NIH IRP Access Planning Policy: Implementation Guidance

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

These additional materials will assist license applicants and licensees as they work with NIH to fulfill the requirements of this NIH Intramural Research Program Access Planning Policy ("IRP Access Planning Policy" or "Policy").

Section A. Access Plans

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.

For the purpose of this Policy, the term "underserved communities" has the definition used in Executive Order 13985.[1] It refers to populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, and may include Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

Plan Elements

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 may request additional or specific information be addressed in an Access Plan. Section E outlines points license applicants and licensees may consider in drafting an access plan and summarizes a range of strategies that may be appropriate to include.

Plan Assessment & Criteria

NIH will consider Access Plans in their entirety and review (1) to ensure that each required element has been included and (2) to assess the reasonableness of those plan elements,

[1] Exec. Order No. 13985, 86 Fed. Reg. 7009 (Jan. 25, 2021).

considering the commercial readiness of the invention and the characteristics of the anticipated product(s). In general, NIH will approve Access Plans that describe appropriate strategies across criteria of affordability, availability, acceptability, and sustainability.

- ***Availability.*** To be available, a product must exist, be manufactured, authorized for sale, and distributed in the applicable region. In evaluating an Access Plan, NIH will consider whether it proposes strategies that would tend to support product availability for the applicable patient populations.
- ***Affordability.*** Affordability implicates factors such as pricing structure, insurance, reimbursement, coverage decisions, and payment models. NIH also recognizes its licensees are often private sector organizations affected by commercial market factors. In evaluating an Access Plan, NIH will consider whether the plan proposes strategies that would tend to support product affordability for the applicable patient populations and relevant stakeholders.
- ***Acceptability.*** An acceptable product was developed and/or is delivered in a manner that resonates with end users and is tolerated for the duration of use. There must also be effective systems for safely delivering the product to patients. In evaluating an Access Plan, NIH will consider whether it proposes strategies that would tend to promote product acceptability.
- ***Sustainability.*** Access is not static, and future patients are likely to need access to products on the market today. Licensees will need to consider predictable and stable approaches for enabling and maintaining the above elements of access (whether those approaches involve the licensees, themselves, or another party). In evaluating an Access Plan, NIH will consider whether it proposes strategies that would tend to promote sustainable patient access.

NIH will also consider the relevant contributions of the parties in evaluating an Access Plan. For example, NIH will consider the nature of its patented technology, how that technology factors into the licensed product, the scope of the license, and the relative contributions of the public and private sector to the product's ultimate development. NIH will work closely with licensees to monitor progress and modify approved Access Plans, when appropriate and in concert with the licensee, to support successful commercial development and implementation of access strategies.

Section B. Waivers

License applicants and licensees may request a waiver or modification to the requirements of the IRP Access Planning Policy, in whole or in part, at any point during the application process or the duration of a license. NIH will evaluate those requests and may grant a waiver or modification upon a showing that access planning 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. For example:

- A waiver may be appropriate if the access planning requirement creates a substantial risk that product development will fail altogether. This may be the case if the market for the product is very small (e.g., population affected by a rare disease) or where there is heightened scientific uncertainty involved with further R&D on the patented technology.
- A waiver may be appropriate if the access planning requirement will negatively impact the long-term viability of the licensed product in the market. This may be the case where there is a risk of later drug shortages or inadequate product quality.

Section C. Submitting and Updating Access Plans

Initial Access Plan Submission

Organizations applying to NIH for licenses within the scope of this Policy are required to submit an Access Plan as a component of their license application. Once approved by NIH, those plans will be incorporated into the licenses granted by NIH.

Updating Access Plans & Reporting on Progress

Licensees are expected to address progress on their approved Access Plan in the periodic progress reports required by their license agreements.[2] If there are no updates, then licensees can state that nothing has changed about their Access Plan. Licensees may also request changes to their approved Access Plans, which NIH will reasonably consider.

Licensees are generally expected to submit a non-confidential version of their Access Plan within 3 months after FDA approval (or a foreign equivalent) that NIH may publish or otherwise make available to third parties.[3] At a minimum, these updated plans should address items that were included in the initial, approved Access Plans the licensees submitted with their license applications. But at the point of regulatory approval, licensees will know more about their products and the patient populations, and that additional clarity and certainty would be reflected in more tailored, concrete access planning.

How to Submit

License applications, including Access Plans, should be submitted to the appropriate Licensing and Patenting Manager at the relevant NIH Institute or Center.

License related reports, notices, and requests (including progress reports, requests to update an Access Plan, and requests for waivers or modifications) should be provided to the NIH Office of Technology Transfer: https://www.techtransfer.nih.gov/royalties/license-notices-reports.

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[2] Licensees generally have an obligation to provide the NIH Office of Technology Transfer (OTT) with periodic reports. NIH's model patent licenses include a section on "Reports on Progress, Benchmarks, Sales, and Payments." *See, e.g.*, *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).

[3] 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.

Section D. Compliance and Enforcement

NIH anticipates that the best public health outcomes will emerge when it can approach access planning with flexibility and in collaboration with partners and licensees. NIH will not consider license applications that fall within the scope of this Policy unless those applications include an Access Plan, and the agency will not grant licenses within the scope of this Policy without an NIH approved Access Plan. While NIH expects licensees will submit acceptable Access Plans in a timely manner, it also anticipates negotiating with licensees in good faith to modify or amend Access Plans, as warranted.

In general, 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 non-compliance. NIH will undertake any such action in accordance with applicable statutes, regulations, and policies.

If a licensee fails to provide progress reports or updated Access Plans as required by a license, or if it refuses to negotiate modifications to an Access Plan in good faith, NIH may take one or more enforcement actions. NIH will first notify the licensee of any concerns and allow the licensee to take appropriate corrective action, likely through, but not limited to, amending Access Plans or negotiating other modifications with NIH.

If compliance issues remain unaddressed, NIH may consider further enforcement action, pending corrective action, including but not limited to:

- Removing indications or geographic scope from the licensed fields of use or otherwise limiting the licensed fields of use;
- Disallowing incentives;
- Wholly or partly removing exclusivity;
- Terminating the license in whole or in part; or
- Requiring the licensee to pay an additional royalty.

Any such enforcement actions will be taken as specified in the license. In such case, NIH may also decline to negotiate amendments or extensions of the license or enter into new licenses with the licensee.

The agency will also take into account the normal course of relevant commercial development programs in deciding whether and how to proceed when enforcing the IRP Access Planning Policy. It will consider sound and reasonable business practices and judgement and the agency will consult the progress reports submitted by the licensee.

Section E. Points to Consider & Potential Strategies to Include when Drafting an Access Plan

These points to consider are intended to provide license applicants and licensees with assistance in developing Access Plans.

1. Product Description

In describing the licensed product(s), license applicants and licensees may include information such as:

- The product type and the intended indication and/or intended use of the product.
- Any plans for developing the patented invention into other products or seeking approval, clearance, de novo classification, or authorization for additional indications.
- Design specifications, including whether the product is being designed primarily for use or administration in a certain setting (e.g., hospital, community).
- Whether the product will be tailored, for example, to have different formulations or dosages across countries, regions, or patient populations.
- A proposed target product profile (TPP), which is a planning tool that can streamline the product development process. It emphasizes starting the process with a clear end goal, and it offers a structured approach to crucial details including intended use, target populations, and safety/efficacy-related characteristics. It includes both minimal and preferred product attributes and gives innovators a defined framework to evaluate their product as it moves through the development process. A TPP is designed to be consulted and updated throughout the process.[4]
- If an Access Plan is being updated after a licensed product has been authorized by a regulatory authority: a summary of the product's label information, e.g., indications and usage, dosage and administration, dosage forms and strengths.

2. Patient Population

Access Plans should describe strategies to support broad patient access for the U.S. population, and 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. License applicants and licensees know the most about the products they are developing, and they are in the best position to identify the applicable patient populations that could benefit from access planning. Access Plans should focus on those populations. For example:

- If there is no demonstrable public health need for the licensed products in a given country or region, for example, if a disease is largely absent from that region, then the licensee can note that limitation.
- If the licensee will not be able to offer the licensed products in a given country or region, for example, if the region is outside the license's field of use, then the access plan can note that limitation.

[4] For more information on TPPs, *see, e.g.*, *Creating a Target Product Profile for New Drug Products*, NIH'S SEED, https://seed.nih.gov/sites/default/files/2023-12/Creating-Target-Profile-for-New-Drug-Products.pdf (last visited Dec. 30, 2024); *Q8(R2) Pharmaceutical Development*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 2009), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q8r2-pharmaceutical-development.

NIH encourages licensees to discuss the applicable patient populations with the agency periodically, so that the parties can resolve any potential concerns as the licensee learns more about the product and market.

In describing the anticipated patient population in an Access Plan, license applicants and licensees may include information such as:

- The estimated size of the intended patient population and the projected growth/reduction of relevant markets during the duration of the license.
- Whether the licensee plans to develop the patented technology to meet the needs of other patient populations, e.g., develop products for a pediatric population.
- Other populations that may also benefit from the licensed product, for which the licensee has no current plans to pursue product development, authorization, or launch.
- Regions or countries where the licensee plans to seek regulatory authorization.
- If an Access Plan is being updated after a licensed product has been authorized by a regulatory authority: a summary of information about the patient population that is included on the product's label, e.g., indications and usage or use in specific populations.

3. Other Necessary Products, Tools, Facilities, or Unique Resources

NIH recognizes that many aspects of access are outside a licensee's control. That is why Access Plans should discuss any other products, tools, facilities, or unique resources that would be necessary for use of the licensed product(s). For example, access to a given product might hinge on other healthcare infrastructure, like proximity to a specialized hospital. Or a patient might need access to a certain diagnostic before receiving a treatment, but access to that diagnostic might be outside the licensee's control. NIH does not expect licensees to resolve all external challenges to patient access. Instead, license applicants and licensees may summarize these other, external features in their Access Plans, and they may consider how to approach mitigation where applicable.

In describing these features in an Access Plan, license applicants and licensees may include information such as:

- Aspects of patient access that are outside the licensee's control, including barriers to equitable access.
- Unique obstacles to product deployment, such as supply chain challenges, distribution channels, or manufacturing needs that could make it difficult to reach certain populations.
- Any unique considerations related to healthcare system capacity.
- Where the licensed product will be administered, or where licensees will encounter or receive it.

4. Strategies to Promote Patient Access

Access-oriented thinking spans the product development lifecycle. Early planning for patient access can deliver the best, most comprehensive solutions—as choices on product design, formulation, clinical trial design, and other aspects of product development can have profound impact on which patients get access to which products.[5] NIH likewise recognizes it is difficult to predict what strategies will truly improve patient access,[6] even after a product is on the market. NIH does not seek to second-guess licensees' good faith efforts to improve access.

Strategies for license applicants and licensees to consider may include, but are not limited to, the following. These are suggested options, and license applicants and licensees are encouraged to identify strategies that make sense for them and their products. When drafting Access Plans, license applicants and licensees may also describe choices already made that would tend to bolster access.

By way of non-limiting example:

Partnering with public health, non-profit, or patient advocacy organizations. Examples could include:

- Establishing product development partnerships during R&D, regulatory authorization, or sales and marketing within and/or beyond the U.S.
- Selling products to organizations that treat underserved populations (e.g., Federally Qualified Health Centers).
- Collaborating on health technology assessments for the licensed products, to reduce duplication of efforts and related costs and to support healthcare decision-making with transparent and accountable evidence about the products.
- Partnering with ministries of health, clinicians, and patient/community-based organizations for service delivery, where appropriate.
- Licensing intellectual property to public health patent pools (e.g., Medicines Patent Pool, WHO HTAP).[7]
- Preparing tailored, culturally sensitive educational materials for a range of domestic and global patient populations.
- Establishing post-trial and/or early access guarantee programs for clinical trial participants.
- Licensees may choose to submit letters of support from their partners, if appropriate.

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[5] For example, a single-dose treatment may be more accessible and affordable for many patients, compared to a multi-dose regimen. And reliance on cold chain could make it difficult to reach patients in some parts of the country and the world.

[6] For example, in some circumstances, subcutaneous administration of a drug may be better than intravenous. But for patients with insurance who lack easy access to a pharmacy but can go to a physician's office for an infusion, then intravenous infusions may be the more accessible option.

[7] *See, e.g.*, MEDICINES PATENT POOL, https://medicinespatentpool.org/ (last visited Dec. 30, 2024); *WHO Health Technology Access Pool*, WORLD HEALTH ORGANIZATION, https://www.who.int/initiatives/who-health-technology-access-pool (last visited Dec. 30, 2024).

Addressing accessibility as a design objective. Examples could include:

- Strategically making access-oriented product development choices (e.g., single dose) or business choices (e.g., pricing structures).
- Conducting patient interviews, needs assessments, and/or health technology assessments early in development.
- Evaluating the appropriateness of a product (such as delivery method and cold-chain requirements) for the applicable patient populations.
- Committing to develop products that can be best delivered in settings that expand access (e.g., developing products that can be delivered in home settings, if that is what patients need).
- Designing appropriately inclusive clinical trials to mitigate gaps in knowledge that impede access.
- Conducting additional studies to understand barriers to and drivers for adoption in applicable patient populations and commit to product development choices or subsequent R&D to overcome those barriers.
- Conducting late phase (IIIb/IV) clinical trials to assess acceptability, feasibility, knowledge, attitudes, and practices on diseases and the licensed product, to support product introduction at a community level in more patient populations.
- Committing to invest in R&D that could support cheaper or more robust innovation, competition, delivery, etc. (e.g., swapping from batch to continuous manufacturing).

Committing to sublicense relevant intellectual property and know-how. Examples could include:

- Committing to license all intellectual property and know-how needed to make a product if the licensee exits a market and/or committing to surviving rights/technology transfer in case of license termination.
- Sublicensing to manufacturers in additional regions or countries on voluntary and mutually agreed to terms, especially in areas where the licensee does not intend to market or sell products.
- Agreeing to sublicense relevant intellectual property on a low- or no-royalty basis, on voluntary and mutually agreed to terms.
- Providing forecasts to regulatory agencies and NIH on product availability for appropriate sublicensing as necessary to avoid disruptions in distribution.
- Forgoing patent protection for certain subsequent inventions.
- Committing to humanitarian sublicenses, for example, in the event of unmet global health demand, inaccessible product distribution in humanitarian settings, or if the licensee is unwilling or unable to improve technological appropriateness.
- Implementing a non-assert declaration, by pledging not to enforce certain patent rights in certain regions/countries and allowing generic or biosimilar versions of a product.

Entering purchasing partnerships or commitments. Examples could include:

- Committing to supply product in each given market(s) for a designated duration.

- Agreeing to sell a designated volume of product to the U.S. government or another designated entity on a cost-plus basis.
- Agreeing to coordinate and set aside a portion of manufactured product for donation or sale to a partner organization on a cost-plus basis.
- Ensuring that donations comply with WHO Guidelines for Medical Donations.[8]
- Producing or manufacturing the licensed products in locations near the applicable patient populations, with the goal to reduce cost and subsequent price.
- Agreeing to scale-up production when new or prescribed patient needs arise.
- Entering licensed products into government run prescription programs.

Submitting additional plans related to commercialization and distribution. Examples could include:

- Proposing product development timelines to develop suitable products that meet a population's unique needs (e.g., additional formulations).
- Committing to seek regulatory authorization for additional indications.
- Using Collaborative Registration Procedures (CRP) or WHO's pre-qualification program to increase the speed and efficiency of registration in global markets.
- Agreeing to file with regulatory organizations, including for emergency use (e.g., WHO Emergency Use Listing).
- Investing in manufacturing innovations that can reduce prices and expand access.

Promoting equitable access and affordability in product deployment. Examples could include:

- Optimizing dose, formulation, and manufacturing processes to reduce cost of goods and the prices patients pay.
- Committing to keep prices in the U.S. equal to those in other developed countries.
- Not raising prices at rates outpacing inflation.
- Pricing products at the lowest sustainable level or connecting product prices to marginal production costs.
- Agreeing to locally-affordable pricing strategies or non-profit pricing models in certain populations or regions.
- Committing to price reductions once preset sales, revenue, or profit thresholds are reached.

Access plans may also address research outputs or other benefit sharing, including public access to publications, data sharing, or community-led or international collaboration in research. Such commitments might supplement, but not replace, patient-focused strategies.

[8] *Donations of Medicines and Medical Devices*, WORLD HEALTH ORGANIZATION, https://www.who.int/teams/health-product-and-policy-standards/medicines-selection-ip-and-affordability/donations (last visited Dec. 30, 2024).