



July 22, 2024

Lawrence A. Tabak
Principal Deputy Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

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

Dear Deputy Director Tabak:

On behalf of COGR, I thank you for the opportunity to provide comments on the draft National Institutes of Health Intramural Research Program Policy “Promoting Equity Through Access Planning” that seeks to require that licensees of certain NIH technologies submit a plan outlining steps they intend to take to promote patient access to those products (“IRP Policy”). COGR is an association of over 200 public and private U.S. research universities and affiliated academic medical centers and research institutes. We focus on the impact of federal regulations, policies, and practices on the performance of research conducted at our member institutions, and we advocate for sound, efficient, and effective regulations that safeguard research and minimize administrative and cost burdens.

In addition to these written comments, COGR also concurs with the comments submitted by AUTM. AUTM is the non-profit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward.

First, and foremost, COGR shares NIH’s aspiration for wide access to innovations and products resulting from federally funded research. COGR and many of its member institutions are signatories to AUTM’s Nine Points to Consider in Licensing University Technology¹. Written in 2007, the guidance states as a core value the inclusion of licensing provisions, when appropriate, that address unmet needs of certain patient populations or geographic areas.

COGR appreciates the suggestions made and insights provided by the participants of the 2023 NIH workshop *Transforming Discoveries into Products: Maximizing NIH’s Levers to Catalyze Technology Transfer* that led to the IRP Policy.

We believe the IRP Policy, as proposed, may unintentionally hinder the ability of NIH to license patents covering the new technologies that start-up companies and others rely on to develop commercial products and services that benefit our nation’s health, security, and economy. The successful transfer of technology from a research laboratory to the commercial market is a lengthy and costly process. It often involves high development costs; risk of technological, regulatory, and market uncertainties; and high failure rates. Access plan requirements have been shown to make finding licensees willing to accept the additional conditions and associated risks more challenging.² Any policy should take into consideration the impact

¹ <https://autm.net/about-tech-transfer/principles-and-guidelines/nine-points-to-consider-when-licensing-university>

² [Frontiers | Implementation and impact of the global access principles at the University of British Columbia: current successes and future challenges \(frontiersin.org\)](#)

its implementation has on increasing risks to the successful commercialization of inventions resulting from NIH-funded research.

COGR appreciates NIH's recognition that the details of the commercialization process are situation-dependent and that licensing terms require different approaches based on specific technologies, patient populations, and market conditions. We also appreciate that NIH recognizes its policy needs to "be reasonable and not seek to force licensees into access obligations that obstruct commercial development or damage the viability and sustainability of a product in the market."

We are concerned about potential "gamesmanship." Given that access plans are to be publicly available, the IRP Policy may provide a roadmap for large companies and others to challenge and harass small companies, including Small Business Innovation Research (SBIR) firms, by requesting the termination or amendment of a license on the basis that a licensee failed to successfully execute an approved access plan. This could ultimately have a negative impact on not only the underserved community but on patient access as a whole.

COGR Response to RFI Elements

In addition to our overarching concerns regarding the impact of access plan requirements on licensing opportunities, COGR offers the following additional comments.

Promoting meaningful access approaches.

An IRP Policy focused on access that is broadly defined to include not only availability of a product, but also affordability, acceptability, and sustainability, should be considered and implemented carefully. Licensees are the experts in transforming early-stage research results into safe, effective products, and their efforts should be focused on creating new products and therapies. In lieu of requiring a licensee to submit an access plan, we recommend NIH modify its own licensing practices and provisions to ensure appropriate access, in lieu of requiring a licensee to submit an access plan. Prior to licensing, NIH could engage with patient advocacy groups and non-profit organizations to determine which patents and jurisdictions are suitable for exclusive licenses and, conversely, where only non-exclusive licenses should be offered. Technology transfer professionals could determine a public health patent pool strategy for the agency and additional standard provisions to include in exclusive license agreements to ensure an appropriate balance between commercialization and access goals is achieved.

Additionally, COGR supports AUTM's observation that NIH will improve the probability of success if the access plan requirement is paired with incentives for a company to invest in and commercialize NIH-owned patents. As AUTM notes, allowing a licensee to voluntarily provided an access plan in exchange for additional benefits "such as additional market exclusivity or other regulatory advantages"³ could facilitate a licensee's steps to address downstream access challenges.

Promoting transparency in biomedical research enterprise and return on investment.

The addition of cost accounting measures as a factor for NIH to consider in evaluating the access plan is problematic. First, it requires the licensee to provide business-sensitive information in a potentially publicly available document. Second, it adversely impacts the ability of NIH to identify a qualified licensee to successfully commercialize IRP inventions, as acknowledged in the GAO report published in 2020⁴.

³ AUTM comments submitted

⁴ GAO report "Biomedical Research NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property" October 2020, Accessible Version (<https://www.gao.gov/assets/720/710328.pdf>)

Finally, requirements to promote equitable access that include such provisions as “committing to keep prices in the U.S. equal to those in other developed countries” and “not raising costs above inflation” should be avoided. The addition of these factors for consideration introduces a significant amount of uncertainty and heightened risk to the incentives for private sector entities and their funders to license subject inventions for commercialization.

Establishing licensee obligations depending on the stage of technology development.

As noted by NIH itself, “as a product moves closer to market, the odds of successful commercialization improve.” It is overly burdensome on both the licensee and NIH to develop, review, and approve an access plan for technologies that are not yet at the point of a pivotal clinical trial (or similar benchmark). Prior to making the R&D investment required to bring a licensed product successfully to market, licensees and their investors require assurance that their rights under a license to practice the subject inventions are not vulnerable to being taken away late in the game by an unpredictable access plan review process.

We applaud the portion of the RFI that states an access plan will be required only at the time of the pivotal clinical trial stage of research and development. However, given the level of investment a licensee has put into R&D by this stage, it is critical that there be clarity about:

- what constitutes an acceptable access plan;
- the conditions under which waivers for such a plan may be obtained from NIH;
- the timeline of access plan review by NIH; and
- the consequences of an access plan being rejected by NIH, and recourse available to the licensee.

Conclusion

Any access policy that could potentially increase uncertainty in the commercialization process and unnecessarily hamper more products being introduced into the market should be carefully considered prior to implementation. If NIH is going to require access plans of its licensees, they should be reserved for later-stage, lower-risk opportunities in which the probability of successful commercialization is higher. There are equally effective steps that NIH can take with respect to its own licensing practices that can facilitate access to NIH-funded patents that would add neither uncertainty to the commercialization process nor additional compliance requirements to the licensee.

Sincerely,



Matt Owens
President