

**UNITED STATES PUBLIC HEALTH SERVICE  
TECHNOLOGY TRANSFER POLICY MANUAL**

**Chapter No. 314**

**NIH Intramural Research Program Access Planning Policy for Commercial Patent Licenses**

**A. PURPOSE**

This Manual Chapter describes the policy for access planning requirements for certain commercial licenses to patents wholly owned by the United States (US) Government, as represented by the Public Health Service (PHS), National Institutes of Health (NIH).

**B. BACKGROUND**

NIH seeks to drive effective partnerships that foster a shared commitment to transforming knowledge into improved health for all. To maximize public return on investment for federally conducted research and to expand patient access to emerging biomedical products, NIH issued the Intramural Research Program Access Planning Policy (IRP Access Planning Policy) on January 10, 2025 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-136.html>). Access planning refers to license applicants and licensees outlining steps they intend to take to promote patient access, as part of a plan for development or marketing as required by 35 U.S.C. § 209 and 37 CFR § 404.5 (hereinafter referred to as a development plan).

**C. POLICY**

Under the IRP Access Planning Policy, an organization applying to NIH for a patent license that would authorize commercialization of drugs, biologics (including vaccines), or devices for the prevention, diagnosis, or treatment of human disease, is required to submit an access plan as part of its license application. Once approved by NIH, access plans will be incorporated into the licenses granted by NIH as part of the licensee's development plan. The policy applies to commercial patent licenses (hereinafter referred to as "license(s)") granted by the NIH, for patents wholly owned by the U.S. government. The policy applies to exclusive, co-exclusive, partially exclusive, and non-exclusive license applications and licenses.

An access plan refers to a license applicant's or licensee's strategy to support broad access to a licensed product.

An organization applying to NIH for a license within the scope of this policy is required to:

- Submit an access plan as part of its 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 its access plan within three (3) months after FDA approval<sup>1</sup> of the licensed product (or approval by a foreign equivalent) that NIH may publish or otherwise make available to third parties.

---

<sup>1</sup> 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.

NIH will not grant licenses within the scope of this policy without an NIH-approved access plan. NIH may waive or modify the requirements of the IRP Access Planning Policy upon a showing by a license applicant or licensee 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.

Nothing in this chapter supplants existing criteria for NIH determinations regarding the issue of licenses. *See, e.g.*, Technology Transfer Policy Manual Chapters 300, 304, 305.

If a licensee does not comply with the terms of the license implementing this policy, NIH may take one or more enforcement actions depending on the severity or duration of noncompliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies.

Access plan requirements and evaluation criteria are described further in the NIH Guide (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-137.html>). Additional information about the IRP Access Planning Policy is available here (<https://www.techtransfer.nih.gov/policy/access-policy>).

**D. EFFECTIVE DATE**

The policy set forth in this Manual Chapter applies to license applications submitted to NIH on or after October 1, 2025.

**E. ADDITIONAL INFORMATION**

For additional information on this Manual Chapter, contact the NIH Office of Technology Transfer at [nihott@mail.nih.gov](mailto:nihott@mail.nih.gov).