Dear Dr. Jones:

The Association of Research Integrity Officers (ARIO) is a network of research integrity officers (RIOs) and the staff and counsel that support them from many different types of US research institutions. Because ARIO members are directly responsible for managing research misconduct allegations, they are uniquely situated to respond to the Office of Research Integrity’s (ORI) current Request for Information (RFI) concerning revisions to the Public Health Service Policies on Research Misconduct, 42 C.F.R. Part 93, (the “regulation”). As President of ARIO, I am writing on behalf of the ARIO Board and its 165 member institutions and appreciate the opportunity to provide input that will directly affect our institutions and institutional processes.

ARIO has already submitted a joint response to this RFI together with the Council on Governmental Relations (COGR), which represents many ARIO member institutions. This addendum represents an effort by a wider range of ARIO members to emphasize and expand upon some of the key points raised in that joint response, especially as intended to help simplify and streamline the research misconduct process.

1. **Keep the definition of research misconduct limited to falsification, fabrication, and plagiarism (FFP).** Broadening of the definition to include issues outside of FFP, *i.e.*, issues of sexual or other forms, of harassment, other detrimental research practices (DRPs), or foreign influence, will require institutions to use the complex and time-consuming research misconduct process to resolve such issues. Since the regulation is written, and is specific for, the purpose of reviewing scientific data, applying the regulation to concerns outside of data review would be unmanageable. Institutions may have, or can develop, other more appropriate processes to handle concerns outside of FFP.

2. **Specifically define the terms “intentionally, knowingly, or recklessly” that is included in the requirements for a finding of research misconduct.** Institutional officials and investigation committees often struggle with the criteria for making a finding of research misconduct at §93.104(b) that states, “The misconduct be committed intentionally, knowingly, or recklessly.” Institutions must be able to consistently describe these different...
state-of-mind terms and standard definitions must be adopted nationally. This is particularly true for the concept of research misconduct committed recklessly, where no definition or guidance has been provided, to date. We recommend that in addition to including a standard definition for these terms in the regulation, ORI also provide specific guidance that distinguishes between these terms and describe examples of research misconduct committed intentionally, knowingly, or recklessly with the evidence to review in each case.

3. **Revise the criteria to warrant an investigation.** We emphasize the importance of creating a path to terminate research misconduct proceedings at assessment or inquiry under certain circumstances, as determined by institutional RIOs and other officials, while also ensuring the integrity of the research record. Institutions often have a very good idea of the evidence available because of the robust sequestration that must occur prior to notification of or the initiation of an inquiry. During assessment and inquiry, the institution has to also carefully look at the role of the respondent(s) in the research at issue. Currently, institutions are obligated to pursue cases through investigation, even when it is clear earlier in the process that findings of research misconduct will have no consequence to the institution or respondent, or that evidence does not exist to support making research misconduct findings.

For cases that will be moving forward to an investigation, we recommend that ORI allow institutions to follow §93.307(d) that states that the inquiry is an initial review of the evidence and does not require a full review of all the evidence related to an allegation and ORI should replace the requirement for an inquiry report with a checklist at §93.307(d). Additionally, the regulation should be revised to specifically state that performing an inquiry does not require a full committee. This could streamline the process and permit institutions to more quickly determine if the allegations warrant a full investigation without having to engage in a laborious and time-consuming committee process that is not necessary to make this determination. Additionally, we recommend allowing institutions to have increased discretion to close cases at inquiry when the evidence leads to any combination of the following circumstances: sufficient evidence proves that the data inconsistencies are a result of honest error; the scope of the allegations are limited and correction of the research record has occurred; the allegations involved papers published over the six-year time limit; the respondent is not continuing research at the institution or in the US; a questioned publication is not highly cited; funding was not based on allegedly falsified data; questioned data is not influencing practices that could affect health and safety of the public, or the institutional actions implemented were sufficient. It is our understanding that these are similar circumstances that ORI assesses when it declines to pursue a research misconduct finding. A critical aspect for closing cases under these circumstances are that institutions would still be required to ensure correction/retraction of the research record, as appropriate. Similar to §93.316, where case closure occurs with an admission, an institution would notify ORI of its plans to close a case under such circumstances.

4. **Timelines for completing an inquiry or investigation.** The current timelines for completing an inquiry (60 days) or an investigation (120 days) are arbitrary time periods that do not
account for the complexity and scope of current cases. Institutions must seek multiple extensions for each phase. Respondents often raise procedural challenges that institutions did not adhere to the regulatory requirements for meeting the time deadlines. We suggest that the regulation state that the time periods serve only as a guideline for institutions to complete the process and specifically state that extensions are a normal and usual part of a research misconduct processes, which are dependent on the complexity and scope of individual cases.

5. **Clarify the concept for broadening the scope of research misconduct proceedings.** The phrase “pursue diligently all significant issues” in the context of inquiries, §93.310(h), and investigations, §93.105(b)(2), has led to draining institutional resources and having all involved individuals endure much longer investigations than the initial allegations would require. In connection with the subsequent use exception under §93.105, research misconduct proceedings can quickly become unmanageable. We believe a solution is three-fold: 1) to allow institutions the discretion to determine when significant issues and leads relevant to the investigation require expanding the scope of an ongoing proceeding, 2) omitting the subsequent use exception under §93.105, and 3) requiring correction of the research record for all concerns identified. These revisions would allow a simpler research misconduct proceeding that can focus on the most critical issues and still ensure the integrity of the research record for all concerns identified.

6. **Clarify the concept of need to know.** Although institutions recognize that confidentiality is a hallmark of research misconduct proceedings, a very strict interpretation of who has a need to know can trigger difficult consequences, particularly when allegations are made public, when respondents move from one institution to another, or when an affected publication needs to be corrected or retracted during the course of a research misconduct process. We strongly recommend that the regulation be revised to include broadening the need-to-know principle to include officials at other institutions, when those institutions (a) may possess records relevant to allegations under review, or (b) employ or fund research being conducted by a respondent found to have committed research misconduct. We also suggest that with ongoing investigations, ORI mediate communication between institutions particularly when a respondent seeks to leave an institution to avoid a research misconduct process. Further, we recommend that journal editors and/or publishers be explicitly included as those who need to know when sufficient fact-finding has identified that data are incorrect or unreliable, while remaining silent on the issue of culpability or intent, in ongoing research misconduct proceedings.

7. **Finally, ARIO supports revision of the hearing process described under Subpart E.** One key recommendation we suggest, limiting the complexity of institutional research misconduct proceedings, is revision of the hearing process under Subpart E. The current hearing process in the Department of Health and Humans Services (HHS) is before an administrative law judge (ALJ), in the Departmental Appeals Board (DAB), who makes a recommendation to the Assistant Secretary for Health (ASH). The ALJ is bound by all Federal statutes and regulations, Secretarial delegations of authority, and applicable HHS
policies. However, research misconduct proceedings are academic reviews of research practice, evaluating behavior in relation to the accepted practices of the relevant research community, and are not legal proceedings. Thus, Subpart E places stringent and demanding legal requirements for ORI to make independent research misconduct findings, which may concur with an institution’s findings. ORI often must reach out to institutions, sometimes years after institutional findings are made, to request additional information. The legal burden for ORI, therefore, seeps into the institutional procedures increasing the burden for carrying out institutional misconduct processes. We believe the hearing process should be replaced with a simpler appeal process that would make research misconduct proceedings easier for ORI, institutions, and respondents to navigate. We recommend a respondent appeal ORI research misconduct findings directly to the ASH in HHS. Departmental appeals of research misconduct are currently performed in other federal agencies, including the National Aeronautics and Space Administration, the National Science Foundation, the Veterans Administration and the Department of Defense, and it simplifies the appeals process while still ensuring due process rights. Moreover, the proposed harmonization with other agencies would have the added benefit of returning the process to its roots and avoiding the misunderstandings that arise when legal conventions are applied to an academic review process.

ARIO appreciates the opportunity offered by ORI to provide input into the revisions of 42 C.F.R Part 93. We hope that the recommendations offered in this letter, based on extensive experience of RIOs managing institutional research misconduct processes, as well as the COGR/ARIO joint letter, will help ORI make suitable and beneficial changes to simplify research misconduct proceedings. Further, any effort by ORI to harmonize procedures with other federal agencies would benefit institutional reviews, particularly for research funded by multiple federal agencies. ARIO remains committed to working with ORI with respect to the research misconduct regulations and welcome any opportunity to partner with or assist ORI in related activities.

Sincerely,

Lauran Qualkenbush
President, ARIO
on behalf of the ARIO Board and its members