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Date: July 22, 2024

Re: Comments on Notice of Draft NIH Intramural Research Program Policy: Promoting  
Equity Through Access Planning

The Association of American Universities (AAU) and the Association of Public and Land-grant Universities (APLU) appreciate the opportunity to share input on this proposed new policy within the Intramural Research Program (IRP) to promote access to products stemming from taxpayer-funded inventions. AAU is an organization of 69 leading U.S. research universities that transform lives through education, research, and innovation. APLU is a membership organization of nearly 250 universities across the nation that fosters a community of university leaders collectively working to advance the mission of public research universities.

In addition to providing these written comments today, AAU and APLU share concerns and echo the sentiments submitted to this solicitation by AUTM and [the Bayh-Dole Coalition](#).

AAU and APLU respect NIH's autonomy over regulating its own intramural R&D. However, we are deeply concerned about the precedent the proposed terms will set for external R&D. It is reasonable to assume that, if these guidelines are adopted, they will ultimately be applied to those receiving NIH extramural funding, which will have detrimental impacts to the research conducted by our university memberships and the wider innovation ecosystem. We strongly urge against the application and implementation of a similar policy to NIH's extramural program.



Furthermore, AAU and APLU are concerned that this draft policy will be mandated for all NIH intramural licensees without evidence that there are overriding concerns with patient access to the products of NIH intramural research. While NIH has repeatedly examined and performed research as to the economic impact of NIH-generated technologies and the IRP, research has not demonstrated a lack of access which would necessitate the imposition of the draft policy across the NIH intramural research enterprise. While patient access is understandably a guiding principle for NIH, it is unclear (a) what gaps in access are currently present; (b) what categories of licensees demonstrate the best or worst patient access metrics; and (c) by what metrics overall that patient access will be measured by across the NIH intramural research enterprise. We believe that, for this draft policy to be most effective in having a demonstrable impact on both short- and long-term patient access, such identifiable gaps should be examined and should inform the evaluation of access plans.

## Conclusion

AAU and APLU appreciate the opportunity to provide feedback on promoting greater equitable access to the products of NIH intramural for patients. Considering stakeholder feedback offered during the RFI process will help inform and further develop proposed policies to ensure that such policies do not have unintended consequences or negative impacts on the ability of the U.S. innovation ecosystem to continue to leverage and commercialize NIH-held intellectual property into the diagnostics, devices, and treatments of the future.

The U.S. must continue to build on its legacy of public-private partnerships in a way both promotes and incentivizes innovation, while not creating additional barriers to access. AAU and APLU look forward to future conversations and stakeholder engagement on discovery, innovation, and enhancing the health of the nation.