



December 11, 2020

Via Email to OASH-ORI-Public-Comments@hhs.gov

Elisabeth A. Handley
Director, Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: RCR RFI

Dear Director Handley:

The Council on Governmental Relations (COGR) is an association of 190 public and private U.S. research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member institutions. One area of significant interest and expertise among COGR member institutions is ensuring the integrity of basic, animal, and human subject research.

COGR appreciates the opportunity afforded by the Office of Research Integrity (ORI) to provide information in response to the October 19, 2020, Request for Information (RFI) [[85 FR 66341](#)]. The RFI seeks information on “best practices, challenges, and needs related to teaching the responsible conduct of research, promoting research integrity, and preventing research misconduct.” ORI states that the information collected will be used “to support the goal of conducting outreach and developing educational resources that best support the Public Health Service (PHS) funded research community.”

The RFI asks a series of questions under each of the following three categories:

1. Using Training and Education to Foster Research Integrity
2. RI/RCR Program Administration and Facilitation of Training
3. RI/RCR Training Sessions

This response focuses on addressing the questions under Category 1. It discusses broad challenges that institutions face in implementing Research Integrity/Responsible Conduct of Research (RI/RCR) educational programs and potential means by which ORI could assist in mitigating those challenges.

Questions from RFI:

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.

What challenges have been encountered?

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

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

Response:

COGR member institutions recognize the importance of RI/RCR training in furthering the comprehensive education of the research workforce, promoting adherence to ethical precepts, and ensuring the quality and reliability of research data. NIH requirements for RI/RCR education date back to 1989, and institutions have diligently worked to develop, maintain, and improve educational programs that fulfill or exceed the requirements set forth in the November 2009 NIH Notice [NOT-OD-10-019](#), *Update on the Requirement for Instruction in the Responsible Conduct of Research* (“RI/RCR Requirements”). In developing and implementing these educational programs, institutions have encountered challenges in three major areas: (a) tailoring RI/RCR education to multiple specific audiences; (b) promoting “buy-in” from senior investigators; and (c) ensuring that RI/RCR educational activities have appropriate subject matter focus and utilize efficient training modalities that work effectively across decentralized environments.

Tailoring RI/RCR Education to Specific Audiences: One major challenge that institutions face in this area is establishing RI/RCR disciplinary-specific training programs that are meaningful to the target audience(s). Although many research integrity principles are uniform across scientific fields, the “nuts and bolts” application of these principles in areas such as citation practice, assignment of authorship, and data management may vary widely across scholarly disciplines. Moreover, successful engagement of trainees in RI/RCR course material frequently relies on case-study driven content ideally tailored to the audience’s field or discipline. Some COGR institutions reported that they have been able to develop successful discipline-specific training when they received dedicated funding to do so. Most freely available RI/RCR resources are not discipline-specific however, and without specially earmarked funding, the development of such programs is extremely cost intensive.

Institutions face similar challenges in developing RI/RCR training programs that are appropriate to the various career stages of trainees. Many RI/RCR training materials are geared toward graduate students and post-doctoral trainees, but it is more difficult to find materials designed for researchers who are more advanced in their careers. Accordingly, institutions would welcome ORI’s development of both discipline-specific and career stage-

specific RI/RCR resources that institutions could adapt and adopt.

Promoting Buy-In from Senior Investigators: The absence of RI/RCR materials aimed at established researchers also points up a related institutional challenge: the difficulty of convincing these researchers that RI/RCR training is important for all members of the research team, not just students and early-stage investigators. Seasoned principal investigators often view RI/RCR training requirements as merely an administrative requirement. ORI's assistance in developing educational resources directed to this audience, with a focus on more recent advancements in research integrity expectations (i.e., concepts underlying rigor and reproducibility), would assist institutions in persuading senior investigators that RI/RCR training adds value to their research team and projects and is not just a "check-the-box" exercise that increases administrative burden.

Ensuring Appropriate Subject Matter Focus and Training Modalities: The subjects encompassed by the NIH RI/RCR Requirements have not substantially changed since they were last updated in 2009. Yet, institutions face the challenge of continually adapting RI/RCR education to encompass current research practices, including today's emphasis on the use of "Big Data" and large multi-site research projects that may include international collaborations. ORI assistance in developing training materials that emphasize data stewardship as a means to enhance research integrity, as well as the development of data management tools for researchers, would assist institutions in ensuring that RI/RCR education is relevant to current research practices. Such efforts will be particularly important with NIH's publication of the *Final NIH Policy for Data Management and Sharing* ([NOT-OD-21-013](#)).

In addition to ensuring the relevance of RI/RCR training to current research practices, institutions also struggle with ensuring that training modalities used for RI/RCR programs are both effective and efficient. Institutions have frequently relied upon on-line modalities to provide baseline RI/RCR training because of its cost-effectiveness and the relative ease with which this training mechanism can be implemented across the decentralized research university environment. In addition, on-line training provides a less burdensome means for documenting that training requirements have been satisfied, particularly in the diverse and distributed academic environment, which presents numerous challenges in the accurate and timely assignment of RCR training requirements. NIH, however, has to some extent disparaged the use of online learning mechanisms and incorporates in-person training standards into the RI/RCR Requirements.

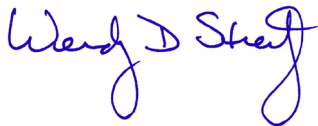
Since the 2009 publication of the RI/RCR Requirements, tremendous improvements have been made in on-line learning, and nothing has made this clearer than the well-placed reliance on on-line, individual learning based educational tools employed during the COVID-19 pandemic. It is no longer obvious that the current iterations of these tools or variations thereof (e.g., the flipped classroom model) are any less effective than stand-alone in-person didactic training sessions for educational content delivery. Accordingly, it may be time to reconsider the role that on-line educational tools can effectively play in RI/RCR training. Nevertheless, in-person RI/RCR training may be the most effective

approach for some training applications, particularly when that training takes place within the setting of the research environment, such as in the case of lab-embedded RCR training. ORI can assist institutions in meeting the challenge of selecting the most appropriate training modality by sponsoring research that generates the data necessary to make evidence-based decisions in this regard. [See, e.g., Dena K. Plemmons, et. al. "[A randomized trial of a lab-embedded discourse intervention to improve research ethics.](#)" *Proceedings of the National Academy of Sciences*. Jan. 2020, 117 (3) 1389-1394; DOI: 10.1073/pnas.1917848117].

Conclusion: The importance of RI/RCR education is well-established, but the most effective and efficient means for providing this education continues to evolve. COGR appreciates ORI's issuance of this RFI to collect information about the wide variety of challenges that institutions face in this area and possible means by which ORI could assist in addressing these challenges.

If you have any questions regarding this response, please contact Kris West, Director of Research Ethics and Compliance at kwest@cogr.edu.

Sincerely,

A handwritten signature in blue ink that reads "Wendy D. Streit". The signature is written in a cursive style with a large, looping 'S' at the end.

Wendy D. Streit
President