

MD 20993-0002, *James.Swink@fda.hhs.gov*, 301-796-6313, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On December 10, 2021, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the BrainsGate Ischemic Stroke System (ISS500) by BrainsGate Ltd. The proposed indications for use, submitted by the sponsor, as stated in the PMA, are as follows: The ISS500 is indicated to increase cerebral blood flow and reduce disability in adult patients with acute ischemic stroke with confirmed cortical involvement in the anterior circulation who are ineligible or have no access to IV-tPA and endovascular thrombectomy. Treatment is to be initiated between 8 and 24 hours from stroke onset (last known well).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/neurological-devices-panel>. Select the link for the 2021 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written

submissions may be made to the contact person on or before November 29, 2021. Oral presentations from the public will be scheduled on December 10, 2021, between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 18, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 19, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at *Artair.Mallett@fda.hhs.gov* or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-23334 Filed 10-25-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information and Notice of Listening Session on Efforts To Advance Health Equity Among Native Hawaiian and Pacific Islander Populations

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information (RFI) and notice of a listening session on efforts to advance health equity among Native Hawaiian and Pacific Islander populations.

SUMMARY: The U.S. Department of Health and Human Services (HHS) Office of Minority Health (OMH) seeks input from Native Hawaiian and Pacific Islander (NHPI) communities, NHPI-serving organizations, and other interested parties regarding efforts of the new Center for Indigenous Innovation and Health Equity (Center). The Center is tasked with supporting education, service and policy development, and research related to advancing sustainable solutions, to address health disparities and advance health equity among NHPI and American Indian/Alaska Native (AI/AN) populations. This is NOT a solicitation for proposals or proposal abstracts.

Please Note: This RFI and notice of a listening session is for planning purposes only. It is not a notice for a proposal and does not commit the federal government to issue a solicitation, make an award, or pay any costs associated with responding to this announcement. All submitted information shall remain with the federal government and will not be returned. All responses will become part of the public record and will not be held confidential. The federal government reserves the right to use the information provided by respondents for purposes deemed necessary and legally appropriate. Respondents are advised that the federal government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents concerning any information submitted. Responses will not be accepted after the due date.

DATES: The virtual listening session will be held on Tuesday, November 2, 2021, from 3:30 p.m.-4:30 p.m. EDT. To register for the listening session, visit <https://www.zoomgov.com/meeting/register/vJlsc-6qj4tGrQwQx2vdmoUfMZmRWXZNds>. Written comments also may be submitted and must be received at the address provided below,

no later than 11:59 p.m. EDT on November 19, 2021.

ADDRESSES: All comments should be emailed to CAPT Samuel Wu at Samuel.Wu@hhs.gov. Please use the subject line "OMH RFI: CIIHE NHPI".

Submitted comments received after the deadline will not be reviewed. Please respond concisely and in plain language. You may use any structure or layout that presents your information well. You may respond to some or all of our four questions below, and you can suggest other factors or relevant questions. You may also include links to online materials or interactive presentations. Proprietary information should be marked clearly and placed it in a separate section or file. Your response will become government property, and we may publish some of its non-proprietary content.

FOR FURTHER INFORMATION CONTACT: CAPT Samuel Wu at Samuel.Wu@hhs.gov.

SUPPLEMENTARY INFORMATION:

Authorized under Section 1707 of the Public Health Service Act, 42 U.S.C. 300u-6, as amended, the mission of OMH is to improve the health of racial and ethnic minority populations through the development of health policies and programs that help eliminate health disparities. OMH awards and other activities are intended to support the identification of effective policies, programs, and practices for improving health outcomes and to promote the sustainability and dissemination of these approaches.

Under the authority of Public Law 116-260 (2021 Consolidated Appropriations Act), Congress directed OMH to create a Center to support education, service and policy development, and research advancing indigenous solutions that ultimately address health disparities among NHPI and AI/AN populations.

I. Background Information

NHPI communities experience persistent health disparities, including higher rates of diabetes, high blood pressure, and obesity, compared to non-Hispanic white populations. Identification and awareness of health outcomes and health determinants are essential steps toward reducing health disparities in minority communities at greatest risk. Research has shown that culturally adapted and culturally grounded health and public health approaches and interventions that are aligned with indigenous communities' cultural values and perspectives are effective in improving clinical outcomes within NHPI and AI/AN communities.

Program Information

In September 2021, OMH announced awards to establish a Center for Indigenous Innovation and Health Equity, for which OMH will provide the organizational structure and operational framework. The Center will support efforts including education, service and policy development, and research related to advancing sustainable solutions to address health disparities and advance health equity in the AI/AN and NHPI populations. Two award recipients will function as a single initiative, coordinated by OMH. Each award recipient will focus on one of the two focus populations: AI/AN or NHPI populations. OMH expects the award recipients to implement the Center by:

- (1) Managing the Center advisory board;
- (2) partnering with academic institutions, indigenous leaders, and NHPI and AI/AN communities on Center activities;
- (3) identifying and disseminating culturally appropriate evidence-based and/or evidence-informed interventions, and lessons learned; and
- (4) designing and providing education and training to support community capacity-building.

The Center's activities are expected to result in:

- (1) Increased community capacity and knowledge of culturally appropriate, evidence-based and/or evidence-informed interventions, and policies that address health disparities among NHPI and AI/AN populations;
- (2) increased utilization of effective strategies to reduce NHPI and AI/AN health disparities; and
- (3) improved NHPI and AI/AN health and reduction of health disparities.

II. Request for Information

Through this RFI and notice of a listening session, OMH is seeking information from NHPI communities, NHPI-serving organizations, and interested parties on the questions below.

III. Questions

- Are there priority health disparity issue(s) affecting NHPI communities that the Center should address?
- How can the Center engage community partners to increase knowledge and adoption of culturally appropriate, evidence-based, and/or evidence-informed interventions, and policies that reduce health disparities among NHPI populations?
- What should the Center consider when disseminating public health messages or promising practices

designed to reduce health disparities to diverse NHPI communities?

- What should the Center consider when addressing barriers to implementing culturally appropriate interventions and policies to advance indigenous health innovation and health equity?

Dated: October 18, 2021.

Samuel Wu, CAPT,
Public Health Advisor.

[FR Doc. 2021-23200 Filed 10-25-21; 8:45 am]

BILLING CODE 4150-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel, November 1, 2021, 09:00 a.m. to November 2, 2021, 06:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on October 13, 2021, FR Doc 2021-22196, 86 FR 56965.

This notice is being amended to change the dates of this meeting from November 1-2, 2021 to November 15-16, 2021. The meeting time remains the same. The meeting is closed to the public.

Dated: October 21, 2021.

Tyeshia M. Roberson-Curtis,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-23318 Filed 10-25-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of CRISPR-Engineered T Cell Therapies for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to