drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions-e2br3-standards).

The electronic format requirements specified in this guidance will be effective 24 months after the publication of this guidance (April 1, 2026). Before the effective date of this requirement, FDA will accept the IND safety reports described in this guidance to FAERS as part of a voluntary submission program.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Providing Regulatory Submissions in Electronic Format: IND Safety Reports.'' 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.

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 under 21 CFR 312.10 for submitting waiver requests and in 21 CFR 312.32 for submitting IND safety reports and reporting serious and unexpected suspected adverse events have been approved under OMB control number 0910–0014. The collections of information for submitting Forms FDA 3500 and 3500A, and for FDA adverse event reporting and electronic submissions using the Electronic Submission Gateway and the Safety Reporting Portal have been approved under OMB control number 0910–0291. The collections of information for submitting periodic adverse drug experience reports have been approved under OMB control number 0910–0230. The collections of information for submitting FAERS reports have been approved under 0910–0308.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, 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.*

Dated: March 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06736 Filed 3–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

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

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a webcast on April 30, 2024. This virtual meeting will be open to the public. Registration is required for the public to attend the meeting, provide comment, and/or distribute material(s) to the ACMH members. Instructions regarding participating in the call and providing written or verbal public comments will be provided after meeting registration occurs.

DATES: The ACMH meeting will be held on April 30, 2024 from 11 a.m. to 12:30 p.m. EDT. If the Committee completes its work before 12:30 p.m., the meeting will adjourn early.

Any individual who wishes to participate in the virtual meeting should register using the Zoom registration link provided below by 5 p.m. EDT on April 24, 2024.

ADDRESSES: The meeting will be held virtually and will be accessible by webcast. Instructions regarding webcast access and providing written or verbal public comments will be given after meeting registration occurs.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, OMH, HHS, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240–453–6816; email: *OMH-ACMH@hhs.gov*.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on the development of goals and program activities related to OMH's duties.

The topics to be discussed during the virtual meeting will be finalizing the recommendations on how OMH and HHS can support community awareness, education and engagement on HHS efforts to implement the revised Office of Management and Budget (OMB) Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15). The final recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to implementation of the revised OMB standards. Information on OMB's Interagency Technical Working Group on Race and Ethnicity Standards can be found on this website: *spd15revision.gov*.

Information about the meeting will be posted on the HHS Office of Minority Health (OMH) website: *www.minorityhealth.hhs.gov*. Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Working Groups*.

Any individual who wishes to attend the meeting must register via the Zoom registration link, *https://www.zoomgov.com/meeting/register/vJIscuuhqzIqHX5wssDFc84ZH-6jdn4NgZg,* by 5 p.m. EDT on April 24, 2024. Each registrant should provide their name, affiliation, phone number, email address, if they plan to provide either written or verbal comment, and whether they have requests for special accommodations, including sign language interpretation. After registering, registrants will receive an automated email response with the meeting connection link. The meeting connection link is unique to each registrant and should not be shared.

Members of the public will have an opportunity to provide comments at the meeting. Individuals should indicate during registration whether they intend to provide written or verbal comment. Public comments will be limited to two minutes per speaker during the time allotted. Written statements are limited to two pages. If the two-page limit is exceeded, the full statement will not be included. Registered members of the public who plan to submit and distribute electronic or printed public statements or material(s) related to this meeting's topic should email the material to *OMH-ACMH@hhs.gov* at least five (5) business days prior to the meeting.

Dated: March 25, 2024.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2024–06850 Filed 3–29–24; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0263]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 31, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0263–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption Form.

Type of Collection: Renewal, three-year extension with non-substantive changes for the *Protection of Human Subjects:* Assurance Identification/IRB Certification/Declaration of Exemption Form OMB No. 0990–0263 Office of the Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting is requesting a three-year extension with non-substantive changes of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form, OMB No. 0990–0263.

The information collected on the form is to provide a simplified method for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to satisfy the requirements of HHS regulations for the protection of human subjects at 45 CFR 46.103 for assurance identification and institutional review board (IRB) certification and declare exemption status. Non-substantive changes include adding instructions that, if additional assurances apply, those details can be indicated in the ''Comments'' section and clarifying that the form element for IRB expiration date does not apply to all projects.

Likely Respondents: Institutions engaged in research involving human subjects where the research is supported by HHS. Institutional use of the form is also relied upon by other Federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule), which is codified for HHS at 45 CFR part 46, subpart A.

ANNUALIZED BURDEN HOUR TABLE

Form name	Number of respondents	Number of responses per respondent	Hours per response	Response burden hours
Protection of Human Subjects: Assurance Identification/IRB Certification/ Declaration of Exemption	13,000	2	0.5	13,000

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–06803 Filed 3–29–24; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grants (R34); NIAID Clinical Trial Implementation Cooperative Agreement (U01); NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44); Investigator Initiated Extended Clinical Trial (R01).

Date: April 30–May 1, 2024.

Time: 9:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20852 (Video Assisted Meeting).

Contact Person: Maryam Feili-Hariri, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F21B, Rockville, MD 20852, 240–669–5026, *haririmf@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 26, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–06859 Filed 3–29–24; 8:45 am]

BILLING CODE 4140–01–P