**Request for Information**

**Federal Technology Transfer Authorities and Processes**

**Last day to submit the responses: July 30, 2018**

### Introduction

In order to advance the President's Management Agenda to modernize government for the 21st century, including the associated Lab-to-Market CAP Goal in coordination with the White House's OSTP, NIST is initiating a Return on Investment (ROI) Initiative [4] with the intent of conducting a comprehensive assessment of the Federal technology transfer system that will identify opportunities to improve Federal technology transfer efforts, policies, and practices. The goal of this effort is to, where appropriate, streamline and accelerate transfer of technology from Federal R&D investments to attract greater private-sector investment for innovative products, processes, and services, as well as new businesses and industries that will create jobs, grow the economy, and enhance national security.

NIST is seeking broad input and participation from stakeholders in Federal R&D, intellectual property, and technology transfer to assist in identifying and prioritizing issues and proposed solutions. This assessment will address: (a) Core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed; (b) approaches to improve efficiency and reduce regulatory burdens for technology transfer to attract private sector investment in later-stage R&D, commercialization, and advanced manufacturing; (c) new partnering models and technology transfer mechanisms with the private sector, academia, other Federal agencies, state, and other public-sector entities to support technology development and maturation; (d) new approaches that will reduce or remove barriers, and enable accelerated technology transfer, with a focus on areas of strategic national importance; (e) better metrics and methods to evaluate the ROI outcomes and impacts arising from Federal R&D investment; and (f) new approaches to motivate significantly increased technology transfer outcomes from the Federal sector, universities, and research organizations.

This information will only be used as input to the Return on Investment initiative. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

### Instructions

This template is designed to facilitate responses to the RFI. Use of this form is optional.

It is not required to fill out all of the sections, for example a participant may elect to only provide input on one question.

Save and email it to [roi@nist.gov](mailto:roi@nist.gov).

# Contact Information

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Questions

1. What are the core Federal technology transfer principles and practices that should be protected, and those which should be adapted or changed?

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| Above all, the fundamental principles of Bayh-Dole need to be preserved. The foundation that Bayh‐Dole relies upon is a strong, reliable U.S. patent system. The present uncertainties plaguing the U.S. patent system create significant hurdles for successful commercialization of federally‐supported R&D and need to be rectified if the United States wants to continue its leadership in bringing new technologies to market. The Department of Commerce should be reinforced to ensure proper and consistent application of the law and regulations. Some examples would include last year's Dept of Education decision that educational software created under its funding must be made freely available. While software often is not patented, in cases where it is, in fact, patentable, the Bayh‐Dole Act allows federal award recipients to choose whether or not to pursue patent protection. If they choose to exercise that right, the invention cannot simply be taken away by the funding agency without complying with the requirements of the Bayh‐Dole Act. There is no indication that the DoEd sought an exceptional circumstances determination, as required, to comply with the law, but it issued a final regulation without being challenged by the Department of Commerce.  In summary, the Bayh‐Dole Act continues to function as intended and should not be modified. While AUTM sincerely appreciates the efforts of NIST to oversee proper implementation of Bayh‐Dole, NIST has many other responsibilities as a science agency. Bayh‐Dole depends on its provisions being properly enforced and protected by the lead agency, and that duty needs to be reinforced and consistently performed as intended by Congress either through a dedicated office at the Department of Commerce or additional resources to NIST to add the expertise required to properly oversee Bayh‐Dole. Additional ideas would include simplifying the process for waivers of US manufacturing in certain cases; and simplifying/clarifying the process to commercialize unpatented items, like software, across all federal agencies. |

1. What are the issues that pose systemic challenges to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D? Please consider those identified in the RFI as well as others that may have inhibited collaborations with Federal laboratories, access to other federally funded R&D, or commercialization of technologies resulting from Federal R&D?

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| Issue 1: Uncertainty about the scope of patent‐eligible subject matter as well as the degradation of the status of patent rights have created significant challenges for those seeking to transfer federally funded technology. Patents lower the perceived risk of investing and help attract private investment dollars to developing early‐stage technology by mitigating competition during the life of the patent. Patents are also a form of marketing and one way of making the for‐profit sector aware of activities within universities and other nonprofits.  Issue 2: The fact that intellectual property created at Universities is a very early-stage technology has required Universities to take a more proactive stance in de-risking technology prior to licensees finding it attractive for licensing.  Issue 3: The grace period (35 USC sec. 102 (b)(1)(B)), as interpreted by the USPTO, is weak and ineffective in excluding as prior art anything other than the inventor's own public disclosure. |

1. What is the proposed solution for each issue that poses a systemic challenge to the effective transfer of technology, knowledge, and capabilities resulting from Federal R&D? Please consider the approaches identified in the RFI.

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| Issue 1: Fix the IPR process to require a) a party using it to have standing, b) permit the patent owner to amend the claims during the process, and c) limit the number of times it can be used before ex parte reexam or litigation are the only options.  Issue 2: Expand federal funding for accelerator and proof-of-concept funding. This can be done in a variety of ways that increase interaction with the business community generally, such as grant review committees with members both from nonprofit and from the for‐profit sector.  Issue 3: The USPTO should broaden its interpretation of 35 USC sec. 102(b)(1)(B) to exclude as prior art third party disclosures that are substantially identical or obvious variations of the subject matter previously disclosed by the inventor. This reinterpretation will strengthen the grace period encouraging more collaboration among universities, federal laboratories and the private sector. |

1. What are other ways to significantly improve the transfer of technology, knowledge, and capabilities resulting from Federal R&D to benefit U.S. innovation and the economy? What changes would these proposed improvements require to Federal technology transfer practices, policies, regulations, and legislation?

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| Suggested Improvement 1: Simplify and streamline current technology transfer reporting requirements. It is critical to advancing technology transfer efforts that current reporting requirements are simplified and improved. Most, but not all, federal agencies use the iEdison system housed at NIH for reporting federally funded inventions. iEdison is a legacy system that has never been properly resourced. It is characterized by an obsolete architecture and multiple required gateways that are extremely burdensome for users. In addition, NIH requires literal compliance with prescribed government support statements on reported patents and has insisted that faulty statements, even on abandoned or expired patents, must be corrected. Moreover, use of iEdison is not mandatory, and several agencies have their own burdensome reporting requirements (e.g. NASA). A uniform, simplified invention reporting system utilizing current information technology standards across all federal agencies should be implemented in place of the current system, with oversight provided by the reestablished Commerce office (recommended in response to the first question). Furthermore, use of this system should be mandatory for all federal funding agencies.  Suggested Improvement 2: Support institutional grants to create new funding for institutional proof of concept/translational research awards. Existing SBIR/STTR funding presumes there is already evidence that specific research or technology has enough value to attract further investment. However, in many cases there still exists a dearth of funding needed to push technologies across the “Valley of Death.” This often prevents universities from moving new research discoveries and technologies quickly into the marketplace and sometimes prevents such transfer entirely. The high‐level of risk associated with these early stage technologies has left companies, angel investors, and venture capitalists even less willing to invest in the proof‐of‐concept, scaling‐up, and modeling required to explore the commercial value of such advances. The current SBIR program begins to address this issue, but it falls short of providing the necessary early stage support for “proof‐of‐concept” research. The proposed TRANSFER ACT, previously passed by the U.S. House of Representatives, builds on the NIH’s Research Evaluation and Commercialization Hub (REACH) program, an early‐stage, “phase zero” proof‐of‐concept pilot program, previously authorized under Section 5127 of the 2011 SBIR/STTR Reauthorization Act (P.L. 112‐81). Institutional grants such as these would help more universities and federal laboratories develop the required infrastructure to work with their faculty to successfully commercialize their research discoveries.  Suggested Improvement 3: Develop new methods to measure and report on effectiveness.  Agencies have received numerous presidential and departmental directives on increasing the rate of technology transfer and economic and societal impact from Federal R&D investments. Each time the directives came with a goal of improving the results of technology transfer and commercialization activities. While agencies were tasked to develop goals and metrics, consistent and universal definitions have not been developed. Success should not be measured primarily by revenue, but rather by contributions to broader economic prosperity and societal impact. New methods and metrics with universal definitions should be developed to effectively capture impacts and improve measurements of effectiveness across the various recipients of federal funding.  Suggested Improvement 4: Consistent interpretation and development of Conflict of Interest Rules. Ease barriers for federally‐funded investigators to participate in commercialization and start‐up activities. If any federal agencies other than NIH plan to promulgate conflict of interest rules, they should be consistent with the standard conflict of interest policies of NSF for a consistent application of conflict of interest rules across agencies. In addition, individual programs, such as the NSF SBIR program, should not add more restrictions beyond the standard agency policy.  Suggested Improvement 5: Create reward and incentive programs to encourage individuals to participate in commercialization activities and create a change in culture. Make commercialization an agency priority by developing and providing real rewards for programs and individuals who take the initiative to heart. In any organization, employees are not going to adopt new behavior when it is apparent that incentives and rewards do not match administrative directives. If technology transfer does not factor into performance reviews, promotions or funding allocations, this leads to cultural barriers in the federal system, from top management to bench scientists. A number of universities have successfully reversed this culture by incorporating technology transfer activities as a factor for gaining tenure and promotion, and bringing on new hires.  Suggested Improvement 6: Remove barriers for universities to work with industry. Amend current tax law to allow for increased public‐private use of bond financed facilities. For example: H.R. 1819 of the 114th Congress would amend the Internal Revenue Code to create more flexible standards under which public‐private research activities at tax‐exempt bond financed research facilities can occur.  Suggested Improvement 7: Remove uncertainty of title under the Bayh‐Dole Act. The new final rule updating the Bayh‐Dole regulations went into effect on May 14, 2018. A contractor must (i) disclose a subject invention to the Government within two months after the inventor discloses it to the contractor's personnel responsible for patent matters, and (ii) elect to retain title within two years after disclosure of the invention to the Government. Under the prior regulations, if the contractor failed to comply with either of these obligations, the agencies could request title within 60 days after learning of the contractor's action or forgo the election. A recent amendment to the regulations at 37 CFR 401.14 (d)(1) removes the time limitation which creates a perpetual cloud on the title or other inadvertent transfers of title which will have a chilling effect that is inconsistent with efforts to commercialize federally funded technologies.  Suggested Improvement 8: Create a collaborative R&D tax credit to encourage increased industry‐university collaboration. To facilitate increased collaborative efforts between universities and industry, language in the basic research tax credit which narrowly defines basic research projects as “not having a specific commercial objective” should be broadened. At a minimum, Congress should delete such language from current law and allow any research expenditures at universities to qualify for the basic research credit. Additionally, industry should receive an additional tax incentive to conduct collaborative research with universities and federal laboratories. This could easily be done by doubling the existing credit from a 20% flat credit to a 40% flat tax credit. |

## Thank you for your time and participation.