

CHAPTER 1

QUESTIONS AND ANSWERS ABOUT THE TECHNOLOGY INNOVATION PROGRAM (TIP)

A. GENERAL INFORMATION

1. What is TIP?

TIP is a cost-shared federal financial assistance program to support, promote, and accelerate innovation in the United States through high-risk, high-reward research in areas of critical national need. High-risk, high-reward research is research that:

- a. has the potential for yielding transformational results with far-ranging or wide-ranging implications;
- b. addresses areas of critical national need that support, promote, and accelerate innovation in the United States and is within NIST's areas of technical competence; and
- c. is too novel or spans too diverse a range of disciplines to fare well in the traditional peer-review process.

The TIP statutory authority is 15 U.S.C. § 278n (see Appendix A). The TIP implementing regulations are set forth in 15 C.F.R. Part 296 (see Appendix B). Both are also available at <http://www.nist.gov/tip/helpful.html>.

2. How can I receive funding?

You must submit a proposal to TIP in response to a notice published in the *Federal Register* announcing a competition and availability of TIP funds (solicitation/request for proposals).

Notices are also posted on the TIP Web site <http://www.nist.gov/tip> and at <http://www.grants.gov> (Announcement of Federal Funding Opportunity).

In addition, you can have your name added to the TIP mailing list by completing an electronic request at http://tipmailing.nist.gov/forms/mailing_list.cfm or by calling 1-888-847-6478 to receive competition announcements.

3. What are areas of critical national need?

Areas of critical national need are those for which government attention is warranted because the magnitude of the problem is large and the societal challenges that need to be overcome are not being addressed, but could be addressed through high-risk, high-reward research. The areas of critical national need to be addressed in a particular competition are described in the *Federal Register* notice announcing the competition.

4. Is there a deadline for submitting a TIP proposal?

Yes. The deadline date(s) are included in the *Federal Register* notice announcing the competition and notices posted on the TIP and grants.gov Web sites. Once a competition is announced, proposals may be submitted until the deadline date(s).

5. What information is required in a TIP proposal?

Information requirements are discussed in detail in Chapters 2 and 3.

6. Does TIP accept unsolicited proposals?

No.

7. How are proposals submitted?

Proposals may be submitted either electronically or in hardcopy. Electronic submissions are encouraged and offer many benefits to the proposer, including no mailing or copying fees. See Chapter 3 for format instructions and Chapter 5 for electronic submission guidance.

8. Where do I submit proposals?

Proposals must be submitted to either of the following locations only and will not be accepted if submitted directly to any TIP staff member:

- a. Electronic: www.grants.gov
- b. Paper copy:

Technology Innovation Program
National Institute of Standards and
Technology
100 Bureau Drive, Stop 4701
Gaithersburg, MD 20899-4701

9. Will confidential/proprietary information in my proposal be protected?

Yes. All individuals who will have access to submitted proposals must sign nondisclosure agreements. The government will protect confidential/proprietary information about business operations and trade secrets possessed by any company or participant to the full extent of the law. To the extent permitted by law, TIP will withhold such information from disclosure pursuant to the following statutes, which can be found at <http://www.nist.gov/tip/helpful.html>.

- a. Freedom of Information Act (FOIA)—5 U.S.C. § 552(b).
- b. Economic Espionage Act—18 U.S.C. § 1832.

- c. Trade Secrets Act—18 U.S.C. § 1905.

In view of the above, proposers are cautioned that proposals are likely to be less competitive if significant details are omitted due to the proposer's reluctance to reveal confidential/proprietary information.

10. Does TIP hold any public meetings or conferences to assist in proposal preparation?

Yes. TIP will hold one or more proposers' conferences after a competition is announced. Proposers' conferences will provide general information regarding TIP, guidance on preparing proposals, and the opportunity for questions and answers. Proprietary technical discussions about specific project ideas with NIST staff are not permitted at these conferences or at any time before submitting the proposal to TIP. Therefore, you should not expect to have proprietary issues addressed at proposers' conferences.

Also NIST/TIP staff will not critique or provide feedback on project ideas while they are being developed by a proposer. However, NIST/TIP staff will, at any time, answer questions about the TIP eligibility and cost-sharing requirements, evaluation and award criteria, selection process, and the general characteristics of a competitive TIP proposal at the Proposers' Conferences and by phone and email.

Attendance at TIP proposers' conferences is not required. Information regarding dates and locations of TIP proposers' conferences is published in the *Federal Register* and posted at <http://www.nist.gov/tip> and <http://www.grants.gov>.

Presentation materials from proposers' conferences will be made available on the TIP Web site.

11. Where can I seek additional help with proposal preparation?

It is the responsibility of proposers to seek the assistance and resources they need for completing a proposal.

a. Proposers may wish to contact the NIST Hollings Manufacturing Extension Partnership (MEP), a nationwide network of locally managed extension centers whose sole purpose is to provide small- and medium-sized manufacturers with the help they need to succeed. The centers provide guidance to high-technology companies seeking resources and teaming

relationships. To contact an MEP center, call 1-800-MEP-4-MFG (1-800-637-4634) or visit MEP's Web site at <http://www.mep.nist.gov>.

b. Proposers may wish to contact independent state, regional, or area specific resources, for example, economic development agencies.

c. University research offices and technology transfer offices are also very often interested in building teaming relationships with the private sector.

12. Whom do I contact if I have questions?

Subject Area	Point of Contact
Administrative, budget, cost-sharing, and eligibility questions	Barbara Lambis Phone: 301-975-4447 Fax: 301-869-1150 E-mail: barbara.lambis@nist.gov
Human and/or animal subjects used in research	Lawrence Uhteg Human & Animal Subjects Advisor Phone: 301-975-8779 Fax: 301-548-1087 E-mail: lawrence.uhteg@nist.gov
Project selection, evaluation and award criteria, and other programmatic questions	Thomas Wiggins, Director Selection Management Office Phone: 301-975-5416 Fax: 301-975-2147 E-mail: thomas.wiggins@nist.gov
Electronic proposal submission	Christopher Hunton Phone: 301-975-5718 Fax: 301-840-5976 E-mail: christopher.hunton@nist.gov
Technical questions related to NIST-1022 and associated forms	Deborah Dubeau Phone: 301-975-3462 Fax: 301-975-2147 E-mail: deborah.dubeau@nist.gov
Foreign-owned company participation	Kathleen McTigue Phone: 301-975-8530 Fax: 301-975-2147 E-mail: kathleen.mctigue@nist.gov
Grant and cooperative agreement rules and regulations	Grants & Agreements Mgmt. Division Phone: 301-975-6328 Fax: 301-840-5976 E-mail: grants@nist.gov

B. ELIGIBILITY

1. Who is eligible to apply?

A U.S.-owned, single, small-sized or medium-sized company doing a majority of its business in the United States or a joint venture may apply for TIP funding. Members of joint ventures that are companies must also be doing a majority of their business in the United States. In addition, a company incorporated in the United States that has a parent company incorporated in another country may apply provided that certain requirements are met as discussed in Section 4 below. The term business or company means a for-profit organization, including sole proprietors, partnerships, limited liability companies (LLCs), and corporations (15 C.F.R. §296.2).

a. **Single Company**—a small-sized or medium-sized company. If the single company proposal includes contractors, the single company must be substantially involved in the R&D, with a leadership role in the project and defining the research agenda.

b. **Joint Venture**—a business arrangement that includes either:

(1) At least two separately owned small-sized or medium-sized for-profit companies that are both substantially involved in the project and both of which are contributing to the cost-sharing requirement, with the lead entity of the joint venture being either a small-sized or medium-sized company; or

(2) At least one small-sized or medium-sized for-profit company and one institution of higher education or other organization, such as a national laboratory, governmental laboratory (not including NIST), or nonprofit research institute, that are both substantially involved in the project and both of which are contributing to the cost sharing requirement, with the lead entity of the joint venture being

either that small-sized or medium-sized company or that institution of higher education.

TIP joint venture members must formally agree (i.e., sign a Joint Venture Agreement as discussed in Chapter 3, Section D) to collaborate on the project. The joint venture may include additional companies, institutions of higher education, and other organizations, such as national laboratories, governmental laboratories (not including NIST), and nonprofit research institutes, that may or may not contribute nonfederal funds to the project.

2. May institutions of higher education, national laboratories, governmental laboratories (not including NIST), and nonprofit research institutes participate as contractors to a single company or to a joint venture?

Yes.

3. May a large-sized company participate?

Yes, provided that certain requirements are met. A large-sized for-profit company may participate and receive funding as a contractor to a single company or joint venture recipient when the contract is awarded in accordance with procedures established under the Procurement Standards required by 15 C.F.R. Part 14. Specifically, the recipient(s) of a TIP award may procure supplies and other expendable property, equipment, real property and other services from any party, including large-sized businesses. A large-sized company may also participate as a joint venture member and provide cost sharing; however, a large-sized company MAY NOT receive federal funds as a joint venture member.

4. May a foreign-owned company participate and receive TIP funding?

Yes, provided that certain requirements are met. A company incorporated in the United States that has a parent company incorporated in another country is eligible to participate and receive TIP funding if it meets the conditions in the TIP legislation (15 U.S.C. § 278n(l)(1)) and regulations (15 C.F.R. §296.5). Before making a final award, TIP will make a foreign-eligibility finding based on these conditions regarding the company's participation in a TIP project. The foreign eligibility finding involves the collection of evidence of whether the following conditions are met:

a. The company's participation in the TIP project would be in the economic interest of the United States, and

b. The home country of the parent company provides all of the following:

(1) Comparable opportunities to those afforded to any other company for U.S.-owned companies to participate in government-funded programs similar to TIP,

(2) Comparable local investment opportunities to those afforded to any other company for U.S.-owned companies, and

(3) Adequate and effective protection of U.S.-owned companies' intellectual property rights.

TIP takes responsibility for gathering information related to the above requirements. The submitting organization must provide with the proposal a form NIST-1022G, Foreign-Owned Company Questionnaire (see Exhibit 10), that relates to the role of the foreign-owned company in the project to help address foreign eligibility requirement 4.a. above. If there is more than one such company, a separate questionnaire must be submitted for each one.

It is important that the information requested on the form NIST-1022G, Foreign-Owned Company Questionnaire, be provided in complete form at the time of proposal submission because it is used to assess the foreign-owned proposer's ability to bring about economic benefits to the United States. Information requested on this questionnaire relates to evidence that the company's participation is in the economic interest of the United States as stated in 4.a. above and includes the following:

(1) A sound justification that the involvement by the company and its role in the project is necessary to achieve the technical objectives and goals of the project;

(2) Evidence that the company makes investments in research, development, and manufacturing in the United States (an example might be the location and square footage of facilities and special equipment where the project will be carried out);

(3) Evidence that the company makes significant contributions to employment in the United States (i.e., number of employees); and

(4) Evidence that the company agrees to promote the manufacture of products within the United States resulting from the TIP-supported technology and to procure supplies from competitive U.S. suppliers. (For instance, will the company incorporate the technology into existing product lines or processes, or will the company develop new products or processes?)

5. Is a foreign-eligibility finding required for foreign contractors?

No. The submitting organization, however, must justify the use of foreign-owned and foreign-located contractors or subsidiaries and explain how their participation will benefit the U.S. economy (see Exhibit 11, form NIST-1022H, R&D Work Performed Outside the United States by the Recipient or Contractor Questionnaire) and the

achievement of project goals. The completed questionnaire should state how and why U.S. sources were judged to be unavailable and inadequate in meeting the project goals. If there is more than one such instance, a separate questionnaire must be submitted for each instance.

6. May a foreign-owned company without a U.S.-incorporated subsidiary receive a TIP award?

No. Foreign-owned companies located outside the United States cannot receive a TIP award. Only U.S.-owned companies and U.S. subsidiaries of foreign-owned companies that meet the requirements stated above are eligible to receive TIP funding.

7. Can a company owned or controlled by non-U.S. citizens and without a foreign parent company receive a TIP award?

No.

8. Can a Cooperative Research and Development Agreement (CRADA) with a U.S. federal government agency be involved in a TIP project?

Possibly. To be acceptable to TIP, CRADA intellectual property provisions may not be in conflict with TIP intellectual property provisions. A description of TIP intellectual property requirements may be found in Section F of this chapter. Any CRADA that is proposed to be part of a TIP proposal will require legal analysis by NIST, and revisions may be required for the CRADA to be in compliance with the TIP statute and regulations. A copy of the CRADA will be requested during the review by the Evaluation Panel for legal analysis. Therefore, parties are encouraged to carefully consider whether a CRADA is appropriate and to contact the Office of the Chief Counsel for NIST (301-975-2803) in

advance of submitting a proposal that includes a CRADA.

9. Can an informal collaboration, that does not impact the proposed funding or cost-share requirements be used to address a critical task in the project?

Possibly. NIST may require that aspects of the informal collaboration be documented to be sure the arrangement is in compliance with the TIP statute and regulations. If the collaboration is key to accomplishing a critical task in the project, the proposer needs to address what alternatives are available if maintaining the informal collaboration fails. Therefore, parties are encouraged to carefully consider whether an informal collaboration is appropriate and to contact the Office of the Chief Counsel for NIST (301-975-2803) or the TIP Selection Management Director in advance of submitting a proposal involving an informal collaboration. A copy of any existing agreements regarding the informal collaboration will be requested during the review by the Evaluation Panel for legal analysis.

C. SELECTION PROCESS AND CRITERIA TO SELECT PROPOSALS

1. How are proposals selected for funding?

Proposals are selected based on a multi-disciplinary peer-review process, as described in 15 C.F.R. §296.20 (see Appendix B). A preliminary review is conducted to determine if the proposal is in accordance with 15 C.F.R. §296.3, complies with the eligibility requirements described in 15 C.F.R. §296.5, addresses award criteria (a) through (c) of 15 C.F.R. §296.22, and is complete. Proposals that are incomplete or do not meet any one of the preliminary review requirements will normally be eliminated. All remaining proposals are then carefully reviewed based on the TIP

evaluation criteria listed in 15 C.F.R. §296.21 and award criteria listed in 15 C.F.R. §296.22. An Evaluation Panel will present funding recommendations to a Selecting Official in rank order for further consideration. The Selecting Official makes the final selections for funding. **The selection of proposals by the Selecting Official is final and cannot be appealed.** The final approval of selected proposals and award of assistance will be made by the NIST Grants Officer. The award decision of the NIST Grants Officer is final and cannot be appealed.

NIST reserves the right to negotiate the cost and scope of the proposed work with the proposers that have been selected to receive awards. This may include requesting that the proposer delete from the scope of work a particular task that is deemed by NIST to be inappropriate for support. NIST also reserves the right to reject a proposal where information exists that raises a reasonable doubt as to the responsibility of the proposer.

2. What criteria are used to select proposals for funding?

Proposals are selected for funding based on the evaluation criteria listed in 15 C.F.R. §296.21 and the award criteria listed in 15 C.F.R. §296.22 as identified below. Additionally, no proposal will be funded unless TIP determines that it has scientific and technical merit and that the proposed research has strong potential for addressing a societal challenge within the TIP-identified areas of critical national need.

Evaluation Criteria: The two components of the evaluation criteria and respective weights as listed in 15 C.F.R. §296.21 are as follows:

(a)(1) The proposer(s) adequately addresses the scientific and technical merit and how the research may result in

intellectual property vesting in a United States entity including evidence that:

- (i) The proposed research is novel;
- (ii) The proposed research is high-risk, high-reward;
- (iii) The proposer(s) demonstrates a high level of relevant scientific/technical expertise for key personnel, including contractors and/or informal collaborators, and has access to the necessary resources, for example research facilities, equipment, materials, and data, to conduct the research as proposed;
- (iv) The research result(s) has the potential to address the technical needs associated with a major societal challenge not currently being addressed; and
- (v) The proposed research plan is scientifically sound with tasks, milestones, timeline, decision points and alternate strategies.

(2) Total weight of (a)(1)(i) through (v) is 50%.

(b)(1) The proposer(s) adequately establishes that the proposed research has strong potential for advancing the state-of-the-art and contributing significantly to the United States science and technology knowledge base and to address areas of critical national need through transforming the Nation's capacity to deal with a major societal challenge(s) that is not currently being addressed, and generate substantial benefits to the Nation that extend significantly beyond the direct return to the proposer including an explanation in the proposal:

- (i) Of the potential magnitude of transformational results upon the Nation's capabilities in an area;
- (ii) Of how and when the ensuing transformational results will be useful to the Nation; and
- (iii) Of the capacity and commitment of each award participant to enable or advance the transformation to the proposed research results (technology).

(2) Total weight of (b)(1)(i) through (iii) is 50%.

Award Criteria: The six components of the award criteria as listed in 15 C.F.R. §296.22 are as follows:

(a) The proposal explains why TIP support is necessary, including evidence that the research will not be conducted within a reasonable time period in the absence of financial assistance from TIP;

(b) The proposal demonstrates that reasonable and thorough efforts have been made to secure funding from alternative funding sources and no other alternative funding sources are reasonably available to support the proposal;

(c) The proposal explains the novelty of the research (technology) and demonstrates that other entities have not already developed, commercialized, marketed, distributed, or sold similar research results (technologies);

(d) The proposal has scientific and technical merit and may result in intellectual property vesting in a United States entity that can commercialize the technology in a timely manner; and

(e) The proposal establishes that the research has strong potential for advancing the state-of-the-art and contributing significantly to the United States science and technology knowledge base; and

(f) The proposal establishes that the proposed transformational research (technology) has strong potential to address areas of critical national need through transforming the Nation's capacity to deal with major societal challenges that are not currently being addressed, and generate substantial benefits to the Nation that extend significantly beyond the direct return to the proposer.

NIST must determine that a proposal successfully meets all six award criteria for the proposal to receive funding under the Program.

Detailed guidance on how to address the evaluation and award criteria are provided in Chapter 2.

3. What factors could result in a proposal not being competitive?

Examples of factors that could result in a proposal not being competitive are:

- a. An incomplete proposal.
- b. Failure to address a societal challenge(s) as described in an area of critical national need identified in the *Federal Register* notice announcing the competition.
- c. Failure to address in detail any evaluation or award criterion.
- d. Omissions of significant details due to the proposer's reluctance to reveal confidential/ proprietary information.
- e. Lack of clear science-based explanation of the high technical risks and their potential rewards that require TIP funding.
- f. Failure to adequately address the question, "What technical issue or issues are preventing progress in addressing the particular societal challenge within an area of critical national need?"
- g. Lack of adequately documenting the novelty of the research or technology with respect to what is currently available. Specifically, it should be clear that other entities have not developed, commercialized, marketed, distributed, or sold similar technologies.
- h. Lack of detail in the technical plan or failure to clearly describe how the path to

innovation will be accomplished. For example:

(1) Use of a trial-and-error approach to generate new technologies or processes based on state-of-the-art techniques that do not result in advancing the methodology beyond trial and error.

(2) Technical risks in the project not described at the scientific level other than that the approach may not work as expected, or there is no clear identification of alternative mitigation strategies for overcoming various risks at each step in the R&D plan.

(3) Straightforward scale-ups based on standard engineering practices or state-of-the-art techniques that will not advance scale-up methodology (e.g., faster, better, cheaper).

(4) Use of proprietary techniques that are already developed in-house to generate novel technologies or processes where there is no expectation to move the technique(s) to a next-generation advancement.

(5) Lack of detail as to how the research has a strong potential for advancing the state-of-the-art and contributing significantly to the U.S. science and technology knowledge base.

(6) Unconvincing case for the need for TIP funding or failure to describe thorough actions taken to already secure non-TIP funding (or lack of evidence of the results of those actions).

D. INELIGIBLE PROJECTS AND INELIGIBLE/UNALLOWABLE COSTS

1. What types of projects are ineligible for TIP funding?

a. Straightforward improvements of existing products or product development.

b. Projects that are Phase II, III, or IV clinical trials. TIP will rarely fund Phase I clinical trials and reserves the right not to fund a Phase I clinical trial. The portion of a Phase I trial that may be funded must be critical to meeting Evaluation Criterion (a)(1) addressing the scientific and technical merit of the proposal. The trial results must be essential for completion of a critical R&D task of the project. The definitions of all phases of clinical trials are provided in the *TIP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects* located at <http://www.nist.gov/tip/helpful.html>.

c. Pre-commercial-scale demonstration projects where the emphasis is on demonstrating that some technology works on a large scale or is economically sound rather than on R&D that advances the state of the art and is high-risk, high-reward.

d. Projects that TIP determines would likely be completed without TIP funds in the same time frame or nearly the same time frame, or with the same scale or scope.

e. Predominantly straightforward, routine data gathering (e.g., creation of voluntary consensus standards, data gathering/handbook preparation, testing of materials, or unbounded research aimed at basic discovery science) or application of standard engineering practices.

f. Projects in which the predominant risk is market oriented—that is, the risk that the end product may not be embraced by the marketplace.

g. Projects with software work, that are predominantly about final product details and product development, and that have *significant* testing involving users outside the research team to determine if the software meets the original research objectives, are likely to be either

uncompetitive or possibly ineligible for funding. However, R&D projects with limited software testing, involving users outside of the research team, may be eligible for funding and contain eligible costs within a TIP award when the testing is critical to meeting Evaluation Criteria and/or Award Criteria and the testing results are essential for completion of a critical task in the proposed research. This type of testing in projects may also be considered to involve human subjects in research.

2. What types of costs are ineligible/unallowable?

The following items, regardless of whether they are allowable under the federal cost principles, are ineligible/unallowable under TIP:

- a. Bid and proposal costs unless they are incorporated into a federally approved indirect cost rate (e.g., payments to any organization or person retained to help prepare a proposal).
- b. Construction costs for new buildings or extensive renovations of existing laboratory buildings. However, costs for the construction of experimental research and development facilities to be located within a new or existing building are allowable provided the equipment or facilities are essential for carrying out the proposed project and are approved by the NIST Grants Officer. These types of facility costs may need to be prorated if they will not be used exclusively for the research activities proposed.
- c. Contractor office supplies and contractor expenses for conferences/workshops.
- d. Contracts to another part of the same company or to another company with identical or nearly identical ownership. Work proposed by another part of the same company or by another company with identical or nearly identical ownership should be shown as funded through inter-organizational transfers that do not contain profit. Inter-organizational transfers should be broken down in the appropriate budget categories.
- e. For research involving human and/or animal subjects, any costs used to secure Institutional Review Board or Institutional Animal Care and Use Committee approvals before or during the award.
- f. General purpose office equipment and supplies that are not used exclusively for the research, e.g., office computers, printers, copiers, paper, pens, and toner cartridges.
- g. Indirect costs, which must be absorbed by the recipient. However, indirect costs are allowable for contractors under a single company or joint venture. (Note that indirect costs absorbed by the recipient may be used to meet the cost-sharing requirement.)
- h. Marketing, sales, or commercialization costs, including marketing surveys, commercialization studies, and general business planning, unless they are included in a federally approved indirect cost rate.
- i. Office furniture costs, unless they are included in a federally approved indirect cost rate.
- j. Patent costs and legal fees, unless they are included in a federally approved indirect cost rate.
- k. Preaward costs.
- l. Profit, management fees, interest on borrowed funds, or facilities capital cost of money. However, profit is allowable for contractors under a single company or joint venture.
- m. Relocation costs, unless they are included in a federally approved indirect cost rate.

n. Tuition costs. However, an institution of higher education participating in a TIP project as a contractor or as a joint venture member or lead may charge TIP for tuition remission or other forms of compensation in lieu of wages paid to students working on TIP projects, but only as provided in OMB Circular A-21, Section J.41. In such cases, tuition remission would be considered a cash contribution rather than an in-kind contribution.

3. Can a university employee establish a company and contract back to his/her university?

Generally, no. This would present a conflict of interest. However, under certain circumstances, for example, if the university's participation is unique and essential to the project, the contracting arrangement may be considered. In such a case, the organization/individual with the conflict of interest may not benefit or profit from the contract. For more information, see the Codes of Conduct guidance in 15 C.F.R. § 14.42 (<http://www.nist.gov/tip/helpful.html>).

4. Can an individual who has a financial or other interest in a company receive a contract from that company?

Generally no. See the previous question and answer.

5. Will TIP fund research performed outside the United States?

Possibly. Although TIP is not precluded from funding research performed outside the United States, proposals involving significant research outside the United States would likely be less competitive when evaluated against the TIP evaluation criteria related to advancing the state of the U.S. science and technology base and generating substantial benefits to the Nation. Any proposed use of a foreign contractor or foreign-located organization

must be justified (see Exhibit 11, NIST-1022H, R&D Work Performed Outside the United States by the Recipient or Contractor Questionnaire). The completed questionnaire must include an explanation of why the work or services cannot be performed equivalently or obtained in the United States. For requirements on research involving human subjects in research activities, or research involving live vertebrate animals proposed to be performed outside of the U.S. see the *TIP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects* located at <http://www.nist.gov/tip/helpful.html>. Contacting the TIP Human and Animal Subjects Advisor is strongly encouraged.

E. FUNDING AND COST SHARING

1. How much funding can a TIP recipient receive, and is cost sharing required?

a. Single small- or medium-sized company recipients can receive up to a total of \$3 million in TIP funding for R&D activities spanning up to 3 years. TIP funds may only be used to pay direct costs. Single company recipients are responsible for funding all of their indirect/overhead costs. Small-sized and medium-sized companies applying as single company proposers must cost share at least 50 percent of the yearly total project costs (direct plus all of the indirect costs). A large-sized company is not eligible to apply for TIP funding. A large-sized company is defined as any business, including any parent company plus related subsidiaries, having annual revenues in excess of \$1.63 billion. This number is based on the May 2008 issue of *Fortune* magazine's Fortune 1000 list. (Note that the revenue amount will be updated annually and will be noted in future annual announcements of availability of funds.)

b. Joint venture recipients can receive up to a total of \$9 million for R&D activities spanning up to 5 years. TIP funds may only be used to pay direct costs. Joint ventures are responsible for funding all of their indirect/overhead costs. Joint ventures must cost share at least 50 percent of the yearly total project costs (direct plus all of the indirect costs).

If an award is issued to a joint venture, each joint venture member will be responsible for meeting its committed cost share in accordance with the approved budget incorporated in the award. No joint venture member will be responsible for the cost-share commitment of any other joint venture member. However, with the agreement of the joint venture members, along with notification to the NIST Grants Officer, a joint venture member that has exceeded its cost-share commitment may allow its excess cost share to be applied to the cost-share deficit of another joint venture member, so that the overall joint venture cost share is met.

2. How does TIP define cost sharing?

Cost sharing is that portion of project costs not borne by the federal government. Sources of revenue to satisfy the required cost share include cash and third party in-kind contributions. Cash may be contributed by any nonfederal source, including but not limited to recipients, state and local governments, companies, and nonprofits (except contractors working on a TIP project). Third party in-kind contributions can be made by any nonfederal source (except contractors working on a TIP project) and include but are not limited to equipment, research tools, software, supplies, and/or services. Except as specified in 15 C.F.R. §296.6, the value of in-kind contributions shall be determined in accordance with 15 C.F.R. § 14.23 (Uniform Administrative Requirements for Grants and Cooperative Agreements With Institutions of Higher Education, Hospitals,

Other Non-Profit, and Commercial Organizations (<http://www.nist.gov/tip/helpful.html>) and will be prorated according to the share of total use dedicated to the TIP project.

Additionally, as with the federal share, cost share must be allowable under the following applicable federal cost principles available at <http://www.nist.gov/tip/helpful.html>:

- a. For-profit companies: 48 C.F.R. Part 31.
- b. Universities: 2 C.F.R. Subtitle A, Chapter II, Part 220 (OMB Circular A-21).
- c. Nonprofit organizations: 2 C.F.R. Subtitle A, Chapter II, Part 230 (OMB Circular A-122).
- d. State and Local Governments: 2 C.F.R., Subtitle A, Chapter II, Part 225 (OMB Circular A-87).
- e. Hospitals: 45 C.F.R. Part 74, Appendix E.

3. What are direct and indirect costs?

Direct costs are those that are directly related to a specific, single-cost objective. Examples include personnel, travel, equipment, contractors, and materials and supplies.

Indirect costs are those costs incurred for common or joint objectives that cannot be readily identified with activities carried out in support of a particular final objective. A cost may not be allocated to an award as an indirect cost if any other cost incurred for the same purpose in like circumstances has been assigned to an award as a direct cost. Because of diverse characteristics and accounting practices it is not possible to specify the types of costs which may be classified as indirect costs in all situations. However, typical examples of indirect costs include general administration expenses, such as the salaries and expenses of executive officers, office rent, personnel administration, fringe benefits, maintenance, library expenses, office supplies, general

purpose office equipment (office computers, printers, copiers, etc.), and accounting. NIST will determine the allowability of indirect costs in accordance with applicable federal cost principles.

4. I am a small startup company and do not have any indirect costs. If funded, the TIP project would be the only project for my company. Will TIP fund a proposal that only has direct costs?

No. If a company claims to have no indirect costs, this suggests to TIP that the company is inexperienced in its fiscal affairs, the company may not be a financially viable business, or the company has no intention of carrying on any business other than performing research for the TIP project.

5. I am a small startup company and expect to cost share through the use of state or other private investors. If those resources fall through after I receive a TIP award, will I be expected to make up the cost-share gap?

Yes. If a single-company or joint venture proposal is selected for funding, the recipient's percentage of cost sharing will be made a part of the award, and will become a mandatory requirement. NIST cannot violate the TIP statutory cost-sharing requirements.

6. Can independent research and development (IR&D) funds be used as cost sharing?

The fundamental expectation for cost sharing is that the proposer's share of the TIP project costs will be funded from nonfederal sources, such as retained earnings or profits, not funds included as an indirect expense that is subsequently allocated for reimbursement under federally funded procurement contracts, grants, and

other agreements. Recovering the proposer's cost share as part of its IR&D/General and Administrative (G&A) allocation to other federally funded projects would be contrary to the kind of financial commitment expected of proposers by the TIP statute.

Proposers MAY NOT classify the nonfederal share of the TIP project costs as an IR&D expense that is subsequently allocated, either as a separate cost or as an element of a G&A cost pool, to federally funded procurement contracts, grants, or other agreements.

Proposers MAY allocate to a TIP project IR&D or G&A costs that include IR&D as an element provided that the IR&D/G&A rate applied to the TIP project is a federally approved indirect cost rate.

F. INTELLECTUAL PROPERTY

1. Who retains title to patentable inventions arising from a TIP-funded project?

For single company award recipients, pursuant to the Bayh-Dole Act (35 U.S.C. 202 (a) and (b)) and "Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy" (February 18, 1983), the entity that invents owns the invention. However, pursuant to 35 U.S.C. 202(a)(i), when a single company or its contractor under a TIP award is not located in the United States or does not have a place of business located in the United States or is subject to the control of a foreign government, NIST will require that title to inventions made by such parties be transferred to a United States entity that will ensure the commercialization of the technology in a timely fashion.

For joint ventures, ownership of inventions arising from a TIP-funded project may vest in any participant in a joint venture, as agreed by the members of the joint venture

(notwithstanding 35 U.S.C. 202 (a) and (b)).
(Participant includes any entity that is identified as a recipient, subrecipient, or contractor on an award to a joint venture.)

Title to any such invention shall not be transferred or passed, except to a participant in the joint venture, until the expiration of the first patent obtained in connection with such invention.

Should the last existing participant in a joint venture cease to exist prior to the expiration of the first patent obtained in connection with any invention developed from assistance provided under TIP, title to such patent must be transferred or passed to a U.S. entity that can commercialize the technology in a timely fashion.

2. Does the federal government have any rights to patentable inventions arising from a TIP-funded project?

Yes. The United States reserves a nonexclusive, nontransferable, irrevocable paid-up license, to practice or have practiced for or on behalf of the United States any inventions developed from a TIP award. The federal government shall not in the exercise of such license publicly disclose proprietary information related to the license. This does not prohibit the licensing to any company of intellectual property rights arising from a TIP-funded project. (15 C.F.R. §296.11(b)(3)). The federal government also has march-in rights in accordance with 37 C.F.R. §401.6.

G. HUMAN AND ANIMAL SUBJECTS

1. Will TIP fund projects involving human subjects and/or live vertebrate animals in research activities?

Yes, provided the research involving human subjects or live vertebrate animals is in compliance with applicable federal

regulations and NIST policies for the protection of human subjects or live vertebrate animals. Human subjects research activities involve interactions with live human subjects or the use of data, images, tissue, and/or cells/cell lines (including those used for control purposes) from human subjects. Research involving human subjects may include activities such as the use of image and/or audio recording of people, taking surveys or using survey data, using databases containing personal information, testing software with volunteers, and many tasks beyond those within traditional biomedical research.

Vertebrate animal research involves live animals that are being cared for, euthanized, or used by the project participants to accomplish research goals or for teaching or testing. The regulations do not apply to animal tissues purchased from commercial processors or tissue banks or to uses of preexisting images of animals (e.g., a wildlife documentary or pictures of animals in newscasts). The regulations do apply to any animals that are transported, cared for, euthanized or used by a project participant for testing, research, or training such as testing of new procedures or projects, collection of biological samples or observation data on health and behavior.

2. Does TIP have any written guidance to help me determine what documentation is required if my project involves human subjects or live vertebrate animals in research activities?

Yes, and it is critical that you review this guidance. TIP has prepared detailed guidance in the *TIP Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects* to help you determine what documentation is required if your research plan contains studies using human subjects, human materials, or live vertebrate animals. This booklet is available at

<http://www.nist.gov/tip/helpful.html> or it can be mailed to you by calling 1-888-847-6478 and requesting a copy. You are also encouraged to call the TIP Human & Animal Subjects Advisor for assistance at 301-975-8779.

3. We are not a biotech company. Could our research involve human subjects?

Yes, it could. Manufacturing, electronic, and information technology projects may use human subjects in a way that falls within the regulations. For example, a software company may propose to test a new approach to software development by having a group of experienced programmers try it and measure their reactions and results with the new tools. The use of human subjects is not limited to biologically based studies; there are numerous examples of nonmedical research proposals that may use human subjects or data with personal information about people. Any use of human subjects requires careful review to determine if and how the regulations apply and may require the submission of certain documents to NIST. A Human Subjects Determination Checklist is included in this Proposal

Preparation Kit in Chapter 4 to assist you in determining whether your proposed research plan has human subjects involvement, which would require additional information in your proposal submission, and possibly more documentation during the Evaluation Panel's consideration of your proposal. See the *TIP Guidelines and Documentation Requirements for Research Involving Human and Animal Subjects* for more specific information on documentation requirements and due dates for documentation.

Examples of human subjects in research activities that may require the submission of certain documents to NIST include, but are not limited to, using human subjects to:

- a. Test software, recording (audio or visual) methods, equipment, therapeutic methods or materials,
- b. Collect data about human subjects through direct interviews, written surveys, or online interactive methods, etc., or
- c. Observe people and their behavior in specified circumstances controlled by the research team.

