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Association of Independent Research Institutes (AIRI) Response to RFI on National Bioeconomy Blueprint

The Association of Independent Research Institutes (AIRI) welcomes the opportunity to provide input on the President's National Bioeconomy Blueprint. The Blueprint recognizes that biological research is an important economic driver, and we applaud the White House Office of Science and Technology Policy (OSTP) for seeking feedback from the research community to maximize the nation's federal research investment. AIRI is a national association of more than 80 independent, not-for-profit research institutes whose primary mission is research. Our relatively small size and greater flexibility provide an environment that is particularly conducive to scientific creativity and innovation. Independent research institutes receive 10 percent of the National Institutes of Health (NIH) peer-reviewed, competitively-awarded extramural grants. On average, AIRI members receive over 10 percent of their funding from the National Science Foundation (NSF) and nearly half of AIRI member institutes receive Department of Defense (DOD) funding.

Independent research institutes often partner closely with neighboring universities and complement their research by targeting specific disease or conditions. In some parts of the country, AIRI member institutes are primary contributors to local and regional economies through job creation and investment in innovation and discovery. It is important to note there is not just one bioeconomy, but rather many layers from international trade and commercialization, to regional efforts and the local research institution. AIRI members have leveraged their roles in the bioeconomy by developing strong partnerships with industry and the federal government to help translate basic research discoveries into applications that improve health and health care.

Grand Challenges

Addressing grand challenges requires an interdisciplinary approach that includes the work of individual researchers, as well as the collaborative approaches of large multidisciplinary centers. Members of AIRI are some of the top recipients of center grants and awards that encourage interdisciplinary collaborations. Independent research institutes operate important centers and core facilities that are supported by NIH center awards and provide essential scientific services to researchers across the country. These centers are research hubs that provide efficient services and enable essential research across many disciplines.

To tackle the biggest research challenges in health, the federal government should develop initiatives that encourage the coordination of existing research among universities, industry and non-profits. These "bioeconomy consortia" could maximize the impact of federally-funded research in specific priority areas set by the Administration. AIRI member institutes have considerable experience working closely with universities and industry, and have found these partnerships essential to moving cutting-edge research into the marketplace.

Research and Development

Traditional life sciences and basic research are central to the nation's bioeconomy and consequently should be predominately featured in the National Bioeconomy Blueprint. As noted earlier, federal funding priorities should include supporting truly interdisciplinary projects. As we enter an era of large-scale projects and multi-disciplinary research, there is a need to ensure that high-risk, high-reward ideas are also supported. However, make these advances possible, continued strong support for basic research is vital as it provides the necessary foundation.

During times of budget constraints, cuts are inevitable, but intermittent funding is particularly destabilizing for science as it is a constantly evolving cycle that depends on previous discoveries, as well as failures. Also, stable and sustained funding for research helps generate the talent base for the researchers of the future. A continued federal investment signals to young scientists the inherent value of their work and helps independent research institutes retain talented investigators.

Moving Life Sciences Breakthroughs from Lab to Market

For specific examples of AIRI member institutes bringing research discoveries into clinical practice and the marketplace, see the attached compilation of AIRI translational research success stories. These are stories of research conducted by independent research institutes and the resulting drug, therapy, diagnostic company or prevention method, as well as the impact on health and health care. Many of these examples highlight companies and other research collaborators, as well as the federal funding that enabled the translational research.

AIRI member institutes would like to be more competitive in the Small Business Innovation Research (SBIR) program, but due to their small size and faculty pool, some of our member institutes find it difficult to meet requirements. More flexibility in the SBIR program for proof-of-concept funding or pre-incorporation activities would allow AIRI members to engage more fully in this activity and bring to the program our considerable experience in working with start-up and small biotech companies. Additionally, allowing Small Business Technology Transfer (STTR) program funds to be used for proof-of-concept programs would replicate success of organizations and approaches such as the Coulter Foundation, in which individual and institutional funding are subject to rigorous evaluation by panels of local experts in translational and proof-of-concept research. These programs have the potential to help move discoveries more effectively and efficiently into the marketplace. More attention to the need for early-stage, proof-of-concept research would certainly improve their success.

Regulatory Barriers

It is essential the Administration continue its efforts to ensure government regulation does not stifle innovation, particularly in the realm of encouraging public-private partnerships. AIRI appreciates that the recently finalized NIH conflicts of interest rule does not impose burdens and requirements that could have had a negative effect on collaborative relationships between universities and industry. As federal agencies continue efforts to regulate potential conflicts of interest, care must be taken to not inadvertently discourage appropriate interactions among research faculty, institutions, and industry. While conflicts of interest must be closely monitored, an emphasis on elimination, rather than management, could produce a chilling effect on research institutions' ability to develop important partnerships and on the Administration's efforts to increase commercialization.

As noted by NIH Director Francis Collins, there are significant layers of reporting and burden that can impede research by consuming valuable and limited resources. For example, effort reporting requires additional personnel and forces scientists to spend many hours accounting for their time, rather than

conducting research. The data and information developed by effort reporting is of very little value to the federal government and certainly does not advance scientific research. Additionally, with so many federal funding opportunities requiring collaboration between multiple partners, sub-recipient regulations must be streamlined to reduce burdens and time spent on paperwork.

Finally, it is imperative that the federal government take specific steps to improve the predictability and transparency of the regulatory system, including assuring that research cost policy rules are applied fairly and consistently across the country. For AIRI member institutes, the disparities in how the Office of Management and Budget (OMB) Circular A-122 principles are applied by the Department of Health and Human Services (HHS) Division of Cost Allocation (DCA) field offices causes significant confusion and disadvantages some institutions for no apparent reason. We continue to work with DCA regional offices on this issue and hope the Administration encourages transparency in this area.

Conclusion

AIRI appreciates the opportunity to contribute ideas to the National Bioeconomy Blueprint. Our institutions' research-focused mission and relative small size position us as strong partners with industry, universities, and the federal government. We play prominent roles in the nation's biomedical and behavioral research enterprise and are proud to make vital contributions to fields including cancer and AIDS research, aging, genomics, neuroscience, and public health awareness. For additional information, please contact Erica Froyd in the AIRI Washington Office at [REDACTED]