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

Acting Director of the Office of AIDS Research, including the development of the Strategic Plan for HIV and HIV Related Research. The meeting will feature the White House Office of National AIDS Policy and highlight investigator and community perspectives regarding perinatal HIV acquisition research.

Place: Office of AIDS Research, Office of the Director, NIH, 5601 Fishers Lane, Rockville, MD 20852, (Virtual Meeting), *https://videocast.nih.gov/watch=54677*.

Contact Person: CAPT Mary Glenshaw, Ph.D., M.P.H., OTR/L, Office of AIDS Research, Office of the Director, NIH, 5601 Fishers Lane, Room 2E61, Rockville, MD 20852, (301) 496–0357, *OARACinfo@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.oar.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 17, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11255 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; Amended Notice of Meetings

Notice is hereby given of a change in the meeting of the Neurological Sciences Training 3 Study Section, NST–3, June 06, 2024, 08:00 a.m. to June 07, 2024, 05:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, and a change in the meetings of the National Institute of Neurological Disorders and Stroke Special Emphasis Panels: NSD–D Member Conflict Review Meeting, May 31, 2024, 02:00 p.m. to 05:00 p.m.; HEAL Initiative: Team Based Science, June 7, 2024, 09:00 a.m. to 06:00 p.m.; and NIH Blueprint and BRAIN Initiative ENDURE Program, July 31, 2024, 10:00 a.m. to 02:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, which were published in the **Federal Register** on May 09, 2024, FR Doc. 2024–10092, 89 FR 39629.

This notice is being amended to change the meeting location of the meeting of the Neurological Sciences Training 3 Study Section, NST–3 to the Holiday Inn & Suites Anaheim, 1240 S Walnut St., Anaheim, CA 92802. This notice is also being amended to change the meeting formats of the three National Institute of Neurological Disorders and Stroke Special Emphasis Panel meetings, NSD–D Member Conflict Review Meeting, HEAL Initiative: Team Based Science, and NIH Blueprint and BRAIN Initiative ENDURE Program, from in-person to virtual. The dates and times of these meetings will remain the same. The meetings are closed to the public.

Dated: May 15, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–11165 Filed 5–21–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–OSA–2024–0064; FXSC142003MON30–245–FF03S00000; OMB Control Number 1018–New]

Agency Information Collection Activities; Pollinator Conservation Social Network Analysis Survey

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before July 22, 2024.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (reference Office of Management and Budget (OMB) Control Number 1018–PCSNAS in the subject line of your comment):

- *Internet (preferred): https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R3–OSA–2024–0064.
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA, 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of