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RE: Public Health Service Policies on Research Misconduct

The American Society for Biochemistry and Molecular Biology is an international nonprofit scientific and educational organization that represents more than 12,000 students, researchers, educators and industry professionals. The ASBMB strongly advocates for strengthening the science, technology, engineering and mathematics (STEM) workforce, supporting sustainable funding for the American research enterprise, ensuring diversity, equity and inclusion in STEM, and addressing emerging issues in the scientific enterprise.

The National Institutes of Health has recorded an alarming <u>increase in research misconduct allegations</u> within the past five years. The ASBMB commends the U.S. Department of Health and Human Services for taking action to clarify and simplify its current policies. Institutions and the scientific community will greatly benefit from the updated policy, ensuring that the U.S. research enterprise is holding to its high standards of research integrity.

The ASBMB appreciates the changes to each subpart as they will deliver concise guidance to institutions for handling research misconduct allegations by clarifying definitions, streamlining the investigative process for open allegations, and processing appeals.

However, the society would like to submit feedback on elements of subparts A, B, C, and D regarding the proposed policies involving confidentiality, small institutions, the interview process of witnesses, and the role of journals.

Recommendation 1: Update section § 93.106 Confidentiality

The society welcomes the addition of language clarifying that journals, and editors, may be included as "those who need to know." However, the Office of Research Integrity (ORI) should consider the repercussions of including publishers, editors and journals in the language of the confidentiality section and how it can affect the investigative process taken by journals. The society suggests that ORI notify journals are when research misconduct cases are closed.



Recommendation 2: Increase the cap to 50 institutional members for small institutions

The ORI's language regarding small institutions typically having "a total of 10 or fewer institutional members" is overly restrictive with respect to ensuring that institutions do not have conflict of interests in conducting reviews. We recommend that the number of institutional members be increased from 10 to 50, consistent with <u>Association of Research Integrity Officers (ARIO)</u> definition of small institutions.

Relatedly, the ASBMB strongly suggests that the ORI consider the burden on smaller institutions and whether institutions with very little Public Health Service funding should also be considered eligible for the provisions of \S 93.303.

Recommendation 3: State whistleblower protections for complainants

The ASBMB appreciates ORI's proposed changes that will not allow respondents to be present during witness interviews. However, the proposed policy of providing respondents with the transcript of the interview sparks concern regarding whistleblower protection of complainants.

Recommendation 4: Journals should remain independent

In the proposed language of § 93.401 of Subpart D, entities will include organizations such as scientific societies that publish scientific journals. The ASBMB welcomes the clarification of the roles of editors, journals and publishers under this subpart. However, we recommend that journals keep their autonomy and remain independent during research misconduct investigations. Additionally, the society suggests that ORI provide clarification on how journals should move forward with a case when an editor needs to abstain from the investigation.