Additional Information for NIST Awards:

I. General

- A. Multi-Year Funding Policy. When an application for a multi-year award is approved, funding will usually be provided for only the first year of the project. If a project is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the sole discretion of NIST. Continued funding will be contingent upon satisfactory performance, continued relevance to the mission and priorities of the individual MSE research grant programs, and the availability of funds.
- **B.** Anticipated Announcement and Award Date. Review of applications, selection of successful applicants, and award processing is expected to be completed by DATE. The earliest start date for awards under this NOFO is expected to be DATE.
- **C. Federal Award Notices.** Successful applicants will receive a Financial Assistance Award Notice (CD-450) from the NIST Grants Officer.
- D. Federal Awarding Agency Review of Risk Posed by Applicants. After applications are proposed for funding by the Selecting Official, the NIST Grants Management Division (GMD) performs pre-award risk assessments in accordance with 2 C.F.R. § 200.206, which may include a review of the financial stability of an applicant, the quality of the applicant's management systems, the history of performance, and/or the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

In addition, prior to making an award where the total Federal share is expected to exceed the simplified acquisition threshold (currently \$250,000), NIST GMD will review and consider the publicly available information about that applicant in the Federal Awardee Performance and Integrity Information System (FAPIIS). An applicant may, at its discretion, review and comment on information about itself previously entered into FAPIIS by a Federal awarding agency. As part of its review of risk posed by applicants, NIST GMD will consider any comments made by the applicant in FAPIIS in making its determination about the applicant's integrity, business ethics, and record of performance under Federal awards. Upon completion of the pre-award risk assessment, the Grants Officer will make a responsibility determination concerning whether the applicant is qualified to receive the subject award and, if so, whether appropriate special conditions that correspond to the degree of risk posed by the applicant should be applied to an award.

- E. Audit Requirements. The Department of Commerce Financial Assistance Standard Terms and Conditions, Section D.01, 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 (i.e., 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 submit to the Grants Officer either: (i) a financial related audit of each DOC award or subaward in accordance with Generally Accepted Government Auditing Standards; or (ii) a project specific audit for each award or subaward in accordance with the requirements contained in 2 C.F.R. § 200.507. Applicants are reminded that NIST, the Department of Commerce Office of Inspector General, or another authorized Federal agency may conduct an audit of an award at any time.
- F. Unique Entity Identifier and System for Award Management (SAM). Pursuant to 2 C.F.R. part 25, applicants and recipients 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.
- G. 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.

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

II. 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 DOC Financial Assistance Standard Terms and Conditions in effect on the date of award. The current version is dated November 12, 2020.
- 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, for more information.
- D. Funding Availability and Limitation of Liability. Funding for the program listed in this NOFO is contingent upon the availability of appropriations. NIST or the Department of Commerce will not be responsible for application preparation costs, including but not limited to 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.

NIST issues this notice subject to the appropriations made available under the current continuing resolution funding the Department of Commerce: Division A of the Further Extending Government Funding Act, Public Law 117-70, December 3, 2021. NIST anticipates making awards for the program listed in this notice provided that funding for Fiscal Year 2022 is continued beyond February 18, 2022, the expiration of the current continuing resolution.

- 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 Federal Government-Owned Intellectual Property. If the applicant anticipates using any Federal Government-owned intellectual property, in the custody of NIST or another Federal agency, to carry out the work proposed, the applicant should clearly identify such intellectual property in the proposal. This information will be used to ensure that no Federal 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 the Federal Government-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 C.03 of the Department of Commerce Financial Assistance Standard Terms and Conditions, dated November 12, 2020. Questions about these requirements may be directed to the Chief Counsel for NIST, (301) 975-2803, nistcounsel@nist.gov.

Any use of Federal Government-owned intellectual property by a recipient of an award under this announcement is at the sole discretion of the Federal Government and will need to be negotiated on a case-by-case basis by the recipient and the Federal agency having custody of the intellectual property 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 a license from the applicable Federal agency. 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 the Federal Government's rights in such inventions will be determined solely by the Federal Government, through NIST as custodian of such inventions, and include the possibility of the Federal Government 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.

This section summarizes the requirements for applications that potentially involve research involving human subjects. Additional information that describes the NIST review process for such applications and provides details regarding the documentation required is available here: NIST Notice of Funding Opportunity Requirements Human Subjects and Live Vertebrate Animal. Both this summary and the additional information provided at the link will be incorporated into any award made under this NOFO.

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 27.1 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 comply 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

¹ NIST uses the Common Rule definitions for research and human subjects research contained in 15 C.F.R. § 27.102.

Administration (FDA), and other Federal agencies on these topics, and all Executive Orders and Presidential statements of policy on applicable topics. The <u>website of the Office of Human Research Protection</u> (OHRP) in the DHHS contains the applicable regulatory, policy and guidance and (includes links to <u>FDA</u>, but may not include all applicable FDA regulations and policies.

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. The IRB must be currently registered with OHRP that is linked to the engaged organization. Organizations that do not have an IRB must demonstrate the ability to expeditiously contract with a commercial IRB to conduct a review of the proposed activities. Also, all engaged organizations must possess a currently valid Federalwide Assurance (FWA) on file from OHRP. The NIST IRB is unable to serve as the IRB for financial assistance recipients.

The NIST Research Protections Office (RPO) reserves the right to conduct an administrative review of all applications that potentially include research involving human subjects and were approved by an authorized non-NIST institutional entity (an IRB or entity analogous to the NIST RPO) under 15 C.F.R. § 27.112 (Review by Institution). Conducting an "administrative review" means that the NIST RPO will review and verify the performing institution's determinations made under the Common Rule and all documentation that support such determinations.

All applications involving human subjects research must clearly indicate, by separable task, all research activities believed to be exempt or non-exempt research involving human subjects, the expected institution(s) where the research activities involving human subjects may be conducted, and the institution(s) expected to be engaged in the research activities. Some documents may be requested for a pre-review during the proposal review process; however, the Grants Officer may allow final versions of certain required documents to be produced at an appropriate designated time post-award. If an award is issued, no research activities involving live vertebrate animals shall be initiated or costs incurred for those activities under the award until the NIST Grants Officer issues written approval. In addition, all re-approvals, amendments, modifications, changes, annual reports and closure will be reviewed by NIST.

This summary and the information provided here <u>NIST Notice of Funding Opportunity</u> Requirements Human Subjects and Live Vertebrate Animal reflect the existing NIST policy and requirements for Research Involving Human Subjects. Should the policy be revised prior to award, a clause reflecting the policy current at time of award may be incorporated into the award. If the policy is revised after award, a clause reflecting the updated policy may be incorporated into the award.

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

H. Research Activities Involving Live Vertebrate Animals or Pre-Existing Cell Lines/Tissues from Vertebrate Animals.

This section summarizes the requirements for applications that potentially involve research involving live vertebrate animals or pre-existing cell lines or tissues from vertebrate animals. Additional information that describes the NIST review process for such applications and provides details regarding the documentation required is available here: NIST Notice of Funding Opportunity Requirements Human Subjects and Live Vertebrate Animal. Both this summary and the additional information provided at the link will be incorporated into any award made under this NOFO.

Any application that proposes research activities involving live vertebrate animals that are to be cared for, euthanized, or used by award recipients to accomplish research goals, teaching, or testing must meet the requirements of the Animal Welfare Act (AWA) (7 U.S.C. § 2131 et seq.), and the AWA final rules (9 C.F.R. Parts 1, 2, and 3), and if appropriate, the Good Laboratory Practice for Nonclinical Laboratory Studies (21 C.F.R. Part 58). In addition, such research activities should be in compliance with the "U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" (Principles).

NIST reserves the right to conduct an administrative review of all applications that potentially include research activities that involve live vertebrate animals, or custom samples from, or field studies with live vertebrate animals. Conducting an "administrative review" means that the NIST RPO will review and verify the performing institution's determinations made under the applicable legal and policy requirements and all documentation that support such determinations. Some documents may be requested for a pre-review during the proposal review process; however, the Grants Officer may allow final versions of certain required documents to be produced at an appropriate designated time post-award. If an award is issued, no research activities involving live vertebrate animals shall be initiated or costs incurred for those activities under the award until the NIST Grants Officer issues written approval. In addition, all re-approvals, amendments, modifications, changes, annual reports, and closure will be reviewed by NIST.

The applicant should clearly indicate in the application, by separable task, all research activities believed to include research involving live vertebrate animals and the institution(s) where the research activities involving live vertebrate animals may be conducted. In addition, the applicant should indicate any activity/task that involves an excluded or custom collection from vertebrate animals, or a field study with animals.

This summary and the information provided here <u>NIST Notice of Funding Opportunity</u> Requirements Human Subjects and Live Vertebrate Animal reflect the existing NIST policy for Research Involving Live Vertebrate Animals. Should the policy be revised prior to award, a clause reflecting the policy current at time of award may be incorporated into the award. If the policy is revised after award, a clause reflecting the updated policy may be incorporated into the award.

For more information regarding research projects involving live vertebrate animals, contact Anne Andrews, Director, NIST Research Protections Office (e-mail: anne.andrews@nist.gov; phone: 301-975-5445).