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October 31, 2022

Department of Health and Human Services  
Office of Research Integrity  
1101 Wootton Parkway, Suite 240  
Rockville, Maryland 20852

**Re: 87 FR 53750: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct**

*Submitted electronically to [OASH-ORI-Public-Comments@hhs.gov](mailto:OASH-ORI-Public-Comments@hhs.gov)*

The Association of American Medical Colleges (AAMC) appreciates the opportunity to provide feedback to the Department of Health and Human Services (HHS), Office of Research Integrity (ORI) on the 2005 Public Health Service Policies on Research Misconduct at 42 CFR Part 93 to help structure any future plans to revise the regulation. The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members comprise all 156 accredited U.S. medical schools; 14 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and nearly 80 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 191,000 full-time faculty members, 95,000 medical students, 149,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC's U.S. membership and expanded its reach to international academic health centers.

As ORI contemplates beginning a regulatory revision process for the 2005 ORI regulation, we would like to emphasize the following points, which are described in more detail within this letter:

- We 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.
- We recommend changing the current language at §93.104 (b) for the requirements for findings of research misconduct to remove the word “recklessly” as part of the criteria for how a misconduct is committed.
- We 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.

## The Definition of Research Misconduct

AAMC believes that the current definition of research misconduct at §93.103, which is limited to fabrication, falsification, or plagiarism in research, is the appropriate definition and allows ORI to operate at the most focused approach and within its clear expertise.

Several proposals in recent years have called for an expansion of the definition of research misconduct, and subsequently the scope of ORI's mission, to include many additional behaviors that have no place in the research ecosystem. We recognize 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. The AAMC strongly concurs that these actions and behaviors have no place in research and should be reported and investigated. However, we agree with the conclusions of a 2017 report from the National Academies<sup>1</sup> that “because such actions are not unique to the research process, they do not constitute research misconduct... (and) should, therefore, be addressed in other ways.”

ORI should not be tasked with building the expertise and processes to address actions that may impact the research environment but are not specific to the conduct of research itself. A broader, coordinated framework of institutional and agency actions should instead address those harmful actions that do not constitute fabrication, falsification, or plagiarism. Such actions are already subject in many cases to existing laws, regulations, funder reporting requirements, and institutional and employment policies that directly address and seek to protect against and respond to these actions. AAMC also understands that in some cases, the existing policies and regulations to address these behaviors are insufficient or have been shown to be ineffective at accomplishing their stated goals and supports reform and revision under the appropriate authority to effectively combat and penalize behaviors such as harassment in the research environment.<sup>2</sup>

## Criteria for Findings of Research Misconduct

The current language at §93.104 for findings of research misconduct require among other things that the misconduct be committed “intentionally, knowingly, *or recklessly*.” Years of institutional attempts to apply the more subjective “recklessness” standard to the concrete requirements of fabrication, falsification, or plagiarism has proven difficult to interpret consistently. We recommend removal of the word “recklessly” from this phrase, to require instead that an institution find that an action constituting research misconduct was committed “intentionally” or “knowingly.”

Too often in a research misconduct proceeding, the terms “reckless” and “negligent” are equated, causing internal committees to debate whether someone should be held responsible for the intentional misconduct of those being supervised “negligently.” Adding to the confusion, in the factors that ORI

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<sup>1</sup> National Academies of Sciences, Engineering, and Medicine 2017. *Fostering Integrity in Research*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/21896>.

<sup>2</sup> See, e.g. the work of the Societies Consortium on Sexual Harassment in STEM ( <https://societiesconsortium.com/> ) in which AAMC is an inaugural member.

may consider in determining remedial HHS administrative actions, §93.408 asks if “the respondent's actions (were) knowing or intentional or was the conduct reckless?,” implying that the three standards should not be considered equivalent and should lead to differential outcomes. Removing “recklessly” from §93.104 would clarify an institution’s obligations.

### **Institutional Inquiry and Investigation**

The AAMC recommends a review of the provisions pertaining to the rules and responsibilities for the institution during the course of an ORI investigation. The current three-part investigational process for institutions is onerous, time-consuming, and difficult to navigate, leaving institutions few opportunities to conclude the process when existing evidence is conflicting or insufficient to warrant continuation. Additionally, the prescriptive nature of the procedures outlined for institutions often prevents the institution from moving forward in the way that is most beneficial to the investigation. We recommend that ORI evaluate the following specific provisions for potential updates:

- We propose that institutions be given greater flexibility over when the process for misconduct is triggered and advances. §93.201 and §93.300 state that an allegation is “a disclosure of possible research misconduct through any means of communication... to an institutional or HHS official” and that institutions must “respond to each allegation of research misconduct for which an institution is responsible.” We recommend that there be clearer guidance within the regulation as to what constitutes an allegation, with the institution given wider latitude to determine when an allegation contains enough specificity to warrant follow up.
- §93.307(d) states that an investigation is warranted if there is (1) “a reasonable basis for concluding that the allegation falls within the definition of research misconduct” and (2) that “preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.” We recommend that the standard in the latter be changed to also require that preliminary information indicate a reasonable basis for concluding a substantial allegation, to prevent institutions from having to move forward with investigations with minimal evidence to meet the “may have substance” clause.
- §93.310(h) indicates that institutions should pursue “any evidence of additional instances of possible research misconduct” discovered during the investigation. This provision can extend and expand the scope of the investigation without limits, and we recommend that there be 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.

Finally, AAMC notes that federal agencies have their own reporting requirements for institutions regarding research misconduct, separate from reporting to ORI. We recommend 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.

We look forward to continued engagement with ORI as it continues the review of this regulation and its effectiveness in handling of allegations of possible research misconduct and fostering the

improved conduct of scientific research. Please feel free to contact me or my colleagues Anurupa Dev, PhD, Lead Specialist for Science Policy ([adev@aamc.org](mailto:adev@aamc.org)) or Heather Pierce, JD, MPH, Senior Director for Science Policy ([hpierce@aamc.org](mailto:hpierce@aamc.org)) with any questions about these comments.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ross McKinney, Jr., MD". The signature is stylized and cursive.

Ross McKinney, Jr., MD  
Chief Scientific Officer

cc: David J. Skorton, MD, AAMC President and Chief Executive Officer