

with two voting questions: (1) whether the iPLEDGE REMS should retain the 19-day lockout period requirement before patients can take an additional pregnancy test to be eligible to receive isotretinoin, and (2) when should the REMS require prescribers to document counseling for patients who cannot become pregnant in the iPLEDGE system. Respectively, majority of the members vote “No” (4 Yeses, 17 Noes, 1 Abstention) to a 19-day lockout period requirement before patients can take an additional pregnancy test to be eligible to receive isotretinoin, and 10 members favored the first option for REMS to require prescribers to document counseling patients who cannot become pregnant with the first prescription as part of patient enrollment. Regarding recommendations on the pregnancy registry requirement and ways in which it could be streamlined to encourage more participation to yield high-quality data, members agreed it is not necessary to continue to collect “follow-up data” (i.e., pregnancy and fetal outcome information) and that more effective communication and transparency are needed regarding how patients’ data will be used if they participate in the iPLEDGE Pregnancy Registry.

Impact: On February 6, 2026, the Agency approved modification to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) to minimize burden on patients, prescribers, and pharmacies while maintaining the use of isotretinoin.

On January 9, 2023, the DODAC met to discuss supplemental biologics license application (sBLA) 125387, aflibercept solution for intravitreal injection, submitted by Regeneron Pharmaceuticals, Inc. The supplement was submitted in response to FDA’s pediatric written request. FDA’s written request was for studies of aflibercept in the treatment of retinopathy of prematurity. Two Discussion Questions were proposed to the panel: (1) Discuss how the studied use of aflibercept in the treatment of retinopathy of prematurity can best be communicated to physicians and the caregivers of these premature infants, and (2) how it should be labeled in a real-world setting. Regarding the first speaking point, the committee acknowledged the benefits of using anti-vascular endothelial growth factor (anti-VEGF) for the treatment of retinopathy of prematurity (ROP), which is evident by the data shown and concluded that due to the general circumstances that the use of this product is made quickly in a neonatal intensive care unit, the instructions for administration must be clearly labeled in the package insert. The second discussion point, the

Committee made recommendations on how the instructions should be centralized in the insert for easy a find, advised what would be classified as clear instructions for practitioners, appropriate dosing and safety precautions for pediatric use.

Impact: The FDA officially approved Eylea (aflibercept 0.4 mg) on February 8, 2023, as the first pharmacologic treatment for ROP in preterm infants—the first pediatric approval for this indication.

7. Explanation of why the committee/subcommittee is essential to the conduct of agency business:

Reasons for Continuation:

The committee plays a critical role in enabling FDA to meet the requirements of sections 505(n)(1) and (s)(1) of the Federal Food, Drug, and Cosmetic Act by providing expert scientific advice and recommendations. Without the Dermatologic and Ophthalmic Drugs Advisory Committee, FDA’s ability to obtain external expert input on issues related to the approval and regulation of the safety and effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders would be significantly limited.

In conclusion, this public interest determination documents that renewing the committee is in the public interest, essential to the conduct of agency business, and that the information to be obtained is not already available through another advisory committee or source within the Federal Government.

This notice is issued under the Federal Advisory Committee Act as amended (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of NIH Tribal Consultations and Listening Session

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In accordance with the National Institutes of Health (NIH), Tribal Consultation Policy, the NIH will

hold two Tribal Consultations and one Tribal listening session at the National Congress of American Indians (NCAI) Annual Convention. The first consultation will discuss two new proposed initiatives of the NIH *All of Us* Research Program. The second consultation will discuss the National Institute of Minority Health and Health Disparities (NIMHD) proposed renewal initiative for the Resource Center for Tribal Epidemiological Centers (RC–TEC). The Tribal Health Research Office will also conduct a listening session to seek Tribal perspectives on the NIH Tribal Data Sovereignty Policy currently under development.

DATES: The events will be held at the following times, all in Pacific time:

Monday, October 19, 2026, from 12:00 p.m. to 2:00 p.m.: Tribal consultation on expanding the data access model and the inclusion of self-identified AI/AN participants’ biospecimens in PRS within the NIH *All of Us* Research Program.

Tuesday, October 20, 2026, from 8:00 a.m. to 9:00 a.m.: NIH Tribal Data Sovereignty Policy listening session.

Tuesday, October 20, 2026, from 4:30 p.m. to 6:00 p.m.: Tribal consultation on the renewal of the NIMHD Resource Center for Tribal Epidemiology Centers.

Written Tribal testimony or comments regarding either Tribal consultation can be submitted to NIHTribalConsultation@nih.gov and must be received by end of day on November 20, 2026.

ADDRESSES: The two Tribal Consultations and one listening session will be held at the Palm Springs Convention Center, 277 N Avenida Caballeros, Palm Springs, CA 92262, during the NCAI 83rd Annual Convention & Marketplace. Specific room assignments are not yet available. Updates will be posted on the NIH THRO Tribal Consultations web page at <https://dpcpsi.nih.gov/thro/tribal-consultations>.

A virtual participation option may be available for one or more sessions. Individuals interested in participating virtually should contact NIH at NIHTribalConsultation@nih.gov. Information regarding virtual participation, if available, will also be posted on the NIH THRO Tribal Consultations web page.

Written Tribal testimony or comments should be submitted by email to NIHTribalConsultation@nih.gov by end of day on November 20, 2026. Submissions should be on Tribal letterhead or otherwise clearly identify the submitting Tribe or Tribal organization.

FOR FURTHER INFORMATION CONTACT:

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Planning, and Strategic Initiatives,
Office of the Director, National
Institutes of Health, Department of
Health and Human Services; email:
THROinfo@nih.gov.

SUPPLEMENTARY INFORMATION:**I. Background and Participation**

NIH recognizes the government-to-government relationship between the United States and federally recognized Indian Tribes and conducts Tribal consultation in accordance with the NIH Tribal Consultation Policy (<https://go.nih.gov/C01PhB8>). The Policy provides a process for meaningful and timely input from Indian Tribes on NIH policies, programs, and research activities that significantly affect Tribes.

NIH invites Tribal Officials and Tribal Representatives, as those terms are defined in the Policy, to provide input during the October 19 and October 20 Tribal consultations. Under the Policy, a Tribal Representative may include an elected Tribal Official acting in an official capacity, or an employee or other representative designated in writing by an elected Tribal Official to represent the Tribe in discussions with the Federal Government.

The October 20 Tribal Data Sovereignty Policy event is a listening session rather than a Tribal consultation. It is intended to inform development of the policy before NIH conducts a separate Tribal consultation.

II. NIH All of Us Research Program Tribal Consultation

On Monday, October 19, 2026, from 12:00 p.m. to 2:00 p.m. Pacific Time, NIH will conduct a Tribal consultation concerning two new initiatives within the *All of Us* Research Program. The *All of Us* Research Program aims to accelerate health research and medical breakthroughs to enable an era of precision medicine for all. *All of Us* is expanding its existing data access model to contain an added level of sensitive participant data that will require mandatory review by an Institutional Review Board. It is also planning to include self-identified AI/AN participants in the PRS initiative involving a large-scale biospecimen analysis effort. This effort will allow researchers external to NIH to apply for access to current participants' samples (such as blood, saliva or urine), including those from self-identified AI/AN participants.

Feedback from Tribal Nations is crucial to shaping the program's

strategies to ensure the use of biospecimens and that access to data aligns with priorities of Tribal and Urban Indian communities. *All of Us* would like to discuss how to (1) responsibly manage self-identified AI/AN participant bio samples in partnered research studies and ensure the research yields meaningful community benefits and (2) manage sensitive data access that honors both an individual's and Tribes' rights.

III. NIH Tribal Data Sovereignty Policy Listening Session

On Tuesday, October 20, 2026, from 8:00 a.m. to 9:00 a.m. Pacific Time, NIH THRO will host a listening session on the NIH Tribal Data Sovereignty Policy currently under development. The session will provide a forum for Tribal Leaders and designees to offer guidance and share perspectives, concerns, and recommendations on how NIH funding announcements, grant mechanisms, and research activities should recognize and uphold the inherent sovereignty of Tribal Nations over data generated by, about, and within their communities.

THRO leadership will hear directly from Tribal Leaders and designees and consider their input as NIH develops the policy, including potential funding opportunity announcement language and grants administration practices. Discussion is expected to address how NIH can better align data collection, management and sharing processes with Tribal laws, codes, and ordinances governing data collection, ownership, access, use, and disposition, including Tribal Institutional Review Board requirements, data-sharing agreements, and Tribal Research Codes.

This listening session is not a Tribal consultation and will not substitute for Tribal consultation on the NIH Tribal Data Sovereignty Policy. NIH will conduct a separate Tribal consultation before the policy is finalized. Information about that Tribal consultation will be announced separately.

IV. NIMHD Resource Center for Tribal Epidemiology Centers Tribal Consultation

On Tuesday, October 20, 2026, from 4:30 p.m. to 6:00 p.m. Pacific time, NIH will conduct a Tribal consultation on proposed revisions to the renewal of the NIMHD Resource Center for Tribal Epidemiological Centers (RC-TEC) initiative. The session will provide an overview of the proposed revisions, their potential implications for Tribal Epidemiology Centers (TECs) and the Tribes they serve, and an opportunity for Tribal input.

The consultation will help ensure that the revised initiative reflects Tribal priorities and the essential role of TECs in strengthening Tribal public health capacity, surveillance, data systems, and health sovereignty. NIH will provide an overview of the proposed revisions to the renewal of the RC-TEC initiative and describe potential key changes, their potential implications for TECs and the Tribes they serve in order to support transparency and strengthen government-to-government engagement.

V. Written Tribal Testimony and Comments

NIH welcomes written Tribal testimony or comments concerning each Tribal consultation. Written submissions should be submitted to NIHTribalConsultation@nih.gov and must be received by end of day on November 20, 2026. Submissions should be on Tribal letterhead or otherwise clearly identify the submitting Tribe or Tribal organization.

Written input for the NIH Tribal Data Sovereignty Policy may be submitted to the NIHTribalConsultation@nih.gov. Solicitation for Tribal testimony for the NIH Tribal Data Sovereignty Policy will occur when the Tribal consultation for the Policy takes place. This Notice is in accordance with Executive Order 13175 Authority to implement and comply with Federal and Departmental policies, procedures, and requirements as it relates to Tribal consultations.

Karina Walters,

Director, Tribal Health Research Office,
National Institutes of Health.

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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 a meeting of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Neurological Disorders and Stroke, including