ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
PHS 398 Career Development Award Supplemental Form	2,251	1	10	22,510
PHS Human Subjects and Clinical Trial Information	54,838	1	13	712,894
Biosketch (424 Electronic)	80,946	1	2	161,892
Data Management and Sharing Plan	73,117	1	2	146,234
PHS Fellowship—Electronic				
PHS Fellowship Supplemental Form (includes F reference letters)	6,707	1	13	87,191
Biosketch (Fellowship)	6,707	1	2	13,414
416–1	29	1	10	290
PHS 416–5	6,707	1	5/60	559
PHS 6031	6,217	1	5/60	518
VCOC Certification	6	1	5/60	1
SBIR/STTR Funding Agreement Certification	1,500	1	15/60	375
NIH Other Transaction				
NIH Other Transaction Application Form	239	1	11	2,629
Total Annual Burden Hours		486,749		2,175,670

Dated: May 13, 2024.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2024–11251 Filed 5–21–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; HEAL Initiative: Non-addictive Analgesic Therapeutics Development [Small Molecules and Biologics] to Treat Pain.

Date: June 17, 2024.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: W. Ernest Lyons, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS, NSC, 6001 Executive Boulevard, Rockville, MD 20852, 301–496–4056, *lyonse@ninds.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS).

Dated: May 16, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11187 Filed 5–21–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health (NIH) Office of Science Policy (OSP): Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is proposing to develop and implement a new policy within its Intramural Research Program (IRP) to promote access to products stemming from taxpayer-funded inventions. NIH seeks input on this draft policy and accompanying draft license agreement language that incorporates patient access in the commercialization process for NIH-owned inventions.

DATES: To ensure consideration, comments must be submitted in writing by July 22, 2024.

ADDRESSES: Comments may be submitted electronically to *Https://osp.od.nih.gov/comment-form-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning/*. Responses to this request for information are voluntary and may be submitted anonymously. You may voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

FOR FURTHER INFORMATION CONTACT: Abby Rives, Director of the Technology Transfer and Innovation Policy, at (301) 496–9838 or *SciencePolicy@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

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. These investments are critical to the health of our scientific enterprise, both in terms of supporting research discoveries and by fueling U.S. leadership in the bioeconomy. Indeed, NIH-owned inventions have provided the foundation for new vaccines, drugs, and medical devices.[1] A recent report estimated that technology licensed from the IRP supported an average of 74,500 jobs and contributed an average of over $13 billion to U.S. GDP each year over the last two decades.[2]

NIH recognizes that all too often, however, patients across the country and across the globe may be unable to access products they need—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 take. For example, millions of adults skip medications due to high costs, and the rising cost of prescription drugs puts many of these products out of reach. Thus, NIH is exploring how it might leverage partnerships to further enhance health through the biomedical research it funds.

In 2023, NIH hosted a workshop in support of this agenda, *Transforming Discoveries into Products: Maximizing NIH's Levers to Catalyze Technology Transfer* (*https://osp.od.nih.gov/events/workshop-on-transforming-discoveries-into-products-maximizing-nihs-levers-to-catalyze-technology-transfer/*), to discuss policies and practices that shape biomedical innovation and promote access to NIH-funded discoveries. At this workshop, NIH heard from participants with experience using ''access planning'' as a means to prospectively address downstream access challenges. Access planning involves incorporating patient access considerations, at a high level, in agreements related to biomedical research and development. The parties commit to revisit access considerations as product development progresses, but the initial agreement terms are intentionally flexible and not prescriptive.

NIH is proposing a new policy within the NIH IRP (see Appendix), to require that licensees that succeed in bringing certain products toward market submit a plan outlining steps they intend to take to promote patient access to those products. This new IRP policy makes it clear that access, defined broadly to include product affordability, availability, acceptability, and sustainability, is of paramount importance in providing a return on taxpayers' investment in biomedical research. This new policy would apply to patent licenses for the commercialization of drugs, biologics, vaccines, or devices. NIH would also employ a tiered approach, where licenses granted for late-stage inventions that are closer to market launch would include more specific, tailored access-oriented provisions, while licenses granted for early-stage inventions would be more flexible to reflect the higher uncertainty associated with technologies that lead to drugs, biologics, vaccines, or devices. Importantly, a final policy approach should 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, while also balancing the need to promote access through reforms to various policies. The agency is proposing a flexible approach that allows appropriately tailored, commercially reasonable strategies to promote patient access across a range of technologies. This RFI is in relation to the licensing of government-owned inventions in accordance with 35 U.S.C. 207 and 37 CFR part 404.

Request for Information

NIH seeks information from all interested individuals and communities, including, but not limited to, patients and patient advocates, small business firms, technology transfer and licensing professionals, investigators, public health organizations, investors, industry partners, healthcare providers, universities, research institutions, and other members of the public. While comments are welcome on all elements of this proposal, input would be most welcome on the specific issues identified below:

1. Promoting meaningful access approaches. NIH intends to provide additional guidance to licensees on examples of acceptable, commercially reasonable approaches for promoting access. NIH is seeking input on the range of activities that could be considered and strategies to mitigate access challenges and expand the reach, and benefit, of drugs, biologics, vaccines, and devices stemming from NIH inventions.

2. Promoting transparency in the biomedical research enterprise and return on investment. The process of bringing a new product through research and development, to market, and into the hands of patients is long, fraught with challenges, and expensive. NIH is interested in hearing from potential partners on how access plans could incorporate transparent cost accounting measures to assist NIH in driving down costs associated with innovation and making clearer what costs are incurred along the way and how those affect product costs.

3. Providing flexibility while achieving clear policy objectives. NIH recognizes that its licensees, their partners, and the public will need confidence around what this policy requires and the standards that would be used to evaluate plans. The agency is seeking input on how to maintain flexibility for licensees to pursue their specific product development and commercialization needs while simultaneously promoting certainty and transparency on access efforts and policy enforcement.

4. Helping licensees achieve access goals. NIH is interested in hearing ideas about how it may be able to help licensees deliver patient access to products that stem from these agreements. Licensees could include such information in access plans or at earlier stages of product development. NIH invites input on additional steps it could take or ways to leverage existing U.S. Government programs and resources to assist in this endeavor.

5. Establishing licensee obligations depending on the stage of technology development. Generally, as a product moves closer to market, the odds of successful commercialization improve, and NIH's proposed policy would take this into account. If the agency has advanced products to the point of a first pivotal clinical trials (*e.g.,* Phase III or the equivalent)—licenses covering those products would include specific, tailored access-oriented provisions that should be clear and understandable. NIH is seeking further input on specific provisions that would meet these objectives.

6. Assessing policy impact. NIH is seeking input on how to assess compliance with the proposed policy and potential metrics for assessing its impact.

Appendix: Proposed Aspects of Draft NIH IRP Policy Promoting Equity Through Access Planning

I. Policy Scope

NIH is proposing a new policy that would apply to inventions made by investigators in the NIH Intramural Research Program (IRP) and owned by the agency. This policy would

[1] *HHS License-Based Vaccines & Therapeutics,* NATIONAL INSTITUTES OF HEALTH TECHNOLOGY TRANSFER, *https://www.techtransfer.nih.gov/reportsstats/hhs-license-based-vaccines-therapeutics* (last visited May 2, 2024).

[2] *Public Health & Economic Impact Study,* NATIONAL INSTITUTES OF HEALTH TECHNOLOGY TRANSFER (May 2023), *https://www.techtransfer.nih.gov/reports/public-health-and-economic-impact-study.*

apply to commercial patent licenses that authorize commercialization of drugs, biologics, vaccines, or devices for the prevention, diagnosis, or treatment of human disease and would include exclusive, co-exclusive, partially exclusive, and non-exclusive licenses. Third-party IP (*i.e.,* patents solely owned by NIH's collaborators and partners) would be outside the scope of this policy. Application of the proposed policy to jointly-owned IP will be considered at a later date.

II. Policy Requirements

NIH proposes adding the following language to NIH IRP model license agreements within the scope of the policy:

''Access Plan'' means Licensee's plan, and incorporating the plan(s) of its sublicensee(s), as applicable, that describes Licensee's strategy to support broad access to Licensed Product(s) for the U.S. population, as well as (a) through the lens of promoting equity for underserved communities such as 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, as defined by Executive Order 13985 and/or (b) populations in low- and middle-income countries, as defined using the World Bank classification system.

The Access Plan 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 Licensed Product; and one or more strategies to mitigate access challenges across criteria including affordability, availability, acceptability, and sustainability. To the extent such Access Plan includes proprietary information [to be defined], upon NIH's request Licensee will also provide a non-confidential version or statement of such Access Plan that NIH may publish or otherwise make available to third parties.

Within 3 months of a Licensed Product entering a first pivotal clinical trial (a Phase III trial or the equivalent), Licensee will provide NIH with an Access Plan (as defined), unless a written waiver or modification is obtained in advance from NIH. NIH agrees to consider such requests for waivers or modifications in good faith.

Within 30 days of NIH's request (no more often than once annually), Licensee agrees to confer with NIH to review Licensee's progress, and to consider in good faith any reasonable modifications suggested by NIH with respect to the Access Plan.

III. Access Plans

Each product will be different, and patient populations and access challenges will vary by product. Access planning presents an opportunity for NIH and its licensees to proactively mitigate access challenges and devise tailored strategies to expand the reach, and benefit, of products. Accordingly, NIH proposes developing guidance for acceptable access plans.

Potential strategies for licensees to consider would include, but not be limited to, one or more of the following:

• *Partnering with public health, non-profit, or patient advocacy organizations.* Examples could include partnerships during research and development, regulatory approval, or sales and marketing; selling product to organizations that treat underserved populations (*e.g.,* Federally Qualified Health Centers); or licensing intellectual property to public health patent pools (*e.g.,* Medicines Patent Pool).

• *Addressing accessibility as a design objective.* Examples could include conducting patient interviews or needs assessments early in development or strategically making product development choices (*e.g.,* single dose) or business choices (*e.g.,* pricing structures) to promote patient access.

• *Committing to sublicense relevant intellectual property and know-how.* Examples could include sublicensing to manufacturers in additional countries or world regions on voluntary and mutually agreed to terms; committing to license all intellectual property and know-how needed to make a product if the licensee exits a market; or agreeing to sublicense relevant intellectual property on a low- or no-royalty basis.

• *Entering purchasing partnerships or commitments.* Examples could include committing to supply product in a given market(s) for a designated duration; agreeing to coordinate and set aside a portion of manufactured product for donation or sale to a partner organization on a cost-plus basis; or agreeing to sell a designated volume of product to the U.S. Government or another designated entity on a cost-plus basis.

• *Submitting additional commercialization plans targeted to other markets.* Examples could include offering product development timelines to develop formulations that meet a population's unique needs or committing to a plan for developing suitable products for additional users.

• *Promoting equitable access and affordability in product development and deployment.* Examples could include committing to keep prices in the U.S. equal to those in other developed countries; not raising costs above inflation; preparing tailored, culturally sensitive educational materials for a range of domestic and global patient populations.

Access plans might include requests for additional support or facilitation to advance access goals. For example, licensees might seek connections to preclinical or clinical trial resources NIH offers, help in developing their access plans, or connections to partner organizations well-versed in access considerations relevant to the technology in question.

Access plans might 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 elements proposed above.

NIH also proposes to include a process for licensees to request a waiver or modification of the access planning provision, in whole or in part. The agency would consider such requests on a case-by-case basis and evaluate them according to criteria that would be identified in the guidance for access plans.

IV. Assessing Efforts To Address Access

NIH recognizes that myriad factors affect access to emerging biomedical technologies, such as:

• *Affordability.* For example, can patients afford the intended product(s), taking into account factors such as pricing structure, insurance, reimbursement, coverage decisions, payment models, and/or international price comparators?

• *Availability.* For example, are products in existence, able to be manufactured, widely available on the market, and approved for sale and distributed across geographical regions?

• *Acceptability.* For example, are products developed and/or delivered in a manner that resonates with end users and is tolerated for the duration of use? Are there effective systems for safely delivering the product?

• *Sustainability.* For example, are there predictable and stable infrastructure at local levels for enabling and maintaining the above elements of access?

NIH does not expect licensees to address each issue but instead address elements of patient access that are relevant to the specific product in question to expand access.

Dated: May 16, 2024.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2024–11188 Filed 5–21–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

Name of Committee: Office of AIDS Research Advisory Council.

Date: June 20, 2024.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: The sixty-sixth meeting of the Office of AIDS Research Advisory Council (OARAC) will include a brief report from the