To: Office of Science and Technology Policy (BIOECONOMY@OSTP.GOV)

From: Teri Willey, Vice President for Technology and Business Development, Mount Sinai Medical Center, New York, NY

DATE: December 5, 2011

RE: Request for Information: Building A 21st Century Bioeconomy

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Thank you for soliciting feedback on this important issue. Below are my recommendations.

Encourage distribution of academic research results for the benefit of the public.

An extremely efficient means of translating basic research discoveries into commercially useful products can be achieved by directly combining the talents of academia and industry through alliances and partnerships. By working closely together through the entire continuum of R&D activities, from idea conception through market launch, such partnerships often provide the best hope of realizing real world benefit from strong academic research. Though many academic institutions have shied away from forming direct R&D alliances with industry out of concern that they would taint the integrity of academic research, more and more institutions are discovering that it is possible to maintain both a high level of academic integrity and productive R&D relationship through carefully crafted partnership and alliance relationships with industry. Indeed, Mount Sinai School of Medicine has embraced this as in integral part of their strategy to assure that the results of research and scholarly activities reach patients to address unmet needs. The federal government can play a critical role in solidifying and encouraging these critical activities, by providing direct support to institutions that embrace the alliance approach. While there are numerous ways in which government can help, there are two in particular for consideration:

1) **Increase the Private Use Exemption.** It would be extremely helpful if the federal government could provide greater clarity and flexibility with regard to the conditions governing research in buildings financed with tax free bonds. One of the major constraints on academic-industry collaborations are the restrictions placed on private use of tax exempt bond financed space, which often come into direct conflict with the goal of increasing such interactions. If industrial partnerships are to increase and flourish in the way envisaged by both the government and many academic institutions, the current allowance of 5% permitted use of said space (the safe harbor) will be an insurmountable obstacle to any appreciable expansion. We would recommend that the government give consideration to an increase in the safe harbor to 25% or above. This will have the double advantage of not only encouraging university-industry collaboration, but would be

a measure that can be taken at zero impact to the government's finances. Moreover, as long as a reasonable - but not excessively low - restriction remains, the government is still guarding against universities becoming out and out "for profit" entities. A real level of control can still being exerted without stifling necessary university - industry cooperation.

2) **Clarification re the America Invents Act.** Patent reform has been on the horizon for several years and has recently come to fruition, at least in part, through the Leahy-Smith America Invents Act (AIA) which was signed into law on Sept. 16, 2011. The Act makes sweeping changes to U.S. patent law and practice, including moving the United States towards a first-to-file system, redefining what constitutes prior art, expanding prior user rights as a defense to infringement, adding new options for challenging patents, revamping administrative proceedings at the USPTO, and modifying the USPTO fee structure. Because patent protection of certain academic research results is critical to creating an incentive to invest in the long term development of new therapies, it is important to understand how these changes in law will impact the ability of academic institutions to advance ideas which require intellectual property management and partnership with industry. Any changes in the law which cast uncertainly of the value of inventions may inhibit investment in early stage ideas. For example, with respect to question 8 in the RFI *what are the challenges associated with existing private-sector models for financing entrepreneurial bioeconomy firms?*, the new post-grant review procedure under the AIA allows anyone to assert that a patent should not have issued for an invention for any reason. The challenge does not need to be based on a prior patent or a prior publication. With the ambiguity of this new provision, will a company invest in a very new technology if the patent that issues for it can be challenged on ethical/quasi-legal grounds? Clarification of these provisions is needed as is their possible impact on financing bio innovation.