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Report on Research Compliance Volume 19, Number 12. November 23, 2022

Groups Seek Substantive Revisions to HHS Misconduct Regs, Investigations

By Theresa Defino

Two organizations representing research institutions and integrity officials have called for a virtual rewrite of the regulations that govern misconduct in Public Health Service-funded studies.

The Association of Research Integrity Officers (ARIO) and the Council on Governmental Relations (COGR) argued in a joint letter in response to a request for information (RFI) that the current regulations are 17 years old, which has given institutions "ample opportunity to see how [they] work in practice."[1]

Among the recommendations in their 12-page letter is to narrow "the scope of inquiries/investigations and the circumstances under which an inquiry or investigation may be closed." The HHS Office of Research Integrity (ORI), which enforces research misconduct regulations, has "interpreted [relevant] provisions to greatly expand the scope of investigations beyond what the allegations and evidence suggest," the organizations wrote.

This "overly broad scope may require universities to spend countless hours attempting to locate and assess information about rarely cited publications, unfunded proposals, unpublished research activities, and laboratory research records many years after their creation. This problem is compounded, and raises key process fairness concerns, when the respondent and/or key witnesses have left the institution and cannot be located or remain non-responsive to requests for information," the groups said. "Requiring institutions to allocate scarce institutional resources to these frequently fruitless tasks hampers institutional efforts to address new or higher-impact concerns, as well as to conduct preventative and educational activities."

They added that institutions should have "discretion to terminate research misconduct proceedings at assessment or inquiry" based on the investigator's "status/non-status as an active researcher" in the United States and the lack of a "factual basis that supports culpability of a respondent."

Request for Harmonization

Whether to end "proceedings" should also depend on the "impact of the questioned research on federal funding (e.g., was funding awarded based on questioned research) and the public scientific record (e.g., was the questioned research limited to the lab, did it result in a publication, and was that publication highly cited)"; the "impact of the questioned research on public health or safety (e.g., does the questioned research impact practices that could influence public health and safety)" and "impact of the questioned research on the research record (e.g., has or will the research record be corrected)," the groups said.

They also "encourage limiting the investigation to a reasonable number of years for which data, reliable testimony, and other evidence can be obtained and accurately assessed." Additionally, ORI should define "intentionally," "knowingly" and "recklessly," and eliminate the 60- and 120-day deadlines to complete inquiries and investigations, respectively.

In conclusion, ARIO/COGR urged ORI "to use its review process as an opportunity to work with other federal

research funding agencies toward harmonization of research misconduct policies."

The Association of American Medical Colleges (AAMC) also submitted a response to the RFI, published in September.[2] ORI said it received a total of 31 responses; they "ranged in nature and length, from short emails to multi-page letters," the agency said in a Nov. 14 post on its website. The comments are not posted, but ORI said it would share them on a "de-identified" basis as "part of the rulemaking process." ARIO/COGR and AAMC made their responses public.

Without providing details, ORI also promised there would be "future opportunities to provide input during the rulemaking process." By law, agencies must allow comments on proposed regulations unless they meet strict criteria for publication as a final rule.

AAMC: Remove 'Reckless' From Regulation

In their four-page response, AAMC leaders stressed that they:[3]

- "Support retaining the current definition of research misconduct at 42 CFR §93.103 as limited to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." In particular, AAMC recognizes "that within this environment, scientists, trainees, and research staff may be adversely affected by many other types of inappropriate or unethical behavior, including but not limited to sexual harassment, bullying, discrimination, and bias," but, like ARIO/COGR, does not want the definition of misconduct expanded to include these behaviors. AAMC "supports reform and revision under the appropriate authority to effectively combat and penalize behaviors such as harassment in the research environment," but this should not include ORI.

- "Recommend changing the current language…for the requirements for findings of research misconduct to remove the word 'recklessly' as part of the criteria for how a misconduct is committed." Institutions have yet to adopt a consistent definition of recklessly and too often equate "reckless" and "negligent," which causes "internal committees to debate whether someone should be held responsible for the intentional misconduct of those being supervised 'negligently.'"

- "Recommend a thorough review of the required institutional processes through the allegation assessment, inquiry and investigation stages, to allow institutions greater flexibility from the initiation to the close of an investigation." Among suggested changes, AAMC is calling for clarity on "what constitutes an allegation, with the institution given wider latitude to determine when an allegation contains enough specificity to warrant follow up." It also is seeking a revision of the requirement that institutions pursue "any evidence of additional instances of possible research misconduct" discovered during the investigation." AAMC is seeking "greater flexibility for how to handle these discoveries during an ongoing investigation, including the potential to move them to a new inquiry or determine that the scope of the existing inquiry would cover the substance that the new allegations purport to address and should run to its conclusion before considering additional information."

AAMC concluded its response by recommending that "ORI, in concert with other federal agencies, clearly communicate the government-wide expectations for when and at what point in the proceeding an institution is required to report the status or findings of an investigation to federal entities other than ORI, in order to standardize and clarify the requirements and expectations across the government."

1 Wendy D. Streitz and Lauran Qualkenbush, "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct," letter to Wanda K. Jones, October 30, 2022, http://bit.ly/3OkeGaV.

2 Theresa Defino, "Still Lacking a Permanent Director, ORI Moves To Broadly Revise 2005 Governing Regulation," *Report on Research Compliance* 19, no. 10 (October 2022), http://bit.ly/3XhuUWl.
3 Ross McKinney Jr., "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct," letter to the Department of Health and Human Services, http://bit.ly/3Xnpmto.