UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE OF THE VICE PRESIDENT – RESEARCH AND INNOVATION

OFFICE OF THE PRESIDENT
1111 Franklin Street, 11th Floor
Oakland, California 94607-5200

Submitted electronically to *OASH-ORI-Public-Comments@hhs.gov*.

October 31, 2022

Dr. Wanda K. Jones
Acting Director, Office of Research Integrity
1101 Wootton Parkway, Suite 240
Rockville, MD 20852

RE: UC Comments in Response to the HHS Regulations RFI, "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct"

Dear Dr. Jones:

I am writing on behalf of the University of California (UC) system with regard to the "Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct" posted in the *Federal Register* on September 1, 2022.

The UC system is comprised of ten campuses, six academic health centers, and three affiliated U.S. Department of Energy national laboratories. As a system, UC receives approximately $6.7 billion annually of extramural awards, more NIH and NSF funding than any other institution in the country. The funds support research conducted throughout all UC locations.

The UC system maintains a longstanding commitment to adhere to the highest standards of intellectual honesty and integrity in research. UC issued its Policy on Integrity in Research in 1990, which highlights rigor, carefulness, and accountability as hallmarks of good scholarship. These values are mirrored in the 2005 Public Health Service (PHS) Policies on Research Misconduct. UC appreciates the effort that the Department of Health and Human Services (HHS), Office of Research Integrity (ORI) is taking to re-evaluate the existing regulations and the opportunity to provide input on the direction of the policies. UC appreciates the working relationship it has with HHS when conducting investigations related to research misconduct, and emphasizes the need for the continued flexibilities to address each unique situation. While we believe most of the sections should be retained, there are certain areas where further guidance and clarity would be helpful. Our specific comments are provided below and were informed by those who work directly with the PHS Polices on Research Misconduct, 42 C.F.R. 93. We recognize that HHS asks for feedback on sections that should be changed, retained, or removed. While our comments respond to this request,

we provided our comments in order of priority. In addition, we highlight areas where changes to the regulations may not be necessary, but additional guidance would be helpful.

Lastly, UC supports the sentiments captured in the comment letter submitted by the Council on Governmental Relations (COGR) and Association of Research Integrity Officers (ARIO).

1. **Sections that should be changed, retained, or removed**

    a. Definition of Research Misconduct [§ 93.103]

UC recommends the definition of research misconduct as fabrication, falsification, or plagiarism in proposing, performing or in reviewing research or in reporting research results should remain the same and not be changed. UC is concerned that efforts to expand the definition of research misconduct at § 93.103, incorporating questionable research practices or poor behavior in research as part of research misconduct, would result in the inappropriate application of the standards used to investigate research misconduct to questionable research practices, e.g., authorship disputes, or dishonest or poor behavior during peer review, or even abusive conduct. Such questionable or problematic research practices should remain outside of the definition of research misconduct. UC believes the current procedures that apply to research misconduct are not suitable for addressing these other behaviors. Additionally, institutions often have other, sometimes state law mandated procedures, to deal with these questionable research practices and behavior. Expansion of the definition could bring these separate and distinct procedural actions in direct conflict with each other.

    b. Requirements for Findings of Research Misconduct [§ 93.104(b)]

UC recommends that the regulations be changed to define the terms “intentionally,” “knowingly,” and “recklessly.” Absent clear definitions and examples, institutions now apply differing standards. Clarification of the terms, with appropriate research misconduct related examples, especially as they relate to the term “recklessly,” would help ensure consistency in investigations and assist institutions in making determinations of culpability.

    c. Distinction between Inquiries and Investigations

UC recommends that ORI maintain its current distinction between an Inquiry and an Investigation. The distinction allows for determining whether sufficient evidence exists without undertaking additional obligations and responsibilities under an Investigation.

d. Timelines [§§ 93.307(g) & 93.311]

UC understands that timelines serve as an important checkpoint for maintaining timely and forward momentum on responses to allegations of research misconduct and continuing communication with ORI. At the same time, UC appreciates the flexibilities that ORI provided when UC has sought extensions for completing an investigation.

At a minimum, UC recommends that ORI harmonize its timelines with other agencies, such as National Science Foundation standards (90 days for inquiries; 180 days for investigations). This enables consistency in the conduct of inquiries and investigations. At the same, we strongly recommend that ORI continue to honor necessary extension requests. Finally, because research misconduct cases have levels of complexity not easily anticipated, UC asks for ORI to consider modifications to timelines that take into consideration individual complexities.

e. Confidentiality [§§ 93.108, 93.300(e), & 93.304(a)]

UC recommends confidentiality provisions include the protection of the confidentiality of witnesses. The regulations already provide for the protection of respondents and complainants, but are silent on witnesses. UC feels strongly that ORI should extend confidentiality protection to witnesses. Witnesses can also be subject to retaliation from principals involved in the cases and may experience reputational harm from being involved in a research misconduct investigation. This extension of confidentiality would allow institutions to take extra steps to prevent these repercussions from happening or address them appropriately if they do.

Finally, UC requests clarity on an institutions ability to maintain confidentiality standards in complex cases, such as those involving multiple institutions with potentially multiple principals at each location. In complex cases such as these, institutions can set expectations amongst themselves on how to apply confidentiality standards and what can be shared amongst the institutions to minimize breaches of confidentiality that may impact cases.

f. Subsequent Use Exception to the Six-year Time Limitation [§ 93.105(b)(1)]

The subsequent use exception as currently written is not sufficiently specific. This results in institutions going through time-consuming searches through old systems and paper records for data on publications from many years ago. Clarity and specificity in the regulations would help reduce over-expansive searches while still ensuring older instances of research misconduct may be investigated. In addition, UC requests guidance on how to apply the subsequent use exception, specifically on the limitations to subsequent use, and requests ORI provide relevant examples of how the subsequent use exception be applied to research misconduct cases.

In addition, UC recommends the regulations describe or provide definitions on what constitutes "other use for the potential benefit of the respondent." Does this refer to monetary benefit or professional benefit? Without parameters institutions are unsure of how to assess potential benefit to the respondent.

2. Areas where guidance would be helpful

a. Activities conducted within an Inquiry versus Investigation

UC understands that an inquiry is a fact-finding and information gathering exercise. An investigation examines that evidence in depth to determine whether research misconduct has been committed by a particular respondent. Nonetheless, the line between inquiry and investigation is not always clear and often times inquiry committee actions bleed into investigative activities. For example, it can be difficult to distinguish the depth of review of the evidence between the two phases. UC recommends ORI provide additional guidance or descriptive examples of the distinction between inquiry and investigation. Clearer parameters would allow institutions to better and more efficiently transition between the inquiry and investigation phases of research misconduct actions.

b. Accepted Practices of the Relevant Research Community [§ 93.104(a)]

UC requests guidance on how institutions identify the "accepted practices of the relevant research community" and what constitutes a significant departure from those practices. There are differing understandings of what this phrase means, depending heavily on different fields of research. This can lead to broad scale review of a respondent's publications, grant applications, etc., which can divert time and effort from the immediate allegation and delay final conclusions and findings. UC recommends ORI provide relevant examples that might be illustrative of a significant departure from accepted research practices.

Thank you for the opportunity to comment. We look forward to continued engagement on this important issue.

Sincerely,

Deborah Motton, Ph.D.
Executive Director
Research Policy Analysis & Coordination
University of California
1111 Franklin St., 11th Fl.
Oakland, CA 94607
(510) 587-6053
Deborah.Motton@ucop.edu