

Public participants may submit written statements in advance of the scheduled meeting. 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 NACRHHS should be sent to Steven Hirsch, using the contact information above at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Steven Hirsch at the address and phone number listed above at least 10 business days prior to the meeting.

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### Opportunity to Co-Sponsor Office of Research Integrity Workshops

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** The Office of Research Integrity (ORI) announces the opportunity for non-federal public and private sector entities to co-sponsor ORI conferences or workshops (ORI Workshops). Potential co-sponsors must have a demonstrated interest and experience in the responsible conduct of research (RCR) or the handling of research misconduct allegations. Potential co-sponsors must be willing to participate substantively in the co-sponsored activity.

Expressions of interest for co-sponsorships of ORI Workshops are received throughout the year at the email address below. ORI co-sponsors a limited number of workshops with other entities each year. Expressions of interest are being received for ORI Workshops that will take place in the next fiscal year (October 2018 through September 2019) or beyond.

Expressions of interest for co-sponsorships should be sent by email to [AskORI@HHS.GOV](mailto:AskORI@HHS.GOV) with "Co-sponsorship for ORI Workshops" in the subject field or by mail to ORI at 1101 Wootton Parkway, Suite 750, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Tracey Randolph, Program Analyst, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453-8200.

**SUPPLEMENTARY INFORMATION:** ORI oversees and directs U.S. Public Health Service (PHS) research integrity activities on behalf of the Secretary of U.S. Department of Health and Human Services (HHS), with the exception of the regulatory research integrity activities of the Food and Drug Administration. ORI is a program office within the Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ORI's Division of Education and Integrity (DEI) has among its duties the responsibility to develop and implement activities and programs to teach RCR and train Research Integrity Officers (RIOs) as well as others that are involved in research integrity, such as Institutional Officials (IOs) and institutional counsel.

Consistent with ORI's mission and the applicable statutory authority, 42 U.S.C. 289b, ORI Workshops aim to provide clarification and technical information on the HHS regulations for handling research misconduct allegations and on education in RCR to foster integrity in research. ORI Workshops are moderately sized, convening over one to three days, and typically accepting between 20 and 50 attendees.

Co-sponsors will assist with workshop and agenda development, coordination, financial management, and meeting logistics in conjunction with ORI staff.

Co-sponsors can charge registration fees to recover costs associated with the events; however, co-sponsors may not set registration fees at an amount higher than necessary to recover related event expenses. Further, co-sponsors are solely responsible for collecting and handling any registration fees collected.

**Eligibility for Co-Sponsorship:** The co-sponsoring entity must have a demonstrated interest and experience in the RCR or the handling of research misconduct allegations. The co-sponsoring entity must participate substantively in the co-sponsored activity, not just provide funding or logistical support.

Each co-sponsorship expression of interest shall describe: (1) The entity's interest and goals in promoting research integrity or the RCR, (2) the entity's prior experience and current readiness to undertake the responsibilities described above, (3) the type of event(s) that the entity is interested in co-sponsoring with ORI, (4) facilities available for the event(s), and (5) any current constraints with respect to dates or facilities. The type of event may be an event from ORI's regular program of recurring events (e.g., RCR Instructor's Workshop) or a special topic of mutual

interest to be developed jointly. The expression of interest should be a bulleted outline, no more than two pages in length, single-spaced, and 11-point font. An entity may submit an expression of interest individually or jointly with other entities describing their relative contributions.

**Evaluation Criteria:** After engaging in exploratory discussions with potential co-sponsors that respond to this notice, the following considerations will be used by HHS officials, as appropriate and relevant, to select the co-sponsor(s):

- Qualifications and capability to fulfill co-sponsorship responsibilities
- suitability of the location of the proposed event in terms of the overall geographical distribution of ORI events
- potential for reaching, generating, and engaging adequate number of attendees from stakeholders
- availability and description of facilities needed to support the workshop
- availability of administrative support for the logistics of hosting such workshops

The selected co-sponsoring organization(s) shall furnish the necessary personnel, materials, services, and facilities to administer its responsibility for the workshop. These duties will be outlined in a co-sponsorship agreement with ORI that will set forth the details of the co-sponsored activity, including the requirements that any fees collected by the co-sponsor shall be limited to the amount necessary to cover the co-sponsor's related event expenses. This co-sponsorship agreement does not represent an endorsement by ORI of an individual co-sponsor's policies, positions, or activities. Additionally, this agreement will not affect any determination concerning activities by the co-sponsors that are regulated by ORI.

Dated: August 9, 2018.

**Scott J. Moore,**

*Deputy Director, Office of Research Integrity.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Advisory Committee on Blood and Tissue Safety and Availability

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) will hold a meeting. The meeting will be open to the public.

**DATES:** The meeting will take place on Thursday, September 13, 2018, from 8:00 a.m.–5:00 p.m. ET.

**ADDRESSES:** Crystal City Marriott at Reagan National Airport, 1999 Jefferson Davis Highway, Arlington, VA 22202.

**FOR FURTHER INFORMATION CONTACT:** Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L100, Washington, DC 20024. Phone: (202) 795–7697; Fax: (202) 691–2102; Email: [ACBTSA@hhs.gov](mailto:ACBTSA@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The ACBTSA provides advice to the Secretary through the Assistant Secretary for Health. The Committee advises on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (e.g., product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues. The Committee has met regularly since its establishment in 1997. The Committee will meet on September 13, 2018 to receive presentations on material pertinent to exploring the topic of “Defining a tolerable risk for infectious diseases from a patient’s perspective.” Historical aspects of combating infectious disease risks in the blood supply, ongoing national and global efforts towards mitigating those risks, and emerging considerations shall be presented to the Committee. The full Committee will receive an interim report from the ACBTSA Blood Sustainability subcommittee and additional topics that are pertinent to

the mission of the Committee may be added to the agenda.

The public will have an opportunity to present their views to the Committee during public comment session scheduled for the meeting. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is required to submit their name, email, and comment summary prior to close of business on September 7, 2018. If it is not possible to provide 30 copies of the material to be distributed at the meeting, then individuals are requested to provide a minimum of one (1) copy of the document(s) to be distributed prior to the close of business on September 7, 2018. It is also requested that any member of the public who wishes to provide comments to the Committee utilizing electronic data projection submit the necessary material to the Designated Federal Officer prior to the close of business on September 7, 2018.

Dated: August 9, 2018.

**James J. Berger,**

*Senior Advisor for Blood and Tissue Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the National Vaccine Advisory Committee

**AGENCY:** National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that a meeting is scheduled to be held for the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public; public comment sessions will be held during the meeting.

**DATES:** The meeting will be held on September 12 and 13, 2018. The meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

**ADDRESSES:** U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW, Washington,

DC 20201. The meeting can also be accessed through a live webcast on both days of the meeting. For more information, visit <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in a public comment session. Individuals who wish to attend the meeting and/or participate in a public comment session should register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>. Participants may also register by emailing [nvpo@hhs.gov](mailto:nvpo@hhs.gov) or by calling (202) 690–5566 and providing their name, organization, and email address.

**FOR FURTHER INFORMATION CONTACT:** Ann Aikin, Acting Designated Federal Officer, National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690–5566; email: [nvac@hhs.gov](mailto:nvac@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program’s responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program. During the September 2018 NVAC meeting, sessions will consist of presentations on valuing vaccines, including presentations on the role of vaccines in combatting antibiotic resistance; vaccine innovation, including presentations on financing, new technologies, and development of new vaccines; lessons from the field, with focus on Ebola and the new Shingles vaccine; and a session on HPV vaccination for cancer prevention. Please note that agenda items will be related to the charge of the Committee and are subject to change as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend in person and need special assistance, such as sign language interpretation or other reasonable accommodations,