

October 31, 2022

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Ex Officio
Elisa A. Hurley, PhD

Wanda Jones, DrPH
Acting Director
Office of Research Integrity
Department of Health and Human Services
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

Submitted via email to OASH-ORI-Public-Comments@hhs.gov

Dear Dr. Jones,

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to respond to the Office of Research Integrity (ORI) "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct" published in the *Federal Register* on September 1, 2022.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science.

PRIM&R applauds and strongly supports ORI's intent to update the Public Health Service (PHS) policies for research misconduct. Over the last decade, the scientific research landscape has been radically transformed by the increased use of emerging digital technologies, open science, and team science. Thus, we believe that a revision of these regulations is long overdue.

PRIM&R understands the importance and value of regulations that define and clearly describe a process for handling allegations of research misconduct to the research community. To that end, PRIM&R endorses the comments submitted by Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard, and Ropes and Gray, LLP. **However, we urge ORI to also take this opportunity to undertake a broader and more wholistic assessment of the current research landscape, specifically as it pertains to research integrity.**

PRIM&R appreciates that the regulatory definition of research misconduct solely as fabrication, falsification, or plagiarism (FFP), allows for an objective investigation process. **However, it is important to also recognize that research integrity (and integrity of the research record) can be**

compromised by violations of other responsible conduct of research (RCR) domains, beyond FFP. For example, faculty producing piecemeal publications under pressure to meet tenure and promotion requirements can skew the literature, or an overcommitted researcher renegeing on their mentoring responsibilities could lead to future scientists not being adequately trained in responsible data stewardship.

To be clear, we are not recommending that any and all detrimental research practices or irresponsible conduct of research be subsumed under the regulatory definition of research misconduct. Rather, **we are suggesting that there is value in acknowledging in the policy the importance of RCR, generally,** especially given that various funding agencies have instituted policies mandating RCR education.¹² Furthermore, even though the PHS policy for research misconduct applies only to publicly funded research, the concept of RCR as introduced by ORI has been widely adopted and has impacted the conduct of all research (not only publicly funded research), as well as the training of future generations of scientists.

In light of the fact that the *Federal Register Notice* states that ORI views this RFI as a part of a brainstorming process, PRIM&R recommends that, in addition to revising the research misconduct policy based on feedback from entities who have considerable experience in implementing the policy in the field, **ORI consider including in the preamble explicit mention of RCR and a description of how the various domains are interconnected and contribute to scientific integrity.** Providing this as a foundation and framework for the policy will not only be a useful educational tool but will also serve to enhance public understanding and trust in the scientific enterprise.

Thank you again for the opportunity to provide input on the revision of the PHS policy on research misconduct. We hope our comments will be useful to the ORI and we are ready to provide any further assistance or input that might be of use. Please feel free to contact me at 617.303.1872 or ehurley@primr.org.

Sincerely,



Elisa A. Hurley, PhD
Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors

¹ <https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html>

² <https://www.nsf.gov/od/recr.jsp>