DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information and Comments on Fostering Research Integrity and the Responsible Conduct of Research

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Request for information (RFI).

SUMMARY: The Department of Health and Human Services (HHS), Office of Research Integrity (ORI) seeks information and comments from entities and individuals regarding activities that foster research integrity and promote the responsible conduct of research under 42 CFR part 93. In particular, ORI is interested in learning about best practices, challenges, and needs related to teaching the responsible conduct of research, promoting research integrity, and preventing research misconduct. ORI will use this information to support the goal of conducting outreach and developing educational resources that best support the Public Health Service (PHS) funded research community.

DATES: Responses to the RFI must be received electronically at the email address provided below no later than 5:00 p.m. ET on the 60th day following the date of publication in the **Federal Register**.

ADDRESSES: Interested parties are to submit comments electronically to *OASH-ORI-Public-Comments@hhs.gov.* Include ''RCR RFI'' in the subject line of the email. Mailed paper submissions and electronic submissions received after the deadline will not be reviewed.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: The Public Health Service Policies on Research Misconduct, 42 CFR parts 50 and 93, establish several requirements regarding the fostering of an environment that promotes research integrity and discourages research misconduct. Institutions must adhere to these requirements to receive PHS funding. Per § 93.300(c), an institution must:

> Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct . . .

ORI conducts outreach and develops educational resources that aid institutional efforts ''to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and . . . respond effectively to allegations of research misconduct. . . .'' 65 FR 30600, 30601 (May 12, 2000). ORI has created materials and offered workshops and other events to assist research institutions in meeting their requirements. ORI is interested in hearing from the biomedical research community on ways that ORI can improve upon its efforts to support institutions in this endeavor. To this end, ORI seeks information and comment from biomedical research institutions about best practices, challenges, and needs related to teaching the responsible conduct of research (RCR), promoting research integrity (RI), and preventing research misconduct.

This RFI focuses on establishing a greater understanding of the needs, best practices, and challenges related to three categories:

(a) Using Training and Education To Foster Research Integrity;

(b) RI/RCR Program Administration and Facilitation of Training; and

(c) RI/RCR Training Sessions.

Information collected in response to this request will be used to inform the development of future educational resources and outreach activities.

Using Training and Education To Foster Research Integrity

ORI seeks to understand the key challenges to using training and educational efforts to foster a climate that encourages research integrity and the responsible conduct of research.

1. What challenges have been encountered?

2. Where those challenges may have been overcome, what has made the difference?

3. Where those challenges have not been overcome, what would make a difference?

RI/RCR Program Administration and Facilitation of Training

ORI recognizes that the approach to and implementation of research integrity/responsible conduct of research (RI/RCR) training programs varies within the biomedical research community. To better understand the nature of these programs as well as best practices, challenges, and needs related to program administration and the facilitation of training, ORI asks the following:

1. How are institutions' RI/RCR programs structured, with respect to courses, format, frequency, scope, and content? What about this structure may be of interest or benefit to others administering RI/RCR programs?

2. How are institutions' programs administered? Who or what group is responsible for: Instruction, programming, administration, oversight, and financial support? Do institutions' research integrity officers (RIO) play a role in the program? Do research mentors play an active role in the program? What additional resources are needed from the administrative perspective?

3. Which members of institutions' research communities participate, as learners, in the RI/RCR training program? What benefits or drawbacks pertain to this composition of program participants?

4. Does current institutional policy mandate participation in the RI/RCR training program? If so, for which members of the research community? If mandated participation requirements extend beyond funding agency requirements, please share the rationale for requiring this participation.

5. What fields of research are represented by the participants in the RI/RCR training program?

6. What topics, related to the research environment, research integrity, and/or the responsible conduct of research, does the program cover?

7. Are any topics covered due to a locally perceived or expressed need? Please explain.

8. Which topics are most popular with participants?

9. Which topics are the most difficult to cover and why? What resources would make inclusion and discussion of these topics easier and/or more effective?

10. Do resource constraints (*e.g.,* materials for instruction, training for instructors, staffing, financial) limit presentation of certain topics? Which topics, and why? What resources would be most useful in addressing this?

RI/RCR Training Sessions

To inform the development of educational and training resources that support the needs of the biomedical research community, ORI seeks information on institutional experiences, practices, and needs related to RI/RCR training sessions.

1. How long, on average, does it take to prepare a new course or training session?

2. How frequently is the material in a training session or course revised? How often are new training sessions or courses developed? How often are old training sessions or courses discontinued?

3. Do training materials and resources used in the course or training session(s) come from outside the institution? If so, where? If the program or instructor creates custom materials and resources for use in the course or training session, please describe any related benefits or drawbacks.

4. What approaches engage learners and create an interactive session (*e.g.,* lectures, seminars, small group discussions, audience polling, problem solving, role play)? Are different approaches used when training faculty, staff, students, or postdoctoral researchers?

5. What types of resources seem most effective or engaging (*e.g.,* videos, infographics, scenarios, case studies, slide decks); how is this assessed? Does this vary depending on the group of learners (*i.e.,* faculty, staff, students, or postdoctoral researchers)?

6. Is the impact of a training session assessed? If so, how, and what metrics gauge success?

7. What do learners ask for, instructionally or programmatically, that can or cannot be addressed?

8. What resources are needed to more fully engage learners and/or address their training related requests?

Collection of Information Requirements

Please note: This RFI is issued solely for information and planning purposes; it does not constitute a solicitation for: Request for Proposals (RFPs), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or to make a grant award. Further, ORI is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in responding to this RFI; all costs associated with responding to this RFI will be solely at the expense of the interested parties. ORI notes that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request.

ORI will actively consider all input as our office plans education and outreach activities. ORI may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or to issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned.

Elisabeth A. Handley,

Director, Office of Research Integrity.

[FR Doc. 2020–22992 Filed 10–16–20; 8:45 am]

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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; Small Business: Respiratory Sciences.

Date: November 9–10, 2020.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Xiang-Ning Li, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5112, MSC 7854, Bethesda, MD 20892, 301–435–1744, *lixiang@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Shared Instrumentation: Genomics Studies.

Date: November 9, 2020.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, *smirnove@csr.nih.gov*.

Name of Committee: AIDS and Related Research Integrated Review Group; HIV Coinfections and HIV Associated Cancers Study Section.

Date: November 12, 2020.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, Bethesda, MD 20892, 301–451–5953, *tuoj@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Radiation Therapy and Biology SBIR/STTR.

Date: November 13, 2020.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, *hongb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Shared Instrumentation: Bioengineering Sciences and Technologies (S10).

Date: November 13, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: James J. Li, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7849, Bethesda, MD 20892, 301–806–8065, *lijames@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–19–367: Maximizing Investigators' Research Award (R35—Clinical Trial Optional).

Date: November 13, 2020.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Elena Smirnova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5187, MSC 7840, Bethesda, MD 20892, 301–357–9112, *smirnove@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Myalgic