



July 30, 2018

Dr. Philip Singerman
Associate Director for Innovation and Industry Services
National Institute of Standards and Technology
U.S. Department of Commerce
100 Bureau Drive
Gaithersburg, MD 20899

Dear Dr. Singerman,

Washington University established its official technology transfer office in 1984. In that time, the office has executed over 260 exclusive license agreements, has created 63 startups licensing university intellectual property, and has had issued almost 1,000 US patents. Our model is one of a customer service operation, supported by the university and focused on deal flow to place technology in the hands of capable industry partners for development.

Washington University appreciates the opportunity to respond to NIST's request for information (RFI) around Federal Technology Transfer Authorities and Processes Docket Number 18022019-819-01 ("NIST RFI"). The University supports the thoughtful and detailed comments submitted by the Association of American Universities (AAU), Association of Public and Land-Grant Universities (APLU), Council on Government Relations (COGR), and the Association of American Medical Colleges (AAMC). This response highlights several points raised by our associations, including AUTM, and provides additional thoughts regarding the questions posed by the NIST RFI.

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

Washington University believes, like many others, that the Bayh-Dole act was revolutionary legislation, which should be protected and strengthened as proposed by AAU et al.

Additionally, Washington University agrees with the concerns expressed by others surrounding the measurement of "Return on Investment." Over the past 5 years, revenue from our technology transfer operations has been driven largely by a partnership of a drug with hopeful indications in Alzheimer's disease and other tauopathies. Prior to that, unique Washington University antibodies seminal to detecting cardiac biomarkers such as troponin, myoglobin, and creatine kinase – which are all readouts for patients presenting heart attack symptoms in the emergency room – drove revenue to the university.

It would be very easy for Washington University to focus on large revenue-driving technologies, but it would be a misrepresentation of the government funding that has been used to support research that has given rise to technologies having important and meaningful translational impact though driving less revenue through technology transfer. Examples of

such Washington University technologies include a drug that enables patients undergoing fertility treatment to receive the treatment once a week rather than daily. Or, the clinical dementia rating (CDR) scale created in our Alzheimer's disease group is used by virtually every clinician who needs to classify dementia associated diseases and by companies in the Alzheimer's space seeking to enroll or assess patients in clinical trials. While these technologies may never generate the revenue of a blockbuster drug, each, nonetheless, has had a substantial impact on the lives of the afflicted patients.

Another recent initiative at Washington University that has had a meaningful, but non-financial, impact is the Quick-Start license. The Quick-Start license, which was established in early 2015, enables faculty members to spin out intellectual property from the university with a hassle-free negotiation process and favorable terms for raising investor funding. The University generates less income from these quick-start licenses relative to what could be realized by partnering with a large existing company as there is no income until sales are achieved by the startup. But, this program has been massively successful in encouraging the entrepreneurial activity throughout the university. In the past three years, the university has spun out 25 companies, which represents 40% of the startup companies launched since the inception of Washington University's technology transfer office in 1984.

To reduce the measurement of R&D investment impact to a financial calculation would fail to consider many of these significant contributions. For this reason, Washington University supports the belief shared by AUTM that "success should not be measured primarily by revenue, but by contributions to broader economic prosperity and societal impact." Consideration should be given to how these types of qualitative variables might be measured.

Question 2: 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.

Although technology transfer has been around for multiple decades, those in the field continue to collectively refine best practices, which have led to an openness and collegiality across the industry. Thus, the systemic challenges that face technology transfer professionals are consistently discussed in an effort to find impact-based solutions that are transferrable across the industry. Some of the issues identified by this collective include the following:

- educating faculty to be technology transfer ambassadors of their own work;
- enabling all university populations to engage with the university tech transfer office; and
- creating an environment that facilitates university-industry partnerships.

Additional issues effectively discussed by the collective are outlined in other responses to this NIST RFI. These issues present challenges to university technology transfer offices and place a serious and seemingly unnecessary administrative burden on the office. These issues include:

- the obligations and inconsistent reporting requirements to various government agencies;

- confusion and bureaucratic pressures in the patent system such as patent eligible subject matter under 35 USC 101 and patent challenge proceedings through the Patent Trial and Appeal Board; and
- concern by industry partners around government march-in rights.

Question 3: 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.

Education of Faculty to be Technology Transfer Ambassadors

Programs outside of the academic institution exist to educate faculty members around commercialization of academic research. Many of these programs are detailed in the AAU and AUTM responses and include the NSF and NIH i-Corps programs. These programs elevate the research done at institutes by educating individuals on how to translate laboratory research to a commercialized product. By expanding programs like these, universities will see an increasing amount of research that has commercialization potential.

Many universities, like Washington University, have a translational research fund. These funds are used primarily to enable researchers with attractive nascent stage technology to perform critical studies under the guise of “translation” in order to attract an industry partner. Unfortunately, in order to cross the “valley of death” and bridge most promising technologies, significant funding is required in order to de-risk the nascent stage technology to a point where a partner entity will enter a license. Our university has injected an educational component in order to access this funding. Applicants must meet with university experts on commercialization and patenting. These meetings that lead up to a competition for funding enable the applicant to think about his/her technology in the context of a future product and be able to communicate commercially-minded gaps associated with de-risking the technology.

Unfortunately, not all universities have commercialization experts at their university to lend to the educational process. Moreover, large universities, like Washington University, do not have experts that cover areas in which the university receives invention disclosures, leaving gaps in who can benefit most from educational programming that does exist. Therefore, all universities could benefit from aggregated best practices and industry-specific training around educating faculty and other innovators to invoke a product development mindset in their research. Additionally, perhaps content can be developed to help universities train and educate faculty and other innovators to better understand what it takes to move from academic research to a commercial product and how to apply this knowledge with the right set of translational studies.

Enabling all University Populations to Engage with the Tech Transfer Office

Unfortunately, many of the current efforts to guide faculty in becoming more aware of product development aspects engages only those that already self-identify as part of the “technology transfer system.” There are populations of researchers who have yet to see themselves, for various reasons, as inventors. These populations are often underrepresented minorities and

women with differential barriers that impede their participation in standard offerings. Therefore, it is incumbent upon institutions and government agencies to develop effective strategies that engage all faculty researchers in technology transfer.

To this end, Washington University instituted a first of its kind women's innovator program, entitled Women in Innovation and Technology (WIT), in order to lower the barriers of engagement by our female faculty population. WIT's design intentionally provides the language of product development and commercialization of academic research to participants and facilitates the development of networks between WIT participants and those in the innovation ecosystem. Since the inception of WIT, representation of females on invention disclosures has grown from around 30% to 49% in a 5 year period. Moreover, the Office of Technology Management has filed 129% more patents on behalf of female faculty members in 3 years after WIT programming than it had in the 3 preceding years. These statistics of engagement suggest that non-standard populations of inventors can be stimulated to engage in technology transfer.

The NSF's ADVANCE and AWARE grants have had success in engaging underrepresented minorities, but more can be done. An understanding of the obstacles that prevent these populations from engaging in technology transfer must be understood by every technology transfer professional and university leadership, and strategies to overcome the barriers must be easy to implement at universities. The AUTM response suggests creating "reward and incentive programs to encourage individuals to participate in commercialization". Washington University agrees with this suggestion and feels that there would be additional value around understanding how these incentives might be applied to underrepresented populations of innovators.

Creating Environments that facilitate university-industry engagement

Another factor contributing to the increased entrepreneurial activity at Washington University is the university's gap fund program. Through this program, many would-be entrepreneurs are exposed to "friendly fire" of investors and industry executives who judge the competition while simultaneously exposing faculty to think like a CEO or CSO of a startup rather than an academician. The gap fund also engages commercialization experts throughout the preparation process so that faculty have given a good amount of thought to concepts other than science, such as market adoption and need.

Many institutions have gap funds, like Washington University's, that attempt to bridge the valley of death between the nascent stage of academic research and the stage of development desired by a typical industry partner. The government also has programs through SBIR and STTR grants, and local organizations (such as BioSTL in the St. Louis region) that educate faculty around small business grants in the hopes of more successful applications from university startup companies.

The success of the programs can be strengthened through increased government support. This suggestion was also recommended by AAU which suggests that Federal agencies provide

support for activities such as executive-in-residence' programs, "venture exchange" programs, and boot camps / virtual proof-of-concept accelerators.

Inconsistent Reporting Requirements to Various Government Agencies

Washington University supports AUTM's statement that "a uniform, simplified invention reporting system utilizing current information technology standards across all federal agencies should be implemented in place of the current system." When reporting requirements were recently modified, it became necessary for Washington University to redeploy budget dollars from a position focused on patenting and licensing to one focused on reporting requirements. This decision has been common in recent years at larger institutions. A simplified reporting system and reporting requirements would enable academic institutions to shift these dollars back to those positions that drive innovation.

Bureaucratic Pressures in the Patent System

Washington University supports the recommendation made by the AAU which encourages "NIST and Congress to consider a number of recent proposals made by the American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association (IPO), and the American Bar Association (ABA) Section of Intellectual Property Law, to replace existing Section 101 with alternative language that we believe would help to reform Section 101."

Sincerely,

A handwritten signature in cursive script, reading "Dedric A. Carter".

Dedric Carter, PhD, MBA
Vice Chancellor for Operations and Technology Transfer
Professor of Engineering Practice