Indiana University is pleased to submit this response to the National Institute of Standards and Technology (NIST) Request for Information (RFI) concerning federal technology transfer policies.

Indiana University, the State of Indiana’s oldest public university, enrolls more than 100,000 students each year at its flagship campus, located in Bloomington, and at six other campuses throughout the state. The IU School of Medicine, the only research-intensive medical school in the state, is housed on IU’s Indianapolis campus.

IU is a long-time leader in technology transfer activities and has contributed to the disclosure of more than 2,900 inventions by IU researchers over the last 20 years. Additionally, IU’s support has led to the filing of more than 4,300 global patent applications and the issuing of nearly 1,100 global patents over the last two decades. IU’s tech transfer activities are carried out by the Innovation and Commercialization Office, which is located within the Office of the Vice President for Research.

Since 1986, federal funding at IU has resulted in more than 1,500 inventions, 1,800 patent applications, and 250 license agreements. Moreover, IU has launched 42 startup companies from federally funded research. Licensing highlights include advances in time of flight mass spectrometry, ion mobility spectrometry, metrics for optimizing clinical optical prescriptions, gene therapy, and therapeutics for prostate cancer and Hepatitis B.

Indiana University is a member of the Association of American Universities (AAU), the Association of Public and Land Grant Universities (APLU), the Council on Government Relations (COGR), and the Association of American Medical Colleges (AAMC). These associations have jointly prepared a response to the RFI that is attached to this submission. IU strongly endorses the recommendations and concerns that are outlined in this document, noting that we encounter the same impediments in our efforts to deliver IU technologies to the marketplace. We highlight particular aspects of our own experience below that reinforce the recommendations.

*New Bayh-Dole Implementing Regulations*

*60-day time period for funding agencies to request title upon learning of a contractor’s failure to disclose an invention or elect title*: This should be reinstated. At IU, we had a recent occurrence in which an inventor initially disclosed an invention that had not been federally funded and a provisional was filed. The inventor subsequently received a federal grant funding additional work that was incorporated into a non-provisional filing. Federal funding was not identified at the time of the non-provisional filing. The omission was corrected. However, the work has significant commercial potential that could have been hindered if there was no time limit for the agency to request title, since potential licensees would have incurred additional risk.

*Required notification period for contractor decisions not to continue non-provisional patent prosecution*: The notice period should be kept at 30 days. Technology transfer practice is to attempt to find an industry partner to support patent costs prior to filing a non-provisional. The 60-day notification period will significantly shorten the time available for identifying a commercial partner and may result in premature abandonment of the provisional patent application.

*New requirement for a contractor to file a non-provisional patent application 10 months after filing a provisional application*: This requirement will potentially shorten the time available for identifying a commercial partner and may result in premature abandonment of the provisional patent application and, thus, failure to realize the potential of the technology.

*Lack of Funding to Support University Technology Transfer*

Lack of gap funding is a significant barrier to technology commercialization. The i-Corps, SBIR, and STTR programs provide significant support and incentives for technology commercialization by startup companies. However, there is still a lack of funding available for the necessary proof-of-concept required after initial discoveries are made. Federal funding for proof-of-concept studies will provide a significant stimulus to technology commercialization. Industry-funded research represents another potential source of proof-of-concept funding; the government needs to create a climate in which industry is more likely to provide such support. The R&D tax credit should be expanded. Moreover, the federal government should consider providing matching grants for industry-sponsored research to stimulate industry-university research collaboration and translational research.

*Patent Costs*

Lack of funding for patent expenses is a major barrier to technology commercialization. Startup companies typically have limited amounts of cash and are unable to support patent costs.

*Patentability for Software and Biotech*

*Clarity over the interpretation of 37 U.S.C. §101*: We are currently incurring delays and additional expenses in prosecution of biotechnology and software patent applications as a result of lack of clarity in subject matter eligibility under 37 U.S.C. §101. Moreover, investors are reluctant to invest in diagnostic and software-based technologies due to the perception that it will be difficult to obtain patent protection. This makes it challenging for startup companies to secure funding.