ENDOCRINE SOCIETY
Hormone Science to Health

December 17, 2020

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

Re: Notice 85 FR 66341 - Request for Information and Comments on Fostering Research Integrity and the Responsible Conduct of Research

Dear Ms. Handley,

On behalf of the Endocrine Society, I appreciate the opportunity to comment on activities that foster research integrity (RI) and promote the responsible conduct of research (RCR). Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization dedicated to research on hormones and the treatment of patients with endocrine diseases. Our members represent all basic, clinical, and applied research interests in endocrinology. We are committed to teaching the responsible conduct of research, promoting research integrity, and preventing research misconduct. In our comments, we identify some of the challenges our members face and propose recommendations for the Office of Research Integrity (ORI) to consider as you develop resources to support the research community.

1. What challenges have been encountered?

The most widespread challenge facing the research community is the need to broadly engage researchers at all career stages with meaningful educational opportunities that involve issues relevant to their work. Training in RCR/RI is highly variable depending on how the trainee or their laboratory/program is funded and whether their institution has the resources and capacity to offer educational programming on fundamental issues related to RCR/RI to all students in relevant programs, including clinical trainees Our members report that RCR/RI training is often only required for individuals who are funded through grants provided by federal research agencies, though institutions may have their own separate requirements.

Where training is required or provided, another challenge is ensuring that educational programming is interactive, useful, and productive for researchers at all career stages. Improvements in RCR/RI will require a meaningful change in research culture driven by educational content that is appreciated and valued, rather than perceived as merely an administrative/compliance requirement. We note that, despite the importance of RCR/RI to generating rigorous and reproducible research outputs, educators responsible for delivering educational programming in RCR/RI are often under resourced and volunteer their time and expertise.

A related challenge beyond the scope of this RFI relates to the need to have adequate infrastructure, systems, and procedures in place to support individuals who expose instances of research misconduct.

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

To make training in RCR/RI more productive, in-person discussions involving peer groups under the direction of an instructor or mentor are extremely beneficial. When possible, illustrations of real-world applicability of ethical issues using case study approaches led by experts are particularly useful. Examples might include journal editors leading cases studies on ethical issues addressed in the process of reviewing a scientific publication, or bioethicists leading case studies of research involving human subjects. Training materials should also be designed with a target educational level in mind; graduate students, postdoctoral fellows, and faculty are likely to face different issues related to RCR/RI in the conduct of their research and/or in peer review of grant applications and research outputs.

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

Given the high variability in training experiences reported by our members, HHS and ORI should explore the development of high-quality curricula that could be deployed nationwide and adopted by multiple fields of research. HHS and ORI could begin by gathering stakeholders, including scientific societies, to discuss how national standards for RCR/RI might be developed and implemented. If necessary, standards could then be used to develop certifications for training in RCR/RI or accreditation for courses or programs specific to scientific disciplines. Models for such standards and programs may be found in curricula published by NIH on research involving human subjects.

Training in fundamental issues related to RCR/RI should also be extended to clinical trainees who conduct basic research. Our members report that clinical trainees, despite being encouraged to contribute to research studies, may not have mandatory training in RCR/RI unless their studies involve human subjects. Consequently, some clinical trainees conducting research may not be aware of existing educational resources to help them handle ethical issues in research.

8. Which topics are most popular with participants?

Reinforcing the benefits of a case study approach, the most useful studies are likely to acknowledge the forces that contribute to problematic behaviors and explore the consequences of irresponsible conduct to their colleagues, to their field of research, and to society. We reiterate that popular topics will consider the learner's career stage. Early-stage PhD students may prefer topics related to mentor-mentee relationships and designing studies that are rigorous without "p hacking". Postdocs may be more interested in authorship and publication issues. Both populations are likely to appreciate learning about ethical approaches to conflict resolution.

As noted above, institutions must have whistleblower protections in place to overcome challenges associated with RCR/RI. Additionally, training on whistleblower protections should be implemented to enable individuals to expose research misconduct without fear of repercussion. Training should clarify the role of the institution in protecting individuals who identify instances of research misconduct, and training individuals in supervisory positions (e.g., on thesis committees) on how to handle whistleblower complaints.

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?

We strongly support the involvement of researchers, clinicians, and students in the design of curricula and as educators in RCR/RI. However, some topics such as implicit bias and conflicts of interest may require individuals with detailed bioethical expertise. Resources, standards, and educational curricula should be designed in collaboration with bioethicists to reduce variability in training experiences for the research community. As noted previously, courses should explore the professional pressures and issues facing researchers at different career stages.

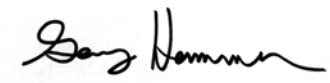
11. What resources are needed to more fully engage learners and/or address their training related requests?

In summary, and from our responses to the previous questions, we recommend that HHS/ORI:

- Develop standards, in collaboration with bioethicists, researchers, and other stakeholders, for RCR/RI.
- Encourage the development of educational curricula based on the RCR/RI standards that can be deployed to basic and clinical researchers across fields for use in-person or in distributed learning environments on a regular basis and with attention to the career stage of the learner.
- Design a library of case studies, involving experts such as journal editors who can address issues that they have encountered and how those issues were overcome.
- Create models to adequately resource the time for educators to implement RCR/RI training.

Thank you for considering our comments. Our members welcome your efforts to conduct outreach and develop educational resources that best support the Public Health Service (PHS) funded research community. If we can be of further assistance in your efforts, please contact Joseph Laakso, PhD, Director of Science Policy at jlaakso@endocrine.org

Sincerely,



Gary D. Hammer, MD, PhD
President
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