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Sheila Garrity, JD, MPH, MBA
Office of Research Integrity (ORI)
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: 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

Dear Ms. Garrity,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Notice of Proposed Rulemaking (NPRM) regarding the Department of Health and Human Services Office of Research Integrity's (ORI) revisions to the Public Health Service (PHS) Policies on Research Misconduct. As a coalition of 26 biological and biomedical scientific societies representing over 110,000 individual scientists, FASEB is committed to fostering a culture of research integrity. We appreciate ORI's efforts to clarify key aspects and definitions of the policy since issuing the Final Rule in 2005. The proposed changes will reduce administrative burden, streamline internal processes for institutions and agencies, and facilitate the research community's unified goal of promoting responsible research conduct.

FASEB's comments focus on proposed revisions to Subpart C related to institutional responsibilities.

§ 93.305 - General Conduct of Research Misconduct Proceedings

FASEB concurs with the updated rules governing evidence collection and sequestration. Allowing institutions to provide copies rather than original research records when conducting research misconduct proceedings will significantly reduce administrative burden by enabling institutions to maximize the capabilities of cloud-based storage and access. Given the importance of precise language in policy interpretation, we appreciate substituting the term "custody" with "obtain" regarding research records, as this appropriately aligns with proposed changes to evidence collection.

Secondly, ORI's added guidance on handling proceedings involving multiple institutions will improve communication and processing efficiency. Instructing a lead institution to obtain all research records and witness testimonies pertinent to an inquiry will allow all involved institutions to conduct thorough

analysis and jointly determine if further investigation is warranted. These measures will prevent redundant proceedings between institutions, significantly alleviating administrative burden.

FASEB recognizes that submission of an "Institutional Record"—comprised of all institutional reports, records, and decisions made at each stage of the proceeding—represents one of the more substantive changes. Institutions filing consistent, comprehensive records will facilitate ORI processing for more expansive records to serve as the basis for decision-making by external investigators. To ensure institutions with limited resources can accommodate these changes, FASEB recommends ORI issue supplementary guidance on how to generate, maintain, and submit Institutional Records. Additional clarification on how records may be shared with ORI or other entities is warranted to protect researcher confidentiality.

§ 93.306 – Institutional Assessment

As the first step in research misconduct proceedings, FASEB appreciates the additional details that clarify expectations, reporting requirements, and timelines. Specifically, we thank ORI for clarifying that institutions are not required to conduct formal interviews, minimizing unnecessary redundancy with further proceedings. FASEB agrees institutions should be responsible for determining which criteria warrant further inquiry, provided that criteria are appropriately documented.

§ 93.307 – Institutional Inquiry

ORI's clarifications about institutional handling of research misconduct inquiries are laudable, as this updated language could encourage institutions to simplify and expedite their inquiry processes. Specifically, FASEB commends the flexibility for institutional discretion in handling inquiries without full investigative measures. Such updated language assists institutions in differentiating between the inquiry and investigative phases of a proceeding, thus preventing unnecessary delays.

§ 93.310 – Institutional Investigation

Recognizing that the investigation phase of proceedings is an important yet time-consuming process for institutions, FASEB commends ORI for clarifying that additional allegations identified during an investigation can be added to an existing investigation rather than opening a new inquiry. This change will particularly alleviate administrative burden for small institutions that may not have the capacity to restart existing investigations should new information or additional respondents be discovered.

Conclusion

FASEB appreciates the opportunity to offer comments on the proposed changes for handling research misconduct proceedings. The changes aim to streamline misconduct proceedings across institutions while protecting respondents during ORI reviews. Institutions will appreciate the clarification of requirements for each phase that reduces extraneous proceedings and ultimately alleviates administrative burden. We commend ORI for prioritizing transparency between parties through access to all pertinent information and protecting respondents through private meetings and non-disclosure assurances.