National Institutes of Health
Intramural Research Program (IRP)
Access Planning Policy

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CONTENTS

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Section I. Background & Purpose

As the world's largest public funder of biomedical research, NIH seeks to drive effective partnerships that foster a shared commitment to transforming knowledge into improved health for all. The agency's Intramural Research Program (IRP) Access Planning Policy is designed to further leverage NIH patent licenses to enhance health and expand patient access to emerging biomedical technologies.

Study after study has shown how NIH-funded and conducted research catalyzes the development of new products and services for disease prevention, diagnosis, and treatment.[1] Indeed, NIH has a decades-long history of licensing inventions made by government scientists in its Intramural Research Program (IRP)—inventions that have provided the foundation for new vaccines, drugs, and medical devices.[2] And partnerships are central to this success. NIH does not develop, distribute, or commercialize technologies itself; it relies on partners, including licensees, to turn inventions into new products and services that can directly impact people's lives. NIH also recognizes that all too often patients across the country and across the globe may be unable to access products they need—for example, a treatment for their disease may not yet exist, or it might exist but be out of reach because it is too expensive or difficult to administer.

With that in mind, under the NIH IRP Access Planning Policy ("IRP Access Planning Policy" or "Policy"), organizations applying to the NIH IRP for certain commercial patent licenses are required to submit Access Plans outlining steps they intend to take to promote patient access to licensed products. [3] Once approved by NIH, those Access Plans will be incorporated into licenses granted by NIH as part of the licensee's development plan.

NIH intends this Policy to be flexible, both to accommodate public health needs and to catalyze opportunities across a variety of emerging biomedical technologies. Each of NIH's patent licenses are unique and can potentially support the development of a broad range of drugs, biologics (including vaccines), and devices. A flexible Policy allows NIH and its licensees to pursue tailored strategies to expand the reach, and benefit, of products.

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[1] *See, e.g.*, *Impact of NIH Research: Improving Health*, NIH (Apr. 10, 2023), https://www.nih.gov/about-nih/what-we-do/impact-nih-research/improving-health (discussing selected examples).
[2] *See, e.g.*, *Public Health & Economic Impact Study*, NIH TECHNOLOGY TRANSFER (May 2023), https://www.techtransfer.nih.gov/reports/public-health-and-economic-impact-study.
[3] NIH's model patent licenses define "licensed products" as "tangible materials, which in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the Licensed Patent Rights that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction." *Model Exclusive Patent License Agreement*, NIH TECHNOLOGY TRANSFER, https://www.techtransfer.nih.gov/sites/default/files/NIH_Patent_License_Exclusive_model_102015_rev092024.pdf (last visited Dec. 30, 2024).

Flexibility is also warranted given the uncertainty associated with product development and patient access. Licensees may discover something new or unexpected in the R&D process, revealing compelling reasons to pivot in product development. NIH does not intend Access Plans to lock licensees into a single direction when there are other more promising paths to pursue.

NIH sought public input on development of this Policy, including strategies for developing appropriate Access Plans and for promoting access under the IRP Access Planning Policy (see *Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning*) that are described in the *Implementation Guidance*. NIH will continue to work with stakeholders and communities to develop additional materials as needed to promote effective implementation of the IRP Access Planning Policy.

Section II. Scope

Under the IRP Access Planning Policy, an organization applying to NIH for a commercial patent license is required to submit an Access Plan—as part of the plan required by 35 U.S.C. 209 and 37 CFR part 404.5—if the applicant is seeking a license that would authorize the commercialization of drugs, biologics (including vaccines), or devices for the prevention, diagnosis, or treatment of human disease. The Policy applies to commercial patent licenses (hereinafter referred to as licenses) granted by the NIH IRP, for patents wholly owned by the U.S. government, e.g., inventions made by investigators in the NIH IRP. The Policy applies to exclusive, co-exclusive, partially exclusive, and non-exclusive license applications and licenses.

The IRP Access Planning Policy does not apply to licenses and applications that are unrelated to the development of drugs, biologics (including vaccines), or devices. For example, NIH does not require Access Plans for license applications that are limited to the sale of reagents for research purposes only (with no clinical or therapeutic scope). The IRP Access Planning Policy also does not apply to patents owned by third parties (i.e., parties external to the U.S. government), and it does not apply to patents that are developed under NIH funding agreements and owned by NIH grantees or contractors.[4]

Section III. Phase-In

The IRP Access Planning Policy applies to license applications submitted to NIH on or after June 1, 2025.

[4] In most cases, NIH funding recipients can retain title to inventions that are conceived or first reduced to practice under a funding agreement. There are exceptions, for example, if the grantee or contractor decides it does not want to file for patents then NIH has the right to obtain title to those inventions. *See, e.g.*, *PHS Technology Transfer Policies and Procedures Manual Chapter No. 602*, NIH TECHNOLOGY TRANSFER (Sept. 20, 2012), https://www.techtransfer.nih.gov/sites/default/files/documents/policy/pdfs/602-policy.pdf. In those cases, if the U.S. government wholly owns a patent and licenses it, then the Access Planning Policy would still apply.

Section IV. Requirements

Organizations applying to NIH for licenses within the scope of this Policy are required to:

- Submit an Access Plan as part of their license application, for NIH review and approval;
- Commit to provide updates on progress and, as appropriate, reassess the approved Access Plan as product development progresses; and
- Submit a non-confidential version of their Access Plan within 3 months after FDA approval of the licensed product (or a foreign equivalent) that NIH may publish or otherwise make available to third parties.[5]

An Access Plan refers to a license applicant or licensee's strategy to support broad access to a licensed product for the U.S. population, and it can include, as applicable, strategies through the lens of promoting equity for underserved communities in the U.S. and for populations in low- and lower-middle-income countries, as defined using the World Bank classification system. Access plans shall include, but not be limited to: a brief description of the licensed product(s); the anticipated patient population(s); other products, tools, facilities, or unique resources that would be necessary for use of the product(s); and strategies to promote patient access across criteria of affordability, availability, acceptability, and sustainability, to the extent such access can be advanced on terms that are commercially reasonable.

NIH will not consider license applications that fall within the scope of the IRP Access Planning Policy unless those applications include an Access Plan. The agency will not grant licenses within the scope of the Policy without an NIH approved Access Plan. Once approved by NIH, these Access Plans will be incorporated into licenses granted by NIH as part of the licensee's development plan.

Section V. Waivers

NIH may waive the requirements of the IRP Access Planning Policy upon a showing by a licensee or license applicant that access planning, in whole or in part, would not be commercially feasible and would hinder the overall benefit of access to the licensed product. The agency anticipates waivers would be very rare and only appropriate in exceptional circumstances.

[5] For ease of reference, in this Policy, when "FDA approval" (and similar terms) are used in discussing drugs, biologics, or devices, the terms refer to FDA permitting the marketing of a product via approval, clearance, de novo classification, or authorization.