Association of American Universities
America's Leading Research Universities

January 4, 2024

MEMORANDUM

To: Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity

From: Lizbet Boroughs, Associate Vice President, Government Relations and Public Policy, Association of American Universities

Subject: **Notice of Proposed Rulemaking – Public Health Service Policies on Research Misconduct (42 CFR Part 93) (Regulatory Information Number (RIN): 0937-AA12)**

Submitted electronically via regulations.gov, Docket ID: HHS-OASH-2023-0014-0001

AAU appreciates the opportunity to share our views on the Notice of Proposed Rule Making on the Public Health Service Policies on Research Misconduct (42 C.F.R. Parts 50 and 93), issued by the Department of Health and Human Services, Office of Research Integrity on October 5, 2023.

The Association of American Universities (AAU) represents 69 leading U.S. research universities, all of which are longstanding partners in research supported by the National Institutes of Health (NIH). Our member universities earn the majority of competitively awarded federal funding for research that improves public health, addresses national challenges, and contributes significantly to our national security and economic strength, while educating and training tomorrow's visionary leaders and innovators. AAU is committed to upholding the highest standards of scientific integrity and is pleased to continue our engagement with the Office of Research Integrity regarding federal guidance relating to research integrity and misconduct.

AAU supports the analysis and comments submitted by our sister organizations, COGR, the Association of Research Integrity Officers (ARIO) and American Public Land-Grant Universities (APLU).

AAU's comments below focus on specific concerns and recommendations we have concerning new requirements in the NPRM that: 1) call for additional institutional processes and procedures at very early stages of the inquiry and investigation process, 2) shorten the current time requirements for institutional inquiries, assessments and investigations, 3) change how inquiries that involve multiple respondents and/or institutions must be conducted, and, finally, 4) AAU would like HHS to provide additional clarity regarding HHS's roles and responsibilities versus those of the institution in misconduct cases, especially those where there is no settlement or finding of research misconduct.

1) **AAU is concerned about the proposed language regarding when and how an institutional inquiry must be undertaken. Specifically, our concerns relate to the language in § 93.307(f)(2) Institutional inquiry and § 93.306 Institutional assessment.**

   § 93.307(f)(2) Institutional inquiry; Honest error and difference of opinion - Proposed Language

We feel it is unnecessary to require institutions to pursue both an inquiry and investigation when there is clear evidence of an honest error or difference of opinion that may unjustly damage a respondent's reputation. In science, it is widely accepted that error can and does occur as part of the scientific process as is the case in most occupations. Requiring an inquiry and investigation to be undertaken in such instances has the potential to undermine researchers' trust in research integrity officers (RIOs) and adversely impact the ability of RIOs and researchers to discuss research best practices, including honest errors, without triggering unwarranted proceedings. Furthermore, if the preliminary evidence at inquiry, including evidence of honest error or difference of opinion, indicates that the allegation does not have substance, an institution should be permitted to decline moving forward to the investigation stage. For an institution to convene an investigation for all cases, including those that can be proven to result from honest error, presents a significant and unnecessary burden on institutions which could also have unwarranted reputational impacts on researchers.

Recommendation: AAU opposes this language and recommends removal of this proposed section.

§ 93.306 Institutional assessment
This newly proposed section is concerning for two reasons – the potential reputational risks it poses for researchers prior to any proof of misconduct and the unnecessary institutional burden it will require. As COGR, ARIO and APLU have noted, the current assessment process is an informal process that precedes the formal inquiry and investigation We maintain that an institution's approach to this early stage should not be prescribed by the federal regulations, particularly due to the already existing very low bar required to proceed to inquiry. It is critical that institutions can ensure a completely confidential and safe environment for the early-stage discussions around potential allegations of misconduct to avoid discouraging complainants from coming forward with concerns and to prevent premature identification of a potential respondents, which has reputational considerations that deserve serious attention.

Requiring an institution to conduct an inquiry for allegations that were not assessed within 30 days and that were not sufficiently credible and specific places unreasonable and unnecessary new requirements and costs on the institution, taking time and funding away which could better be spent in direct support of research. This includes the burden and disruption imposed by sequestering relevant research records when no inquiry may be warranted. As ARIO noted in their comments, even more troubling is the negative impact on an individual respondent who would be subject to an inappropriate inquiry purely because of administrative delay that falls outside of the respondent's control. In addition, to the extent documentation is created as part of the assessment, it should not be a record that can be made public, especially if the allegation is not one that meets the bar for inquiry to guard against unwarranted reputational harm.

Recommendation: AAU urges that §93.306 (b)(2) (1-3) be deleted.

2) **AAU is concerned that the Proposed Regulations for prescribed deadlines in §93.307(a)(1) (strict 30-day deadline for assessment); §93.307(h) (60-day deadline to complete inquiry); §93.311(a) (180-day deadline to complete investigation); §93.314 (120-day deadline to complete appeals process) are problematic and will impede an institution in performing due diligence and ensuring due process for researchers.**

§ 93.307(h)(1) Institutional inquiry; Time for completion – Proposed Language

Requiring that an inquiry be initiated 30 days after receipt of the allegation, regardless of whether a full assessment has been completed, is concerning. Due diligence requires securing expert opinions and careful review of records. The mandated 30-day window, especially in circumstances where multiple respondents or institutions may be involved, is not always possible and will overly restrict the time required to fully assess if an inquiry is actually required.

Recommendation: AAU suggests extending the proposed timeframe to 90 days to provide sufficient time to determine whether an allegation should move to inquiry.

§ 93.307(h)(2): Institutional Inquiry; Time for Completion

As our colleagues from ARIO noted, the proposed 60-day time limit has been shown to be too short for the majority of inquiries. The 60-day time limit leaves institutions at risk for lawsuits when respondents legally challenge the institutional processes that take longer than listed in the regulation.

Recommendation: AAU suggests changing (h)(1) to read, "The institution should strive to complete the inquiry within 60 days…"

Similarly**, § 93.311(a)** (180-day deadline to complete investigation) and **§93.314** (120-day deadline to complete appeals process) do not allow sufficient time to ensure due process and the necessary careful effort required to complete an investigation and appeals process.

Recommendation: The language in both sections be changed, respectively, to read, "The institution should strive to complete the investigation within 180 days…" and "…strive to complete the appeals process within 120 days."

3) AAU is concerned with the NPRM's treatment of misconduct cases involving multiple respondents and requests additional clarity when multiple institutions are involved in misconduct cases.

In addition to our concerns with the changes under **§93.306** to the assessment processes described above, situations with multiple respondents and institutions involved also require careful consideration and additional clarity.

§ 93.305(d) General conduct of research misconduct proceedings; Multiple respondents –
The inclusion of a requirement that every co-author, co-investigator on funding proposals, collaborator, and lab member must be considered as a potential respondent does not comport with fair procedures and due process. Such a presumption is unfairly detrimental to individuals whose knowledge or involvement in misconduct cases is minimal. Considering and then designating respondents throughout the process of inquiry should be presumptive, not a process that requires ruling out every individual with a professional nexus to the research in question.

Recommendation: AAU suggests ORI remove the language, or at a minimum, change wording from "must be considered as potential respondents" to "may be considered as potential respondents."

93.305(e) Multiple Institutions

AAU appreciates ORI's proposed clarification on how to handle integrity cases that include two or more institutions. Research can be a collaborative endeavor involving teams from different universities and investigations can be complex.

Recommendation: AAU requests ORI provide further clarification on determining a lead institution for these joint reviews and clearly describing roles and responsibilities for the same for effectiveness in managing concerns spanning across multiple institutions.

4) **AAU requests clarification and changes concerning the Department of Health and Hunan Services' (DHHS) misconduct notification process and when the DHHS can issue public notices of research misconduct, especially in instances where there is no settlement or finding of research misconduct.**

§93.401 Interaction with other entities and interim actions

Recommendation: AAU requests that ORI amend this section to include an obligation on ORI's part to notify the institutional certifying official of any such notices or referrals by ORI that take place while the research misconduct proceedings are in process at the institution.

§ 93.410 Final HHS action with no settlement or finding of research misconduct
Subsection (b) – This subsection permits ORI to "publish notice of institutional research misconduct findings and implemented institutional actions related to the falsified, fabricated, or plagiarized material in the research record, but not the names or other identifying information of the respondent(s), if doing so is within the best interests of HHS to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, or to conserve public funds."

This requirement fails to consider institutional, state, and local privacy and confidentiality requirements. It also deprives institutions of the right to request confidential treatment of information provided to the federal government that is outlined in the federal Freedom of Information Act. agrees with our sister associations and strongly recommends that ORI should not publish institutional findings and actions if they do not make their own federal finding. The public notice of institutional findings may likely reveal the identity of involved respondent or individuals and such a notice may be inconsistent with established confidentiality requirements.

Recommendation*: *AAU recommends deleting this subsection.

In closing, AAU joins with our sister organizations in recommendation that ORI reexamine the NPRM's "Summary of Impacts and Threshold Analysis." The Proposed Regulations will substantially increase – not decrease – the complexity of the research misconduct review process. We also urge ORI to increase its estimate of the time it will take institutions to update and adopt policies and processes to address the Proposed Regulations and to provide supporting quantitative data for its estimate.

We also strongly agree with COGR that "ORI reconsider the timeline for implementation as specified in the NPRM's preamble. Currently, this timeline anticipates providing institutions no more than six to nine months implementation time, with publication of the final rule in the summer of 2024, and an effective date of January 1, 2025. Significant time will be required for institutions to review the final regulations and update their policies and processes. In addition to amending their policies and procedures, institutions also will need to revise any

training that they have on their processes and communicate the changes to the regulated community. Accordingly, we strongly encourage ORI to provide institutions with at least a one-year implementation period after the date on which the final rule is published. Such an extension would be particularly beneficial for smaller institutions with fewer staff and resources."

Thank you. AAU looks forward to continued engagement with ORI on this NPRM and issues of mutual interest to ensure the highest quality of science.