November 16, 2018

Dr. Mike Lauer, Deputy Director
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National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Subject: Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH, NOT-OD-19-020 ("Guide Notice")

Dear Dr. Lauer:

Our three organizations share with the NIH a deep awareness of the importance of scientific integrity. Science should be performed well, using well established norms and processes, and we are aware that misconduct in research happens. When it does, it wastes money, time, and may harm patients when interventions or therapeutic decisions are made on the basis of inaccurate information. Given that shared understanding, we write because the institutions we represent are deeply concerned that the October 17 Guide Notice (NOT-OD-19-020), Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH (the "Guide Notice"), requires reporting to NIH when the institution "suspects" research misconduct that "might impact the conduct of an NIH-supported project," or "suspects" that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research. We are concerned that the line for reporting is vague and may lead to problems for investigators, institutions, and the NIH.

The risk of reporting based solely on a suspicion of research misconduct is that the respondent and other researchers involved with the project – even if they are not the respondents in the case – could suffer irreparable reputational damage. Many research misconduct cases result in no findings of falsification, fabrication or plagiarism and, under the Public Health Service Policies on Research Misconduct, 42 CFR Part 93 (2005) ("PHS Regulations"), the Respondent must be presumed innocent. Reporting based on a "suspicion" jeopardizes this important presumption. Moreover, simply being associated with a grant where there is said to be a "suspicion" of research misconduct could taint the reputation of a student, postdoc, or investigator who may have had no involvement in the activity at issue. The purpose of the confidentiality provisions in the PHS Regulations is to protect all involved and to instill confidence in a fair process. Reporting to the funding agency on a mere suspicion is at odds with the fact-driven, due-process laden research misconduct process required under the PHS Regulations.

The PHS Regulations do not require, or even contemplate, routine reporting from recipient institutions to funding agencies. But they do specify that "ORI may notify affected PHS offices and funding components at

any time to permit them to make appropriate interim responses to protect the health and safety of the public, to promote the integrity of the PHS supported research and research process, and to conserve public funds." (93.401(b)) Reporting directly from ORI to NIH would seem to be the most efficient and consistent method of communication to NIH. In addition, in an already litigious environment, it seems likely that some respondents will seek legal recourse to prevent institutions from reporting to the NIH or in response to reporting. Reporting from ORI to NIH would avoid such legal proceedings, and enable institutions to focus on carrying out the research misconduct review.

Institutions are also concerned that the Guide Notice does not specify how NIH might use the information reported to it. Unlike the Guide Notice, the PHS Regulations require that when ORI notifies affected funding components of potential research misconduct, "[t]he information provided will not be disclosed as part of the peer review and advisory committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding." (93.401(b)) Is the same true if an institution reports directly to NIH? How will NIH use the information institutions report? The Guide Notice should clarify what are permitted or prohibited uses of the information reported.

Finally, the research misconduct process is resource-intensive, requiring significant faculty and administrator time to carry out complex factual reviews. To the extent that NIH is now requiring an additional step in the process – of assessing whether there is "suspicion" of research misconduct – that increases the heavy burden institutions already bear in resolving these cases. This assessment would be particularly difficult when there is no definition of what constitutes "suspicion," or how it differs from a determination that the allegation is sufficiently credible and specific to warrant an inquiry, or has sufficient substance to warrant an investigation – determinations that institutions already routinely make under the PHS Regulations.

Although we are most concerned about reporting on a mere suspicion, we are also concerned and confused by the requirement to report when an institution "finds" or "learns" that falsified, fabricated, or plagiarized information has affected the integrity of NIH-supported research. Institutions cannot make findings of falsification, fabrication or plagiarism without a full investigation in accordance with the PHS Regulations. It is also not clear in what context an institution would "learn" of research misconduct without conducting a full investigation. Would this be limited to where a subrecipient might report a finding to a prime awardee? Additional clarification regarding NIH's expectations would be helpful here.

Prior to this notice, institutions have worked with ORI to perform complete evaluations of potential misconduct that are then further evaluated by ORI. Typically ORI validates the work done at an institutional level, but they have an investigative staff to perform that work. As a result of this notice, whenever the level of suspicion in information conveyed to OER becomes actionable (i.e. OER will need to do an evaluation of the investigation to decide that the suspicion is likely to be misconduct), that decision will typically be part of a complicated process. This process will create redundant and duplicative work for the institutions, ORI, and the NIH. Institutions will need to keep track of whom they've told what, and inconsistencies and omissions are likely. In short, ORI was created for a reason, and failures of ORI and the NIH to communicate should not be a reason to create an entirely new reporting system with apparently different and still undefined standards for actionability.

Rather than requiring reporting when the institution "finds, learns or suspects" that research misconduct that may affect NIH-funded research, NIH should consider adopting the notification requirement of section 93.318 of the PHS Regulations (42 CFR sec. 93.318). This section requires an institution to report immediately to ORI at any time during a research misconduct proceeding if certain special circumstances exist. These special circumstances include where:

a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects
b) HHS resources or interests are threatened
c) Research activities should be suspended

d) There is reasonable indication of possible violations of civil or criminal law
e) Federal action is required to protect the interests of those involved in the research misconduct proceeding
f) The research institution believes the research misconduct proceeding may be made public prematurely
so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved
g) The research community or public should be informed.

Although we endorse the current system of ORI reporting to NIH to protect health and safety and research integrity (93.401(b)), NIH could also require that if any of the special circumstances above are present, the institution must report to NIH as well as ORI. This approach would trigger reporting to NIH without conflicting with the confidentiality and due process obligations that are paramount to the integrity of the research misconduct process. And it would protect NIH's resources by requiring reporting if such resources are threatened.

We take issue, however, with the prospect of reporting a mere suspicion of research misconduct. Research misconduct cases may have significant, even career-ending, consequences for those involved, even if the respondent is ultimately exonerated. Reporting a suspicion of research misconduct violates the spirit and letter of the PHS Regulation and undermines the due process we strive to protect in research misconduct cases.

As always, we appreciate the opportunity to voice our concerns and we look forward to hearing from you. Should you have additional questions, please do not hesitate to contact us.

Signatory Associations:

Council on Governmental Relations (COGR)
American Association of Medical Colleges (AAMC)
Association of Research Integrity Officers (ARIO)

cc: Carrie D. Wolinetz, PhD, Associate Director for Science Policy, NIH
Patricia Valdez, PhD, Research Integrity Officer, NIH
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About the signatory associations: The Council on Governmental Relations (COGR) is an association of 187 research universities and affiliated academic medical centers and research institutes. COGR concerns itself with the impact of federal regulations, policies, and practices on the performance of research conducted at its member universities. The Association of American Medical Colleges (AAMC) is dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members comprise all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and more than 80 academic societies. The Association of Research Integrity Officers (ARIO) represents over 120 members institutions and its mission is to serve as 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.