The reorganization will improve FDA's ability to carry out its public health mission by realigning and dedicating resources within the organization to modernize clinical trials. The clinical trial innovation work tracks will place DCI at the forefront to robustly meet policy development, implementation, and analysis needs in areas such as Artificial Intelligence (AI), Digital Health Technologies (DHTs), Real-World Evidence (RWE), and other rapidly advancing sectors in the dynamic clinical trial ecosystem.

The CDER, OMP, Office of Medical Policy Initiatives retitled the Division of Clinical Trial Quality to the Division of Clinical Innovations.

The reorganization will enhance the office's ability to attract and retain a diverse workforce representative of our nation and bring like scientists and policy experts together from across the organization, thereby facilitating collaboration and efficient use of shared resources while advancing key innovations in drug development. By developing responsive policies, the Division of Clinical Innovations will modernize the policy environment to ensure that CDER is providing the needed regulatory perspective to guide the appropriate use of such tools and technologies.

The FDA's CDER, OMP has been restructured as follows:

DCDH ORGANIZATION. The CDER OMP (DCDH) is headed by the Director, OMP and includes the following:

Office of Medical Policy (DCDH)
Office of Prescription Drug Promotion (DCDHA)
Division of Advertising and Promotion Review II (DCDHAA)
Division of Advertising and Promotion Review I (DCDHAB)
Division of Promotion Policy, Research and Operations (DCDHAC)
Office of Medical Policy Initiatives (DCDHB)
Division of Medical Policy Development (DCDHBA)
Division of Medical Policy Programs (DCDHBB)
Division of Clinical Innovations (DCDHBC)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2024–30333 Filed 12–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Council) has scheduled a public meeting. Information about ACBSCT and the agenda for the meeting can be found on the ACBSCT website at *https://bloodstemcell.hrsa.gov/about/advisory-council.*

DATES: Thursday, January 23, 2025, 3:00 p.m.–5:00 p.m. Eastern Standard Time.

ADDRESSES: This meeting will be held virtually by webinar. A link to register and join the meeting will be posted at least 10 days prior to the meeting at *https://bloodstemcell.hrsa.gov/about/advisory-council.*

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Designated Federal Official, Division of Transplantation, Health Systems Bureau, HRSA, 5600 Fishers Lane, 8W–67, Rockville, Maryland 20857; 301–443–8036; or *ACBSCTHRSA@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACBST provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under the authority of 42 U.S.C. 274k (Section 379 of the Public Health Service Act), Public Law 109–129, as amended. The Council may transmit its recommendations through the Administrator of HRSA on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory.

The agenda for the January 23, 2025, meeting is being finalized and may include the following topics: graft versus host disease and late effects, strategies for selecting cord blood units for transplantation, HHS' approach for reviewing the state of the science and recommendations on the appropriateness of the inclusion of adult stem cells and birthing tissues as new types of therapies in the C.W. Bill Young Cell Transplantation Program, and other areas to increase blood stem cell donation and transplantation. Agenda items are subject to change as priorities dictate. Refer to ACBSCT's website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings; oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACBSCT should be sent to Shelley Tims Grant, using the contact information above at least 3 business days prior to the meeting. Individuals who plan to attend and need special assistance or other reasonable accommodations should notify ACBSCT at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–30604 Filed 12–20–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60 Day Notice for Extension of Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: Indian Health Service Customer Service Satisfaction and Similar Surveys

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments. Request for extension of approval.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the information collection Office of Management and Budget (OMB) Control Number 0917–

0036, ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.'' This notice announces our intent to submit this previously approved information collection, which expires February 28, 2025, to the OMB for approval of an extension and solicit comments on specific aspects for the proposed information collection.

DATES: Consideration will be given to all comments received by February 21, 2025.

ADDRESSES: Submit comments to Patricia Lawton by *email at Patricia.Lawton@ihs.gov.*

Comments submitted in response to this notice will be made available to the public by publishing them in the 30-day **Federal Register** Notice for this information collection. For this reason, please do not include information of a confidential nature, such as sensitive personal information or proprietary information. If comments are submitted via email, the email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

A copy of the draft supporting statement is available at *www.regulations.gov* (see Docket ID IHS_FRDOC_0001).

SUPPLEMENTARY INFORMATION: The IHS is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995, as amended, and its implementing regulations. This notice is soliciting comments from members of the public and affected agencies as required by 44 U.S.C. 3506(c)(2)(A) and 5 CFR 1320.8(d) concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques of other forms of information technology, *e.g.,* permitting electronic submission of responses.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery: Indian Health Service Customer Service Satisfaction and Similar Surveys.

Type of Information Collection Request: Three year extension approval of this information collection.

OMB Control Number: 0917–0036.

Abstract: The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. Qualitative feedback is information that provides useful insights on perceptions and opinions, but is not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

The Agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the Agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study;
- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; and
- With the exception of information needed to provide remuneration for participants of focus groups and cognitive laboratory studies, personally identifiable information (PII) is collected only to the extent necessary and is not retained.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Current Actions: Extension of approval for a collection of information.

Type of Review: Extension.

Affected Public: Individuals and households, businesses and organizations, and Tribal governments.

Estimated Number of Respondents: 105,000.

Below are projected annual average estimates for the next 3 years:

Average Expected Annual Number of activities: 100.

Average number of Respondents per Activity: 1050.

Annual responses: 105,000.

Frequency of Response: Once per request.

Average minutes per response: 10.

Burden hours: 17,500.

There are no direct costs to respondents to report.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 60-days of the date of this publication.

Roselyn Tso,

Director, Indian Health Service.

[FR Doc. 2024–30541 Filed 12–20–24; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Role of tau in non-neuronal dysfunction in Alzheimer's Disease (AD) and Related Disorders (RD).

Date: February 5, 2025.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Nesar Uddin Akanda, M.D., Ph.D., Scientific Review Officer National Institute of Aging, National Institute of Health, 5601 Fishers Lane, Room 2E405, Rockville, MD 20852, (301) 594–8984, *nesar.akanda@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 17, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–30560 Filed 12–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Mechanisms of the age-related changes in gait biomechanics and the impact on the increased metabolic cost of walking.

Date: February 20, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Nesar Uddin Akanda, M.D., Ph.D., Scientific Review Officer, National Institute of Aging, National Institute of Health, 5601 Fishers Lane, Room 2E405, Rockville, MD 20852, (301) 594–8984, *nesar.akanda@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 17, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–30558 Filed 12–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Inequities in Digital Health for Older Adults with Cognitive Decline and ADRD.

Date: February 21, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Rajasri Roy, Ph.D., MPH, Scientific Review Officer, National Institute of Aging, National Institute of Health, 5601 Fishers Lane, Room 100, Rockville, MD 20852, (301) 496–9666, *rajasri.roy@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 17, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–30563 Filed 12–20–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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