

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. Members will participate via teleconference.

DATES: The meeting will be held on October 3, 2018, from 11 a.m. to 3:30 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Avenue, Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. For those unable to attend in person, the meeting will also be webcast and will be available at the following link: <https://collaboration.fda.gov/vrbpac1018>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-5771, serina.hunter-thomas@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 3, 2018, the VRBPAC will meet in an open session to discuss and make recommendations on the selection of strains to be included in an influenza virus vaccine for the 2019 southern hemisphere influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will

be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 26, 2018. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 18, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 19, 2018.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Secretary's National Advisory Committee on Rural Health and Human Services (NACRHHS) has scheduled a public meeting. Information about NACRHHS and the agenda for this meeting can be found on the NACRHHS website at <https://www.hrsa.gov/advisory-committees/rural-health/index.html>.

DATES: September 10, 2018, 8:30 a.m.–5:15 p.m. ET; September 11, 2018, 8:30 a.m.–5:15 p.m. ET; September 12, 2018, 8:30 a.m.–11:15 a.m. ET.

ADDRESSES: On September 10, the address for the meeting is The Duke Endowment, 800 East Morehead Street, Charlotte, NC 28202.

On the morning of September 11, NACRHHS will break into subcommittees. One subcommittee will travel to Happy Valley Medical Center, 1345 NC Highway 268, Lenoir, NC 28645. The other subcommittee will travel to Winnsboro Smiles Dental Clinic, 124 N Congress Street, Winnsboro, SC 29180. In the afternoon, at approximately 4:00 p.m. ET., NACRHHS will reconvene at the AC Hotel Charlotte City Center, 220 E Trade Street, Charlotte, NC 28202.

On September 12, the address for the meeting is AC Hotel Charlotte City Center, 220 E Trade Street, Charlotte, NC 28202.

FOR FURTHER INFORMATION CONTACT: Steven Hirsch, Administrative Coordinator at the Federal Office of Rural Health Policy, HRSA, 5600 Fishers Lane, 17W59D, Rockville, Maryland 20857; 301-443-7322; or shirsch@hrsa.gov.

SUPPLEMENTARY INFORMATION:

NACRHHS provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning both rural health and rural human services.

During the September meetings, NACRHHS will discuss the issues of chronic obstructive pulmonary disease, one of the leading causes of mortality in rural areas, and the provision of oral health services in rural areas. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments.

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 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.