ANNOUNCEMENT OF FEDERAL FUNDING OPPORTUNITY (FFO) Small Business Innovation Research (SBIR) Technology Commercialization Assistance Program (TCAP)

EXECUTIVE SUMMARY

- Federal Agency Name: National Institute of Standards and Technology (NIST), United States Department of Commerce (DoC)
- Funding Opportunity Title: Small Business Innovation Research (SBIR) Technology Commercialization Assistance Program (TCAP)
- Announcement Type: Initial
- Funding Opportunity Number: 2013-NIST-SBIR-01
- Catalog of Federal Domestic Assistance (CFDA) Number: 11.609, Measurement and Engineering Research and Standards
- **Dates:** Electronic applications must be received no later than 11:59 p.m. Eastern Time, Friday, March 15, 2013. Paper applications must be received by NIST by 5:00 p.m. Eastern Time on Friday, March 15, 2013. Proposals received after the respective deadline will not be reviewed or considered. Review, selection, and award processing is expected to be completed in April 2013. The approximate start date for an award under this FFO is expected to be early June 2013.
- Proposal Submission Address: See Section IV in the Full Announcement Text of this FFO.
- Funding Opportunity Description: NIST invites applications for a program involving technical and business engagement activities directed at small firms participating in NIST's SBIR Program. The recipient will provide NIST SBIR Phase I and/or Phase II awardees with technical and business expertise and resources to identify optimum pathways to promote successful transition of the Phase I and/or Phase II results to commercialization.
- Funding Availability: In FY 2013, NIST anticipates funding approximately one (1) project at the level of approximately \$100,000 per year for initial planning purposes, with project performance periods of up to five (5) years, consistent with NIST multi-year funding policies (see Section II.2. of this FFO). Approximately \$100,000 may be available for new awards in FY 2013, subject to the availability of funds. Initial funding that may be obligated under this announcement will be adjusted during pre-award budget negotiations (see Section V.2.b.) to reflect the anticipated number of SBIR participants, and thereafter as necessary. In addition to the multi-year funding policy described in Section II.2. of this FFO, obligated funding amounts may be adjusted higher or lower from year to year to appropriately reflect SBIR participation.
- Funding Instrument: Cooperative Agreement
- Who Is Eligible: Nonprofit organizations, accredited institutions of higher education, state or local governments, or commercial organizations in the United States or its territories.
- Cost Sharing Requirements: Cost sharing is not required.

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FULL ANNOUNCEMENT TEXT

I. Funding Opportunity Description

The National Institute of Standards and Technology (NIST) announces funding for a recipient organization to advance the mutual interests of NIST, the recipient, and the public through technical and business engagement activities involving U.S. companies participating in NIST's Small Business Innovation Research Program (SBIR) program. Authority for the Small Business Innovation Research (SBIR) Technology Commercialization Assistance Program (TCAP) is pursuant to and consistent with NIST authority at 15 U.S.C. § 272(b) and (c) and the technical assistance program for SBIR awardees under 15 U.S.C. § 638(q).

NIST promotes U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life. NIST's Technology Partnerships Office (TPO) works with regional, state and local economic development organizations, technology incubation centers, public-private business development initiatives and other organizations and partnerships to facilitate the transfer of technologies developed within NIST scientific laboratories to the private and nonprofit sectors through licensing and/or collaboration. NIST scientists conduct research, create technologies and make discoveries in nearly every scientific and technological field. TPO encourages commercialization of these results through programs and activities that advance mutual interests of NIST and its partners, and in turn, the general public. See http://www.nist.gov/tpo/.

TPO's activities include NIST's SBIR program, in which NIST funds small businesses conducting scientific and engineering related research and development (R&D) projects responding to specific technical areas at NIST (15 U.S.C. Sec. 638). The SBIR program is a competitive three-phase program that awards R&D funds to qualified small businesses. The program encourages technological innovation and conversion of Federal R&D into commercial applications.

The NIST SBIR program provides contracts to qualified small business firms to fund innovative research projects that support NIST's strategic priorities. The NIST SBIR program has three phases. Phase I is a six month contract to conduct a technical feasibility study. All Phase I awardees may then submit a Phase II proposal. In Phase II, each awardee continues the research effort. In Phase III, the small business uses non-SBIR funds to commercialize the product developed during previous phases. For more information, including topic areas for NIST SBIR, see http://www.nist.gov/tpo/sbir/.

The NIST SBIR TCAP will provide support to a recipient organization that shares NIST's goals of advancing innovation, accelerating technology commercialization, and advancing U.S. small business and science and technology interests. Through the NIST SBIR TCAP program, the recipient will provide SBIR Phase I and/or Phase II awardees with technical and business expertise and resources to identify optimum pathways to promote successful transition of the Phase I and/or Phase II results to

commercialization.

Through this program, the recipient will engage with SBIR awardees in technical and business development activities such as:

- 1) making better technical decisions concerning SBIR projects;
- 2) solving technical problems that arise during the conduct of SBIR projects;
- 3) minimizing technical risks associated with SBIR projects; and
- developing and commercializing new commercial products and processes resulting from the SBIR projects.

The recipient will identify the current state of each SBIR awardee's research results and provide appropriate advice and assistance about commercialization pathways. Since each SBIR awardee may be at a different level of product development, the recipient will work with each SBIR awardee to customize activities that best support the SBIR awardee. The recipient should also advise the SBIR awardee on leveraging other programs, such as making use of the NIST Hollings Manufacturing Extension Centers. See www.nist.gov/mep.

In order to facilitate the recipient's conduct of these commercialization assessments, NIST will provide the recipient with non-proprietary information available on each SBIR awardee. The recipient will then seek more specific technical and business information from each SBIR awardee. The SBIR awardees have the option to not participate in this assistance effort that is available to them and may choose to utilize similar support from an organization other than the recipient under this program. In the event that a SBIR awardee opts to not participate in this program, the recipient is not expected to provide services to that SBIR awardee.

II. Award Information

- 1. Funding Instrument. The funding instrument used in this program will be a cooperative agreement. The nature of NIST's "substantial involvement" will generally be collaboration with the recipient in carrying out the scope of work, and in particular, coordinating with the SBIR awardee. Additional forms of substantial involvement that may arise are described in the DoC Grants and Cooperative Agreements Manual, which is available at http://www.osec.doc.gov/oam/grants management/policy/doc grants manual/default.htm.
- 2. Multi-Year Funding Policy. When a proposal for a multi-year award is approved, funding will usually be provided for only the first year of the program. If a project is selected for funding, NIST has no obligation to provide any additional funding in connection with that award. Continuation of an award to increase funding or extend the period of performance is at the sole discretion of NIST. Continued funding will be contingent upon satisfactory performance, continued relevance to the mission and priorities of the program, and the availability of funds.
- 3. Funding Availability. In FY 2013, NIST anticipates funding approximately one (1) project at the level of approximately \$100,000 per year for initial planning purposes, with project performance periods of up to five (5) years, consistent with NIST multi-year funding policies (see Section II.2. of this FFO). Approximately \$100,000 may be available for new awards in FY 2013, subject to the availability of funds. Initial funding that may be obligated under this announcement will be adjusted during pre-award budget negotiations (see Section V.2.b.) to reflect the anticipated number of SBIR participants, and thereafter as necessary. In addition to the multi-year funding policy described in Section II.2. of this FFO, obligated funding amounts may be adjusted higher or lower from year to year to appropriately reflect SBIR participation.

III. Eligibility Information

- 1. **Eligible Applicants.** Applicants must be nonprofit organizations, accredited institutions of higher education, state or local governments, or commercial organizations in the United States or its territories.
- 2. Cost Sharing. Cost sharing is not required.
- 3. Other

Pre-Applications. NIST is not accepting pre-proposals or white papers under this FFO.

IV. Application and Submission Information

1. Address to Request Application Package. The standard application package, consisting of the standard forms, i.e., SF-424, SF-424A, SF-424B, SF-LLL, and the CD-511, is available at www.grants.gov. For applicants without Internet access, the standard application package may be requested by contacting the NIST personnel listed below.

Mary Clague, National Institute of Standards and Technology, 100 Bureau Dr., Mail Stop 220, Gaithersburg, MD 20899 (Phone: 301-975-4188, email: mary.clague@nist.gov).

2. Content and Form of Application Submission

a. Required Forms and Documents

- (1) SF-424, Application for Federal Assistance. The SF-424 must be signed by an authorized representative of the proposer organization. The FFO number 2013-NIST-SBIR-01 must be identified in item 12 of the SF-424. The list of certifications and assurance referenced in item 21 of the SF-424 is contained in the SF-424B
- (2) SF-424A, Budget Information Non-Construction Programs
- (3) SF-424B, Assurances Non-Construction Programs
- (4) CD-511, Certification Regarding Lobbying
- (5) SF-LLL, Disclosure of Lobbying Activities (if applicable)
- (6) **Technical Proposal**. The Technical Proposal is a word-processed document of no more than fifteen (15) pages responsive to the program description (see Section I. of this FFO) and the evaluation criteria (see Section V.1. of this FFO). It should contain the following information:
 - a) Executive Summary. The Executive Summary should briefly describe the proposed project, consistent with the evaluation criteria (see Section V.1. of this FFO).
 - b) **Technical Experience**. A description of the applicant's understanding of the requirements and knowledge of the SBIR program, NIST topic areas as identified on the NIST SBIR web site, and related markets and industries, sufficient to permit evaluation of the proposal, in accordance with the Technical Experience evaluation criterion (see Section V.1.a of this FFO).

- c) Qualifications of the Applicant. A description of the qualifications and proposed operational or management activities of key personnel who will be assigned to work on the proposed project, in accordance with the Qualifications of the Applicant evaluation criterion (see Section V.1.b of this FFO).
- d) Methodology and Project Management Plan. A description of the applicant's proposed methods and approach to project management to engage with SBIR awardees in technical and business development activities. This section should be the primary means by which the proposal will be evaluated according to the Methodology and Project Management Plan evaluation criterion (see Section V.1.c.of this FFO).
- (7) **Budget Narrative**. There is no set format for the Budget Narrative; however, it should provide a detailed breakdown of each of the object class categories as reflected on the SF-424A.

The proposed budget should reflect planned costs, but the recipient must charge actual costs to the award consistent with cost principles applicable to the type of recipient in accordance with 15 C.F.R. 14.27 or 24.22, as applicable. In any event, the maximum reasonable, allowable, and allocable cost to the award for the project may not exceed \$5,000 per SBIR firm per year. The recipient should have an accounting system that tracks costs per SBIR firm and an allocation plan for activities that may be shared among multiple SBIR firms. Profit or fee is not an allowable cost.

(8) 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.

If submitting the proposal electronically via Grants.gov, items IV.2.a.(1) through IV.2.a.(5) above are part of the standard application package in Grants.gov and can be completed through the download application process. Items IV.2.a.(6) through (8) must be completed and attached by clicking on "Add Attachments" found in item 15 of the SF-424, Application for Federal Assistance. This will create a zip file that allows for transmittal of the documents electronically via Grants.gov. Proposers should carefully follow specific Grants.gov instructions at www.grants.gov to ensure the attachments will be accepted by the Grants.gov system. A receipt from Grants.gov indicating a proposal is received does not provide information about whether attachments have been received.

If submitting a proposal by paper, all of the required proposal documents should be submitted in the order listed above.

b. Proposal Format

- (1) Application language. English
- (2) **Double-sided copy.** For paper submission, print on both sides of the paper.
- (3) **E-mail submission.** Will not be accepted.
- (4) **Font.** Easy to read font (10-point minimum). Smaller type may be used in figures and tables, but must be clearly legible.

- (5) Line spacing. Single.
- (6) **Margins.** One (1) inch top, bottom, left, and right.
- (7) **Number of paper copies.** For paper submission, one (1) signed, stapled original and two (2) stapled copies are required. If original application is in color, the copies must also be in color. If submitting electronically via Grants.gov, paper copies are not required.
- (8) **Page layout.** Portrait orientation only.
- (9) **Page numbering.** Number pages sequentially.
- (10) **Paper size.** 21.6 by 27.9 centimeters (8 ½ x 11 inches).
- (11) **Staple paper submission.** For paper submissions, staple the original signed application and each of the two (2) copies securely with one (1) staple in the upper left-hand corner.
- 3. Submission Dates and Times. Electronic applications must be received no later than 11:59 p.m. Eastern Time, Friday, March 15, 2013. Paper applications must be received by NIST by 5:00 p.m. Eastern Time on Friday, March 15, 2013.

Proposals not received by the specified due date and time will not be considered and will be returned without review. NIST determines whether proposals submitted by paper have been received by the deadline by the date and time it was physically received by NIST at its Gaithersburg, MD campus. For electronic submissions, NIST will consider the date and time stamped on the validation generated by www.grants.gov as the official submission time.

NIST strongly recommends that proposers do not wait until the last minute to submit a proposal. NIST will not make allowance for any late submissions, including but not limited to incomplete Grants.gov registration, delays in mail delivery caused by Federal Government security screening of U.S. Postal Service mail, or for delays by guaranteed express mailing and/or couriers. To avoid any potential processing backlogs due to last minute Grants.gov registrations, proposers are highly encouraged to begin their Grants.gov registration process early.'

In the event of a natural disaster that interferes with timely proposal submissions, NIST may issue an amendment to this FFO to change the proposal submission due date.

- Intergovernmental Review. Proposals under this Program are not subject to Executive Order 12372.
- **5. Funding Restrictions.** Profit or fee is not an allowable cost.
- 6. Other Submission Requirements
- a. Proposals may be submitted by paper or electronically.
 - (1) Paper proposals must be submitted in triplicate (an original and two copies) to the NIST personnel identified in Section IV.1. of this FFO.
 - (2) Electronic proposals must be submitted via Grants.gov at www.grants.gov, under announcement 2013-NIST-SBIR-01.
 - a) Submitters of electronic proposals should carefully follow specific Grants.gov instructions to ensure the attachments will be accepted by the Grants.gov system. A receipt from

Grants.gov indicating a proposal is received <u>does not provide information about whether attachments have been received</u>. For further information or questions regarding applying electronically for the 2013-NIST-SBIR-01 announcement, contact Christopher Hunton by phone at 301-975-5718 or by e-mail at christopher.hunton@nist.gov.

- Applicants are strongly encouraged to start early and not wait until the approaching due b) date before logging on and reviewing the instructions for submitting a proposal through Grants.gov. The Grants.gov registration process must be completed before a new registrant can apply electronically. If all goes well, the registration process takes three (3) to five (5) business days. If problems are encountered, the registration process can take up to two (2) weeks or more. Applicants must have a Dun and Bradstreet Data Universal Numbering System (DUNS) number (See Section VI.2.b) and must maintain a current registration in the Federal government's primary registrant database, the System for Award Management (https://www.sam.gov/), as explained on the Grants.gov Web site. After registering, it may take several days or longer from the initial log-on before a new Grants.gov system user can submit a proposal. Only authorized individual(s) will be able to submit the proposal, and the system may need time to process a submitted proposal. Applicants should save and print the proof of submission they receive from Grants.gov. If problems occur while using Grants.gov, the applicant is advised to (a) print any error message received and (b) call Grants.gov directly for immediate assistance. If calling from within the United States or from a U. S. territory, please call 800-518-4726. If calling from a place other than the United States or a U. S. territory, please call 606-545-5035. Assistance from the Grants gov Help Desk will be available around the clock every day, with the exception of Federal holidays. Help Desk service will resume at 7:00 a.m. Eastern Time the day after Federal holidays. For assistance using Grants.gov, you may also contact support@grants.gov.
- c) Information essential to successful submission of proposals on the Grants.gov system is detailed in the For Applicants section found in red on the left side of the www.grants.gov home page, and all potential applicants should pay close attention to the information contained therein. The All About Grants, Applicant FAQs, and Submit Application FAQs sections found under the Applicant Resources option are particularly important.

Important: All applicants, both electronic and paper submitters, should be aware that adequate time must be factored into applicants' schedules for delivery of their proposal. Submitters of electronic proposals are advised that volume on Grants.gov may be extremely heavy on the deadline date, and if Grants.gov is unable to accept proposals electronically in a timely fashion, applicants are encouraged to exercise their option to submit proposals in paper format. Submitters of paper proposals should allow adequate time to ensure a paper proposal will be received on time, taking into account that Federal Government security screening for U.S. Postal Service mail may delay receipt of mail for up to two (2) weeks and that guaranteed express mailings and/or couriers are not always able to fulfill their quarantees.

Refer to important information in Section IV.3. Submission Dates and Times, to help ensure your proposal is received on time.

b. Amendments. Any amendments to this FFO will be announced through Grants.gov. Applicants can sign up for Grants.gov FFO amendments or may request copies from Mary Clague by telephone at (301) 975-4188, or by email to mary.clague@nist.gov to request copies.

V. Application Review Information

1. Evaluation Criteria

The evaluation criteria that will be used in evaluating these proposals and assigned equal weights are as follows:

- **a. Technical Experience**. The extent to which the applicant demonstrates an understanding of the requirements and knowledge of the SBIR program, NIST topic areas as identified on the NIST SBIR web site, and related markets and industries, will be evaluated.
- b. Qualifications of the Applicant. The qualifications and experience of the applicant's organization and staff to carry out the objectives of the proposal as described in Section I of this FFO will be evaluated. The extent to which the applicant has access to the necessary technical experts and overall support to accomplish the project objectives will be evaluated. The applicant's relevant knowledge, skills, and abilities to enhance the ability of the SBIR Phase I and/or SBIR Phase II awardees to write commercialization plans will be considered as part of this criterion. Information on past performance relative to this project will also be considered as part of this criterion.
- c. Methodology and Project Management Plan. The extent to which the applicant's proposed methods and approach to managing the project and identifying and resolving problems will ensure the quality of its performance. The reviewers will consider the following: how the applicant plans to engage with SBIR Phase I and/or Phase II awardees in technical and business development activities; clear and measurable performance objectives; and the likelihood that the approach would be successful in achieving the objectives and addressing challenges that may arise in the course of an engagement with an SBIR I and/or SBIR II awardee.
- **d. Budget Narrative.** An assessment of the budget against the proposed activities will be conducted to determine the practicality of the proposed budget with respect to carrying out the objectives of the proposal as described in Section I of this FFO.

2. Review and Selection Process

- a. Initial Administrative Review of Proposals. An initial review of timely received proposals will be conducted to determine eligibility, completeness, and responsiveness to this FFO and the scope of the stated program objectives. Proposals determined to be ineligible, incomplete, and/or non-responsive may be eliminated from further review.
- **b.** Full Review of Eligible, Complete, and Responsive Proposals. Proposals that are determined to be eligible, complete, and responsive will proceed for full reviews in accordance with the review and selection processes below:

At least three technically qualified reviewers will evaluate each proposal based on the evaluation criteria (see Section V.1. of this FFO) and assign a numeric score for each proposal. If non-Federal reviewers are used, reviewers may discuss the proposals with each other, but scores will be determined on an individual basis, not as a consensus. Reviewers will assign each proposal a score, based on the proposal's responsiveness to the evaluation criteria. Based on the reviewers' scores, a rank order will be prepared and provided to the Selecting Official.

The Selecting Official, who is the NIST Technology Partnerships Office (TPO) Director or designee, will make final proposal selections. The Selecting Official shall select a proposal for award based upon the rank order of the proposals, and may select a proposal out of rank based on one or more of the following selection factors: the results of the reviewers' evaluations; relevance to the program objectives as set forth in the Funding Opportunity Description (Section I.) set forth in this FFO; and the availability of funds.

In accordance with the Federal appropriations law expected to be in effect at the time of project funding, NIST anticipates that the selected applicant will be provided a form and asked to make a

representation regarding any unpaid delinquent tax liability or felony conviction under any Federal law.

NIST reserves the right to negotiate the budget costs with a proposer that has been selected to receive an award, which may include requesting that the proposer remove certain costs. (Initial funding that may be obligated under this announcement will be adjusted during pre-award budget negotiations to reflect the anticipated number of SBIR participants, and thereafter as necessary.) Additionally, NIST may request that the proposer modify objectives or work plans and provide supplemental information required by the agency prior to the award. NIST also reserves the right to reject a proposal where information is uncovered that raises a reasonable doubt as to the responsibility of the proposer. NIST may select part, some, all, or none of the proposals. Final approval of the selected proposal and issuance of award will be made by the NIST Grants Officer. The award decisions of the NIST Grants Officer are final.

3. Anticipated Announcement and Award Dates. Review, selection, and award processing is expected to be completed in April 2013. The approximate start date for an award under this FFO is expected to be early June 2013.

4. Additional Information

- a. **Proposal Replacement Pages**. Proposers may not submit replacement pages and/or missing documents once a proposal has been submitted. Any revision must be made by submission of a new proposal that must be received by NIST by the submission deadline.
- b. Notification to Unsuccessful Proposers. Unsuccessful proposers will be notified in writing.
- c. **Retention of Unsuccessful Proposals.** One (1) copy of each non-selected proposal will be retained for three (3) years for record keeping purposes and the other two (2) copies will be destroyed. After three (3) years the remaining copy will be destroyed.

VI. Award Administration Information

Award Notices. Successful applicants will receive an award from the NIST Grants Officer. The
award cover page, i.e., CD-450, Financial Assistance Award is available at
http://ocio.os.doc.gov/s/groups/public/@doc/@os/@ocio/@oitpp/documents/content/dev01_002513.p
df
and the DoC Financial Assistance Standard Terms and Conditions (January 2013) are available at
http://www.osec.doc.gov/oam/grants_management/policy/documents/DOC_Standard_Terms_and_Conditions_01_10_2013.pdf.

2. Administrative and National Policy Requirements

- **a. DoC Pre-Award Notification Requirements.** The DoC Pre-Award Notification Requirements for Grants and Cooperative Agreements, 77 FR 74634 (December 17, 2012), are applicable to this FFO and are available at https://www.federalregister.gov/articles/2012/12/17/2012-30228/department-of-commerce-pre-award-notification-requirements-for-grants-and-cooperative-agreements.
- b. Employer/Taxpayer Identification Number (EIN/TIN), Dun and Bradstreet Data Universal Numbering System (DUNS), and System for Award Management (SAM) All applicants for Federal financial assistance are required to obtain a universal identifier in the form of DUNS number and maintain a current registration in the Federal government's primary registrant database, SAM. On the form SF-424 items 8.b. and 8.c., the applicant's 9-digit EIN/TIN and 9-digit DUNS number must be consistent with the information in SAM (https://www.sam.gov/) and Automated Standard Application for Payment System (ASAP). For complex organizations with multiple EIN/TIN and

DUNS numbers, the EIN/TIN and DUNS numbers MUST be the numbers for the applying organization. Organizations that provide incorrect/inconsistent EIN/TIN and DUNS numbers may experience significant delays in receiving funds if their proposal is selected for funding. Confirm that the EIN/TIN and DUNS number are consistent with the information on the SAM and ASAP.

Per 2 C.F.R. Part 25, each applicant must:

- (1) Be registered in the Central Contractor Registry (CCR) before submitting a proposal noting the CCR now resides in SAM;
- (2) Maintain an active CCR registration, noting the CCR now resides in SAM, with current information at all times during which it has an active Federal award or a proposal under consideration by an agency; and
- (3) Provide its DUNS number in each application or proposal it submits to the agency.

The applicant can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one business day. The CCR or SAM registration process may take five or more business days to complete. If you are currently registered with the CCR, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your CCR registration annually. This may take three or more business days to complete. Information about SAM is available at SAM.gov. See also 2 C.F.R. Part 25 and the Federal Register notice published on September 14, 2010, at 75 FR 55671

c. Collaborations with NIST Employees. All proposals 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 proposal prior to the merit review.

d. Use of NIST Intellectual Property. If the applicant anticipates using any NIST-owned intellectual property to carry out the work proposed, the applicant should identify such intellectual property. This information will be used to ensure that no NIST employee involved in the development of the intellectual property will participate in the review process for that competition. In addition, if the applicant intends to use NIST-owned intellectual property, the applicant must comply with all statutes and regulations governing the licensing of Federal government patents and inventions, described in 35 U.S.C. §§ 200-212, 37 C.F.R. Part 401, 15 C.F.R. § 14.36, and in Section B.21 of the DoC Pre-Award Notification Requirements, 77 FR 74634 (December 17, 2012). Questions about these requirements may be directed to the Chief Counsel for NIST, (301) 975-2803.

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

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

e. Research Projects Involving Human Subjects, Human Tissue, Data or Recordings Involving

Human Subjects Including Software Testing. Any proposal that includes research involving human subjects, human tissue/cells, data or recordings involving human subjects, including software testing, must meet the requirements of the Common Rule for the Protection of Human Subjects ("Common Rule"), codified for the Department of Commerce (DoC) at 15 C.F.R. Part 27. In addition, any such application that includes research on these topics must be in compliance with any statutory requirements imposed upon the Department of Health and Human Services (DHHS) and other Federal agencies regarding these topics, all regulatory policies and guidance adopted by DHHS, the Food and Drug Administration, and other Federal agencies on these topics, and all Executive Orders and Presidential statements of policy on these topics.

NIST reserves the right to make an independent determination of whether an applicant's research involves human subjects. If NIST determines that your research project involves human subjects, you will be required to provide additional information for review and approval. If an award is issued, no research activities involving human subjects shall be initiated or costs incurred under the award until the NIST Grants Officer issues written approval. Retroactive approvals are not permitted.

NIST will accept applications that include exempt and non-exempt human subjects research activities. Non-exempt human subjects research activities will be required to have protocols approved by an Institutional Review Board (IRB) currently registered with the Office for Human Research Protections (OHRP) within the DHHS and that will be performed by entities possessing a currently valid Federal-wide Assurance (FWA) on file from OHRP that is appropriately linked to the cognizant IRB for the protocol. Information regarding how to apply for an FWA and register and IRB with OHRP can be found at http://www.hhs.gov/ohrp/assurances/index.html. The applicant should clearly indicate in the proposal, by separable task, all research activities believed to be exempt or non-exempt research involving human subjects and the expected institution(s) where the research activities involving human subjects may be conducted.

Generally, NIST does not fund research involving human subjects in foreign countries. NIST will consider, however, the use of **preexisting** tissue, cells, or data from a foreign source on a limited basis if all of the following criteria are satisfied:

- (1) the scientific source is considered unique,
- (2) an equivalent source is unavailable within the United States,
- (3) an alternative approach is not scientifically of equivalent merit, and
- (4) the specific use qualifies for an exemption under the Common Rule.

Any award issued by NIST for the program announced in this FFO is required to adhere to all Presidential policies, statutes, guidelines, and regulations regarding the use of human embryonic stem cells. The DoC/NIST follows the NIH Guidelines by supporting and conducting research using only human embryonic stem cell lines that have been approved by NIH in accordance with the NIH Guidelines. Detailed information regarding NIH Guidelines for stem cells is located on the NIH Stem Cell Information website: http://stemcells.nih.gov. The DoC/NIST will not support or conduct any type of research that the NIH Guidelines prohibit NIH from funding. The DoC/NIST will review research using human embryonic stem cell lines that it supports and conducts in accordance with the Common Rule and NIST implementing procedures, as appropriate.

Any request to support or conduct research using human embryonic stem cell lines not currently approved by the NIH, will require that the owner, deriver or licensee of the human embryonic stem cell line apply for and receive approval of the registration of the cell line through the established NIH application procedures: http://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm. Due to the timing uncertainty associated with establishing an embryonic stem cell line in the NIH registry, the use of existing human embryonic stem cell lines in the NIH Embryonic Stem Cell Registry may be preferred by applicants or current award recipients. The NIH Embryonic Stem Cell Registry is located at: http://grants.nih.gov/stem_cells/registry/current.htm.

An applicant or current award recipient proposing to use a registered embryonic stem cell line will be required to document an executed agreement for access to the cell line with the provider of the cell line, and acceptance of any established restrictions for use of the cell line, as may be noted in the NIH Embryonic Stem Cell Registry.

If the applicant's proposal appears to include research activities involving human subjects the following information may be requested during the proposal 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 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 FWAs or IRB registrations are being applied for, that should be clearly stated.

Additional documentation may be requested, as warranted, during review of the applicant's proposal, but may include the following for research activities involving human subjects that are planned in the first year of the award:

- (1) A signed (by the study principal investigator) copy of each applicable final IRB-approved protocol;
- (2) A signed and dated approval letter from the cognizant IRB(s) that includes the name of the institution housing each applicable IRB, provides the start and end dates for the approval of the research activities, and any IRB-required interim reporting or continuing review requirements;
- (3) A copy of any IRB-required application information, such as documentation of approval of special clearances (i.e., biohazard, HIPAA, etc.) conflict-of-interest letters, or special training requirements:
- (4) A brief description of what portions of the IRB submitted protocol are specifically included in the applicant's proposal submitted to NIST, if the protocol includes tasks not applicable to the proposal, 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 issued, a draft of the proposed protocol may be requested;
- (6) Any additional clarifying documentation that NIST may request during review of proposals to perform the NIST administrative review of research involving human subjects.
- f. Research Projects Involving Live Vertebrate Animals. Any application that includes participation in research involving live vertebrate animals, that are being cared for, euthanized, or used by the project participants to accomplish research goals, teaching, or testing, must be in compliance with 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. In addition, such applications must meet the requirements of the Animal Welfare Act (7 U.S.C. § 2131 et seq.), 9 C.F.R. Parts 1, 2, and 3, and if appropriate, 21 C.F.R. Part 58. These regulations 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 animal

materials from commercial processors of animal products or to animal cell lines or tissues from tissue banks. The applicant should clearly indicate in the proposal, 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.

NIST reserves the right to make an independent determination of whether your research involves live vertebrate animals. If NIST determines that your research project involves live vertebrate animals, you will be required to provide additional information for review and approval. If an award is issued, no research activities involving live vertebrate animals subjects shall be initiated or costs incurred under the award until the NIST Grants Officer issues written approval.

If the applicant's proposal appears to include research activities involving live vertebrate animals the following information may be requested during the proposal review process:

- (1) The name(s) of the institution(s) where the animal research will be conducted;
- (2) The assurance type and number, as applicable, for the cognizant 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 (if currently approved);
- (4) If the review by the cognizant Institutional Animal Care and Use Committee (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.

Additional documentation will be requested, as warranted, during review of the proposal, but may include the following for research activities involving live vertebrate animals that are planned in the first year of the award:

- (1) A signed (by the Principal Investigator) copy of the IACUC approved Animal Study Proposal (ASP);
- (2) Documentation of the IACUC approval indicating the approval and expiration dates of the ASP; and
- (3) If applicable, a nonduplication-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 issued, a draft of the proposed ASP may be requested.
- (5) Any additional clarifying documentation that NIST may request during review of proposals to perform the NIST administrative review of research involving live vertebrate animals.
- g. Funding Availability and Limitation of Liability. Funding for the program listed in this FFO is contingent upon the availability of appropriations. In no event will NIST or DoC be responsible for proposal preparation costs if this program fails to receive funding or is cancelled because of agency priorities. Publication of this FFO does not oblige NIST or DoC to award any specific project or to obligate any available funds.
- h. Collaborations Making Use of Federal Facilities. All proposals 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 proposal prior to the merit review. Examples of some facilities that may be available for collaborations are listed on the NIST Technology Services Web site, http://www.nist.gov/user-facilities.cfm.

3. Reporting

- a. Reporting Requirements. In lieu of the reporting requirements described in Sections A.01 Financial Reports and B.01 Performance (Technical) Reports of the DoC Financial Assistance Standard Terms and Conditions dated January 2013 (http://www.osec.doc.gov/oam/grants_management/policy/documents/DOC_Standard_Terms_and_Conditions_01_10_2013.pdf), the following reporting requirements shall apply:
 - (1) **Financial Report.** The recipient will be required to submit an SF-425, Federal Financial report in triplicate (an original and two (2) copies), on a quarterly basis for the periods ending March 31, June 30, September 30, and December 31 of each year. Reports will be due within 30 days after the end of the reporting period.
 - (2) **Performance (Technical) Report.** The recipient shall be required to submit a technical progress report in triplicate (an original and two (2) copies), on a quarterly basis for the periods ending March 31, June 30, September 30, and December 31 of each year. Reports will be due within 30 days after the end of the reporting period. A final technical progress report shall be submitted within 90 days after the end of the award. Technical progress reports shall contain information as prescribed in 15 C.F. R. 14.51.
 - (3) **Progress report.** The recipient shall provide a quarterly progress report to NIST that provides details of the status of work provided to each SBIR awardee.
- b. OMB Circular A-133 Audit Requirements. Single or program-specific audits shall be performed in accordance with the requirements containing in OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations," and the related Compliance Supplement. OMB Circular A-133 requires any non-Federal entity (i.e., including non-profit institutions of higher education and other non-profit organization) that expends Federal awards of \$500,000 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 Circular. Proposers are reminded that NIST, the DoC Office of Inspector General or another authorized Federal agency may conduct an audit of an award at any time.
- c. Federal Funding Accountability and Transparency Act of 2006. In accordance with 2 C.F.R. Part 170, all recipients of a Federal award made on or after October 1, 2010, are required to comply with reporting requirements under the Federal Funding Accountability and Transparency Act of 2006 (Pub. L. No. 109-282). In general, all recipients are responsible for reporting sub-awards of \$25,000 or more. In addition, recipients that meet certain criteria are responsible for reporting executive compensation. Proposer must ensure they have the necessary processes and system 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.

VII. Agency Contact(s)

Questions should be directed to the following contact persons:

Subject Area	Point of Contact
Programmatic and technical questions:	Mary Clague NIST SBIR Phone: 301-975-4188 Email: mary.clague@nist.gov
Technical Assistance with	Christopher Hunton

Grants.gov submissions	Phone: 301-975-5718
_	Fax: 301-840-5976
	E-mail: <u>christopher.hunton@nist.gov</u>
Grant rules and regulations	Scott McNichol
	Phone: 301-975-5603
	Fax: 301-840-5976
	E-mail: scott.mcnichol@nist.gov

VIII. Other Information

More information on NIST SBIR program, including past solicitations and awardee, information is available at http://www.nist.gov/sbir.

NIST is not obligated to make any award as the result of this FFO.