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Dr. Courtney Silverthorn
Deputy Director of the Technology Partnerships Office
National Institute of Standards and Technology
100 Bureau Drive, MS 2201
Gaithersburg, MD 20899

RFI response: Federal Technology Transfer Authorities and Processes

Dear Dr. Silverthorn:

I write on behalf of Yale University in response to the NIST Request for Information (RFI) concerning Federal Technology Transfer Authorities and Processes (Docket No. 180220199-819-01). We applaud this timely and important review of best practices and regulatory obstacles as part of the Administration's effort to support and encourage the transfer of federally-sponsored research into the commercial sector, where discoveries are developed into new products and services for the American public. We appreciate this opportunity to share our experiences.

Yale endorses the more extensive comments and recommendations submitted by the Association of American Universities (AAU), the Association of Public & Land-grant Universities (APLU), the Association of American Medical Colleges (AAMC), the Council on Government Relations (COGR), and the American Council on Education (ACE) as well as those submitted by the Association of University Technology Managers (AUTM), and specifically those relating to the critical importance of the Bayh-Dole Act in fostering innovation, the restrictions on the public-private use of facilities financed by tax-exempt bonds, and the need for clarification surrounding the interpretation and the use of march-in rights under Bayh-Dole. In addition, we want to underscore several priorities for Yale that were mentioned in the two comment letters, including the conflict of interest requirements, the lack of support for technology transfer, and the need for tort immunity for assignee-licensors of federal inventions.

As part of our mission to create, preserve, and disseminate knowledge, Yale University, working through a revitalized Office of Cooperative Research (OCR), made a conscious decision in the 1990s to change the academic culture around technology transfer. Instead of continuing a more passive approach toward applicable research, which focused on patents and licensing of technology, the University decided to focus on the transfer of inventions and discoveries flowing from faculty research for the benefit of society and, in so doing, help drive innovation and economic growth in Connecticut and for the Nation.

As a result, in 2017, OCR supported the launch of 11 new faculty ventures, with \$70.9 million in aggregate funding, as well as five new student ventures through the Yale Entrepreneurial Institute. In addition, Yale faculty disclosed more than 200 inventions, with more than 1,350 active patents worldwide. By way of comparison, Yale averaged two or three invention disclosures per year before 1982. As you look to identify best practices in the academic setting and apply these learnings to federal agencies and national laboratories, we would emphasize the need for resources because technology transfer is largely outside the scope of conventional research awards funded by NIH, NSF, and other agencies.

Conflict of Interest

Yale is committed to ensuring that research and other activities of our faculty are conducted in accordance with the principles of openness, trust and free inquiry that are fundamental to the autonomy of the University and the responsible stewardship of the public trust. As we pursue the dual goals of the creation of new knowledge and the transfer of that knowledge into the commercial marketplace, we are cognizant that conflicts, financial and other, will need to be identified and managed to reduce or eliminate any real or perceived bias. That said, the Department of Health and Human Services' 2011 revisions to regulations on individual conflicts of interest, and the 2016 changes as part of the Uniform Guidance, established more stringent and prescriptive standards and thresholds for conflict of interest disclosure, assessment and management. They also created new training requirements about policy and procedure. As noted by the Associations, an item of particular concern is the new reporting threshold of \$5,000, lowered from \$10,000, with little empirical basis for the change.

Licensing transactions have the potential to create possible conflicts of interest, especially those involving start-up companies with which the university and the faculty inventor have a continuing relationship. For an example in the procurement context, under the Uniform Guidance, a faculty-employee is prohibited from participating in a purchase or the administration of a contract, if s/he has a conflict of interest. Yet, that same faculty-employee may be a principal investigator in a university lab that receives federal support who is working on a research project with recurring commercial applications. If that faculty-employee works with the university to spin-off a new startup, then his or her lab would be barred from purchasing the resulting product or service, creating a disincentive for that faculty-employee to undertake the hard work necessary to create the startup in the first place.

Although the core concepts behind conflict of interest regulations and policies are important, some of 2011 changes and other provisions impose significant costs on universities, discourage faculty-employees from pursuing the commercialization of inventions, and do not materially improve efforts to ensure objectivity in research. Following the completion of the Congressionally-mandated review of conflict of interest regulations and policies, it is our hope that a thoughtful, uniform regulatory framework will do more to balance our shared interest in the rigorous protection of research integrity and human safety with the federal government's interest in the commercialization of federally-sponsored research.

Support for Technology Transfer

As noted in the Associations' letters, a significant obstacle to the development of early stage university discoveries is a lack of funding for the proof-of-concept and the validation studies that are necessary to demonstrate commercial appeal. In an effort to bridge the so-called "valley of death" and advance technology to a point where it can attract additional support from industry and/or achieve technology transfer, Yale has been fortunate to have the generous support of the Blavatnik Family Foundation, which provides vital resources to help faculty in the life sciences accelerate the development of early stage discoveries into medical or commercial applications, either through licenses to existing biopharmaceutical companies and start-up firms or major industry-sponsored research agreements. Key to the current and future success of the Blavatnik Fund is an external Advisory Committee, composed of industry leaders, that assesses proposals based on unmet need, indication of commercial interest, and the involvement of an engaged, committed faculty member, and the practice of reinvesting a portion of the earned revenues, ensuring that the Fund will be evergreen.

Unfortunately, not all research universities have access to private philanthropy focused on commercialization efforts, and the Blavatnik Fund continues to receive many more high-quality proposals from Yale faculty than it can support in a year. For those reasons, we endorse the Associations' recommendation for direct federal investment in universities or for regional not-for-profits to help bridge the innovation gap. In addition, we believe the federal government should do more to encourage and disseminate best practices of existing accelerator programs at universities where technology transfer is a priority. As one example, the Academic Venture Exchange (AVX) may serve as a model for other colleges and universities who are looking to find specific investors to develop their discoveries. As part of AVX, Yale, MIT, Harvard, Penn and others have entered into use agreements that would allow this platform to create the best match between specific discoveries and interested entrepreneurs. For example, Yale might have a relationship with a proven pharmaceutical CEO but no drug ready for commercialization. In that case, we would connect the CEO with another AVX institution to enable them to obtain the funding and support necessary to bring their market-ready drug to the public.

Tort Immunity

As correctly noted in the RFI, negotiations over indemnification are a significant impediment, and they are a frequently negotiated provision in university commercialization agreements. Although the university has conducted the research and created the technology, we have a limited role in its final commercialization and dissemination. Since the University cannot predict or control how the technology will be manufactured and marketed, we are unable to obtain private insurance in the way that industry might. Therefore, to protect the University from any risk in end-product decisions that could lead to the harm of innocent parties, we insist on being indemnified to eliminate our exposure to liability. This can slow negotiations and, if the issue is left unresolved, put a final agreement at risk.

To address this concern, we would recommend the creation of a liability safe harbor such that the University could not be sued for the end product. In other words, there would be no plaintiff reach-through to the University if we did nothing more than issue a patent license. Although a reach-through is not specifically granted, the law is unclear and this lack of certainty leads to defensive negotiations. With a safe harbor, the University could drop our indemnification negotiations and focus on resolving larger issues.

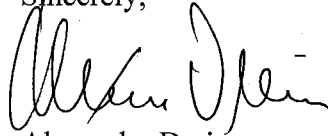
In addition to the priorities listed above, we support the following reforms:

- **Patent Trial and Appeals Board Proceedings.** Although Yale supported Inter Partes Review as a means of streamlining patent adjudications, its implementation has disadvantaged patent holders and created uncertainty for university licensees, both of which are discouraging investments in university discoveries. To restore patent certainty and the status of patent rights, we strongly support the Associations' recommended modifications to the PTAB and IPR proceedings, including a harmonized claim construction standard for the federal courts and the International Trade Commission, a consistent burden-of-proof standard in IPR proceedings and district courts, and the restoration of the right of patent holders to sue for damages if their patents are subject to reexamination on the basis of false evidence or other abuse, harmed by fraud on the court, or abuse of process.
- **New Bayh Dole Implementing Regulations.** Under the prior regulations, if a contractor had failed to meet his/her obligations, either to disclose the invention to the government or to elect to retain title, the government could request title within 60 days or forgo the election. The 2018 implementing regulations removed the time limitation for the government. We share the Associations' concern about this change. To avoid inadvertent transfers of title, or a cloud on the title of a late disclosed patent, the previous time limit should be restored.
- **Broader Framework for Successful Technology Transfer.** In the past, the government has attempted to determine the return on investment from federally sponsored university research by focusing on the number of patents, licenses, and

revenues instead of the full range of university contributions to local, regional, and national economies. At the same time, too many university technology transfer offices are focused on generating licensing revenue for the university instead of facilitating innovation for societal impact. To guard against this narrow construction, we urge you to think broadly of the many returns on the federal investment, including the education and training of students, faculty consulting, the generation of new knowledge, and the open publication of research results, all of which support the efforts of industry and government in the development of a robust national economy.

We greatly appreciate the efforts of NIST to improve technology transfer at universities and national laboratories, and we welcome future opportunities to comment as NIST considers new programs and initiatives to support universities and national laboratories in their endeavors to achieve broad societal and economic benefits.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alexander Dreier', written in a cursive style.

Alexander Dreier
Senior Vice President for Institutional
Affairs and General Counsel