
 - past experience or familiarity with the IEPU designation;
 - past experience in the following disciplines: federal technology transfer, entrepreneurship, technology assessment, evaluation of best practices in research and commercialization, technology-based economic development (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
 - previously demonstrated ability to achieve positive outcomes in endeavors with program objectives that are similar to those of this NOFO as described in Section I. of this NOFO.
- d. Match of Budget to Proposed Work. (0 15 points) Assessment of the budget compared to the proposed work to ascertain the reasonableness of the request.
- 2. Selection Factors. The Selecting Official, who is the Deputy Director of the Technology Partnerships Office, or designee, will generally select and recommend an application for award based on the rank order of the applications (see Section V.3. of this NOFO), but may 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 nondisclosure agreements covering such information, when applicable.

- a. Initial Administrative Review of Applications. An initial review of timely received applications will be conducted to determine eligibility, completeness, and responsiveness to this NOFO and the scope of the stated program objectives. 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 lack of which may easily be rectified or cured.
- **b.** Full 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 subject matter and objectives of the NOFO 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 will be determined on an individual basis, not as a consensus. Based on the reviewers' scores, a rank order will be prepared and provided to the Selecting Official for further consideration. The Selecting Official will then recommend funding recipients 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 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 gualified to receive the subject award and, if so, whether appropriate special conditions that correspond to the degree of risk posed by the applicant should be applied to an award.
- **4.** Anticipated Announcement and Award Dates. The earliest anticipated start date for awards made under this NOFO is expected to be November 2017.
- 5. Additional Information
- **a. Notification to Unsuccessful Applicants.** Unsuccessful applicants will be notified in writing.
- **b.** Retention of Unsuccessful Applications. An electronic copy of each non-selected application will be retained for up to three (3) years for record keeping purposes.

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 <u>http://go.usa.gov/SBYh</u> and <u>http://go.usa.gov/SBg4</u>.
- b. Department of Commerce Financial Assistance Standard Terms and Conditions. The Department of Commerce will apply the Financial Assistance Standard Terms and Conditions dated March 31, 2017, accessible at <u>https://go.usa.gov/xXRxK</u>, to this award. 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 <u>http://go.usa.gov/hKkR</u>. Refer to Section VII. of this NOFO, Federal Awarding Agency Contacts, Grant Rules and Regulations, if you seek the information at this link and it is no longer working or you need more information.
- d. Funding Availability and Limitation of Liability. Funding for the program listed in this notice is contingent upon the availability of appropriations. In no event will NIST or the Department of Commerce be responsible for proposal preparation costs if these programs fail to receive funding or are cancelled because of agency priorities. Publication of this announcement 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. All applications should include a description of any work proposed to be performed by an entity other than the applicant, and the cost of such work should ordinarily be included in the budget.

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 redacted 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 NISTowned 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 DoC Financial Assistance Terms and Conditions dated March 31, 2017, found at <u>http://go.usa.gov/xXRxK</u>. Questions about these requirements may be directed to Chief Counsel for NIST, (301) 975-2803, <u>nistcounsel@nist.gov</u>.

Any use of NIST-owned intellectual property by an applicant 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.

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 who 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: <u>http://www.hhs.gov/ohrp/humansubjects/index.html</u> 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 <u>about</u> 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 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 <u>http://www.hhs.gov/ohrp/assurances/index.html</u>. 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 review⁹ 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 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

⁹ 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.

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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 <u>does not</u> have a cognizant IRB to provide an exemption determination, the following information may be requested during the review process so that NIST can evaluate whether an exemption under the Common Rule applies (see 15 C.F.R. § 27.101(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 deidentification 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 IRBrequired 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-offunding 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: <u>anne.andrews@nist.gov</u>; 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: <u>https://www.nist.gov/labs-major-programs/user-facilities</u>.

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, <u>http://go.usa.gov/xXRxK</u>, 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 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 (<u>http://go.usa.gov/xkVgP</u>) and Department of Commerce Financial Standard Terms and Conditions, Section A.01 (<u>http://go.usa.gov/xXRxK</u>). 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 of 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 Administrative and National Policy Requirements (see Section VI.2. of this NOFO) and other terms and conditions governing the award, the recipient may be required 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, <u>http://go.usa.gov/cTBwC</u>, for maintaining the currency of information reported to SAM that is made available in FAPIIS about<u>+</u> certain civil, criminal, or administrative proceedings involving the recipient.
- b. Audit Requirements. 2 C.F.R. 200 Subpart F, adopted by the Department of Commerce through 2 C.F.R. § 1327.101 requires any non-Federal entity (i.e., including non-profit institutions of higher education and other 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. 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 (Pub. L. 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 contact persons:

Subject Area	Point of Contact
Programmatic and Technical Questions	Kathleen McTigue Phone: 301-975-8530 E-mail: <u>kathleen.mctigue@nist.gov</u>
Technical Assistance with Grants.gov Submissions	Christopher Hunton Phone: 301-975-5718 E-mail: <u>grants@nist.gov</u> Or <u>www.grants.gov</u> Phone: 800-518-4726 E-mail: <u>support@grants.gov</u>
Grant Rules and Regulations	Nuria Martinez Phone: 301-975-6215 E-mail: <u>nuria.martinez@nist.gov</u>

VIII. Other Information

1. Protected and Proprietary 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, Federal agents and contractors, and/or by non-Federal personnel, all of whom enter into appropriate conflicts of interest and nondisclosure 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. 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.