









MEMORANDUM

TO: Sheila Garrity, J.D., M.P.H., M.B.A.

Director, Office of Research Integrity (ORI)

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FROM: Association of American Medical Colleges (AAMC): Contact – Heather Pierce,

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DATE: October 23, 2023

RE: Request for Extension of Comment Period for Notice of Proposed Rulemaking on

Public Health Service Policies on Research Misconduct

On behalf of our organizations representing the higher education and research community, we are writing in regard to Notice of Proposed Rulemaking on Public Health Service Policies on Research Misconduct (NPRM) published in the Federal Register¹ on October 6, 2023. Our member institutions are deeply committed to ensuring the integrity of federally funded research both proactively, and, when necessary, through the effective and efficient conduct of proceedings to review and consider allegations of possible research misconduct.

We deeply appreciate ORI's efforts to review and revise the Public Health Service Policies on Research Misconduct based "on the experience that ORI and institutions have gained" since the regulations were published in 2005. The proposed changes to the research misconduct regulations are extensive in number and magnitude, and they will substantially impact our member institutions' policies and processes for handling allegations of research misconduct. Yet the NPRM affords the regulated community only 60 days to review the changes; compare them with existing requirements; discuss their meaning and impact with researchers, RIOs, and persons responsible for their implementation; and develop and draft comments. Additionally, the Thanksgiving Day holidays will impede the ability to conduct these review activities, thus further curtailing the comment period.

¹ 88 FR 69583

These are the first major revisions to the research misconduct regulations that research institutions have seen in 18 years, and they deserve nothing less than a detailed analysis by members of the regulated community. To permit the regulated community to conduct this vital review, including an analysis of cost impacts, we respectfully request that ORI consider extending the comment period for an additional 45 days that would end on January 19, 2024.

We thank ORI in advance for its consideration of this request, and we look forward to a favorable response.