



ASSOCIATION OF
PUBLIC &
LAND-GRANT
UNIVERSITIES

December 7, 2023

Submitted Electronically to: <https://www.regulations.gov>

Sheila Garrity, JD, MPH, MBA
Director, Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Response to Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct (Regulatory Information Number 0937-AA12)

Dear Director Garrity:

The Association of Public and Land-grant Universities (APLU) appreciates the opportunity to provide comments in response to the Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct (“NPRM”) published in the October 6, 2023, issue of the Federal Register [[88 FR 69583](#)]. The NPRM sets forth “Proposed Regulations” that make substantial changes to the current research misconduct regulations that took effect in 2005 (“2005 Regulations”).

APLU is a research, policy, and advocacy organization dedicated to strengthening and advancing the work of public universities. With a membership of more than 250 public research universities, land-grant institutions, state university systems, and affiliated organizations, APLU's agenda is built on the three pillars of increasing degree completion and academic success, advancing scientific research, and expanding engagement. Annually, our U.S. member campuses enroll 4.2 million undergraduates and 1.2 million graduate students, award 1.2 million degrees, employ 1.1 million faculty and staff, and conduct \$48.7 billion in university-based research.

APLU's members are committed to protecting the integrity of federally supported research and complying with research regulations. We appreciate the Office of Research Integrity's (ORI) efforts to provide a more robust structure for institutions to use in the review of allegations of research misconduct.

APLU appreciates the work of the Council on Governmental Relations (COGR) and the Association of Research Integrity Officers (ARIO) in analyzing the Proposed Regulations. APLU supports the recommendations in their comment letters to this NPRM.

APLU's comments will focus on areas the NPRM that may significantly increase institutional administrative burden or unnecessarily place reputational risks or liabilities on institutions or researchers.

Overarching Concern Regarding the Assessment of Allegations

In contrast to the 2005 Regulations, the Proposed Regulations introduce a highly structured procedure for the initial assessment of allegations. This approach limits institutional discretion in determining that an allegation is noncredible, without merit, or falls outside the scope of the PHS regulations on research misconduct. The 2005 Regulations already set a low threshold for moving allegations to the inquiry stage. The Proposed Regulations' more mandated and highly structured approach will lead to some meritless inquiries that risk harming the respondent's reputation and

the reputations of their collaborators. It will also dramatically increase the cost to the research enterprise to conduct a meritless inquiry.

At the inquiry stage, the Proposed Regulations prohibit institutions from considering defenses like honest error or difference of opinion, unfairly burdening respondents and institutions, and prolonging the review process. This proposed regulation risks stigmatizing human error in science; it may reduce prompt reporting and self-correction by researchers, or even have a chilling effect on legitimate scientific discourse and disagreement within the research community, as researchers may fear triggering a formal research misconduct proceeding over a difference of opinion. It also may discourage researchers from openly sharing findings and data before peer review, fearing honest errors could initiate this process. Further, formalizing the assessment process and the mandate to produce an "assessment" report will discourage reporting and substantially increase institutional administrative burdens.

Comments on the specific provisions of the Proposed Regulations

§ 93.102(a) Applicability

- APLU recommends ORI remove the new requirement that institutions be “responsible for the compliance of their subrecipients with this part” as (i) it is unclear what the term “responsible for” entails, and (ii) this requirement would create a significant burden on institutions. Instead, APLU suggests that ORI replace this requirement with an obligation on institutions to confirm with their subrecipients that the subrecipients have an assurance on file with ORI stating that the subrecipient has developed and will comply with an administrative process for responding to allegations of research misconduct in PHS-supported research that complies with 42 C.F.R. Part 93.

§93.105 Time Limitations (b)(1)(i) – (ii) Exceptions to the six-year limitation, Subsequent use exception

- APLU recommends that ORI remove the subsequent use exception and instead establish a specific period of limitations. This approach minimizes the need for institutions to conduct time-consuming and often fruitless searches for evidence that no longer exists. It also helps ensure that respondents are not unfairly required to defend against charges with unavailable evidence and witnesses. Additionally, ORI should delete the requirement that institutions “inform ORI of the relevant facts before concluding the exception does not apply.” We strongly urge keeping the 2005 regulations where institutions decide when the exception is applicable.

§93.306 Institutional assessment

- APLU strongly recommends that ORI retain the language in the 2005 regulations and to entirely delete section 93.306 in the Proposed Regulations, which requires a more formalized approach for assessing an allegation.

§93.307 Institutional Inquiry

- **Subsection (a)(1)** – APLU recommends that ORI remove this subsection that requires progression to inquiry if an assessment is not completed within 30 days. This arbitrary 30-day deadline will result in advancing unwarranted allegations that have the potential to harm the respondent and their research collaborators.
- **Subsections (f) (2 and 3)** – APLU recommends deleting these subsections. They prevent an institution from reaching a conclusion of honest error or difference of opinion at the inquiry stage, even when there is sufficient evidence to support such a

finding. This constraint risks exposing the respondent to an unnecessary investigation process, potentially damaging their reputation, and increases the burden on the respondent, institution, and resources in the research enterprise.

§93.410 Final HHS action with no settlement or finding of research misconduct - Subsection (b)

- APLU recommends this subsection be deleted. ORI should not publish cases in which there has not been a finding of research misconduct. First, this provision may conflict with institutional, state, and local privacy regulations. But of utmost concern is that it can potentially damage the reputations of collaborators and co-authors on the impacted projects or publications, particularly those with no findings of research misconduct.

Definitions

We reiterate below suggested changes to specific definitions within the Proposed Regulations as recommended by COGRand ARIO:

Clarify Definition of Allegation

§93.203 Allegation - The Proposed Regulations should make clear that allegations do not include non-specific statements of research misconduct and general online public comments. We recommend the following modification to the definition of allegation:

Allegation means a purposeful disclosure of possible research misconduct through any means of communication that specifically alleges wrongdoing encompassed by this part and is brought directly to the attention of an HHS official, an institution's research integrity officer, or another institutional official whose duties encompass matters of research integrity. This definition excludes public comments posted online (or in similar public forums) that are not brought to the attention of the foregoing officials.

Clarify the Preponderance of evidence for a finding of research misconduct

§ 93.231 Preponderance of the evidence - ORI should clarify the language about "what the fact at issue" is for this policy. We recommend the following definition:

A preponderance of the evidence means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not. For a finding of research misconduct, the fact at issue is whether there was fabrication, falsification, or plagiarism in proposing, performing, reviewing, or reporting research that was a significant departure from accepted practices of the relevant research community and that was committed intentionally, knowingly, or recklessly.

Define Recklessly in terms of research misconduct

§93.234 Recklessly - We encourage ORI to modify the definition of "Recklessly" to define it in terms of research misconduct and to avoid conflating it with "knowingly":

Recklessly means that:

- The respondent, in proposing, performing, or reviewing research, or in reporting research results, was consciously aware of a substantial risk that such conduct could result in falsification, fabrication, or plagiarism; and

- In the face of this substantial risk, the respondent, either by action or inaction, failed to do what a researcher of ordinary prudence in the relevant research community would have done under these circumstances to mitigate the risk.

§93.305 General conduct of research misconduct proceedings

Subsection(d) Multiple Respondents -- The section's wording should be modified to clarify that individuals should be named as respondents only when sufficient evidence supports this designation. We recommend substituting "may" for "must" in the second sentence and adding the following text to the end of this sentence: "if there is sufficient evidence to support such inclusion."

§93.307 Institutional Inquiry

Subsection (d) – This subsection mandates institutions sequester "all" evidence. It should be revised to state that institutions have an obligation to use reasonable efforts to sequester evidence that is within their custody and control and that has been determined to be reasonably relevant to the matter at hand.

Anonymity

ORI also asked for comments about whether to include provisions in a final rule to allow for anonymity for complainants or witnesses who request it. We distinguish complaints made anonymously to the institution from a request for confidentiality or anonymity from a complainant or witness to the extent possible (e.g., deidentifying them in transcripts of interviews that the respondent receives to prevent retaliation.) APLU urges caution about allowing complaints made anonymously for an allegation of research misconduct as it may compromise the integrity of investigations and the overall research environment. Complaints made anonymously could hinder the ability to thoroughly assess the credibility and motive behind an allegation, potentially leading to unfounded or malicious claims. Anonymous complaints may lead to a surge in unverified or vague allegations, diverting resources toward investigating less credible claims. As is the current policy and practice, we recommend that institutions be left to weigh whether an anonymous allegation has merit and is fact-based and specific enough to warrant an inquiry.

Conclusion

Thank you for your consideration of APLU's views as ORI moves forward to update its policies on research misconduct. Research misconduct, including fabrication, falsification, or plagiarism, in federally funded research is a threat to the integrity of the scientific record and engenders public mistrust in science. Improving transparency and reproducibility of scientific results, increasing scientific rigor, and building and maintaining public trust in science are important principles that drive the work of APLU and our member institutions.

APLU looks forward to further engaging on these issues. Please do not hesitate to let me know how APLU can be a resource in these efforts.

Sincerely,



Mark Becker
President, Association of Public & Land-Grant Universities