VIEWPOINT

Proposed Increases in Government Authority Over Research Misconduct Proceedings

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Viewpoint

Public scrutiny of academic research continues to intensify, as evidenced by recent resignations of prominent university leaders, retractions of articles by leading scientists, and a proliferation of media coverage concerning research misconduct, which is most often defined as falsification or fabrication of research data, or plagiarism. Science bloggers have emerged as powerful contributors of allegations, with critical blog posts frequently triggering formal research misconduct proceedings. Physician-scientists are in the crosshairs of intensified enforcement with regard to their research publications, making more important the intricacies of research misconduct proceedings for all reported research, from bench science to data research to clinical trials. While a small number of misconduct cases dominate the media, physician-scientists and the public generally have little visibility into the thousands of research misconduct proceedings conducted each year at institutions across the US. This is by design, as federal regulations underpinning and dictating how institutions process allegations require confidentiality. However, the US Department of Health and Human Services' Office of Research Integrity (ORI) has proposed substantial amendments to the regulations that, if adopted, would steer the entire process for reviewing allegations of misconduct into a more legalistic framework less familiar to physician-scientists than the peer review approach that the current regulations approximate.

> [Office of Research Integrity] proposals suggest that the academic community should prepare itself for more regulatory directives and less autonomy in reviewing data integrity allegations.

Institutional policies typically specify that the fact-finding processes in research misconduct proceedings should be conducted by a research integrity officer who initially assesses allegations, and subsequently by committees typically comprising physician-scientists and other faculty with expertise in the research under scrutiny. These faculty first convene as an inquiry committee and later, if good cause is found, a successor faculty group convenes as an investigation committee. The prominent role of faculty in adjudicating misconduct reflects a consistent approach since the first research misconduct regulations were implemented in 1989 for research funded by the US Public Health Service, which includes the National Institutes of Health.[1] That approach—a purposeful choice—reflects the complexities of research misconduct cases that are best managed by institutions themselves, which in turn rely on faculty subject matter experts who understand the relevant field of study and the nuances of its standards. Federal regulations only cover misconduct in federally funded research, such as work that is supported by funds from the National Institutes of Health, National Science Foundation, Department of Energy, and Department of Defense, among others. Yet as a compliance matter, due to the ubiquity of federal research funding, institutions typically apply the federally mandated standards to all research misconduct proceedings, even those relating to privately or foundation-funded research. Thus, changes in federal regulations or guidance have direct impact on how all research misconduct allegations are handled within universities and medical centers.

In 2023, after a years-long period of soliciting public comment and tightening its own practices and interpretation of the existing regulations to be responsive to public concerns about integrity in science, ORI proposed amendments to the regulations applicable to Public Health Service–funded work that call into question and would undermine the historical near-complete reliance on a peer review, intrainstitutional process for analyzing research misconduct allegations.[2] In that proposal, ORI signals an enhanced emphasis on its own role in overseeing institutional misconduct proceedings. In general, ORI's current role is to provide guidance to institutions during ongoing proceedings but to refrain from substantively evaluating allegations or the institution's handling of the investigation until after the institution has completed its investigation, reported its findings to ORI, and implemented institutional actions.[3] Although ORI has the power to intervene if an institution neglects its responsibilities, ORI rarely exercises this authority. By contrast, the proposed changes to the regulations would impose rigid standards as to what institutions can and cannot do at key stages of a research misconduct proceeding and would give ORI substantial authority to oversee, direct, and alter institutional proceedings. If these proposed changes are adopted, the locus of control of research misconduct proceedings would shift from peer review committees acting within an institutional framework to the federal authority acting within a more prescriptive process.

Four key examples are illustrative of this proposed shift. First, ORI specifically proposes that if an initial assessment of allegations takes longer than 30 days to

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complete, the institution must initiate an inquiry in lieu of completing the assessment. This would be a highly consequential change. The initial scoping of potential research misconduct allegations can be complex and frequently involves unique, case-specific circumstances. A 30-day time frame to complete an assessment may be possible in certain situations, but in many other cases, it is not feasible within 30 days to assess the merit of the allegations, determine who should be a respondent, and sequester materials. Moreover, automatic initiation of an inquiry after 30 days would be unfair procedurally for researchers against whom nonmeritorious allegations have been raised. A "no exceptions," 30-day time frame would essentially foreclose engaging in dialogue with potential complainants, who may need to be counseled and assured of nonretaliation. Finally, research misconduct allegations often implicate other concerns, including human and animal research, harassment, and discrimination. It can take time—often longer than 30 days—for institutions to sort through allegations to understand how to process them under the right regulatory and policy frameworks.

Second, ORI is proposing to limit the discretion of faculty committees by imposing prescriptive requirements as to when allegations can be dismissed during initial inquiry and requiring that they be adjudicated in a detailed investigation. Specifically, ORI has proposed that "[a] conclusion of honest error or difference of opinion must not be made at the inquiry stage."[2] Presumably, ORI has proposed this change to ensure that findings of honest error are made only after meaningful review of the relevant evidence, and not simply because a committee has accepted an assertion by the accused that an honest mistake occurred or that no mistake was made at all. Rigid insistence that "honest error" cannot be determined at inquiry would prevent quick disposition of cases when institutions and faculty committees have determined that a mistake was made and can be readily corrected by reference to original, contemporaneously recorded data. Indeed, such a ban on honest error findings could suggest that nearly all of the thousands of errata and corrigenda issued annually, if brought forward as allegations of research misconduct, would require a full investigation to adjudicate because such corrections or errata are often the result of honest error.

Third, ORI has proposed that all interviews with witnesses (including complainants) must be formally transcribed and all interview transcripts made available to the respondent. At present, transcripts are only required for interviews at the in-depth investigation stage and not during initial assessment and inquiry, and institutions retain discretion as to whether transcripts of witness interviews are made available to respondents. Requiring transcripts for all interviews at all stages of a proceeding would predictably deter persons from coming forward with information early in a proceeding when the research integrity officer and inquiry committee are just beginning to puzzle out whether an allegation has substance and often are dealing with reluctant witnesses. Further, the possibility of a respondent's reviewing all transcripts would make witnesses reluctant to participate and less candid in testimony provided—for example, senior faculty respondents can influence career prospects of witnesses. Requiring transcripts for all interviews and making them available to respondents might satisfy a desire for legal transparency and formality but would veer sharply away from the historical model of academic peer review in confidential settings.

Fourth, ORI has proposed that "[v]oting or split decisions by the investigation committee members"[2] are impermissible—in other words, investigation committees must reach unanimous decisions on each allegation before them. Requiring unanimous decisions would fundamentally change the role of the investigation committee from a group of peers who deliberate findings and are free to disagree with a process in which disparate viewpoints are formally prohibited. This proposal, if adopted, would obviate established approaches that allow for dissent in committee decisions.

ORI proposals suggest that the academic community should prepare itself for more regulatory directives and less autonomy in reviewing data integrity allegations. ORI has received nearly 300 comments in response to these proposals, many reflecting the concerns raised here. Optimally, ORI would not move forward with these specific changes. But academic and medical institutions should understand the public, political, and ethical pressures on ORI to make oversight of research integrity more robust and can relieve some of those pressures by making their own processes more exacting, more efficient, and, to the extent possible, more transparent in regard to ultimate outcomes of specific cases. Ensuring at present that the research community takes all research misconduct allegations seriously, reviews them carefully, and resolves them expeditiously and fairly, without deference to the stature or position of those whose work has been questioned, would seem essential to avoid the escalation of regulatory strictures and to improve public trust in the scientific research enterprise.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Mr Caron reported being counsel at Ropes & Gray LLP, an international law firm that represents multiple universities, research institutions, and academic medical centers affected by the issues explored in this Viewpoint. In particular, Mr Caron frequently serves as an acting or interim research integrity officer, overseeing research misconduct inquiries and investigations on behalf of institutions. Mr Barnes reported being a partner at Ropes & Gray. Dr Bierer reported receiving personal fees from Ropes & Gray for assisting with research misconduct inquiries and investigations. Based on their experience with research misconduct proceedings, Mr Caron, Mr Barnes, and Dr Bierer drafted a comment letter in response to the Office of Research Integrity's Notice of Proposed Rulemaking that is the subject of this Viewpoint. A draft of the comment letter was subsequently reviewed and co-signed by representatives from 9 other academic and medical institutions. The comment letter is available at https://www.ropesgray.com/-/media/files/articles/2024/01/20240104_research-misconduct-notice-of-proposed-rulemaking-respose-letter-.pdf.

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