

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.