#### ANNOUNCEMENT OF FEDERAL FUNDING OPPORTUNITY

### AMENDMENT – EXECUTIVE SUMMARY

- **Federal Agency Name:** Technology Innovation Program (TIP), National Institute of Standards and Technology (NIST), Department of Commerce
- Funding Opportunity Title: Technology Innovation Program
- **Announcement Type:** Amendment
- Funding Opportunity Number: TIP-2010-B01
- Catalog of Federal Domestic Assistance (CFDA) Number: 11.616, Technology Innovation Program
- **Dates:** The due date for submission of proposals is 11:59 p.m. Eastern Time, Thursday, July 15, 2010.
- Proposal Submission Address:
  - Paper submission: National Institute of Standards and Technology

Technology Innovation Program 100 Bureau Drive, Stop 4701 Gaithersburg, MD 20899-4701

- Electronic submission: www.grants.gov
- Funding Opportunity Description: The Technology Innovation Program (TIP) National Institute of Standards and Technology (NIST), United States Department of Commerce (DoC), is soliciting high-risk, high-reward research and development (R&D) proposals.
- **Total Amount to be Awarded:** Fiscal year 2010 appropriations include funds in the amount of approximately \$25 million for new TIP awards.
- Anticipated Amounts: TIP anticipates funding approximately 25 projects. A single company can receive up to a total of \$3 million with a project period of performance of up to 3 years. A joint venture can receive up to a total of \$9 million with a project period of performance of up to 5 years.
- Funding Instrument: Cooperative Agreement
- **Who Is Eligible:** Single companies and joint ventures may apply for TIP funding as provided in 15 C.F.R. §§296.2, 296.4, and 296.5. Nonprofit organizations must meet the eligibility criteria set forth in 15 CFR 296.5(a)(2).
- **Cost-Sharing Requirements:** At least 50 percent of the yearly total project costs (direct plus all of the indirect costs).

### **AMENDMENT TEXT**

## **Background**

On April 19, 2010, the National Institute of Standards and Technology (NIST) published a notice in the Federal Register announcing the solicitation of proposals for the fiscal year 2010 Technology Innovation Program (TIP) competition. NIST is issuing an amended Federal Register notice to correct the award start date, to correct the description of a nonresponsive proposal listed under Element 3 of the Manufacturing Area of Critical National Need addressed in the notice, and to clarify the function of the white paper referenced in the notice.

## **Description of Amendment to Federal Funding Opportunity**

NIST is amending the Federal Funding Opportunity (TIP-2010-B01) to correct the description of a nonresponsive proposal listed under Element 3 of the Manufacturing Area of Critical National Need addressed in the notice, and to clarify the function of the white paper referenced in the notice. Note that the amendment to the FFO does not include a change in the anticipated start date that is included in the amended FRN notice since the original FFO notice includes the correct anticipated start date.

Due to a drafting error, NIST incorrectly indicated that projects with a primary focus on device development are considered nonresponsive projects. NIST's intent was to indicate that projects without a primary focus on addressing specific process bottlenecks are considered nonresponsive. This error is corrected by replacing the last bullet under the examples of proposals addressing *critical process* advances that will be considered nonresponsive. The language "Projects with a primary focus (people, equipment, time and/or funds) on device development." is replaced with "Projects that do not have a primary focus (people, equipment, time and/or funds) on addressing specific process bottlenecks."

The entire revised bulleted list under the examples of proposals addressing critical process advances that will be considered nonresponsive is restated below for the public's convenience.

Examples of proposals addressing **critical process advances** that will be considered nonresponsive are:

- Any manufacturing process that offers only incremental improvement over existing processes;
- Processes that are intended **primarily** for military/weaponry applications (e.g. warhead manufacture, chemical/biological warfare materials production);
- Manufacturing processes that cannot be performed in the U.S. due to existing laws or regulations;
- Projects primarily focused on production of non engineered cells or tissues as therapeutics;
- Projects involving straightforward scale-up of biopharmaceuticals with incremental improvements in the manufacturing processes;

- Projects that involve incremental improvements in traditional processes for biomolecule production (e.g. vaccine production in chicken eggs, hormones such as insulin extracted from pig tissue);
- Biomanufacturing projects that primarily focus on processes for production of nonbiopharmaceutical products (e.g. production of biofuels or small molecule drugs);
- Projects that primarily focus on drug discovery or design of new biomaterials;
- Projects that primarily focus on discovery of new production cell systems;
- Projects that use living genetically modified vertebrate animals, invertebrate animals, or plants as bioreactors for biopharmaceutical production;
- Production or scale up of scaffolds or biomaterials used in scaffold design that are not a part of the manufacturing of engineered tissues; and
- Projects that do not have a primary focus (people, equipment, time and/or funds) on addressing specific process bottlenecks.

NIST is also clarifying that the white paper "Manufacturing and Biomanufacturing: Materials Advances and Critical Processes" referenced in the description of Area of Critical National Need: Manufacturing (75 FR 20327) only provides background information related to the selection of this Critical National Need and the associated societal challenges; it does not specifically describe the scope of the Notice of Availability of Funds.

#### ANNOUNCEMENT OF FEDERAL FUNDING OPPORTUNITY

### **EXECUTIVE SUMMARY**

- **Federal Agency Name:** Technology Innovation Program (TIP), National Institute of Standards and Technology (NIST), Department of Commerce
- Funding Opportunity Title: Technology Innovation Program
- Announcement Type: Initial Announcement
- Funding Opportunity Number: TIP-2010-B01
- Catalog of Federal Domestic Assistance (CFDA) Number: 11.616, Technology Innovation Program
- **Dates:** The due date for submission of proposals is 11:59 p.m. Eastern Time, Thursday, July 15, 2010.
- Proposal Submission Address:
  - Paper submission: National Institute of Standards and Technology

Technology Innovation Program 100 Bureau Drive, Stop 4750 Gaithersburg, MD 20899-4750

- Electronic submission: www.grants.gov
- Please note that the NIST site is closed to the general public, and applicant personnel and couriers
  will not be permitted onto the NIST site in order to deliver proposals. Also note that the NIST
  Visitors Center is not permitted to accept proposals on behalf of the Technology Innovation
  Program.
- Paper submissions will be accepted from the U.S. Mail or similar commercial carrier that routinely delivers mail to NIST.
- Funding Opportunity Description: The Technology Innovation Program (TIP), National Institute of Standards and Technology (NIST), United States Department of Commerce (DoC), is soliciting high-risk, high-reward research and development (R&D) proposals.
- **Total Amount to be Awarded:** Fiscal year 2010 appropriations include funds in the amount of approximately \$25 million for new TIP awards.
- Anticipated Amounts: TIP anticipates funding approximately 25 projects. A single company can receive up to a total of \$3 million with a project period of performance of up to 3 years. A joint venture can receive up to a total of \$9 million with a project period of performance of up to 5 years.
- Funding Instrument: Cooperative Agreement

- Who Is Eligible: Single companies and joint ventures are eligible to receive TIP funding as provided in 15 C.F.R. §§296.2, 296.4, and 296.5.
- **Cost-Sharing Requirements:** At least 50 percent of the yearly total project costs (direct plus all of the indirect costs).
- Where to obtain the TIP Proposal Preparation Kit: The April 2010 Kit is available at <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>. Requests for a paper copy of the Kit can be made by calling 1-888-847-6478.
- Public Meetings (Proposers' Conferences): TIP will hold three public meetings (Proposers' Conferences) to provide general information regarding TIP, to offer guidance on preparing proposals, and to answer questions. 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, proposers should not expect to have proprietary issues addressed at the 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 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 the TIP Proposers' Conferences is not required.

The TIP Proposers' Conferences will be held on the following dates and times, and at the following locations:

1) April 28, 2010, 9 a.m. - 2 p.m. Eastern Time: NIST Red Auditorium, 100 Bureau Drive, Gaithersburg, MD. Pre-registration is required by 5 p.m. Eastern Time on April 23, 2010, for the Proposers' Conference being held at NIST Gaithersburg, MD. Due to increased security at NIST, NO on-site registrations will be accepted and all attendees MUST be pre-registered. Photo identification must be presented at the NIST main gate to be admitted to the April 28, 2010 conference. Attendees must wear their conference badge at all times while on the NIST campus. Electronic Registration at <a href="http://www.nist.gov/public\_affairs/confpage/100428.htm">http://www.nist.gov/public\_affairs/confpage/100428.htm</a>.

No registration fee will be charged at the Proposers' Conference. Presentation materials from the Gaithersburg, MD Proposers' Conference will be made available on the TIP Web site. The Gaithersburg, MD Proposers' Conference will be webcast details will be available at the TIP Website: <a href="http://www.nist.gov/tip">http://www.nist.gov/tip</a>

2) May 4, 2010, 1 p.m. - 5 p.m. Pacific Time Embassy Suites Hotel Los Angeles International Airport – South, 1440 Imperial Avenue, El Segundo, CA 90245

3) May 6, 2010, 9 a.m. – 1 p.m. Eastern Time

Detroit Marriott Renaissance Center, Renaissance Dr N, Detroit, MI 48243

No Pre-registration is required for the Proposers' Conferences in Los Angeles, CA or Detroit, MI.

### **FULL ANNOUNCEMENT TEXT**

## I. Funding Opportunity Description

The America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act, Pub. L. 110-69 (August 9, 2007), codified at 15 U.S.C. §278n, was enacted to invest in innovation through research and development and to improve the competitiveness of the United States. Section 3012 of the COMPETES Act established TIP for the purpose of assisting United States businesses and institutions of higher education or other organizations, such as national laboratories and nonprofit research institutions, 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 has the potential for yielding transformational results with far-ranging or wide-ranging implications; 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 is too novel or spans too diverse a range of disciplines to fare well in the traditional peer review process. The TIP implementing regulations are published at 15 C.F.R. Part 296, and included in the TIP Proposal Preparation Kit as Appendix B.

TIP is soliciting proposals under this fiscal year 2010 competition in the area of critical national need entitled "Manufacturing" as described below.

## **Area of Critical National Need: Manufacturing**

The goal of the research outcome/impacts from this competition is to provide manufacturers and end users improved access to adequate quantities of materials based on new advances at competitive costs that allow evaluation and utilization of these materials in innovative ways, and new manufacturing processes that can transform the way products are made. TIP's funding strategy for this competition will emphasize three important elements: 1) Process scale-up, integration and design for materials advances; 2) Predictive modeling for materials advances and materials processing; and 3) Critical process advances related to the manufacturability of materials and manufacturing of both new and existing products. These three elements of the societal challenge of accelerating the use of materials advances and advances in critical processes will be addressed as outlined in the white paper "Manufacturing and Biomanufacturing: Materials Advances and Critical Processes" (http://www.nist.gov/tip/cur\_comp/index.cfm).

Materials performance is often a critical consideration and controlling factor in the innovation process. High strength alloys are used to build stronger, lighter and safer vehicles; superalloys are used to make higher efficiency gas turbines; composites make larger, more efficient wind turbine blades and provide improved performance in aerospace applications; and nanomaterials are finding their way into better performing batteries, energy storage devices, electronic inks, high voltage transmission lines, and health care related applications (e.g., imaging and therapeutics). Ceramics have new uses in improving electronic and photonic devices, and glasses have many next-generation applications such as wireless communication, displays, optical telecommunication, integrated circuits, and ion exchange membranes for fuel cells. Overcoming scale-up issues of moving novel materials advances from the laboratory into manufacturing through "faster, better, cheaper" methods is just one way to help manufacturers be more successful and competitive. Critical processes are generally manufacturing processes that have the greatest impact on one or more of the following characteristics: product quality, product yields from raw materials, scrap rates, efficiency of raw material consumption, and/or other measures of efficiency. Many critical manufacturing processes are not flexible enough to easily incorporate novel materials advances into new products and many critical processes limit the nation's capacity to supply existing strategically

important products. Finding technical solutions to these challenges in manufacturing can give the comparative advantages necessary for retaining manufacturing in the United States. Outlined in this announcement are three key areas related to the manufacturability of materials advances and enhanced processing capabilities and descriptions of the supporting technical challenges that need to be addressed. If successful, the manufacturing solutions envisioned will have the potential to:

Create significant improvements in new and existing products and in their manufacture by accelerating the utilization of materials advances and overcoming critical manufacturing process bottlenecks to improve the competitiveness of U.S. manufacturers in the global marketplace.

"Materials advances" are defined for purposes of this funding opportunity as:

Materials that have been developed to the point that unique functionalities have been identified and these materials now need to be made available in quantities large enough for innovators and manufacturers to test and validate in order to develop new products.

The unique functionality that these materials represent will require new levels of understanding in the sciences of materials processing and process control. Nanomaterials, for example, will require manipulation and measurement at the atomic level. In alloys, the measurements and control would be at the microscale (and eventually at the nanoscale) with an emphasis on anisotropic features of the micro (nano) structure. With composites, ceramics, and glasses, measurements and control would be at the mesoscale and would take advantage of the anisotropic layering of the process. Control of one material or phase within another will also be an important consideration.

A "<u>critical process</u>" is defined for purposes of this funding opportunity as:

A process that has a significant impact on capacity, output, quality, variability, efficiencies, performance, flexibility, etc., as well as a manufacturer's competitiveness and success.

Process improvements made through high-risk, high-reward research and development, rather than simple engineering improvements or redesign, could lead to significant and quantifiable improvements in process output measures. As an example from last year's news headlines, consider the vaccine production response to the H1N1 flu outbreak. Experts were able to decode the virus to prepare a vaccine in record time, but encountered problems supplying the large volumes of vaccine needed in a timely fashion. Vaccines are grown in chicken eggs in a process that dates back to World War II. Each egg is in effect its own factory with product variability and purity issues. Development of new processes for production of recombinant vaccines as well as processes for real time monitoring and analysis could address these problems and would help to not only respond rapidly to new virus outbreaks, but could also reduce the cost of clinical trials through better scale-up methodologies. Addressing these challenges and needs could also impact other industries such as chemicals, biofuels, etc.

### Element 1 - Process scale-up, integration, and design for materials advances

New materials typically are developed in a laboratory setting, and then samples are given to endusers for alpha and beta testing. During this testing phase, it can take considerable time and experimentation to understand how the materials can be incorporated into a new product in a way that maintains and utilizes their unique functionality. Scaling-up from laboratory quantities to larger volumes, validating properties, and then incorporating the materials into product

manufacturing lines is often non-linear and does not follow straightforward scaling laws, due to the unique functionality that has been obtained from the materials advances.

## Element 2 - Predictive modeling tools for materials advances and materials processing

Predictive modeling capabilities are key to developing new processes, scaling-up these processes, and understanding how to utilize the unique functionality of materials advances. Modeling capabilities are needed principally to:

- a. Analyze and understand why newly discovered materials do what they do and then extrapolate their behavior to new uses: and
- b. Incorporate this knowledge more efficiently into process design tools so new products can be made while maintaining the unique functionality of the materials as predicted.

### Element 3 – Critical process advances

As the availability of new materials increases and the modeling of their behavior becomes more refined, there is a complementary need to improve processing or manufacturing methods. Highrisk, high-reward approaches are needed to exploit the properties of the materials advances into new and more advanced products as well as support the processing of existing materials in new and different ways, resolving key bottlenecks or critical problems such as energy consumption, processing time, scrap rates, quality, and throughput. Current methods of manufacturing often are not rapidly adaptable to making new or different products, and are often not optimized towards making existing products faster, more cheaply, and more sustainably. Improving processes used in the manufacture of new and existing products is an imperative for the continued global competitiveness of U.S. manufacturers. Agile, flexible, and increasingly interoperable systems are necessary enhancements to base manufacturing technologies in order to meet new productivity challenges.

Significant biomanufacturing process improvements are needed to enhance safety, quality, and consistency of biopharmaceuticals while reducing the manufacturing cost. For example, current sensing technologies typically require manual sampling, are not rapid or robust to cleaning agents or processes, and are not sufficiently reliable for imbedding in the manufacturing environment as automated technology. Critical process advances are needed, enabling rapid on-line sensing and analytical capabilities. New tools are needed for bioprocess optimization, control and improvement to enable a cost-effective batch or continuous manufacturing process. Processes that involve integrated sensing and detection capabilities for measuring multiple parameters will be useful. Moreover, purification and separation process advances involving novel membranes and affinity reagents are needed for cost-effective downstream processing in biopharmaceutical manufacturing processes.

The first two proposed elements for <u>Manufacturing and Biomanufacturing</u>: <u>Materials Advances and Critical Processes</u> require research in new technologies. The table below can be used to illustrate possible relationships between key challenges. TIP would expect solutions to the first two elements to map into one or more cells in Table 1 below. It is possible that the areas below could also impact or involve health care applications and/or biomanufacturing approaches.

**TABLE 1:** 

Technological Needs		Nanomaterials	Superalloys, Alloys & Smart Materials	Composites	Ceramics	Glasses
Processing of Materials	Scale-up from					
	Laboratory					
	Quantities /					
	Controls					
	Incorporate					
	into New Uses					
	/ Maintain					
	Functionality					
Predictive Modeling	Rules /					
	Understand					
	Why It Does					
	What It Does					
	Process					
	Modeling /					
	<b>Design Tools</b>					

For the first element, **process scale-up, integration, and design for materials advances**, new processes will need to be developed. These processes will increase to commercial scale the quantity and quality of available advanced materials; or help incorporate these materials into new, revolutionary products based on a new material's properties. These scaled-up processes may be a next generation or an entirely new process. For example, forging ever-larger parts cannot be solved by building ever-larger forges (which becomes prohibitively expensive), but instead by developing new techniques such as partial forging.

New instrumentation and measurement capabilities also will be needed to support these new processes. These instruments will need to measure real-time process parameters such as the properties that provide the unique capabilities of the advanced materials (e.g., composition). In addition, instruments for real-time inspection are needed to ensure and/or verify materials are being correctly incorporated into manufactured products that require the revolutionary functions of these new materials.

Proposals addressing **process scale-up, integration, and design for materials advances** will be considered responsive if they include scale-up of materials in one of the specified five materials classes (listed in Table 1) that are derived from biological or other sources and consist of one or more of the following:

- A single process to achieve the goals of the scale-up, or multiple processes integrated together into a coherent solution (i.e., diverse processes or multiples of a single process for "intensification");
- Scale-up of materials processes to manufacture and apply coatings that are within the scope requirements for the material types (nanomaterials; superalloys, alloys and smart materials; composites; ceramics; and glasses, including bulk metallic glasses); or
- Scale-up of materials processes for healthcare applications (e.g., imaging, therapeutics, etc.).

Some examples of responsive proposals (not all-inclusive) include:

- Nano structured silica from rice plant or algae
- Oxide nanoparticles produced by microorganisms
- Quantum dot- based nanocomposites produced by genetically engineered viruses (e.g. M13 bacteriophage)
- Cellulose/polyethylene oxide nanocomposites produced by genetically engineered bacteria (Acetobacter Xylium)
- Biologically produced silver carbon composites for optically functional thin film
- Biologically produced natural fiber reinforced aerogel composites
- Composites made with chitosan derived from crustacean shells

Proposals addressing <u>process scale-up</u>, <u>integration and design for materials advances</u> must address <u>all</u> of the following issues:

- Address one or more of the materials areas specified in this announcement
- Quantify the baseline processing capabilities
- Describe how the results of the process scale-up could lead to new products and manufacturing process capabilities
- Provide quantification and qualification of the estimated output of the final project results
- Scale-up of the quantities produced during the project must be targeted to increase by a factor of 1,000 fold or more (unit quantity per unit time) as compared to the baseline
- A detailed scientific rationale and description of the challenges to accomplish scale-up of the process(es) must be included.

Proposals addressing **process scale-up, integration, and design of materials advances** will be considered more competitive if they:

- Include validation methodologies by or with processors or end users and/or
- Address sustainability issues

Proposals addressing **process scale-up, integration, and design for materials advances** will be considered nonresponsive if they:

- Have the primary focus of the proposal on materials that are not included within Table 1 (i.e. pure polymers)
- Focus primarily on the application of material coatings using a material not included in Table 1
- Do not provide a quantitative technical discussion of baseline capabilities (state-of-the-practice or state-of-the-art)

For the second element, **predictive modeling for materials advances and materials processing**, new tools are needed to enable researchers to use constitutive relations and rules (with validation) concerning the underlying behavior of materials (understanding structure vs. function) and the changes to behavior due to manufacturing processes. For example, new tools will need to account for the scale-dependent behavior of materials advances. This capability will enable a better and quicker understanding of why materials do what they do. These efforts will also enable extrapolation of that knowledge beyond the laboratory conditions for which they were developed, and will therefore need new validation and verification capabilities. In addition, critical knowledge is needed about why certain decisions or

assumptions were made, in order to incorporate new modeling capabilities for laboratory results into process design and modeling. Again, new validation and verification methodologies will be essential.

With successful development of these tools, processes, and technologies, the manufacturing communities will have significantly improved capabilities to quickly incorporate advanced materials breakthroughs into revolutionary products based on new materials functionality, and thus establish new competitive advantages in a global economy.

Proposals addressing <u>predictive modeling for materials advances and materials processing</u> must address all of the following issues:

- Address one or more of the materials areas given in Table 1
- Quantify the baseline modeling capability
- Describe how the results of the proposed modeling capabilities could lead to new products and manufacturing process capabilities

Proposals for <u>predictive modeling for materials advances and materials processing</u> must also address <u>one or both</u> of the following:

- Develop constitutive relationships and rules that describe the behavior and the process of the materials at a level that is useful for describing laboratory results, as well as for developing a greater understanding of the materials for end users and/or
- Develop or use the constitutive relationships and rules to develop process design tools for the manufacturing processes for these materials advances

Proposals addressing <u>predictive modeling for materials advances and materials processing</u> will be considered more competitive if they address:

- Collaboration by or with those who manufacture the materials, in order to validate the models and/or
- How users will specifically benefit from the acceleration and implementation of the proposed models in support of materials reliability (i.e. final properties or mechanical performance) and materials behavior before and after processing

Proposals addressing <u>predictive modeling for materials advances and materials processing</u> that do not include validation of models will be considered less competitive.

Proposals addressing <u>predictive modeling for materials advances and materials processing</u> will be considered nonresponsive if they:

- Have the primary focus of the proposal on materials that are not included within Table 1 (i.e., pure polymers)
- Focus primarily on the application of material coatings using a material not included under Table 1
- Do not provide a quantitative technical discussion of baseline capabilities (state-of-the-practice or state-of-the-art)

The third element, **critical process advances**, requires modifications in manufacturing processes that augment and expand current limited capabilities. Applications could include those oriented towards the creation of novel methods to fabricate unique components from complex, difficult-to-machine materials (advanced engineering materials or smart materials), or the design and implementation of real-time, sensor-based, feedback-optimized systems for discrete, continuous or batch manufacturing processes. A discrete manufacturing example could be a process for making customized parts such as medical implants, using techniques such as additive manufacturing, near net-shape fabrication, or partial forging. Processes are needed for the manufacture of parts possessing complex geometries from existing and novel materials while preserving the properties of the material. A batch process example would be improved process monitoring and in situ analytical tools, enabling a reduction in batch-to-batch variability and an improvement in quality, and quantity of biopharmaceuticals or other products produced in a more reliable and cost-effective manner.

A table for guidance on categorizing applicable processes and pathways to critical process advances is given below. TIP would expect solutions to the third societal challenge to map into one or more of the cells in Table 2 below.

TABLE 2:

State-Of-The-Art Approaches to Critical Manufacturing Process	Process			
Advances for:	Batch	Discrete	Continuous	
Improving quality				
Increasing throughput				
Reducing costs				
Enhancing sustainability				
Enabling new capabilities				
Improving agility				
Other improvements				

Proposals addressing <u>critical process advances</u> will be considered responsive if they address improvements in **quality**, **throughput**, **costs**, **sustainability**, **new capabilities**, and **agility**, relative to the state-of-the-art for the process being proposed.

In drafting a proposal addressing <u>critical process advances</u> applicants should address topics in their area of interest such as:

• If a proposal offers improvements in several of these categories, the multiple improvements could be combined. For example, a proposed new process might offer half the setup time and triple the rate of production compared to existing processes.

- Benefits are not necessarily "linear"; for example, a component of a machine might benefit from increased strength or durability up to a point, beyond which there is little incremental benefit.
- Because manufacturing processes generally involve tradeoffs, a proposed new process may involve improvements in some areas and tradeoffs in other areas. For example, a proposed process might offer a factor of six **cost reduction** but a **production rate decrease** of a factor of two, and the net benefit of the tradeoff will be evaluated.
- Proposals should quantify to the extent possible every aspect of the advance in state of the art (as shown by the rows in the Table 2 above), including any that may offer decreased benefit as a tradeoff to further increase the advance in another area. Claimed benefits must be quantified for particular target application(s). (Example: "a new forging and heat treatment process for automobile axles will allow 50% lighter parts to be used and cut manufacturing cost by x%, improving fuel economy by y%, and ultimately reducing greenhouse gas emissions by z million tons per year.")
- The evaluation process should not make assumptions about performance parameters that are not discussed. For example, if a proposal claims lower cost but does not mention quality, reviewers will have to consider the possibility that quality is being sacrificed to save on cost, and such a proposal will be less competitive than one that offers comparable cost saving together with a claim for quality equal to or better than current products.

The term "biomanufacturing" as used throughout this notice and in the FFO announcement refers to manufacturing of biopharmaceuticals. Biopharmaceuticals are complex pharmaceutical products manufactured by biotechnology. Two types of biomanufacturing are considered: bioprocessing for production of biopharmaceuticals such as recombinant proteins as vaccines, therapeutics, or as molecular probes for diagnostics, and advanced biofabrication and processing for production of cell or tissue-based biopharmaceuticals such as engineered cells and engineered tissues as therapies. Engineered tissues are complex structures involving cells, scaffolds and signaling molecules. Manufacturing of either type of biopharmaceuticals is within the scope of the competition.

Proposals addressing <u>critical process advances</u> will be considered responsive if they provide improvements in one or more critical processes integrated together into a coherent solution to significantly enhance process efficiencies and reduce process variability. Some examples of responsive proposals (not all-inclusive) include:

- New biomanufacturing process capabilities enabling rapid on-line monitoring of production cell health and function (e.g. cell viability, metabolism, contaminants) and on line monitoring of the structure and function of engineered cells or tissues when developed as therapeutics.
- Advanced bioprocesses for rapid on-line analysis of biopharmaceuticals (e.g. protein glycoforms, three-dimensional structure, aggregates, immunogenicity and contaminating bacteria, viruses, mycoplasma, production cell proteins and nucleic acids).
- Advanced active control feedback systems for monitoring and controlling complex bioprocesses and high throughput microreactor/bioreactor array systems for optimizing production cell systems (e.g. engineered Chinese Hamster Ovary or CHO cells, insect cells, microorganisms, or algae).
- Advances in critical processes in cost effective scale up of engineered cells or engineered tissues.
- New, automated processes for producing parts using composite materials.
- Affordable fabrication methods for lightweight components manufactured from low cost titanium powders.
- Reduction of energy intensity and demand, carbon dioxide and greenhouse gas emissions in glassmaking or other high energy consuming sectors.

- Precision additive manufacturing of medical devices.
- Low cost technologies for advancing the uses of nanomaterials in a variety of end products.

# Responsive proposals addressing <u>critical process advances</u> must address <u>all</u> of the following issues:

- Address how the improved manufacturing processes are transformational compared to the stateof-the-art;
- Describe how the results of the research will lead to new and improved manufacturing processes enabling safe, cost effective and reliable production and new and improved products such as customized medical implants, large bearings, etc.;
- Describe why the technological solutions are high-risk and high-reward in nature; and
- Provide quantification and qualification of the estimated output of the final project results.

#### Proposals addressing **critical process advances** will be considered more competitive if they:

- Include multiple improvement areas from the table above;
- Include validation methodologies by or with processors or end users; and/or
- Address sustainability issues.

## Examples of proposals addressing <u>critical process advances</u> that will be considered nonresponsive are:

- Any manufacturing process that offers only incremental improvement over existing processes;
- Processes that are intended **primarily** for military/weaponry applications (e.g. warhead manufacture, chemical/biological warfare materials production);
- Manufacturing processes that cannot be performed in the U.S. due to existing laws or regulations;
- Projects primarily focused on production of **non engineered** cells or tissues as therapeutics;
- Projects involving straightforward scale-up of biopharmaceuticals with incremental improvements in the manufacturing processes;
- Projects that involve incremental improvements in traditional processes for biomolecule production (e.g. vaccine production in chicken eggs, hormones such as insulin extracted from pig tissue);
- Biomanufacturing projects that primarily focus on processes for production of non-biopharmaceutical products (e.g. production of biofuels or small molecule drugs);
- Projects that primarily focus on drug discovery or design of new biomaterials;
- Projects that primarily focus on discovery of new production cell systems;
- Projects that use living genetically modified vertebrate animals, invertebrate animals, or plants as bioreactors for biopharmaceutical production;
- Production or scale up of scaffolds or biomaterials used in scaffold design that are not a part of the manufacturing of engineered tissues; and
- Projects with a primary focus (people, equipment, time, and/or funds) on device development.

## **Additional Requirements for All Manufacturing Proposals**

TIP proposals are strengthened and generally considered most competitive when the proposed research plan includes validation by others of the research goals. When preparing a proposal, it is necessary to quantify and qualify the ability of the research results to "Transform the Nation's Capacity to Deal with Major Societal Challenges". The claims that any proposal makes relative to this key criterion are strengthened by validation of the research results with one or more end user(s) of the technology. The proposal may make assertions by narrative and referenced third-party documentation. The addition of

"letters of interest" in the research results by potential end users adds strength to a proposal. Ultimately, the addition of one or more end users in a validation task implementing the research results would present the strongest case for commitment to the planned research goals.

Examples of validation tasks within each of the three elements might include:

- <u>Process scale-up, integration, and design for advanced materials</u>: Create a prototype using the advanced material produced from the research.
- <u>Predictive modeling for advanced materials and materials processing</u>: Apply modeling capability by implementing the new model information as a key knowledge component into a process or product.
- <u>Critical process advances</u>: Integrate the research results into processes for optimization, control and improvements in manufacturing and product analysis (e.g. composites, metals, chemicals, biopharmaceuticals).

# Nonresponsive projects under this area of critical national need include:

- Projects whose principal focus is on discovery of new materials;
- Efforts related to the physical extraction of raw materials;
- Straightforward improvements to existing processes or materials without the potential for a transformational increase in performance to the technical requirements;
- Integration projects using only existing state-of-the-art processes, models or materials;
- Software development that is predominantly straightforward, routine data gathering using applications of standard software development practices; and
- Projects that do not include a quantitative baseline and quantitative metrics for tracking research.

In addition to the competition-specific nonresponsive projects, the following are nonresponsive projects:

- Straightforward improvements of existing products or product development.
- 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 <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>.
- 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.
- 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.
- Predominantly straightforward, routine data gathering (e.g., creation of voluntary consensus standards, data gathering/handbook/specification sheet preparation, testing of materials, or unbounded research aimed at basic discovery science) or application of standard engineering practices.
- Projects in which the predominant risk is market oriented—that is, the risk that the end product may not be embraced by the marketplace.

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, or vertebrate animals, 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 or vertebrate animals in research and require compliance with applicable Federal regulations and NIST policies for the protection of human subjects or live vertebrate animals

## II. Award Information

Fiscal year 2010 appropriations include funds in the amount of approximately \$25 million for new TIP awards. Approximately 25 total awards are anticipated. The anticipated start date is January 1, 2011. The period of performance depends on the R&D activity proposed. A single company can receive up to a total of \$3 million with a project period of performance of up to 3 years. A joint venture can receive up to total of \$9 million with a project period of performance of up to 5 years.

Continuation funding after the initial award is based on satisfactory performance, availability of funds, continued relevance to program objectives, and is at the sole discretion of NIST.

The funding instrument used in TIP awards is a cooperative agreement. Through the use of the cooperative agreement, TIP fosters public/private partnerships to accomplish a public purpose to support, promote, and accelerate innovation in the United States through high-risk, high-reward research in areas of critical national need. TIP plays a substantial role beyond the levels required normally for program stewardship of grants. This includes but is not limited to monitoring of the technical progress against established milestones, and maintaining fidelity against the TIP award and evaluation criteria; review and approval of key personnel, including the Principal Investigator (PI) and designated staff other than the PI; significant changes in project participants that impact the technical approach; and tracking impact statements for use in the TIP Annual Report.

### **III. Eligibility Information**

## 1. Eligible Applicants/Proposers

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 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 company of the joint venture being either an eligible small-sized or medium-sized company; or

(2) At least one small-sized or medium-sized eligible 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 the small-sized or medium-sized company or the 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 of the TIP Proposal Preparation Kit) 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.

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 \$ 1.7208 billion. This number is based on the May 2009 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.)

c. Nonprofit organizations must meet the eligibility criteria set forth in 15 CFR 296.5(a) (2) which explains the eligibility criteria for companies.

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 country of incorporation 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 of the TIP Proposal Preparation Kit), that relates to the role of the foreign-owned company in the project to help address the foreign eligibility requirement. If there is more than one such company, a separate form NIST-1022G, Foreign-Owned Company 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 and includes the following:

- a. 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;
- b. 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);
- c. Evidence that the company makes significant contributions to employment in the United States (i.e., number of employees); and
- d. Evidence that the company agrees to promote the manufacture within the United States of products 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?)

# 2. Cost-Sharing or Matching Requirement

- 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 provide a cost share of at least 50 percent of the yearly total project costs (direct plus all of the indirect costs).
- 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 provide a cost share of 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.

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 <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>) and will be prorated according to the share of total use dedicated to the TIP project.

Additionally, as with the Federal share, any costs included as cost share must be allowable under the following applicable Federal cost principles available at <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>:

- 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.

Letters of commitment, letters of support, and letters of corroboration, documenting efforts to secure other funding, required or as appropriate, are identified in the TIP Proposal Preparation Kit in Chapter 2.

# IV. Application/Proposal and Submission Information

## 1. Application/Proposal Package

The April 2010 version of the TIP Proposal Preparation Kit must be used to prepare and submit all proposals under the fiscal year 2010 competition. The Kit is available at <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>. Requests for a paper copy of the Kit can be made by calling 1-888-847-6478.

The Kit contains proposal cover sheets, other required forms, and all the necessary guidelines for developing a TIP proposal. Information on electronic proposal submissions via grants.gov is also available in the Kit. All proposals must be prepared in accordance with the guidelines in the Kit.

### 2. Content and Form of Application/Proposal Submission

All paper (hard copy) and electronic proposal submission requirements are discussed in detail in Chapters 2, 3 and 4 of the TIP Proposal Preparation Kit. The Kit also includes the "Human Subjects Determination Checklist" in Chapter 6, and General Instructions for Submitting TIP Proposals Electronically via Grants.gov in Chapter 7 to assist potential proposers in their proposal preparation and submission. Additionally, all of the required forms are included in the TIP Kit as Exhibits.

TIP does not accept pre-proposals, unsolicited proposals, or letters of intent.

#### 3. Submission Dates and Times

The due date for submission of proposals is 11:59 p.m. Eastern Time, Thursday, July 15, 2010. This deadline applies to any mode of proposal submission, including express mailing and electronic. Do not wait until the last minute to submit a proposal. TIP will not make any allowances for late submissions, including incomplete Grants.gov registration or delays by guaranteed overnight couriers. To avoid any potential processing backlogs due to last minute registrations, proposers are highly encouraged to start their Grants.gov registration process at least four weeks prior to the proposal submission due date.

Any proposals not received by the due date will not be considered and will be returned to the proposer without review. TIP determines whether a proposal has been submitted before the deadline by date/time

receipt of proposals as they are physically received in the TIP office or in the case of electronic submission, as the time stamped on the automatically generated notification indicating successful submission.

Important: Applicants submitting both electronic and paper format proposals should be aware that adequate time must be factored into proposers' schedules for delivery of the proposal. Applicants submitting electronic proposals are advised that volume on Grants.gov is currently extremely heavy, and if Grants.gov is unable to accept proposals electronically in a timely fashion, proposers are encouraged to exercise their option to submit proposals in paper format. Applicants submitting paper proposals should allow adequate time to ensure a paper proposal will be received on time, taking into account that guaranteed overnight carriers are not always able to fulfill their guarantees.

## 4. Executive Order 12372 (Intergovernmental Review of Federal Programs)

Proposals under this program are not subject to Executive Order 12372.

# 5. Funding Restrictions

- a. The federal share of a project funded under the Program shall not be more than 50 percent of total project costs.
- b. Federal funds may be used only for direct costs and not for indirect costs, profits, or management fees. However, indirect costs may be used to meet the cost-sharing requirement.
- c. Regardless of any approved indirect cost rate applicable to the award, the maximum dollar amount of allocable indirect costs for which the recipient may use as cost-sharing shall be the lesser of the line item amount of indirect costs contained in the approved budget of the award, or the recipient's share of the total allocable indirect costs of the award based on the indirect cost rate approved by an oversight or cognizant federal agency and current at the time the cost was incurred, provided the rate is approved on or before the award end date.
- d. No large-sized business may receive funding as a recipient or subrecipient of an award under the Program. When procured in accordance with procedures established under the Procurement Standards required by part 14 of Subtitle A of title 15 of the Code of Federal Regulations, recipients may procure supplies and other expendable property, equipment, real property and other services from any party, including large-sized businesses.
- e. **Unallowable/Ineligible Costs**. The following items, regardless of whether they are allowable under the federal cost principles, are ineligible/unallowable under TIP:
  - (1) 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).
  - (2) Construction costs for new buildings or extensive renovations of existing 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 in advanced 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.

- (3) Contractor office supplies and contractor expenses for conferences/workshops.
- (4) 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 interorganizational transfers that do not contain profit. Inter-organizational transfers should be broken down in the appropriate budget categories.
- (5) 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.
- (6) 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.
- (7) Indirect costs, which must be absorbed by the recipient. However, indirect costs are allowable for contractors under a single company or joint venture award. (Note that indirect costs absorbed by the recipient may be used to meet the cost-sharing requirement.)
- (8) 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.
- (9) Office furniture costs, unless they are included in a federally approved indirect cost rate.
- (10) Patent costs and legal fees, unless they are included in a federally approved indirect cost rate.
- (11) Preaward costs: i.e., any costs incurred prior to the award start date.
- (12) 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.
- (13) Project development planning (e.g. patent and literature searches) and creation of milestones. For example, proposals that plan on developing milestones only if an award is received and after literature searches are performed under the award are generally not competitive. Costs for literature searches in general are ineligible.
- (14) Relocation costs, unless they are included in a federally approved indirect cost rate.
- (15) Salaries: NIST limits the salaries of project personnel to not exceed Level I of the Executive Schedule (\$199,700 as of January 2010 <a href="http://www.opm.gov/oca/10tables/html/ex.asp">http://www.opm.gov/oca/10tables/html/ex.asp</a>).
- (16) Tuition costs are generally not allowed as direct costs on projects. 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 paid as, or in lieu of, wages to students performing necessary work. These are allowable, provided the requirements are met under 2 C.F.R. Subtitle A, Chapter 2, Part 220, Appendix A. 45 (formerly OMB Circular A-21, Section J.41). In such cases, tuition remission and other forms of compensation paid to students shall be treated as direct costs in accordance with the actual work being performed, and listed in the budget under "Other." Tuition remission may be charged on an average rate basis.

- 6. **Other Submission Requirements**. TIP proposals may be submitted in electronic or in hardcopy format as follows:
  - Electronic submission: <u>www.grants.gov</u>
  - Please see the TIP Proposal Preparation Kit April 2010 Chapter 7 for full details on electronic submissions http://www.nist.gov/tip/helpful-resources.cfm.
  - Paper submission: National Institute of Standards and Technology

Technology Innovation Program 100 Bureau Drive, Stop 4750 Gaithersburg, MD 20899-4750

- Please see the TIP Proposal Preparation Kit April 2010 Chapter 4 for full details on paper submissions <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>.
- Please note that the NIST site is closed to the general public, and applicant personnel and couriers
  will not be permitted onto the NIST site in order to deliver proposals. Also note that the NIST
  Visitors Center is not permitted to accept proposals on behalf of the Technology Innovation
  Program.
- Paper submissions will be accepted from the U.S. Mail or similar commercial carrier that routinely deliver mail to NIST.

Please refer to important information in Submission Dates and Times above to help ensure your proposal is received on time.

# V. Application/Proposal Review Information

1. **Criteria.** 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, pursuant to 15 U.S.C. 278n(c), no proposal will be funded unless TIP determines that it meets all of the award criteria listed in 15 C.F.R. § 296.22. Detailed guidance on how to address the evaluation and award criteria is provided in Chapter 2 of the TIP Proposal Preparation Kit, which is available at <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>.

**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;
- (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.

- 2. **Selection Factors.** In making final selections, the Selecting Official will select funding recipients based upon the Evaluation Panel's rank order of the proposals and the following selection factors:
  - a. Assuring an appropriate distribution of funds among technologies and their applications,
  - b. Availability of funds, and/or
  - c. Program priorities.
- 3. **Program Priorities.** TIP is soliciting proposals under this fiscal year 2010 competition in the area of critical national need entitled "Manufacturing" as described in the Funding Opportunity Description section above.
- 4. **Review and Selection Process.** Proposals are selected based on a multi-disciplinary peer-review process, as described in 15 C.F.R. §296.20. 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; was submitted to a previous TIP competition, and if so, has been substantially revised; 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 by an Evaluation Panel consisting of Federal employees using the TIP evaluation criteria listed in 15 C.F.R. §296.21 and award criteria listed in 15 C.F.R. §296.22. The Evaluation Panel will present funding recommendations to the 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.

#### 5. Additional Information

- a. TIP proposals will be ranked in numerical order.
- b. Proposers may not submit replacement and/or revised pages and/or documents for any portion of a proposal once that portion has been submitted unless specifically requested by NIST.
- c. One copy of each non-responsive or non-selected proposal will be retained in accordance with the records retention schedule for record keeping purposes. The remaining copies will be destroyed. After the records retention schedule is fulfilled the remaining copy will be destroyed.

#### VI. Award Administration Information

- 1. **Anticipated Announcement and Award Date.** Awards are expected to be made by the end of November 2010.
- 2. **Award Notices**. Successful proposers/applicants will receive an award document (CD-450 Financial Assistance Award) signed by the NIST Grants Officer. The award will include the award period, the budget, special award conditions, TIP General Terms and Conditions, DoC Financial Assistance Standard Terms and Conditions, and will incorporate the applicable federal cost principles, and

applicable policy and regulatory references that will govern the award. The award will be mailed to the successful proposer/applicant via surface mail in triplicate and requires a counter-signature on all three copies by an authorized official at the organization. The recipient should retain one original and return the other two copies to the address listed in the award document. The award document, i.e., CD-450 and award terms and conditions are available at <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>.

- 3. Administrative and National Policy Requirements. DoC Pre-Award Notification Requirements. The Department of Commerce Pre-Award Notification Requirements for Grants and Cooperative Agreements are contained in, 73 FR 7696 (February 11, 2008), apply to this notice. On the form SF-424 R&R items 5. and 6., the applicant's 9-digit Employer/Taxpayer Identification Number (EIN/TIN) and 9-digit Dun and Bradstreet Data Universal Numbering System (DUNS) number must be consistent with the information on the Central Contractor Registration (CCR) (www.ccr.gov) and Automated Standard Application for Payment System (ASAP). For complex organizations with multiple EIN/TIN and DUNS numbers, the EIN/TIN and DUNS number MUST be the numbers for the applying organization. Organizations that provide incorrect/inconsistent EIN/TIN and DUNS numbers may experience significant delays in submitting their proposals through grants.gov and receiving funds if their proposal is selected for funding.
- 4. **Reporting.** Award recipients shall provide access to information that is required to assess the project's progress throughout the project life cycle. The following reports are required:
  - a. **Technical Performance Reports.** Award recipients shall submit technical performance reports in triplicate (one original and two copies). Two copies shall be submitted to the Project Manager and the original report to the NIST Grants Officer in the same frequency as the Federal Financial Report (SF-425). Technical performance reports shall contain information as prescribed in 15 C.F.R. §14.51.
  - b. **Impact Assessment Reports.** Award recipients shall submit impact assessment reports as stipulated in the award terms and conditions.
  - c. **Financial Reports.** For recipients under this program, Article A.01 of the DoC Financial Assistance Standard Terms and Conditions dated 2008 is revised as follows:

Award Recipients shall submit a "Federal Financial Report" (SF-425) on a calendar quarter basis for the periods ending March 31, June 30, September 30, and December 31, or any portion thereof. Reports are due no later than 30 days following the end of each reporting period. A final SF-425 shall be submitted within 90 days after the expiration date of the award.

All financial reports shall be submitted in triplicate (one original and two copies) to the NIST Grants Officer.

5. **Intellectual Property Requirements.** 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.

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 intellectual property 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. *Intellectual property* means an invention patentable under title 35, United States Code, or any patent on such an invention, or any work for which copyright protection is available under title 17, United States Code. (15 C.F.R. §296.2.)

6. Projects Involving Human Subjects. Research involving human subjects must be in compliance with applicable Federal regulations and NIST policies for the protection of human subjects. 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. A Human Subjects Determination Checklist is included in the April 2010 TIP Proposal Preparation Kit in Chapter 6 (http://www.nist.gov/tip/helpful-resources.cfm) 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 & Animal Subjects for more specific information on documentation requirements and due dates for documentation located at http://www.nist.gov/tip/helpful-resources.cfm or by calling 1-888-847-6478. President Obama has issued Exec. Order No. 13,505, 74 Fed. Reg. 10667 (March 9, 2009), revoking previous executive orders and Presidential statements regarding the use of human embryonic stem cells in research. On July 30, 2009, President Obama issued a memorandum directing that agencies that support and conduct stem cell research adopt the "National Institutes of Health Guidelines for Human Stem Cell Research" (NIH Guidelines), which became effective on July 7, 2009, "to the fullest extent practicable in light of legal authorities and obligations." On September 21, 2009, the Department of Commerce submitted to the Office of Management and Budget a statement of compliance with the NIH Guidelines. In accordance with the President's memorandum, the NIH Guidelines, and the Department of Commerce statement of compliance, NIST will support and conduct research using only human embryonic stem cell lines that have been approved by NIH in accordance with the NIH Guidelines and will review such research in accordance with the Common Rule and NIST implementing procedures, as appropriate. NIST will not support or conduct any type of research that

the NIH Guidelines prohibit NIH from funding. NIST will follow any additional polices or guidance issued by the current Administration on this topic.

7. **Projects Involving Live Vertebrate Animals**. Research involving live vertebrate animals must be in compliance with applicable Federal regulations and NIST policies for the protection of live vertebrate animals. 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. Detailed information regarding the use of live vertebrate animals in research plans and required documentation is available in the *TIP Guidelines and Documentation Requirements for Research Involving Human & Animal Subjects* located at <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a> or by calling 1-888-847-6478.

## VII. Agency Contact(s)

Subject Area	Point of Contact		
Administrative, budget, cost-sharing, and	Michael Walsh		
eligibility questions	Phone: 301-975-5455		
	Fax: 301-869-2147		
	E-mail: michael.walsh@nist.gov		
Human and/or animal subjects used in	Lawrence Uhteg		
research	Human & Animal Subjects Advisor		
	Phone: 301–975–8779		
	Fax: 301-548-1087		
	E-mail: lawrence.uhteg@nist.gov		
Project selection, evaluation and award	Thomas Wiggins, Director		
criteria, and other programmatic questions	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: <a href="mailto:christopher.hunton@nist.gov">christopher.hunton@nist.gov</a> mailto		
Technical questions related to NIST-1022	Deborah Dubeau		
and associated forms	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	Grants & Agreements Mgmt. Division		
regulations	Phone: 301-975-5718		
	Fax: 301-840-5976		
	E-mail: grants@nist.gov		

## **VIII. Other Information**

- 1. **Confidential Information:** 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 <a href="http://www.nist.gov/tip/helpful-resources.cfm">http://www.nist.gov/tip/helpful-resources.cfm</a>.
  - 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.

2. **Public Meetings (Proposers' Conferences):** TIP will hold three public meetings (Proposers' Conferences) to provide general information regarding TIP, to offer guidance on preparing proposals, and to answer questions. 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, proposers should not expect to have proprietary issues addressed at the 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 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 the TIP proposers' conferences is not required.

The TIP Proposers' Conferences will be held on the following dates and times, and at the following locations:

April 28, 2010, 9 a.m. - 2 p.m. Eastern Time: NIST Red Auditorium, 100 Bureau Drive, Gaithersburg, MD. Pre-registration is required by 5 p.m. Eastern Time on April 23, 2010 for the Proposers' Conference being held at NIST Gaithersburg, MD. Due to increased security at NIST, NO on-site registrations will be accepted and all attendees MUST be pre-registered. Photo identification must be presented at the NIST main gate to be admitted to the April 28, 2010 conference. Attendees must wear their conference badge at all times while on the NIST campus. Electronic Registration at <a href="http://www.nist.gov/public\_affairs/confpage/100428.htm">http://www.nist.gov/public\_affairs/confpage/100428.htm</a>.

No registration fee will be charged at the Proposers' Conferences. Presentation materials from the Gaithersburg, MD Proposers' Conference will be made available on the TIP Web site. The Gaithersburg, MD Proposers' Conference will be webcast details will be available at the TIP Website: <a href="http://www.nist.gov/tip">http://www.nist.gov/tip</a>

May 4, 2010, 1 p.m. - 5 p.m. Pacific Time Embassy Suites Hotel Los Angeles International Airport – South 1440 Imperial Avenue, El Segundo, CA 90245

May 6, 2010, 9a.m. -1 p.m. Eastern Time Detroit Marriott Renaissance Center Renaissance Dr N. Detroit, MI 48243

No Pre-registration is required for the Proposers' Conferences in Los Angeles, CA or Detroit, MI.