December 18, 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: Request for Information (RFI) and Comments on Fostering Research Integrity and the Responsible Conduct of Research (RCR) (85 FR 66341)

Dear Director Handley,

The Association of Research Integrity Officers (ARIO) is a national organization of representatives from universities, research institutes, and academic medical centers that provides a dedicated platform for Research Integrity Officers, their staff, and general counsel to discuss, develop, and share best practices and strategies for handling research misconduct allegations and promoting ethical research.

On behalf of ARIO, I am responding to the Office of Research Integrity’s (ORI) October 19, 2020, request for information related to fostering research integrity and the responsible conduct of research. We appreciate the opportunity to respond to this request.

ARIO fully endorses the December 11, 2020 letter submitted by the Council on Government Relations (COGR) in response to the RCR RFI. Many ARIO member institutions are also represented in the COGR membership. In addition to the themes articulated by COGR, ARIO emphasizes the following points:

**Explicit Institutional Support Enhances Research Integrity**

A significant challenge encountered in fostering a widespread culture of research integrity relates to the fact that many institutions have a tacit expectation that research integrity is an essential part of the responsibilities shared by all members of the research community. In order to avoid bystander effects, in which a responsibility shared equally by a great many people can sometimes fail to elicit high priority, attention and/or accountability, **ARIO believes that institutional support for research integrity should be prioritized, publicized and emphasized through clear policies, procedures, and practices; appropriate dedicated staffing and resources; and the identification, empowerment, and support of faculty champions.** Faculty engagement in RCR education and in setting standards for research integrity directly affects trainees, staff and lab practices. Faculty education and buy-in drives more efficacious RCR as well as the establishment and maintenance of a culture of research integrity. Strong, visible support by institutional leadership, and the development of institutional expectations for authorship, mentoring, use of electronic lab notebooks, research data retention, etc., create a
foundation on which faculty, students, and staff can build solid research practices. Providing institutions and researchers with tools and resources for laboratory and research best practices enhances the environment and sets standards to clearly articulate what should be done and what faculty can use to guide their conduct.

Establishing institutional procedures and protections for whistleblowers, and incorporating outreach to educate the community, ensures those who have concerns can safely raise them. Beyond research misconduct, though, there are other concerns that compromise research integrity including questionable research practices, mentoring and authorship problems, and data management. Focusing only on the most egregious issues, like research misconduct, may send a tacit (inadvertent and counterproductive) message to researchers that these other concerns do not merit attention, and may thereby allow more pervasive issues to go unaddressed and potentially compromise research.

**ORI Support Should Fund Research for Assessment Tools and Metrics**

To determine what can really make a difference, there remains much to be learned about how to best educate our communities on RCR. **ARIO believes validated assessment tools and a clear understanding of what types of RCR education actually affect the research culture are needed.** How do we measure responsible research conduct? How do we know if we have a culture of research integrity? What types of RCR training actually educate trainees and faculty to conduct responsible research? All of these questions remain largely unanswered and open for much debate. We can all agree that RCR training that merely “checks the box” doesn’t result in greater research integrity, but what does?

**ARIO believes that ORI has the ability to tackle many of these issues through the research it funds,** in particular by supporting substantive research on research misconduct, research integrity, and RCR education effectiveness, among other topics. This research must be in touch with institutional efforts, practical, and based in details and real institutional experiences. There is a need for research to develop clear metrics and measures for evaluating RCR programs, framed by responsible research practices and meaningful policies and guidance along with train-the-trainer resources. **ARIO believes that the research that ORI funds should make an impact in the community and ORI-disseminated information should be relevant and meaningful in promoting research integrity.** Reporting solely on numbers of cases may not provide a full context. For example, there is a perception in the research community that increased RCR efforts can be seen as effective if research misconduct allegations decrease, whereas a contrary possibility is that larger numbers of research misconduct cases may in fact reflect institutional success in outreach and the creation of a safe environment for concerns to be brought forward.

The community would welcome resources and tools to integrate RCR into rigor and reproducibility efforts, mentorship and basic instruction in research. Such efforts would support the notion that RCR is not about compliance, but that it is fundamental to high quality research and supports the success of their programs.
Conclusion

In conclusion, ensuring engagement at all levels, including institutional leadership, faculty, students, staff and other trainees is critical to ensuring cultures that promote and support research integrity. Emphasis on how to do things well and with integrity, along with resources and best practices to buttress these standards could establish goals and effectively shape research environments for conducting solid research. Establishing a tool kit of policies, procedures, practices, and standards to support faculty in managing their labs with a focus on research integrity would be beneficial for all.

ARIO remains willing and looks forward to partnering with ORI in its efforts to foster research integrity and the responsible conduct of research. Please contact me directly (lhaney@northwestern.edu) to discuss any questions you might have or if ARIO can be of assistance.

Sincerely,

[Signature]

Lauran Qualkenbush, President