Notice of Funding Opportunity (NOFO)
NIST Rapid Assistance (for) Coronavirus Economic Response Grant Program

Executive Summary

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

- **Funding Opportunity Title:** NIST Rapid Assistance for Coronavirus Economic Response (RACER)

- **Announcement Type:** Initial

- **Funding Opportunity Number:** 2021-NIST-MFGUSA-RACER-01

- **Assistance Listing (CFDA Number):** 11.619: Arrangements for Interdisciplinary Research Infrastructure

- **Dates:** Applications must be received at Grants.gov by no later than 11:59 p.m. Eastern Time, Monday, July 26, 2021. Applications received after this deadline will not be reviewed or considered. Paper applications will not be accepted.

  When developing the submission timeline, please keep in mind that: (1) all applicants are required to have current registrations in the electronic System for Award Management (SAM.gov) and Grants.gov; (2) the free annual registration process in SAM.gov (See section IV.3. of this NOFO) generally takes between three and five business days but can take more than two weeks; and (3) applicants will receive e-mail notifications over a period of up to two business days as the application moves through intermediate systems before the applicant learns via a validation or rejection notification whether NIST has received the application. (See Grants.gov for full information on application and notification through Grants.gov). **Please note that a federal assistance award cannot be issued if the designated recipient's registration in SAM.gov is not current at the time of the award.**

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

- **Funding Opportunity Description:** NIST invites Manufacturing USA institutes to propose high-impact projects designed to fund awards for research, development, and testbeds to prevent, prepare for, and respond to coronavirus.

- **Anticipated Amounts**: NIST anticipates funding individual projects up to $5 million for projects involving a single institute, and up to $15 million for projects involving

multiple institutes. Project durations are limited to:

- For projects up to $5 million, the period of performance is up to two (2) years.
- For projects funded at greater than $5 million, the period of performance is up to three (3) years.

See section II.2. in the full announcement text of this NOFO. Awards are subject to the availability of funding.

- **Funding Instrument:** Cooperative agreement.

- **Eligibility:** Eligibility for this program is limited to current Manufacturing USA institutes not receiving financial assistance under 15 U.S.C. § 278s(e), as amended, at the time of proposal submission. The Manufacturing USA institutes[1] eligible to submit applications under this funding opportunity are: AFFOA, AIM Photonics, America Makes, ARM, BioFabUSA, BioMADE, CESMII, CyManII, IACMI, LIFT, MxD, NextFlex, PowerAmerica, RAPID, & REMADE. No other entities are eligible to submit applications.

  An applicant institute may work individually or include proposed subawards to other institutes. Note that NIIMBL may not receive funding under this NOFO but may participate in projects as an unfunded collaborator.

  Please note that members of the institutes, individuals, and organizations not associated with the institutes are NOT eligible to apply under this NOFO; however, they may participate as part of an institute's team.

- **Cost Sharing Requirements:** Non-federal cost share is not required.

- **Public Website and Frequently Asked Questions (FAQs):** NIST has a public website https://www.nist.gov/oam/rapid-assistance-coronavirus-economic-response-racer-grant-program that provides a "Frequently Asked Questions" page, webinar registration, and other information pertaining to this Funding Opportunity. Applicants must submit all such questions in writing to manufacturingusa@nist.gov with "2021-NIST-MFGUSA-RACER-01 Questions" in the subject line.

  NIST will hold an informational webinar on June 2, 2021 to provide general information regarding this NOFO, offer general guidance on preparing applications, and offer the opportunity for the public to ask questions. Proprietary technical

[1] An organization (university or non-profit) that runs or hosts an institute may submit an application on the institute's behalf.

questions about specific proposal ideas will not be permitted, and NIST will not critique or provide feedback on any proposal ideas during the webinar or at any time before submission to Grants.gov. However, NIST will provide information about eligibility requirements, the evaluation criteria, and the review process during the webinar. There is no cost to attend the webinar, but participants must register in advance by sending email to manufacturingusa@nist.gov with "RACER Webinar" in the subject line. Participation in the webinar is not required and will not be considered in the application review and selection process.

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Full Announcement

I. Program Description

The National Institute of Standards and Technology (NIST) is publishing this Notice of Funding Opportunity (NOFO) pursuant to 15 U.S.C. § 278s(f), as amended, and Section 7501 of the American Rescue Plan Act of 2021 (Pub. L. 117-2).

1. Program Overview

COVID-19 hit with a speed and force that commanded the best in government, academia, and industry to gather at an unprecedented pace and accelerate innovations to address the needs of our nation. Many organizations and individuals across the country looked for ways to help.

In 2020, the Manufacturing USA network, comprised of federal agencies and their sponsored manufacturing innovation institutes, assembled and utilized the flexibility, skills and knowledge of their nationwide membership to address issues and begin developing solutions. These public-private partnerships convened members from industry, academia, and government enabling a rapid response to the developing needs across America based on their access to information and ability to deploy resources. The institutes' relevant and

efficient plans, along with $73 million in Coronavirus Aid, Relief, and Economic Security (CARES) Act funds distributed through the Department of Commerce (DOC) and Department of Defense (DoD), allowed them to execute more than 36 technology development and education and workforce development projects.[2]

In the earliest stages of the pandemic, the Manufacturing USA® institutes assessed the global and domestic manufacturing situation. At that time, their analysis indicated an urgent need for better domestic supply chains, data analysis, and novel manufacturing products and processes. After a year of fighting COVID-19, our nation is still dealing with the pandemic and facing a deep economic crisis. The American Rescue Plan Act of 2021 (Pub. L. 117-2) lays out a plan to change the course of the pandemic and build a bridge towards economic recovery.

With thousands of small manufacturers, two-thirds of Fortune 50 U.S. manufacturers, and nearly every top ranked research and engineering university in the country working together on the biggest manufacturing challenges of the day, the institutes within the Manufacturing USA network are positioned to stimulate the U.S. economy and to support research, development, and testbeds to prevent, prepare for, and respond to coronavirus.

2. Manufacturing USA Coronavirus Funding Opportunities

Objective: Fund high-impact projects proposed by AFFOA, AIM Photonics, America Makes, ARM, BioFabUSA, BioMADE, CESMII, CyManII, IACMI, LIFT, MxD, NextFlex, PowerAmerica, RAPID, or REMADE designed to support research, development, and testbeds to prevent, prepare for, and respond to coronavirus.

Goal: Make use of expertise found within institutes of the Manufacturing USA network and its member organizations to develop innovative agile responses to coronavirus health and economic threats.

Institutes within the Manufacturing USA may work alone or with other institutes on collaborative projects.

Please note that the examples below are not an exhaustive list of potential proposal topics, but examples. Any proposals for research, development, and testbeds to prevent, prepare for, and respond to coronavirus will be considered responsive to this NOFO.

Illustrative project ideas *may* include, but are not limited to, innovative medical and non-medical countermeasures; strengthening state and community resilience by leveraging

[2] https://www.manufacturingusa.com/reports/manufacturing-usa-rapid-response-covid-19-report

institute capabilities; creating testbeds or small scale production facilities; establishing or reshoring critical supply chains; or workforce development and training for a skilled advanced manufacturing workforce.

For example, institutes may leverage technical expertise within the Manufacturing USA network to work on:

- **Medical and non-medical countermeasures**: Retool manufacturing facilities to reshore the supply chain for critical raw materials through advanced manufacturing approaches; reduce the energy and environmental impact of manufacturing; adding smart sensing to allow digital tracking of supply chain; enhance advanced automation and digital controls to alleviate shortages; and develop agile, intensified, integrated, and automated manufacturing platforms.
- **Strengthen state and community resilience**: Leverage institute capabilities to support state or other non-federal efforts to develop local manufacturing capabilities to respond to coronavirus and other public health crises. Attract organizations with critical pandemic response capabilities to partner in developing new strategies and mechanisms to promote greater manufacturing resilience.
- **Testbeds or small scale production facilities**: Create additional small-scale production centers or testbeds that can be made available to companies for short-term production of limited-need goods, start-up validation testing, or for use by the institute for workforce training.
- **Workforce development and training for a skilled advanced manufacturing workforce:** Develop innovative ways to create a pipeline of skilled workers ready to take on more challenges, increase company productivity, improve innovation, and increase diversity through multiple entry points that let workers develop their skills while advancing their careers. For example, this may be done through building awareness, skill development, internships; hybrid training programs, industry-influenced certifications, training reimbursements, curriculum development, and expanding partnerships to attract candidates from untapped talent pools.

In forming project teams, NIST strongly supports outreach to, recruitment of, and engagement with a diverse array of project participants. Institute applicants are encouraged to maximize the extent of geographic and institutional diversity among project participants.

NOTE: The NIST Hollings Manufacturing Extension Partnership (MEP) National Network is comprised of NIST MEP on the NIST Gaithersburg campus, 51 MEP Centers located in all 50 states and Puerto Rico, and over 1,400 trusted advisors and experts at more than 385 MEP service locations. NIST encourages applicants to review the resources available through the MEP National Network, particularly for connecting applicants with potential subrecipients, contractors, or other collaborators.

Projects proposed but not funded in the 2020-NIST-MFGUSA-NEAP-01 competition may be resubmitted to this competition with an updated technical proposal and budget information.

II. Federal Award Information

1. Funding Instrument

The funding instrument that will be used for awards issued pursuant to this NOFO is a cooperative agreement. The nature of NIST's "substantial involvement" will generally include collaboration with the recipient organization in developing, implementing the approved scope of work, in accordance with 2 CFR § 200.01.

2. Funding Availability

NIST anticipates funding individual projects up to $5 million for projects involving a single institute and up to $15 million for projects involving multiple institutes. Project durations are limited to:

- For projects up to $5 million, the period of performance is up to two (2) years.
- For projects funded at greater than $5 million, the period of performance is up to three (3) years.

Awards are subject to the availability of funding.

III. Eligibility Information

1. Eligible Applicants

Eligibility for this program is limited to current Manufacturing USA institutes not receiving financial assistance under 15 U.S.C. § 278s(e), as amended, at the time of proposal submission. The Manufacturing USA institutes[3] eligible to submit applications under this funding opportunity are: AFFOA, AIM Photonics, America Makes, ARM, BioFabUSA, BioMADE, CESMII, CyManII, IACMI, LIFT, MxD, NextFlex, PowerAmerica, RAPID, & REMADE. No other entities are eligible to submit applications.

An applicant institute may work individually or include proposed subawards to other institutes. Note that NIIMBL may not receive funding under this NOFO but may participate in projects as an unfunded collaborator.

[3] An organization (university or non-profit) that runs or hosts an institute may submit an application on the institute's behalf.

Please note that members of the institutes, individuals, and organizations not associated with the institutes are NOT eligible to apply under this NOFO; however, they may participate as part of an institute's team.

2. Cost Sharing or Matching.

Non-federal cost sharing is not required for awards issued pursuant to this NOFO.

3. Funding Limitations.

Applications for product development and/or commercialization are not considered responsive to this NOFO. Profit or fee is not an allowable cost. In addition, a recipient or a subrecipient may not charge profits, fees, or other increments above cost to an award issued pursuant to this NOFO.

4. No Double Charging Against Other Federal Awards or Contracts.

Costs charged against awards issued pursuant to this NOFO, whether paid by federal or non-federal funds, may not also be charged as costs against any other federal award (i.e., no double-billing of costs).

IV. Application and Submission Information

Applications must be received at Grants.gov by no later than 11:59 p.m. Eastern Time, Monday, July 26, 2021 . Applications received after this deadline will not be reviewed or considered. Paper applications will not be accepted.

1. Address to Request Application Package

The application package is available at Grants.gov under Funding Opportunity Number 2021-NIST-MFGUSA-RACER-01.

2. Content and Form of Application Submission

A. **Required Forms and Documents.**

The application must contain the following:

(1) SF-424 (R&R), Application for Federal Assistance.

a. The SF-424 must be signed by an authorized representative of the applicant organization.
   a. For SF-424 (R&R), Items 5, 14, and 19, use the Zip Code + 4 format (##### - ####) when addresses are called for.
   b. For SF-424 (R&R), Item 17, the list of certifications and assurances

is contained in the Federal Financial Assistance Certifications and Representations (Certs and Reps) as part of the SAM.gov entity registration.

c. SF-424 (R&R), Item 18. If the SF-LLL, Disclosure of Lobbying Activities form (item (5) below) is applicable, attach it to field 18.

Instructions for filling in the SF-424 (R&R) can be found on Grants.gov, as well as at the NIST Grants Management Division SF-424 Research & Related (R&R) Application Package Guidance.

(2) Research & Related Budget (Total Fed + Non-Fed).

The budget should reflect anticipated expenses for the full term of the project, considering all potential cost increases, including cost of living adjustments.

The budget should be detailed in these categories:

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

A separate detailed R&R Budget must be completed for each budget period during the proposed award (e.g., annual basis). To add additional budget periods (e.g., year 2), click "Add Period" embedded at the end of the form. Information regarding the Research & Related Budget (Total Fed + Non-Fed) is available in the R&R Family Section of Grants.gov.

(3) CD-511, Certification Regarding Lobbying.

Enter "2021-NIST-MFGUSA-RACER-01" in the award number field. Enter the title of the application, or an abbreviation of that title, in the project name field.

(4) Research and Related Other Project Information.

Answer the highlighted questions and use this form to attach the Project

Narrative (item (6) below), Resume(s) (item (7) below), the Indirect Cost Rate Agreement (item (9) below), the Letters of Commitment (item 11) below), the Data Management Plan (item (12) below), and the Current and Pending Support Form (item (13 below). Instructions for completing the Research and Related Other Project Information can be found in the Grants.gov R&R Forms Repository as well as in the NIST Grants Management Division SF-424 Research and Related (R&R) Application Package Guidance.

Please note that the Project Summary/Abstract is not relevant to this competition. However, Grants.gov requires an attachment to field 7 of the Research and Related Other Project Information form to successfully pass through Grants.gov. Please attach a document to field 7 stating, "A Project Summary/Abstract is not relevant to this competition".

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

(6) Project Narrative.

The Project Narrative is a word-processed document of no more than twenty (20) pages, which is responsive to the program description (see section I. of this NOFO) and to the evaluation criteria (see section V.1. of this NOFO).

The Projective Narrative should contain the following information:

- Table of Contents. (does not count toward the page limit)

- Executive Summary. An executive summary of the proposed project consistent with the objectives, requirements, and priorities of this program. 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 and does not count towards the page limit for the Project Narrative.

  Please note, if an applicant's proposal is selected for funding, NIST may use all or a portion of the executive summary in a press release, or for other public information and outreach purposes. Applicants are advised not to incorporate information that concerns business trade secrets or other confidential commercial or financial information as part of the executive summary. See also 15 CFR § 4.9(c) concerning the designation of business information by the applicant.
- Project – Rationale. The applicant should provide sufficient information to understand the rationale, scope, and purpose of the

proposed project. It should answer questions such as:

What is the problem/technical challenge that you are attempting to address?

Why is now the right time? How the project's work will contribute to research, development, or testbed efforts to prepare, prevent, and respond to coronavirus.

Who benefits from this project?

This section should identify how this project will complement or contribute to the mission of the institute. Where appropriate, identify similar regional, national, or technical efforts and identify the uniqueness or complementary nature of the proposed project to those other efforts.

- Project Plan and Execution – Merit. Provide a detailed project execution plan of the proposed project that includes information on how the project is organized; a rough project schedule, measurable milestones, activity location(s), and major deliverables, and key players. If any sub-projects are identified, they also need a clear project plan and a statement on how they contribute to the overarching project's objective. This section should identify any potential risks and plans to mitigate those risks.

  Teaming is encouraged to bring together key expertise, access to facilities, or specialized goods and services if this will result in a larger national or regional impact. Be sure to discuss what each organization brings to the project and what each will do.

  NOTE: As described in Section I. of this NOFO, the NIST Hollings Manufacturing Extension Partnership and its Centers may be a useful resource for connecting applicants with potential subrecipients, contractors, or other collaborators. In all cases, required Letters of Commitment should be provided (see Section IV.2.A.(11) of this NOFO).

- Project Impact, Outcomes, and Dissemination. A detailed discussion of the: (i) anticipated impacts of the proposed project both to the nation, and to the institute and its mission; (ii) methodology for identifying and evaluating project outcomes as they relate to preventing, preparing for, or responding to coronavirus; and (iii) dissemination of project results. This section should provide a discussion of the proposed project impacts, proposed project

evaluation, and proposed information dissemination activities.

Applicants should identify in this section specific project tasks, measurable milestones, and outcomes resulting from the proposed project, as well as a methodology for identifying and analyzing project outcomes.

Applicants must also provide details about approaches for sharing lessons learned and best practices resulting from the project, including information dissemination sharing to and with small and medium manufacturers (SMM) and the Manufacturing USA network of institutes. Applicants must also address why their project activities are unlikely to receive private sector financial support.

- Project Management, Resources, and Budget. This section should provide a description of the proposed project sufficient to permit evaluation of the proposed project management structure, resources (including facilities), and project budget at the sub-project level (if appropriate). It should answer questions such as:

  Are the right people working on the project?
  Is the project sufficiently resourced (people, facilities)?
  If there are sub-projects, how do they relate to one another and to the main project?
  What plans are in place to track and report project milestones?

  The applicant should specify plans for the proper and efficient organization, staffing, and management (including but not limited to the key personnel).

  Applicants should also demonstrate the relevance and cost effectiveness of the proposed project budget through the written budget narrative.

(7) Resume(s).

Resumes are required for all key personnel, including the principal investigator. Resumes are limited to one (1) page per individual. Additional 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. The

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

The Budget Narrative does not count against the twenty (20) page limit of the Project Narrative. The budget narrative should clearly identify budget at the sub-project level, as needed.

Information needed for each category is as follows (categories not listed are automatically generated by the form or are not relevant to this competition):

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

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

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

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

c. **Equipment Description** – Equipment is defined as an item of property that has an acquisition cost of $5,000 or more (unless the organization has

established lower levels) and an expected service life of more than one year. The budget justification should list each piece of equipment, the cost, and a description of how it will be used and why it is necessary to the successful completion of the proposed project. Please note that any general use equipment (computers, etc.) charged directly to the award should be allocated to the award according to expected usage on the project.

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

e. **Participant/Trainee Support Costs** – Participant support costs are stipends, subsistence allowances, travel, and registration fees paid to or on behalf of participants or trainees, who are not employees of your organization, for conferences or training projects. The budget justification should indicate the names or number of participants or trainees, a description and calculation of costs per person, a description and date of the event, and a description of why the cost is necessary for the successful completion of the proposed project.

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

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

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

(9) *Indirect Cost Rate Agreement.*
If indirect costs are included in the proposed budget, provide a copy of the approved negotiated agreement if this rate was negotiated with a cognizant Federal audit agency. If the rate was not established by a cognizant Federal audit agency, provide a statement to this effect. If the successful applicant includes indirect costs in the budget and has not established an indirect cost rate with a cognizant Federal audit agency, the applicant will be required to obtain such a rate in accordance with Section B.06 of the Department of Commerce Financial Assistance Standard Terms and Conditions, dated November 12, 2020.

Alternatively, in accordance with 2 C.F.R. § 200.414(f), applicants that do not have a current negotiated (including provisional) indirect cost rate except for those non-Federal entities described in appendix VII, paragraph D.1.b. of 2 CFR 200 may elect to charge a de minimis rate of 10 percent of modified total direct costs (MTDC). 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) *Subaward Budget Form*
The Research & Related Subaward Budget Attachment Form is required if sub-recipients and contractors are included in the application budget.

Instructions for completing subaward budget forms are available by visiting the R & R Family section of the Grants.gov Forms Repository and scrolling down to the R & R Subaward Budget Attachment(s) Form and selecting "Instructions."

(11) *Letters of Commitment.*
Letters that commit specific resources (not just funding) to the project are required for any subawards or contracts to known third parties, effectively forming a team, as described in Section IV.2.A.(6). The Letter of Commitment should indicate organization's willingness to participate as a contractor, subrecipient, or unfunded partner, as applicable, describe what work they will do in relation to the Project Narrative, and specify the associated cost (if any) of the proposed subaward or contract to the applicant (see Section I. of this NOFO).

(12) Data Management Plan.

Consistent with NIST Policy 5700.00[4], *Managing Public Access to Results of Federally Funded Research,* and NIST Order 5701.00[5], *Managing Public Access to Results of Federally Funded Research*", applicants must include a Data Management Plan (DMP).

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).

The DMP 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, including after the end of the award's period of performance; and a plan describing whether and how data generated by the identified activities will be reviewed and made available to the public.

A template for the DMP, an example DMP, and the rubric against which the DMP will be evaluated for sufficiency is available at https://www.nist.gov/open. An applicant is not required to use the template as long as the DMP contains the required information.

If an application stands a reasonable chance of being funded and the DMP is determined during the review process to be insufficient, the program office may reach out to the applicant to resolve deficiencies in the DMP. If an award is issued prior to the deficiencies being fully rectified, the award will include a Specific Award Condition (SAC) stating that no research activities shall be initiated or costs incurred for those activities under the award until the NIST Grants Officer amends the award to indicate the SAC has been satisfied.

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

(13) Current and Pending Support Form.

Any application that includes investigators, researchers, and key personnel must identify all sources of current and potential funding, including this

[4] https://www.nist.gov/system/files/documents/2018/06/19/final_p_5700.pdf
[5] https://www.nist.gov/system/files/documents/2019/11/08/final_o_5701_ver_2.pdf

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

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

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

B. Attachment of Required Documents

Items IV.2.A.(1) through IV.2.A.(4) above are part of the standard application package in Grants.gov and can be completed through the download application process.

Item IV.2.A.(5), 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.(5), the SF-LLL, Disclosure of Lobbying Activities form is applicable to this proposal, attach it to field 18 of the SF-424 (R&R), Application for Federal Assistance.

Item IV.2.A.(6), the Project Narrative, should be attached to field 8 (Project Narrative) of the Research and Related Other Project Information form by clicking on “Add Attachment”.

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

Items IV.2.A.(7), Resumes, IV.2.A.(9), the Indirect Cost Rate Agreement, IV.2.A.(12), the Data Management Plan, and IV.2.A.(13), the Current and Pending Support Form, must be completed and attached by clicking on "Add Attachments" found in item 12 (Other Attachments) of the Research and Related Other Project Information form.

Item IV.2.A.(11), Letters of Commitment, if applicable to the submission, should be attached by clicking on "Add Attachments" found in item 12 (Other Attachments) of the Research and Related Other Project Information form.

Item IV.2.A.(10), the Subaward Budget Form(s), if applicable to the submission, should be attached to the Research & Related Subaward Budget (Total Fed + Non-Fed) Attachment(s) Form in the application package.

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

Applicants should carefully follow specific Grants.gov instructions 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 will receive a series of e-mail messages over a period of up to two business days before learning whether a Federal agency's electronic system has received its application.

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

After submitting the application, check the status of your application here: CHECK APPLICATION STATUS. If any, or all, of the required attachments are absent from the submission, follow the attachment directions found above, resubmit the application, and check again for the presence of the required attachments.

If the directions found at https://www.grants.gov/help/html/help/index.htm#t=GetStarted%2FGetStarted.htm are not effective, please contact the Grants.gov Help Desk immediately. If calling from within the United States or from a U.S. territory, please call 800-518-4726. E-mails should be addressed to support@grants.gov. Assistance from the Grants.gov Help Desk will be available around the clock every day, with the exception of Federal holidays. Help Desk service will resume at 7:00 a.m. Eastern Time the day after Federal holidays.

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

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

C. Application Format

(1) Paper, email, 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 displayed in landscape orientation. Any figures, graphs, images, or pictures will count toward the page limits for the Project Narrative.

(*3) Font. Easy to read font (11-point minimum)*. Smaller type may be used in figures and tables but must be clearly legible.

(4) Page limit. The Project Narrative is limited to twenty (20) pages double spaced.

(5) Page limit exclusions:

- SF-424 (R&R), Application for Federal Assistance;
- Research & Related Budget (Total Fed + Non-Fed);
- CD-511, Certification Regarding Lobbying;
- Research and Related Other Project Information;
- SF-LLL, Disclosure of Lobbying Activities;
- Table of Contents;
- Executive Summary;
- Resume(s) of 1 page per person;
- Budget Narrative and Justification;
- Indirect Cost Rate Agreement;
- Subaward Budget Form;
- Letters of Commitment;
- Data Management Plan;
- Current and Pending Support Form.

(6) Page layout. The proposal must be in portrait orientation.

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

(8) *Page numbering*. Number pages sequentially.

(9) *Application language*. English. All documents must be in English, including but not limited to the initial application, any additional documents submitted in response to a NIST request, all reports, and any correspondence with NIST.

(10) *Typed document*. All applications, including forms, must be typed; handwritten forms will not be accepted.

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

3. Unique Entity Identifier and System for Award Management (SAM).
Pursuant to 2 CFR 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 CFR § 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. Intergovernmental Review.
Applications under this program are not subject to executive order 12372.

5. How to Submit an Application.

A. **Applications must be submitted via Grants.gov**.

(1) Applicants should carefully follow specific Grants.gov instructions to ensure that all attachments will be accepted by the Grants.gov system. A receipt from Grants.gov indicating an application is received does not provide information about whether attachments have been received. For further information or questions regarding

applying electronically for the 2021-NIST-MFGUSA-RACER-01 announcement, contact the Grants.gov help desk at 800-518-4726.

(2) Applicants are strongly encouraged to start early and not wait 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. The typical registration process takes three to five business days. If problems are encountered, the registration process can take two weeks or more. Applicants must have a valid unique entity identifier number and must maintain a current registration in the federal government's primary registrant database, the system for award management (https://www.sam.gov/SAM/), as explained on the Grants.gov web site (also see 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, except for Federal holidays. Help desk service will resume at 7:00 a.m. Eastern time the day after federal holidays. For assistance using Grants.gov, the applicant may also contact support@grants.gov.

(3) To find instructions for submitting an application on Grants.gov, applicants should refer to the "applicants" tab in the banner just below the top of the Grants.gov home page. Clicking on the "applicants" tab produces two exceptionally useful sources of information, applicant actions and applicant resources, which applicants are advised to review.

Applicants will receive a series of e-mail messages over a period of up to two business days before learning whether a federal agency's electronic system has received its application.

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

The 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 ascertain whether the application was rejected with errors and the reasons for the rejection, the applicant must log in to Grants.gov, select "applicants" from the top navigation, and select "track my application" from the drop-down list. If the status is "rejected with errors," the applicant may still seek to correct the errors and resubmit the application. If the applicant does not correct the errors, the application will not be forwarded to NIST by Grants.gov.

B. **Amendments**: Any amendments to this NOFO will be announced through Grants.gov.

V. Application Review Information

1. Evaluation Criteria.

NIST will use the following criteria in evaluating applications and assigning scores, with a maximum score of 100. The four criteria below will be weighted equally (maximum of 25 points each). Reviewers will evaluate:

A. Project – Rationale: The extent to which the proposal identifies appropriate areas of focus; aligns with the institute(s) mission(s); enhances the U.S. advanced manufacturing infrastructure; and advances discovery and understanding of, or improves the Nation's ability to prevent, prepare for, and respond to coronavirus by supporting research, development, or testbed activities.

B. Project Plan and Execution – Merit: The coherence (conception and organization) of the applicant institute's approach. Identifies clear project goals, objectives, and deliverables that are specific, measurable, achievable, and trackable, and the extent to which the application effectively addresses national advanced manufacturing needs issues that are relevant to the national response to prepare, prevent, and respond to coronavirus, including but not limited to, those described in Section I.2. of this NOFO.

C. Project Impact, Outcomes, and Dissemination: The likelihood that the proposed project will make a substantial contribution to the national efforts to prevent, prepare for, and respond to the coronavirus pandemic through research, development, and testbed activities. A clear methodology for identifying and analyzing project outcomes as well as plans to track the outcomes.

D. Project Management, Resources, Budget:

i. The extent to which the management structure promotes collaboration across the project team.

ii. The extent to which applicant identifies clearly defined roles for the team and how their skills align to the project goals.

iii. The extent to the applicant institute and project team have access to the necessary facilities and expertise to accomplish the project objectives.

iv. An assessment of the budget against the proposed scope of work to ascertain the reasonableness of the request. The extent to which the budget provides a clear picture of all expenditures involved in carrying out a project at the sub-project and subrecipient level (as appropriate).

2. 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, or non-Federal personnel who have entered into conflict of interest and confidentiality agreements covering such information, where applicable.

A. **Initial Administrative Review of Applications**. All applications received in response to this NOFO will be reviewed as received to determine whether they are eligible, complete, and responsive to this NOFO. Applications determined to be ineligible, incomplete, and/or non- responsive will not be reviewed. However, NIST, in its sole discretion, may continue the review process for an application that is missing non-substantive information which may easily be rectified or cured during the review process.

B. **Merit Review**. Each application will be reviewed by at least three technically qualified individual reviewers who will evaluate each application based on the evaluation criteria for this program (see section V.1. of this NOFO). Each reviewer will provide a written technical assessment against the evaluation criteria and based on that assessment will assign each application a numeric score, with a maximum score of 100. The reviewers may discuss an application with each other, but scores will be determined on an individual basis, not as a consensus.

C. **Program Review**. An Evaluation Panel will conduct a programmatic review of the applications that completed merit review. The Evaluation Panel will consist of at least three (3) persons and will be comprised of any mix of NIST staff, and other federal agency employees with appropriate professional and technical expertise. The Evaluation Panel may submit written questions to applicants to clarify information in an application. The Evaluation Panel will prepare and provide a final adjectival rating of the applications to the Selecting Official for further

consideration, taking into consideration the relevance of an application to the program goals and objectives described in Section I., the results of the merit reviewers' evaluations, including scores and written comments, and any additional information obtained from the applicant by the Evaluation Panel. The adjectival ratings are:

- Fundable, Outstanding;
- Fundable, Very Good;
- Fundable; or
- Unfundable.

For decision-making purposes, applications receiving the same adjectival rating will be considered to have an equivalent ranking, although their technical review scores will not necessarily be the same.

D. **Selection Factors**

The selection factors for this competition are:

- Alignment with the NOFO objectives
- Alignment with the Manufacturing USA purposes and activities.
- Whether the project duplicates other projects funded by NIST or other Federal agencies.
- The geographic diversity of project participants or outcomes, which may include the number of states in which project participants are located and the distribution of project work among urban, suburban, and rural communities.
- The institutional diversity of project participants, which may include the extent of active project participation of small- and medium-sized manufacturing enterprises; women, minority, and veteran owned manufacturing enterprises; state, local, and Tribal governments; and career and technical education schools and community colleges in addition to research universities.
- The availability of funding.

E. **Selection**. The Selecting Official is the director of NIST Advanced Manufacturing National Program Office, or designee. The Selecting Official makes the final recommendation to the NIST Grants Officer regarding the funding of applications under this NOFO.

The Selecting Official shall generally select and recommend applications for award based on the adjectival rating of the applications and one or more of the selection factors. In addition, in accordance with the program's authorizing legislation, the Selecting Official will make a determination whether the project is (1) in the national interest and (2) unlikely to receive private sector financial support.

F. **Pre-award Negotiations**. NIST reserves the right to negotiate the budget costs with any applicant selected to receive an award, which may include requesting that the applicant removes certain costs. In addition, NIST may request that successful applicants modify objectives or work plans and provide supplemental information required by the agency prior to award. NIST may select some, all, or none of the applications, or part(s) of any application. In some cases, NIST may ask applicants to consider combining projects. The final approval of selected applications and issuance of awards is the responsibility of the NIST Grants Officer. The award decisions of the NIST Grants Officer are final.

G. **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 CFR § 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 specific conditions that correspond to the degree of risk posed by the applicant should be applied to an award.

3. Anticipated Announcement and Award Date

Review of applications, selection of successful applicants, and award processing is expected to be completed within 90 calendar days of receipt of a complete application.

4. Additional Information

A. **Notification to Unsuccessful Applicants**. Unsuccessful applicants will be notified by e-mail.
B. **Retention of Unsuccessful Applications**. Unsuccessful applications will be retained in accordance with the general record schedule 1.2/021.

VI. Federal Award Administration Information

1. Federal Award Notices.

Successful applicants will receive an award package from the NIST Grants Officer.

2. Administrative and National Policy Requirements

A. **Uniform Administrative Requirements, Cost Principles and Audit Requirements**. Through 2 CFR § 1327.101, the Department of Commerce adopted uniform administrative requirements, cost principles, and audit requirements for federal awards at 2 CFR part 200, which apply to awards in this NOFO. 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 Department of Commerce Financial Assistance Standard Terms and Conditions in effect on the date of award made under this NOFO. The current version, dated November 12, 2020, is accessible here. Refer to section VII. of this NOFO, Federal Awarding Agency Contacts, Grant Rules and Regulations, if you need more information.
C. **Pre-award Notification Requirements**. The Department of Commerce will apply the Pre-award Notification Requirements for Grants and Cooperative Agreements dated December 30, 2014 (79 FR 78390), accessible at http://go.usa.gov/hKkR. Refer to section VII. of this NOFO, Federal Awarding Agency Contacts, Grant Rules and Regulations, if you need more information.
D. **Funding Availability and Limitation of Liability**. Funding for the program listed in this NOFO is contingent upon the availability of appropriations. NIST or the Department of Commerce will not be responsible for application preparation costs, including but not limited to the program's failure to receive funding or cancellation due to agency priorities. Publication of this NOFO does not oblige NIST or the Department of Commerce to award any specific project or to obligate any available funds.
E. **Supporting Documentation**. Prior to award or following the issuance of an award, NIST may require recipients to provide draft copies of sub-tier agreements, including subawards and contracts, as well as subrecipient performance monitoring plans.

F. **Reporting**.

(1) *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 November 12, 2020, apply to awards in this program:

a. Financial reports. Each award recipient shall submit an SF-425, Federal Financial Report, on a semi-annual basis for the period ending March 31 and September 30 of each year. Reports will be due within 30 days after the end of each reporting period. The recipient shall submit a final SF-425 within 120 days after the expiration date of the award.

b. Research Performance Progress Report (RPPRs). Each award recipient will be required to submit a RPPR report on a semi-annual basis for the periods ending March 31 and September 30 of each year. A final RPPR shall be submitted within 120 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 an RPPR, the recipient must include their revised DMP with the next RPPR following the revision to the DMP. The revised DMP must include all the requirements described in Section IV.2.A.(12). of this NOFO.

c. Patent and Property Reports. From time to time, and in accordance with the Uniform Administrative Requirements set forth in 2 C.F.R. part 200 and in accordance with other terms and conditions governing the award, the recipient may be required to submit property and patent reports.

d. Recipient Integrity and Performance Matters. In accordance with section 872 of public law 110-417 (as amended; see 41 U.S.C. 2313), if the total value of a recipient's currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of an award made under this NOFO, then the recipient shall be subject to the requirements specified in Appendix XII to 2 C.F.R. part 200, http://go.usa.gov/cTBwC, for maintaining the currency of information reported to SAM that is made available in FAPIIS about certain civil, criminal, or administrative proceedings involving the recipient.

(2) *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.

(3) *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 .

G. **Research Activities Involving Human Subjects, Human Tissue, Data or Recordings Involving Human Subjects Including Software Testing**. Any application that includes research activities involving human subjects, human tissue/cells, or data or recordings from or about human subjects, must satisfy the requirements of the Common Rule for the Protection of Human Subjects ("Common Rule"), codified for the Department of Commerce at 15 C.F.R. Part 27. Research activities involving human subjects that fall within one or more of the classes of vulnerable subjects found in 45 C.F.R. Part 46, Subparts B, C, and D must satisfy the requirements of the applicable subpart(s). In addition, any such application that includes research activities on these subjects must be in compliance with all applicable statutory requirements imposed upon the Department of Health and Human Services (DHHS) and other Federal agencies, all regulations, policies and guidance adopted by DHHS,

the food and drug administration (FDA), and other Federal agencies on these topics, and all Executive Orders and Presidential Statements of policy on applicable topics. (Regulatory Resources: http://www.hhs.gov/ohrp/humansubjects/index.html which includes links to FDA regulations, but may not include all applicable regulations and policies).

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

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

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

1) *Intervention* includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
2) *Interaction* includes communication or interpersonal contact between investigator and subject.
3) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator associated with the information) in order for obtaining the information to constitute research involving human subjects.
4) *Identifiable biospecimen* includes a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

See 15 CFR § 27.102 (definitions).

1) **Requirement for federal wide assurance**. If the application is accepted for [or awarded] funding, organizations that have an Institutional Review Board (IRB) are required to follow the procedures of their organization for approval of exempt and non-exempt research activities that involve human subjects. Both domestic and foreign organizations performing exempt research requiring limited IRB review or 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 Federal Wide Assurance (FWA) on file from OHRP. Information regarding how to apply for an FWA and register an IRB with OHRP can be found at http://www.hhs.gov/ohrp/assurances/index.html. See 15 CFR § 27.103. NIST relies only on OHRO-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 research protections office (RPO) reserves the right to conduct an administrative review[6] 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 CFR §.27.112 (review by institution). If the NIST RPO 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 RPO.

3) Required documents for proposal review. All applications involving human subjects research must clearly indicate, by separable task, all research activities believed to be exempt or non-exempt research involving human subjects, the expected institution(s) where the research activities involving human subjects may be

[6] Conducting an "administrative review" means that the NIST RPO will review and verify the performing institution's determination for research not involving human subjects or exempt human subjects research. In addition, for exempt research requiring limited IRB review and non-exempt human subjects research, the NIST RPO will review and confirm that the research and performing institution(s) are in compliance with 15 C.F.R. Part 27, which means RPO will 1) confirm the engaged institution(s) possess, or are covered under a Federalwide Assurance, 2) review the research study documentation submitted to the IRB and verify the IRB's determination of level of risk and approval of the study for compliance with 15 C.F.R. Part 27, 3) review and verify IRB-approved substantive changes to an approved research study before the changes are implemented, and 4) review and verify that the IRB conducts a continuing review at least annually, as appropriate.

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 that do not meet the criteria for requiring a limited IRB review, and the performer of the activity or the supplier and/or the receiver of the information or biospecimens from human

subjects does not have a cognizant IRB to provide an exemption determination, the following information may be requested during the review process so that NIST can evaluate whether an exemption under the Common Rule applies (see 15 CFR § 27.104(b) and (d)):

(1) The name(s) of the institution(s) where the exempt research will be conducted.
(2) The name(s) of the institution(s) providing the biospecimens or information from human subjects.
(3) A copy of the protocol for the research to be conducted; and/or the biospecimens or information from human subjects to be collected/provided, not pre-existing samples (i.e., will proposed research collect only information without personal identifiable information, will biospecimens or information be de-identified and when and by whom was the de-identification performed, how were the materials or data originally collected).
(4) For pre-existing biospecimens or information from human subjects, provide copies of the consent forms used for collection and a description of how the biospecimens or information were originally collected and stripped of personal identifiers. If copies of consent forms are not available, explain.
(5) Any additional clarifying documentation that NIST may deem necessary in order to make a determination whether the activity/task or use of biospecimens or information from human subjects is exempt under the Common Rule.

d. **Research review with an IRB**. If the application appears to NIST to include research activities (exempt or non-exempt) involving human subjects, and the proposed performer of the activity has a cognizant IRB registered with OHRP, and linked to their federal wide 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 copy of each applicable final IRB-approved protocol.
(2) A signed and dated approval letter from the cognizant IRB(s) that includes the name of the institution housing each applicable IRB, provides the start and end dates for the approval of the research activities, and any IRB- required interim reporting or continuing review requirements.
(3) A copy of any IRB-required application information, such as documentation of approval of special clearances (i.e., biohazard, HIPAA, etc.) Conflict-of- interest letters, or special training requirements.
(4) A brief description of which portions of the IRB submitted protocol are specifically included in the application submitted to NIST, if the protocol includes tasks not included in the application, or if the protocol is supported by multiple funding sources. For protocols with multiple funding sources, NIST will not approve the study without a non-duplication-of-funding letter indicating that no other federal funds will be used to support the tasks proposed under the proposed research or ongoing project.
(5) If a new protocol will only be submitted to an IRB if an award from NIST is issued, a draft of the proposed protocol.
(6) Any additional clarifying documentation that NIST may request during the review process to perform the NIST administrative review of research involving human subjects. (see 15 CFR § 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 research protections office (e-mail: anne.andrews@nist.gov; phone: (301) 975-5445).

H. **Research Activities Involving Live Vertebrate Animals or Pre-Existing Cell Line/Tissues From Vertebrate Animals**. Any application that proposes research activities involving live vertebrate animals that are to be cared for, euthanized, or used by award recipients to accomplish research goals, teaching, or testing must meet the requirements of the Animal Welfare Act (AWA) (7 U.S.C. § 2131 et seq.), and the AWA final rules (9 C.F.R. Parts 1, 2, and 3), and if appropriate, the Good Laboratory Practice for Nonclinical Laboratory Studies (21 C.F.R. Part 58). In addition, such research activities should be in compliance with the "U.S. Government Principles for Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" (Principles). The Principles and guidance on these Principles are available in the National Research Council's "Guide for the Care and Use of Laboratory Animals,'' which can be obtained from National Academy Press, 500 5th Street, N.W., Department 285, Washington, DC 20055, or as a free PDF online at http://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals- eighth.

1) **Administrative Review**. NIST reserves the right to conduct an administrative review[7] of all applications that potentially include research activities that involve live vertebrate animals, or custom samples from, or field studies with live vertebrate animals. If the application includes research activities, field studies, or custom samples involving live vertebrate animals, the applicant will be required to provide additional information for review and approval. In addition, NIST will verify the applicant's determination(s) of excluded samples from vertebrate animals. The documents required for funded proposals are listed in each section below. Some may be requested for a pre-review during the proposal review process; however, the Grants Officer may allow final versions of certain required documents to be produced at an appropriate designated time post-award. If an award is issued, no research activities involving live vertebrate animals shall be initiated or costs incurred for those activities under the award until the NIST Grants Officer issues written approval. In addition, all re-approvals, amendments, modifications, changes, annual reports and closure will be reviewed by NIST.

[7] Conducting an "administrative review" means that the NIST RPO will review and verify the performing institution's IACUC's approval of research with live vertebrate animals, and confirm that the research and performing institution(s) have an appropriate assurance and are in compliance with applicable regulations. RPO will 1) confirm the engaged institution(s) possess, or are covered under an applicable assurance, 2) review the research study documentation submitted to the IACUC and verify the IACUC's determination of level of risk and approval of the study for compliance with applicable regulations, 3) review and verify IACUC-approved substantive changes to an approved research study before the changes are implemented, and 4) review and verify that the IACUC receives an annual report for the study and conducts an appropriate continuing review at least every three years.

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

a) **Excluded Collections from Vertebrate Animals**: The requirements for review and approval by an Institutional Animal Care and Use Committee (IACUC) do not apply to proposed research using preexisting images of animals or to research plans that do not include live animals. These regulations also do not apply to obtaining stock or pre-existing items from animal material suppliers (e.g., tissue banks), such as pre-existing cell lines and tissue samples, or from commercial food processors, where the vertebrate animal was euthanized for food purposes and not for the purpose of sample collection.

For pre-existing cell lines and tissue samples originating from vertebrate animals, NIST requires that the proposer provide documentation or the rationale for the determination that the cell line or tissue is pre-existing and not a custom collection from live vertebrate animals for an activity/task within the proposal. NIST may require additional documentation to review and/or support the determination that the cells and/or tissues from vertebrate animals are excluded from IACUC review.

b) **Custom Collections Harvested from Live Vertebrate Animals**: NIST requires documentation for obtaining custom samples from live vertebrate animals from animal material suppliers and other organizations (i.e., universities, companies, and government laboratories, etc.). Custom samples includes samples from animal material suppliers, such as when a catalog item indicates that the researcher is to specify the characteristics of the live vertebrate animal to be used, or how a sample is to be collected from the live vertebrate animal.

c) **Field Studies of Animals**: Some field studies of animals may be exempt under the Animal Welfare Act from full review and approval by an animal care and use committee, as determined by each institution. Field study is defined as "… a study conducted on free-living wild animals in their natural habitat...". 9 C.F.R. § 1.1. However,

this term excludes any study that involves an invasive procedure or that harms or materially alters the behavior of an animal under study. Field studies, with or without invasive procedures, may also require obtaining appropriate federal or local government permits (marine mammals, endangered species, etc.). If the applicant's institution requires review and approval by an animal care and use committee, NIST will require that documentation to be provided as described below.

d) **For custom collections or studies with live vertebrate animals that require review and approval by an animal care and use committee the following documentation is required**:

(1) Requirement for Assurance. An applicable assurance for the care and use of the live vertebrate animal(s) to be used in the proposed research is required. NIST may request documentation to confirm an assurance, if adequate confirmation is not available through an assuring organization's website. The cognizant IACUC where the research activity is located may hold one or more assurances applicable to the research activity that are acceptable to NIST. These four assurances are:

i. Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) indicated by the OLAW assurance number, i.e., A-1234;

ii. USDA Animal Welfare Act certification indicated by the certification number, i.e., 12-R-3456;

iii. Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) indicated by providing the organization name accredited by AAALAC as listed in the AAALAC Directory of Accredited Organizations; and

iv. Letter of Assurance of compliance with the Animal Welfare Act, the U.S. Government Principles, and National Marine Fisheries Service (NFMS) IACUC policy that is valid for five years and provided by a NMFS Regional IACUC for activities with marine mammals or sea turtles (NMFS Policy Directive 04-112).

e) **Documentation of Research Review by an IACUC**: If the applicant's application appears to include research activities, field studies, or custom sample collections involving live vertebrate animals the

following information regarding review by an applicable IACUC may be requested during the application review process:

1. The name(s) of the institution(s) where the research involving live vertebrate animals will be conducted and/or custom samples collected.
2. The assurance type and number, as applicable, for the cognizant Institutional Animal Care and Use Committee (IACUC) where the research activity is located. [For example: Animal Welfare Assurance from the Office of Laboratory Animal Welfare (OLAW) should be indicated by the OLAW assurance number, i.e. A-1234; an USDA Animal Welfare Act certification should be indicated by the certification number i.e. 12-R-3456; and an Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) should be indicated by AAALAC.]
3. The IACUC approval date for the Animal Study Protocol (ASP) (if currently approved).
4. If the review by the cognizant IACUC is pending, the estimated start date for research involving vertebrate animals.
5. If any assurances or IACUCs need to be obtained or established, that should be clearly stated.
6. If any special permits are required for field studies, those details should be clearly provided for each instance, or indicated as pending.

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

1. A copy of the IACUC approved ASP.
2. Documentation of the IACUC approval indicating the approval and expiration dates of the ASP.
3. If applicable, a non-duplication-of-funding letter if the ASP is funded from several sources.
4. If a new ASP will only be submitted to an IACUC if an award from NIST is issued, a draft of the proposed ASP may be requested.
5. Any additional clarifying documentation that NIST may

request during review of applications to perform the NIST administrative review of research involving live vertebrate animals.

This clause reflects the existing NIST policy for Research Involving Live Vertebrate Animals. Should the policy be revised prior to award, a clause reflecting the policy current at time of award may be incorporated into the award.

If the policy is revised after award, a clause reflecting the updated policy may be incorporated into the award.

For more information regarding research projects involving live vertebrate animals, contact Linda Beth Schilling, Senior Analyst (e-mail: linda.schilling@nist.gov; phone: 301- 975-2887).

I. **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 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.

J. **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: User Facilities | NIST.

K. **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.

VII. Federal Awarding Agency Contacts

Questions should be directed to the following:

Subject area	Point of contact
Programmatic and technical questions	Lisa Jean Fronczek Phone: 301-975-6633 E-mail: lisa.fronczek@nist.gov

Technical assistance with Grants.gov submissions	grants.gov Phone: 800-518-4726 E-mail: support@grants.gov
Grant rules and regulations	Dean Iwasaki Phone: 301-975-8449 E-mail: dean.iwasaki@nist.gov

VIII. Other Information

1. **Public Website, Frequently Asked Questions (FAQs) and Webinar:**

   NIST has a public website https://www.nist.gov/oam/rapid-assistance-coronavirus-economic-response-racer-grant-program that provides a "Frequently Asked Questions" page, webinar registration, and other information pertaining to this Funding Opportunity. Applicants must submit all such questions in writing to manufacturingusa@nist.gov with "2021-NIST-MFGUSA-RACER-01 Questions" in the subject line.

   NIST will hold an informational webinar on June 2, 2021 to provide general information regarding this NOFO, offer general guidance on preparing applications, and offer the opportunity for the public to ask questions. Proprietary technical questions about specific proposal ideas will not be permitted, and NIST will not critique or provide feedback on any proposal ideas during the webinar or at any time before submission to Grants.gov. However, NIST will provide information about eligibility requirements, the evaluation criteria, and the review process during the webinar. There is no cost to attend the webinar, but participants must register in advance by sending email to manufacturingusa@nist.gov with "RACER Webinar" in the subject line. Participation in the webinar is not required and will not be considered in the application review and selection process.

2. **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 CFR § 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 USC sec. 552, are found at 15 CFR 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 NOFO 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.