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Research&Innovation

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January 4, 2024

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

Re: Notice of Proposed Rule Making on the Public Health Service Policies on Research Misconduct

Dear Ms. Garrity:

This letter is submitted on behalf of Cornell University, in response to the Notice of Proposed Rule Making (the "NPRM") on the Public Health Service ("PHS") Policies on Research Misconduct (42 C.F.R. Parts 50 and 93), issued by the Department of Health and Human Services ("HHS"), Office of Research Integrity ("ORI") on October 5, 2023.

Cornell is an Ivy League R1 research university and land grant institution conducting world class research in the physical and social sciences, medicine, engineering, agriculture, and many other areas of high social and economic impact. As reported in the National Science Foundation's Higher Education Research and Development Survey, Cornell's research expenditures in 2022 were $1.3 billion, with the share funded by HHS being $390 million. As a world leader in research, we are fully committed to conducting research ethically and with complete integrity. Our policies governing research integrity cover not only federally defined research misconduct, but also research related misconduct that is not explicitly fabrication, falsification, or plagiarism.

We understand the importance of having regulations that clearly describe, for the regulated community, the process for handling allegations of research misconduct and we applaud ORI's efforts to update and improve PHS' policy on research misconduct. We generally find the proposed changes in the NPRM helpful, although some would benefit from greater clarity. A few of the proposed changes are problematic and we comment on these below.

Cornell University endorses all the comments and proposed edits submitted by the Association of Research Integrity Officers ("ARIO"), an association that provides a dedicated platform for Research Integrity Officers, their staff, and general counsel to discuss, develop, and share best practices and strategies for handling research

misconduct allegations and promoting ethical research. Cornell also endorses the comments submitted by the Council on Government Relations ("COGR") who advocate for policies and practices that fairly reflect the mutual interests and separate obligations of federal agencies and research institutions as they relate to research and graduate education.

The ARIO and COGR comments express our view of the NPRM very well, and we have nothing of substance to add in expressing our gratitude for some of the proposed changes and our concerns about others. However, we feel there would be some benefit in voicing our specific concerns about the proposals to (1) require that respondents receive complete interview transcripts, (2) add requirements to the assessment, and (3) not allow honest error and difference of opinion as reasons to close an inquiry without an investigation. Our concerns are as follows.

1. **Interview transcripts:**

The proposed language for § 93.305(g)[5] is *"The respondent must not be present during the witnesses' interviews but must be provided a transcribed copy of the interview."* We support the recommendations by ARIO and COGR that transcripts should not be required for interviews conducted in the assessment and inquiry stages and we support the ARIO recommendation that exceptions be allowed to the requirement to provide transcripts to the respondent. It is our further recommendation that the requirement to provide complete transcripts to the respondent be deleted in its entirety.

It is our experience that witnesses are often very reluctant to come forward, especially when the respondent is a principal investigator, and the witness is a student in the respondent's group. A witness fearful of retaliation is not convinced by efforts to protect their identity by redacting their name from a transcript. In many cases, the only way we have found to convince a witness to disclose pertinent information in an interview is to assure them that the respondent will not see the transcript.

Requiring the respondent to have access to all interview transcripts will have a profoundly chilling effect on witnesses and significantly harm our ability to properly conclude investigations.

2. **Assessment requirements:**

We agree with the recommendations by ARIO and COGR, for the reasons they eloquently provide, that the assessment should remain an informal process without requirements prescribed by federal regulation. In addition, we believe that the proposed new version of § 93.306, *Institutional assessment*, if implemented, will encourage many institutions to treat the assessment as nothing more than a check that the allegations are comprehensible and related to research misconduct. This will cause inquiries to be required for spurious or completely unfounded allegations with otherwise unnecessary effort to sequester evidence and put researchers in the position of being formal respondents with the risk of adverse consequences for their reputations.

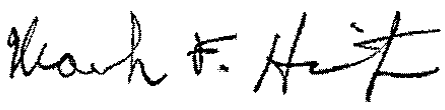
3. Honest error and difference of opinion as reasons to close an inquiry:
We agree with the recommendations by ARIO and COGR that the proposed requirement § 93.307(f)(2)(i) "*A conclusion of honest error or difference of opinion must not be made at the inquiry stage*" should be deleted. If sufficient evidence is presented, from parties other than the respondent, that the alleged behavior is a result of honest error or is a difference of opinion with the complainant, then requiring a formal investigation into the matter is a waste of institutional resources and unnecessarily risks damage to the respondent's reputation.

We further note that the proposed versions of § 93.306 and § 93.307(f)(2)(i) together are likely to cause institutions to treat the assessment and inquiry as nothing more than a stage of documenting the allegation and initial evidence provided by the complainant, as a preliminary step to an inevitable formal investigation. In addition to adding unnecessarily to the institution's administrative burden, many researchers will unnecessarily suffer the trauma of being the respondent in an investigation and suffer the risk of reputational damage.

4. Prohibition against voting or split decisions
Cornell echoes the substantive concerns raised by ARIO and COGR regarding the proposed prohibition in § 93.313(l)(2) against "voting or split decisions by the investigation committee members" in the final recommendation. We find the implications of this prohibition gravely concerning. If members of a committee cannot, in professional good conscience, agree, why should their individual voices be silenced? If a majority agrees, why should a single hold-out stop a recommendation? Similarly, if a majority agrees, why should the disagreeing member(s) be put in a position to choose reluctant agreement without an opportunity to record a dissenting view? Such a restriction does nothing to enhance the quality of outcomes, inhibits the full exchange of ideas in a process whose primary goal is continual improvement across the research enterprise, and risks chilling participation on the very committees at the forefront of the endeavor.

We appreciate the opportunity to provide input to ORI on the proposed revisions to the PHS Policies on Research Misconduct. We hope that the comments and recommendations included herein, and in the comments provided by ARIO and COGR, will assist ORI in its mission to improve the regulations. We also ask ORI to seriously consider the significant nature of the concerns outlined in this letter and note that if these concerns cannot be adequately addressed in the new rule, our preference would be to remain under the current regulations at 42 CFR Part 93. Should you have any questions regarding this letter, do not hesitate to contact the undersigned.

Sincerely,



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