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Sheila Garrity, JD, MPH, MBA  
Director, Office of Research Integrity  
Department of Health and Human Services  
1101 Wootton Parkway, Suite 240  
Rockville, MD 20852

**Re: Response to Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct (RIN 0937-AA12; 88 FR 69583)**

*Submitted electronically at <https://www.regulations.gov>*

Dear Director Garrity:

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment on the Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct (NPRM) published October 6, 2023 by the Department of Health and Human Services (HHS) Office of Research Integrity (ORI). The proposed revisions to 42 CFR part 93 represent a significant change to the regulations published in 2005 and an opportunity to improve substantially the federal and institutional processes designed to address certain threats to the integrity of scientific research, data, and publications.

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 are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 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 participation in the AAMC by U.S. and international academic health centers.

Overall, we are in agreement that the 2005 regulations could be improved by reevaluating the necessity of certain proscriptive processes and better balancing the consistency that comes from rigorous requirements with the flexibility needed for institutions to address a wide range of situations. While the NPRM accomplishes some of these goals, there are areas where the proposed revisions increase burdens on institutions, complainants, or respondents without a clear benefit, and reflect missed opportunities to make more substantial changes that would improve the process for all

participants. In addition to the comments we provide here, we commend to ORI the many letters from academic institutions with extensive experience implementing these regulations as well as other associations, such as COGR, that have compiled detailed recommendations.

### **The Definition of Research Misconduct**

The AAMC appreciates ORI's retention of the three categories of activity which comprise the definition of research misconduct. As described in our letter in response to a 2022 RFI, AAMC has long supported the 2005 definition of research misconduct at §93.103, which is limited to fabrication, falsification, or plagiarism in research. Institutional training, policies, and practices have evolved over the last 18 years to ensure that research misconduct matters are more clearly recognized and consistently addressed. Problematic behaviors and actions such as sexual harassment, bullying, inadequate mentorship, or discrimination adversely affect the research environment but are not specific to proposing, performing, or reviewing research, or in reporting research results and are therefore best addressed at the institutional level.

### **Clarification of “Recklessly”**

We appreciate the recognition by ORI that institutions have had difficulty with the term “recklessly” when applying §93.104. This provision requires that a finding of research misconduct be based on conduct that was committed “intentionally, knowingly, or recklessly.” As authors and commenters have written over several years, institutions struggle with when there is sufficient evidence to conclude that a respondent “committed misconduct recklessly.” In our comments to the 2022 RFI from ORI, we suggested that “recklessly” be removed from §93.104 to clarify that a finding of research misconduct must be based on a standard that a respondent acted “intentionally or knowingly.” Knowing about a risk and failing to address it or adequately supervise could still constitute misconduct under the remaining definition.

We agree that if “recklessly” is retained in the regulations, it should be defined. However, we do not find that the proposed new definitions of “knowingly” and “recklessly” adequately distinguish these two terms. Being able to differentiate between the two and provide HHS with the means to conclude which applies to the situation at hand is critical. When HHS assesses mitigating and aggravating factors in taking administrative actions after a finding, §93.408 asks “Were the respondent's actions knowing or intentional or was the conduct reckless?” This suggests that “reckless misconduct” deserves different remedial actions than other misconduct. We recommend that the definition of recklessly be expanded to provide more guidance to institutions. If it is ORI's intention to consider inadequate supervision a potential application of misconduct committed “recklessly,” that example should be provided explicitly.

### **Revisions to Institutional Procedures**

The AAMC previously recommended that ORI conduct a comprehensive review of the requirements for institutions in the inquiry and investigation processes, noting that the 2005 regulations put into place an “onerous, time-consuming, and difficult to navigate” three-step set of requirements in which “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 were hopeful that subsequent community listening sessions or an NPRM would address these long-standing concerns

while setting forth revisions that would: 1) allow institutions to quickly close out cases which were determined to have no merit or are found midway through the process to be the result of honest error; 2) best protect the confidentiality and reputations of complainants, respondents, institutions, graduate students in affected labs, faculty colleagues, and collaborators; and 3) minimize barriers to good faith allegations of research misconduct. The NPRM does not yet reflect a revised set of regulations that accomplish these objectives. We suggest that ORI consider making the following revisions, among others recommended by the biomedical research community.

- **Remove or extend newly added timelines for certain stages of the investigation.** Recognizing the advantage of having research misconduct investigations move as swiftly as possible for the benefit of all involved, we are concerned about the penalties and burdens to institutions, respondents, and ORI itself for failing to meet certain deadlines. For example, §93.307(a)(1) would require an allegation to move directly to inquiry if the assessment is not completed within 30 days. We see no benefit to forcing an institution to move forward with a meritless claim when not warranted and note that this has a potential detrimental effect on a respondent whose case is moved forward because the institution failed to act, not because the allegation supported an inquiry. Similarly, §93.408(h)(2) adds burden to both institutions and to ORI by requiring a request for an extension if the inquiry goes beyond 60 days. Institutional documentation of the need to go beyond certain timeframes based on the breadth or complexity of a case should be sufficient in all cases.
- **Ensure that additional processes and requirements do not discourage internal reporting of good faith allegations.** Several of the proposed revisions could prevent potential complainants from making credible allegations or fully participating as a witness for fear of retaliation or loss of confidentiality. The requirement at §93.305(g) that all interviews must be transcribed creates a disincentive for witness participation, particularly at early stages of the institutional activity, and the added expense could disincentivize the institution from seeking out and including all relevant witnesses.
- **Revise the burdensome requirements for institutions to create and provide to ORI reports throughout the internal process, especially in early stages of the investigation.** A significant change to the 2005 regulations is the proposed “robust and required institutional record as part of the research misconduct investigative process.” This record, detailed in §93.305, would now include: “the assessment report, inquiry report, investigation report, decision(s) made by the institutional deciding official, and the complete record of any institutional appeal, any other records the institution used for the research misconduct proceeding, documentation related to the determination that records are irrelevant or duplicate and therefore not included, and a single index listing all documents in the institutional record.”

The research misconduct process, including the sequestration of records, is already a highly disruptive and onerous process that can halt or interrupt the work of entire departments as well as the work of collaborators. Adding the creation and submission of an even greater institutional record neither furthers ORI’s goals of accelerating the pace of institutional investigations nor does it enhance the quality of the information already provided to ORI in an investigation report. The conclusion of a research misconduct investigation has always included considerable interaction between ORI and the institution, including discussion of the sufficiency of the investigation report and accompanying documents. We recommend

that the requirements for the “institutional record” be substantially scaled back, including by removing the assessment report and the index of documents that are not included in the record. In addition, ORI should consider the impact of increasing the volume and distribution of records regarding the investigation on the careers and reputations of those connected to the work but not under investigation. From graduate students to co-authors at other institutions, the creation and submission of additional mid-investigation reports to ORI creates additional opportunities for the identification of those associated with research under scrutiny, especially at public universities or those subject to local freedom of information laws.

### **Implementation Timeline**

The NPRM notes that the expected timeline for finalization and implementation of the final rule could be as little as 4 months. We are concerned that this is insufficient time to revise all relevant institutional policies and implement the changes across all institutions. We recommend that the implementation deadline be no earlier than 1 year from the final rule, as the process for major policy changes with related training and communication efforts typically takes several months.

As reflected in the comments from AAMC and from academic institutions that have considerable experience implementing the 2005 regulations on research misconduct, ORI has an opportunity to enhance the process for the oversight of investigations into allegations of research misconduct in research under the U.S. Public Health Service. Codifying a fair, credible, and efficient process into regulation demonstrates the collaboration between the federal government and academic institutions in safeguarding the integrity of research, creates a system that protects the careers and reputations of those who report and found not to have committed misconduct, and ultimately increases the public’s trust in the conduct and outcomes of research. This revision should be undertaken with an understanding of the strengths and shortcomings of the 2005 regulations. As proposed, useful clarifications and improvements are outweighed by the increases in documentation, reports, processes, and varied timelines, all of which require new policies and tracking systems. We question whether the system is strengthened or improved by many of these new requirements.

We appreciate the opportunity to provide these suggestions and to remain engaged with ORI throughout the process of revising these regulations to improve research misconduct investigations. Please feel free to contact me ([hpierce@aamc.org](mailto:hpierce@aamc.org)) or my colleague Anurupa Dev, PhD, Director of Science Policy and Strategy ([adev@aamc.org](mailto:adev@aamc.org)) with any questions about these comments.

Sincerely,



Heather H. Pierce, JD, MPH  
Acting Chief Scientific Officer  
Senior Director for Science Policy and Regulatory Counsel

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