

Vulnerabilities and Actionable Process Steps

- Chapter Three—Mitigation Strategies for Actionable Process Steps
- Chapter Four—Mitigation Strategies Management Components: Food Defense Monitoring
- Appendix—Food Defense Plan Worksheets

We intend to announce the availability for public comment of additional and expanded chapters of the draft guidance as we complete them.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on food defense measures against intentional adulteration for the regulation "Mitigation Strategies to Protect Food Against Intentional Adulteration." 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. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 507 have been approved under OMB control number 0910–0789.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: June 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–13222 Filed 6–19–18; 8:45 am]

BILLING CODE 4164–01–P

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), Standards Subcommittee Meeting.

Date and Times: Tuesday, July 17, 2018: 9:00 a.m.–5:00 p.m. (EDT), Wednesday, July 18, 2018: 8:30 a.m.–3:00 p.m. (EDT)

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 705A, Washington, DC 20201.

Status: Open. There will be three opportunities for public comment during the meeting: At the end of the first day, at the end of the morning of the second day, and prior to the meeting close on the second day.

Purpose: The NCVHS Charter stipulates that the Committee study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information and report to the Secretary of Health and Human Services (HHS) with recommendations and legislative proposals for such standards and electronic exchange. NCVHS also is charged with advising HHS on health data collection needs and strategies, and reviewing and monitoring the Department's data and information systems to identify needs, opportunities, and problems.

In this regard, NCVHS is taking a contemporary look at the health terminology and vocabulary landscape in order to advise the HHS Secretary regarding: (1) The changing environment and implications for timing and approach to health terminology and vocabulary standards adoption; (2) Needs, opportunities, and problems with development, dissemination, maintenance, and adoption of health terminology and vocabulary standards; and (3) Actions that HHS might take to improve development, dissemination, maintenance, and adoption of standards.

NCVHS is holding an expert roundtable meeting, in conjunction with the National Library of Medicine (NLM) in order to: (1) Assess strengths, weaknesses and gaps in the U.S. health terminology and vocabulary (T/V) environment; (2) Consider areas for near term improvement in the development,

maintenance, dissemination and adoption of named code sets; (3) Discuss opportunities for improved governance, coordination and communication across terminology and vocabulary developers and their stakeholders; (4) Identify top priority gaps in the U.S. health terminology and vocabulary coverage; and (5) Envision a roadmap for introducing improvements over the next decade. Invited experts will have the opportunity to provide extensive input to the subcommittee as it studies these questions and finalizes an Environmental Scan report of the current state of the U.S. health terminology and vocabulary (T/V) environment.

The times and topics for this meeting are subject to change. Please refer to the posted agenda for any updates.

Contact Persons 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, telephone (301) 458–4715. Information pertaining to meeting content may be obtained from Vivian Auld, National Institutes of Health, National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland, 20894–3833, telephone (301) 496–7974. Summaries of meetings and a roster of Committee members are available on the NCVHS website: www.ncvhs.hhs.gov, where further information including a meeting agenda and instructions to access the live audio broadcast of the meeting will be posted.

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

Dated: June 14, 2018.

Laina Bush,

Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2018–13179 Filed 6–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 and/or contract applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with grant and/or contract applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Special Emphasis Panel for Contract Review.

Date: July 10, 2018.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W530, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Shamala Srinivas, Ph.D., Scientific Review Officer, Office of Referral, Review, and Program Coordination, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W530, Bethesda, MD 20892–9750, 240–276–6442, ss537t@nih.gov.

Name of Committee: National Cancer Institute Initial Review Group; Subcommittee A—Cancer Centers.

Date: July 19, 2018.

Time: 8:00 a.m. to 3:45 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Shamala Srinivas, Ph.D., Scientific Review Officer, Office of Referral, Review, and Program Coordination, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W530, Bethesda, MD 20892–9750, 240–276–6442, ss537t@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: June 13, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–13263 Filed 6–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) 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 General Medical Sciences Special Emphasis Panel; Review of IPERT Applications.

Date: July 26, 2018.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott at Metro Center, 775 12th Street NW, Washington, DC 20005.

Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12, Bethesda, MD 20892, 301–594–2849, dunbarl@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: June 14, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–13265 Filed 6–19–18; 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 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; Cardiovascular and Respiratory Academic Research Enhancement Awards.

Date: July 12, 2018.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, 301–435–2365, aitouche@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR18–596: Molecular Mechanisms of Alzheimer's Disease, Synaptic Function and Neurodevelopment.

Date: July 17, 2018.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, hamelinc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Amyloid Polymorphisms and Glycosylation in Alzheimer's Disease.

Date: July 17, 2018.

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: Brian H Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, brianscott@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Chemo/Dietary Prevention and Cancer Biomarkers.

Date: July 17, 2018.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

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