

II. FDA Determination of Alignment of Third-Party Food Safety Standards Voluntary Pilot Program

A. Scope and Selection Attributes

FDA is seeking requests for participation from members of the public, including owners of third-party human food safety standards, who are interested in participating in a voluntary pilot program to determine whether third-party food safety standards align with food safety requirements in the PCHF and the Produce Safety regulations. Upon being selected to participate in the program, participants will submit their standards for assessment. FDA plans to select and assess up to five private third-party human food safety standards for alignment with food safety requirements in the PCHF or the Produce Safety regulation. Participants in the pilot program will be asked to provide FDA with technical feedback on the pilot. The Agency will use its discretion in choosing participants for assessment based on (in no particular order):

- (1) The order the requests for participation are received;
- (2) the desired diversity of third-party human food safety standards for assessment in the pilot (e.g., PCHF, Produce Safety); and
- (3) the Agency's determination of available resources to conduct the assessment given the level of effort and other priorities.

FDA reserves the right to request additional information or clarification from participants in the pilot and to rescind participation if the additional information or clarification is not promptly and accurately provided.

B. Duration

The pilot will run for 1 year from the date of publication of this notice and will conclude on October 26, 2021. FDA reserves the right to extend the pilot for more time as needed. To assure we have adequate time to assess the standards during the pilot period, we are asking members of the public, including owners of third-party human food safety standards, to submit their request to participate in the pilot program by November 25, 2020.

C. Submission of Requests To Participate

Members of the public, including owners of third-party human food safety standards, that are interested in participating should submit a written request to participate to Franciel Ikeji (see **FOR FURTHER INFORMATION CONTACT**). Electronic requests should be submitted to StandardsAlignmentPilot@

fda.hhs.gov. We strongly encourage interested persons to electronically submit their requests to participate. Written and electronic requests to participate in the pilot program should be submitted by November 25, 2020.

The request to participate should include the following information: Company and contact name; contact phone number; and contact email address. Additionally, although not required for consideration, FDA is particularly interested in whether you are the owner of a third-party food safety standard, and the type of food safety standard you have developed (e.g., produce safety, human processed food). For a limited number of applicants that FDA identifies as possible candidates for participation in the pilot, FDA may ask you to submit a completed FDA Food Safety Audit Comparison Template <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm602286.htm>. If the pilot participant chooses to submit an alternative comparison tool, the format should enable FDA to easily compare the third-party food safety standard to the relevant FDA regulations (i.e., placing the relevant requirements of FDA's regulations in numerical order to the left of any third-party food safety standards). FDA may also ask pilot participants for additional information on submitted food safety standards.

D. Assessment and Alignment of Program Standards

The pilot program will be conducted from October 26, 2020 to October 26, 2021 and may be extended as needed. Each person that submits a request to participate will be notified that FDA has received the request. This notification only acknowledges that FDA has received the request and does not guarantee that FDA will accept you for participation in the pilot. By the conclusion of the pilot, participants will be notified as to whether FDA determined the food safety standard to be in alignment or not in alignment with the relevant FDA regulation.

FDA will publish information on its website regarding the third-party standards that FDA determines to be in alignment with FDA regulations.

E. Evaluation of Pilot Program

FDA intends to evaluate the pilot program on several factors, including, but not limited to, the resources required to review and assess third-party standards for alignment with relevant FDA regulations, the ability of pilot participants to provide adequate information to enable FDA to make a

determination of alignment, and whether FDA Audit Comparison Templates are a helpful tool in making alignment determinations. After FDA evaluates the pilot program, the Agency will utilize the information to evaluate the resources and tools required to conduct alignment reviews.

Dated: October 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-23398 Filed 10-23-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Meeting

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

Name: National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

Dates and Times: Wednesday, November 18, 2020: 10:00 a.m.–5:30 p.m. EST.

Thursday, November 19, 2020: 11:30 a.m.–4:00 p.m. EST.

Place: Virtual.

Status: Open.

Purpose: At the November 18–19, 2020, meeting, the Committee will receive briefings from HHS officials, hold discussions on several health data policy topics and discuss its work plan for the upcoming 12-month period. The Committee will welcome four new members.

The Subcommittee on Standards will provide an update on follow up work from its hearing held in August 2020 to solicit information about the costs and benefits of a new operating rule for connectivity and two operating rules for the prior authorization transaction proposed by the Council for Affordable Quality Healthcare (CAQH), Committee on Operating Rules for Information Exchange (CORE). The Committee will also consider recommendations anticipated from the Office of the National Coordinator for Health Information Technology's (ONC) Health Information Technology Advisory Committee (HITAC), Task Force on Intersection of Clinical and Administrative Data (ICAD), on which four NCVHS members have participated. The Committee will consider next steps for a project to identify and recommend a path toward convergence of administrative and

clinical data in light of the Task Force recommendations. The Committee has invited a representative of the new Office of Burden Reduction and Health Informatics, Centers for Medicare and Medicaid Services, to provide an update on the work of the Office and the potential intersection with the NCVHS work plan.

The Subcommittee on Privacy, Confidentiality, and Security will provide an update on the September 14, 2020, hearing that focused on data collection and use during a public health emergency and identify next steps for development of guidelines for methods and approaches to collect, use, protect, and share data responsibly during a pandemic or long-term nationwide public health emergency.

Members will consider major themes for the NCVHS 14th Report to Congress, which is planned for release in the first half of 2021. Members will consider and discuss priorities for Committee focus and revise the Committee work plan based on the two days of meeting proceedings.

A public comment period will be offered on both days. Meeting times and topics are subject to change. Please refer to the agenda posted at the NCVHS website for any updates.

Contact Person for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, or via electronic mail to vgh4@cdc.gov; or by telephone (301) 458-4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website, <https://ncvhs.hhs.gov/>, where further information including an agenda and instructions to access the broadcast of the meeting will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488-3210 as soon as possible.

Sharon Arnold,

Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2020-23668 Filed 10-23-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Special Emphasis Panel, December 3, 2020, 9:00 a.m. to 5:30 p.m. This notice was published in the **Federal Register** on September 29, 2020, 85 FR 189, Page 61020.

This notice is being amended to change the date and time to December 17, 2020 from 10:00 a.m. to 5:30 p.m. The meeting is closed to the public.

Dated: October 20, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-23584 Filed 10-23-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Ocular Surface, Cornea, Anterior Segment Glaucoma and Refractive Error.

Date: November 17, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435-1252, cinquej@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Metabolism.

Date: November 20, 2020.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, Bethesda, MD 20892, (301) 435-1044, chenhui@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Disease Prevention and Management, Risk Reduction and Health Behavior Change.

Date: November 23, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Michael J McQuestion, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114 MSC 7808, Bethesda, MD 20892, (301) 480-1276, mike.mcquestion@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-19-367: Maximizing Investigators' Research Award (R35—Clinical Trial Optional).

Date: November 23-24, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David Balasundaram, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, (301) 435-1022, balasundaramd@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-20-131: Mammalian Models for Translational Research.

Date: November 23, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806-2515, chatterm@csr.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; HIV Molecular Virology, Cell Biology, and Drug Development Study Section.

Date: November 23-24, 2020.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).