

unintended consequences. The recommendations in this draft guidance may guide stakeholders on designing nonclinical studies that uses NGS methods and bioinformatics to evaluate the potential safety risks associated with off-target editing and loss of genome integrity in human GE products submitted in support of Investigational New Drug applications and Biologics License Applications.

The recommendations provided in this draft guidance are in addition to the nonclinical, clinical, and CMC considerations discussed in the "Guidance for Industry: Human Gene Therapy Products Incorporating Human Gene Editing" dated January 2024.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Safety Assessment of Genome Editing in Human Gene Therapy Products Using Next-Generation Sequencing." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop any final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 relating to the submission of Investigational New Drug Applications, including clinical trials, have been approved under OMB control number 0910–0014. The collections of information contained in 21 CFR part 601 relating to the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 1271 relating to human gene therapy products have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics->

guidances, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07285 Filed 4–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS OMH Call for Nominations for Center for Indigenous Innovation and Health

AGENCY: Office on Minority Health (OMH), Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) hereby gives notice that OMH is accepting nominations of candidates to serve as primary and alternate delegates for the Center for Indigenous Innovation and Health Tribal Advisory Committee (CIIH TAC). OMH established the CIIH TAC to provide Tribal leaders a forum to exchange views, share information, and provide feedback to OMH on the development of activities addressing the four CIIH priority areas. The CIIH TAC shall support, but not supplant, government-to-government consultation activities that OMH undertakes.

DATES: Tribal leaders are encouraged to submit their nomination letters for CIIH TAC delegates by May 18, 2026, at the address listed below. OMH will continue to receive nominations until all CIIH TAC primary and alternate delegate positions are filled.

ADDRESSES: All nominations should be emailed to minorityhealth@hhs.gov. Please use the subject line "CIIH TAC Nomination."

FOR FURTHER INFORMATION CONTACT: For information and guidance about the nomination process for CIIH TAC delegates, please contact CDR Matthew Johns, OMH Tribal Affairs and Strategic Partnerships Lead, at Phone: (202) 365–0639 or Matthew.Johns@hhs.gov. Once approved, sample CIIH TAC nomination letters will be made available on the OMH website: <https://minorityhealth.hhs.gov/>.

SUPPLEMENTARY INFORMATION:

Background: Authorized under Section 1707 of the Public Health Service Act, 42 U.S.C. 300u–6, as amended, the mission of OMH is to

provide national leadership, resources, and coordination to improve the health of racial and ethnic minority populations and American Indians and Alaska Natives (AI/AN) and eliminate health disparities.

Through the Joint Explanatory Statement (JES) accompanying Public Law 116–260 (2021 Consolidated Appropriations Act), Congress directed OMH to create the CIIH to advance Indigenous solutions that ultimately address health disparities in AI/AN and Native Hawaiian and Pacific Islander populations. Congress identified four CIIH priority areas: research, education, service, and policy development. The JES accompanying the subsequent annual appropriations acts has included language for OMH to continue funding the CIIH.

TAC Membership: The CIIH TAC will consist of three delegate positions from any of the geographic areas served by the Indian Health Service (IHS) and three National At-Large Member positions.

The CIIH TAC charter establishes a two (2) year term length for each delegate. There are vacancies for all IHS areas due to the ending of the CIIH TAC members' 2-year terms.

Eligibility: The CIIH TAC delegates must be: (1) Elected Tribal officials from a federally recognized Tribe acting in their official capacity as elected officials of their Tribe, with authority to act on behalf of the Tribe; or (2) individuals designated by an elected Tribal official. Designees must have the authority to act on behalf of the Tribal official and the Tribe and be qualified to represent the views of the American Indians and Alaska Natives (AI/AN) Tribes in the area from which they are nominated. No delegate of the CIIH TAC may be an employee of the federal government.

Nomination Procedures: CIIH TAC candidates must be nominated by an elected Tribal leader. The nomination letter must be on Tribal letterhead and signed by an elected Tribal leader, and must include the following information:

- Name of the nominee
- Nomination Type (*Primary Delegate, National At-large Delegate, Alternate Delegate*)
- Nominee's official title
- Name of the nominee's tribe
- Date of nominee's election to official Tribal position and term length
- Nominee's contact information (mailing address, phone, and email)
- Nominee's expertise that is relevant to the CIIH TAC
- Name of Tribal leader submitting the nomination
- Official title of Tribal leader submitting the nomination

- Contact information for Tribal leader submitting the nomination and/or the administrative office for the Tribal government

Once approved, sample CIIH TAC nomination letters will be made available on the OMH website: <https://minorityhealth.hhs.gov/>.

Selection Process: OMH is responsible for selecting and finalizing CIIH TAC delegates. Eligible nominees will be considered in the following priority order:

1. Tribal President/Chairperson/Governor
2. Tribal Vice-President/Vice-Chairperson/Lt. Governor
3. Elected or Appointed Tribal Official
4. Designated Tribal Official with authority to act on behalf of the Tribal Leader

In the event there are multiple nominations for a given IHS area, OMH will determine the delegates based on a review of the submitted nomination materials. Nominees will be notified of the status of delegate selection in mid-2026.

Mahyar Mofidi,

Deputy Assistant Secretary for Minority Health, Director, HHS Office of Minority Health.

[FR Doc. 2026-07267 Filed 4-14-26; 8:45 am]

BILLING CODE 4150-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people living with the disease and their caregivers. During the second meeting of 2026, Advisory Council members will hear updates from federal agencies on activities during the last quarter and presentations focused on advancements in long-term services and supports and Alzheimer's disease care. Presenters will discuss faith-based and community partnerships in long-term services and support, expanding access to early diagnosis and quality dementia care, the Navigating Aging Needs Navigator Tool, and the Respite for All-faith and community-

based care model. The meeting may include a presentation on lessons learned from implementing an innovative service delivery model for people living with Alzheimer's disease or related dementias and their caregivers.

DATES: The meeting will be held on Monday, April 27, 2026, from 1:00 p.m. to 5:00 p.m.

ADDRESSES: The meeting will be a hybrid of in-person and virtual and will be held in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. It will also stream live at www.hhs.gov/live.

FOR FURTHER INFORMATION CONTACT: Maria-Theresa Okafor, 771-223-7102, maria-theresa.okafor@hhs.gov. *Note:* The meeting will be available to the public live at www.hhs.gov/live.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: Alzheimer's disease and related dementias, long-term services and support, faith and community-based care, and the Guiding an Improved Dementia Experience (more commonly known as GUIDE) model.

Procedure and Agenda: The meeting will be webcast at www.hhs.gov/live and video recordings will be added to the National Alzheimer's Project Act website¹ when available after the meeting. This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. Participants joining in person should note that seating may be limited. Those wishing to attend the meeting in person must send an email to napa@hhs.gov and put "April Meeting Attendance" in the subject line by Monday, April 20 so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email. Please note that individuals entering HHS owned, leased, or operated facilities must

¹ <https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa>

present a REAL ID compliant credential or another federally approved form of identification. Below is the list of acceptable forms of ID.

- State-issued Enhanced Driver's License
- U.S. passport²
- U.S. passport card³
- DHS trusted traveler cards (Global Entry, NEXUS, SENTRI, FAST)
- U.S. Department of Defense ID, including IDs issued to dependents
- Permanent resident card
- Border crossing card
- An acceptable photo ID issued by a federally recognized⁴ Tribal Nation/Indian
- Tribe, including Enhanced Tribal Cards (ETCs)
- HSPD-12 PIV card
- Foreign government-issued passport
- Canadian provincial driver's license or Indian and Northern Affairs Canada card
- Transportation worker identification credential
- U.S. Citizenship and Immigration Services Employment Authorization Card (I-766)
- U.S. Merchant Mariner Credential
- Veteran Health Identification Card (VHIC)

Comments: Time is allocated on the agenda to hear public comments from 4:20 p.m. to 4:55 p.m. The time for oral comments will be limited to two (2) minutes per individual. To provide a public comment, please register by emailing your name to napa@hhs.gov by Monday, April 20, 2026. Registered commenters will receive both a dial-in number and a link to join the meeting virtually; individuals will have the choice to either join virtually via the link, or to call in only by using the dial-in number. **Note:** There may be a 30-45 second delay in the livestream video presentation of the conference. For this reason, if you have pre-registered to submit a public comment, it is important to connect to the meeting by 4:05pm to ensure that you do not miss your name and allotted time when called. If you miss your name and allotted time to speak, you may not be able to make your public comment. Public commenters will not be admitted to the virtual meeting before 3:50 p.m. but are encouraged to watch the meeting at www.hhs.gov/live. Should you have

² <https://travel.state.gov/content/travel/en/passports.html>.

³ <https://travel.state.gov/content/travel/en/passports/need-passport/card.html>.

⁴ <https://www.federalregister.gov/documents/2021/01/29/2021-01606/indian-entities-recognized-by-and-eligible-to-receive-services-from-the-united-states-bureau-of>.