

James Berger, MS, MT (ASCP), SBB, Senior Advisor for Blood and Tissue Policy, Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 330 C Street SW, Room L001 Switzer Building, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT:

James Berger, MS, MT (ASCP), SBB, Senior Advisor for Blood and Tissue Policy; Telephone: (202) 795-7608; Fax: (202) 691-2101; Email address: tickbornedisease@hhs.gov. Website information about activities of the Working Group, as well as the charter for the Working Group, which has been filed with the Library of Congress, can be found at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/index.html>.

SUPPLEMENTARY INFORMATION: Section 2062 of the 21st Century Cures Act requires establishment of the Tick-Borne Disease Working Group. The Working Group is governed by provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees. The 21st Century Cures Act is intended to advance the research and development of new therapies and diagnostics and make substantial federal investments in a wide range of health priorities. The Working Group is a non-discretionary federal advisory committee.

Objectives and Scope of Activities. The Secretary of Health and Human Services is responsible for ensuring the conduct of and support for epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases. The Working Group provides assistance for this effort. The Working Group membership provides expertise and reviews all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

Membership and Designation. The Working Group consists of 14 voting members who represent diverse scientific disciplines and views. The composition includes seven federal members and seven public members. The federal members consist of one or more representatives of each of the following HHS agencies: Office of the Assistant Secretary for Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the National Institutes of Health. The

non-federal public members consist of representatives of the following categories: Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases; scientists or researchers with expertise; patients and their family members; and nonprofit organizations that advocate for patients with respect to tick-borne disease. Individuals who are appointed to represent federal entities are classified as regular government employees. The public members are classified as special government employees. Invitations of membership is extended to other agencies and offices of the Department of Health and Human Services and other individuals as determined by the Secretary to be appropriate and beneficial for accomplishing the mission of the Working Group.

The federal members are appointed to serve for the duration of time that the Working Group is authorized to operate. Participation of the appointed federal members is at the discretion of their respective agency head. The public members are invited to serve overlapping terms of up to four years. Any public member who is appointed to fill the vacancy of an unexpired term will be appointed to serve for the remainder of that term. A non-federal public member may serve after the expiration of their term until their successor has taken office, but no longer than 180 days. Terms of more than two years are contingent upon renewal of the charter of the Working Group. Pursuant to advance written agreement, public members of the Working Group will receive no stipend for the advisory service that they render as members of the Working Group. However, public members will receive per diem and reimbursement for travel expenses incurred in relation to performing duties for the Working Group, as authorized by law under 5 U.S.C. 5703 for persons who are employed intermittently to perform services for the federal government and in accordance with federal travel regulations.

Estimated Number and Frequency of Meetings. The Working Group will meet not less than twice a year. The meetings will be open to the public, except as determined otherwise by the Secretary, or another official to whom authority has been delegated, in accordance with the guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c).

Nominations: Nominations, including self-nominations, of individuals who have the specified expertise and knowledge will be considered for appointment as public voting members of the Working Group. A nomination

should include, at a minimum, the following for each nominee: (1) A letter of nomination that clearly states the name and affiliation of the nominee, the basis for the nomination, and a statement from the nominee that indicates that the individual is willing to serve as a member of the Working Group, if selected; (2) the nominator's name, address, and daytime telephone number, and the address, telephone number, and email address of the individual being nominated; and (3) a current copy of the nominee's curriculum vitae or resume, which must be limited to no more than 10 pages.

Every effort will be made to ensure that the Working Group is a diverse group of individuals with representation from various geographic locations, racial and ethnic minorities, all genders, and persons living with disabilities.

Individuals being considered for appointment as public voting members will be required to complete and submit a report of their financial holdings. An ethics review must be conducted to ensure that individuals appointed as public voting members of the Working Group are not involved in any activity that may pose a potential conflict of interest for the official duties that are to be performed. This is a federal ethics requirement that must be satisfied upon entering the position and annually throughout the established term of appointment on the Working Group.

Dated: November 5, 2018.

James J. Berger,

Senior Advisor for Blood and Tissue Policy, Designated Federal Officer, Tick-Borne Disease Working Group.

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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; Member Conflict: AIDS and AIDS Related Research.

Date: December 4, 2018.

Time: 10:00 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, (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301-451-2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Structure/Function Relationships.

Date: December 6, 2018.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435-1239, guthrie@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Adult Cognition, Perception, and Psychopathology.

Date: December 6, 2018.

Time: 3:00 p.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).

Contact Person: Wind Cowles, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, Bethesda, MD 20892, 301-437-7872, cowleshw@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Immunopathology and Immunotherapy.

Date: December 6, 2018.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Nicholas J. Donato, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040, Bethesda, MD 20892, 301-827-4810, nick.donato@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Role of Maternal-Child Interactions in Brain Development Related Disorders.

Date: December 7, 2018.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 237-9838, bhagavas@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-17-340: HIV Protease Evolution and Drug Resistance.

Date: December 7, 2018.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Eduardo A. Montalvo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7852, Bethesda, MD 20892, (301) 435-1168, montalve@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Molecular Cellular Endocrinology.

Date: December 10, 2018.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Liliana N. Berti-Mattera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4215, Bethesda, MD 20892, 301-827-7609, liliana.ber-ti-mattera@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: December 11, 2018.

Time: 10:00 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, (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301-451-2796, bdey@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 9, 2018.

Ronald J. Livingston, Jr.,
Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel; NIAID, 2018 Omnibus BAA (HHS-NIH-NIAID-BAA2018) Research Area 002: Advanced Development of Vaccine Candidates for Biodefense and Emerging Infectious Diseases.

Date: December 6-7, 2018.

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

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3F40B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-9823, (240) 669-5036, poeky@mail.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel; NIAID, SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44 Clinical Trial Required).

Date: December 14, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: J. Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G11A, National Institutes of Health/ NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892-9823, 240-669-5045, sundstromj@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel; NIAID, Clinical Trial Planning Grant (R34).

Date: December 18, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.