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Columns: Currents in Contemporary Bioethics

Maintaining the Integrity of the Biomedical Research Record Through Timely, Appropriate Corrective Action

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Abstract

Researchers, academic institutions, and journals have an ethical obligation to correct the research record expeditiously and publicly to maintain the integrity of science.

Keywords: research integrity; publication ethics; research record; corrective action; corrections; retractions; expressions of concern

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Scientific journals are the primary medium through which biomedical research results are disseminated to the research community and the broader public. These results guide new developments in research programs, product discovery, and clinical care. Failure to remediate inaccurate or unreliable published data can not only misdirect and delay scientific progress but also harm human health. As a result, data found to be inaccurate or unreliable must be promptly corrected — whether in publications, grants, or patents — regardless of who generated the data and regardless of whether the problem was the result of misconduct, negligence, or honest error. However, the research community lacks a transparent and prompt process by which published data are subjected to corrective action. As a result, inaccurate or unreliable data often remain in the published research record long after a problem is discovered, if they are ever corrected at all.

The delay in correcting published data can result in unnecessary and sometimes dangerous interventions in patients based on the problematic data, lead to investment in needless derivative research, and contribute to the growing problem of public mistrust of the scientific research enterprise. In addition, in its 2024 revision to the federal research misconduct regulations under 42 CFR Part 93 (Part 93), the US Department of Health and Human Services Office of Research Integrity (ORI) signaled a particular interest in correcting the research record by explicitly noting that obligations of confidentiality in research misconduct proceedings do not bar communications to journals, editors, and publishers.[1] Therefore, to preserve the integrity of the biomedical research record and to protect patient and research participant safety, research institutions and scholarly journals need an efficient and uniform approach to correcting and, when necessary, retracting published research.

Differing Approaches to Corrective Action

Although researchers have primary responsibility for the validity of their published data, journals that publish the work and institutions at which the researchers conduct their research have a shared interest in ensuring the validity of the scientific record — journals because of their duty to be gatekeepers of the results published under their watch, and institutions because of their academic and research missions and attendant responsibility for the results published by their researchers. Therefore, if researchers do not contact the relevant journal about a concern that their published data are invalid or inaccurate, the cognizant institution has the responsibility to do so. The cognizant institution in research misconduct cases is typically the institution at which the relevant research was conducted, which is also the institution in the best position to analyze the relevant evidence, if only because the research records most likely reside there. When in possession of a credible concern

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about inaccurate or unreliable published data, journals (which include for these purposes their publishers) typically take one of the following options for corrective action: (a) issue a retraction, which often indicates that the study results are inaccurate or have been falsified or fabricated; (b) publish a corrigendum, which often indicates an honest error was made by the author(s) for which accurate source data are available to publish; or (c) issue an expression of concern, which is often used to raise public awareness that an article may be unreliable. Alternatively, journals may choose not to take any action and remain silent. Despite their shared interest in research integrity, journals and institutions face a number of challenges with respect to taking timely and appropriate corrective actions, including some challenges that have been explored in the context of research misconduct.[2]

Problems with published research data may be identified as a result of institutional research misconduct proceedings. Most US-based academic institutions are subject to federally mandated procedures that the institution must follow if it receives or becomes aware of an allegation of research misconduct. The National Institutes of Health (NIH), the largest public funder of biomedical research, requires research misconduct proceedings to adhere to regulations under Part 93. During or after an institutional research misconduct proceeding, an institution, author, or even complainant may inform journal editors that certain published data have been found to be inaccurate or unreliable and may request a corrective action or may suggest that the editors make their own determination about a corrective action.

Problems with published research data may also come to light outside of a research misconduct context and can be raised by anyone, including an individual unaffiliated with the relevant institution or journal. For example, an author may inform the journal editors of data that the author has reason to believe are inaccurate or unreliable, or the journal editors may receive an email with allegations from a member of the general public — including from websites like PubPeer, which enables users to post anonymously regarding possible concerns about others' published work.

Within the sphere of biomedical research, there is no uniform approach to taking corrective action. Unlike institutions that are subject to Part 93, journals are not subject to federal legal obligations for data integrity review. As a result, journals vary in their approaches to determining whether a data integrity concern has merit and how to resolve it, including with respect to whether and how to take corrective action.[3] Journals may develop and rely upon internal policies for defining whether and how a corrective action should be issued, or they may defer to policies from professional organizations. Arguably, among the most comprehensive and influential of such policies are those issued by the Committee on Publication Ethics (COPE), a professional organization that educates editors, publishers, universities, and research institutes on publication ethics and maintains guidelines in this area. In 2024, COPE published a new version of its "Guidance to Research Institutions and Journals on Research Integrity and Publication Misconduct Cases" (the Cooperation Guidelines), which references COPE's separate guidance document on retractions (the Retraction Guidelines).[4] Similarly influential is the International Committee of Medical Journal Editors (ICMJE), a working group of medical journal editors who make recommendations on best practices in the conduct and reporting of research published in medical journals.[5] In its guidance to journal editors on managing allegations of scientific misconduct, ORI defers to the corrective action recommendations of ICMJE, and ICMJE in turn defers to the recommendations of COPE.[6] There are a number of other guidelines on publication integrity that touch on corrective action, such as those issued by the Cooperation & Liaison between Universities & Editors (CLUE), which is an international group of professionals in publication ethics and research integrity who address issues on cooperation and communication between institutions and journals about data integrity issues, and those issued by the Council of Science Editors, a membership organization for editorial professionals publishing in the sciences that provides guidance on the communication of scientific information.[7]

Prevalence and Latency of Corrective Action

The research community has begun examining whether published data receive appropriate corrective action as often and quickly as necessary.[8] Though challenging to quantify, the number of corrections and retractions in the published record is thought by many to be lower or slower than is warranted.[9]

Institutions frequently have difficulty ensuring that journals, their editors, and their publishers act upon the institution's corrective action recommendation. When an institution has identified problematic data as part of a research misconduct proceeding, the institution is able to withdraw a patent or grant associated with a researcher's unreliable data because the institution is typically the named party, but the institution does not control a journal's actions. While some journals respond promptly to institutional requests for corrective actions to published research, others do not visibly act upon or communicate their receipt of information about an institution's concerns with published work. Anecdotally, in our positions as research integrity officers, we have often had difficulty convincing journal editors to take corrective action even at the conclusion of a research misconduct proceeding after a fulsome review of published data by committees of academics. When corrective actions are taken, they are often published well after the relevant data have been found to be inaccurate or unreliable, and in many cases, only after assiduous and repeated efforts to persuade journal editors to act.[10]

In addition, journals traditionally view their relationship as with the author, not the author's institution, in part because the journal enters into a contractual relationship with the authors of a published work through author agreements, which are executed by the journal and author(s) upon either submission or, more typically, acceptance for publication. As a result, some journals defer to authors who have pushed back on institutional recommendations, even if the authors have not provided any compelling evidence to dispute the institution's findings of serious problems with the published data. CLUE recommends that journals in receipt of data integrity allegations should "in most cases" request a response from those suspected of misconduct prior to contacting the researcher's institution, which COPE echoes.[11] However, ORI's guidance suggests editors should, as a general rule, contact the institution prior to contacting authors.[12] We agree with ORI's guidance given that excluding institutions from the conversation between journal editors and authors regarding data integrity concerns precludes appropriate information sharing and increases the risk that relevant data may be compromised prior to being accessed and analyzed by the institution as part of its obligations under Part 93 or other relevant funding or oversight agency requirements.[13]

Whether the published data at issue were identified in a research misconduct proceeding or otherwise, journals' deference to authors may preclude or delay corrective action. Often, journals communicate exclusively with authors about data integrity concerns and seek unanimous agreement from all authors of a published work

before retracting the piece. However, simply receiving responses back from all co-authors, let alone reconciling their opinions on the issue, may take months or years, if it is possible at all. Authors routinely resist institutional recommendations for retraction, seeking to relitigate adverse research misconduct determinations and/or to prevent perceived damage to their careers from a retraction.

Journal editors' apparent reluctance to correct or retract papers seems to arise from good intentions — mainly, the importance that both journals and institutions place on accurately determining the reliability of the data at issue before taking corrective action. Institutions and journals may seek certainty in their analysis, informing a corrective action because of the risk that one of the authors may challenge the action or that taking such action will tarnish the reputation of the institution, journal, and the relevant authors.[14]

An additional challenge to timely and efficient corrective actions stems from the fact that many institutions have historically felt constrained by Part 93's obligation to maintain confidentiality of each research misconduct proceeding they conduct, viewing it as a possible bar to communicating with journal editors to correct the research record. However, ORI's 2024 modifications to Part 93 reflect that the agency expects institutions to communicate to journals, editors, and publishers, when necessary, which should help to mitigate these concerns.[15] When journals and institutions do engage in dialogue about the integrity of certain published data in the context of a research misconduct proceeding, each party's desire to wait until the culmination of the proceeding causes delays in pursuing corrective action. Institutions often wait to contact the journal about corrective actions until the institutional research misconduct proceeding has been completed, and journals often wish to wait until the end of the research misconduct proceeding before issuing any type of corrective action. Such actions may ostensibly align with the COPE Retraction Guidelines, which state that "it may be appropriate to wait for the outcome [of an institutional research misconduct proceeding] before issuing a retraction," though its Cooperation Guidelines state that "Retraction can occur before institutional investigations of misconduct have been completed."[16] We believe that when data are recognized as unreliable or inaccurate, corrective action should occur independently of the research misconduct proceeding, while keeping all misconduct-related information confidential.[17] Conducting research misconduct proceedings serves a complementary but different purpose than that of protecting the research record. The ultimate goal of a research misconduct proceeding is to determine whether it is more probable than not that the relevant research was falsified, fabricated, or plagiarized intentionally, knowingly, or recklessly by one or more specific individuals. On the other hand, the ultimate goal of preserving the research record is to ensure the integrity and veracity of published research findings, which has nothing to do with a finding of culpability relating to a specific individual.[18] Unlike a finding of research misconduct under Part 93, determining that corrective action is necessary does not require the identification of a specific culpable individual with the relevant level of intent — it simply requires a determination about the unreliability of published data.

In regard to assigning fault and identifying causes of unreliable published data, the Council of Science Editors recommends "identifying the responsible party and reason for the error — whether or not it constitutes misconduct" in each correction.[19] Similarly, the COPE Retraction Guidelines state that "If retraction is due to the actions of some, but not all, authors of a publication, the notice of retraction should mention this when possible."[20] Given that the role of journal editors is not to determine culpability, intentionality, or cause, their insisting on indicating culpability in a corrective action is likely to lead to needless controversy for the journal and authors, and generally adds further complexity and stigma to corrective action. For these reasons, a journal that determines to retract a paper would be well served to state a basis by reference to specific problematic data and leave alone the identification of any known responsible party or parties.

We advocate for a culture change in which a journal's taking, or an institution's advocating for, appropriate corrective action is viewed as an academic and ethical strength, whereas a failure to do so is appropriately regarded as a failure of the journal to fulfill its responsibility to safeguard the published research record, and the institution to uphold the integrity of data published by its researchers. The biomedical research community should seek ways to encourage calibrated corrective actions to preserve the integrity of the biomedical research record and to protect patient and research participant safety. In the table below, we build upon and, in some cases, disagree with and deviate from, relevant existing

Table 1. Recommendations to Improve Prevalence and Latency of Corrective Action

- Biomedical research journals should include the following elements in their author agreements, which are executed by the journal and author(s) upon either submission or, more typically, acceptance for publication:
  - a statement that the journal retains the right to contact, communicate, and engage with the author(s)'s institution(s) independently and at any time about the research;[21]
  - a statement that all articles that contain data about which there has been an institutional finding of unreliability that is reasonably attributable to intentional, knowing or reckless actions by authors will be retracted;[22]
  - a notice that the journal will promptly issue a notice of concern, corrigendum, or retraction as soon as there is a credible concern regarding the accuracy or reliability of published data, based on the nature of information received by the institution and author(s), and will subsequently and promptly retract any such notice of concern upon demonstration of data integrity;[23]
  - a statement that the agreement of any, some, or all authors is not required for the journal to issue a statement of concern, corrigendum, or retraction regarding a published work;[24]
  - a statement that the authors' failure to maintain source data supporting all of the work depicted in a publication is itself a basis for retraction, given the authors' representations at the time of submission regarding their possession and retention of source data;
  - a statement that data from a repeat or similar experiment are not sufficient to pursue correction in lieu of retraction, if original data are not available to corroborate the original published work;
  - a statement that the corresponding author will serve as the point of contact for journals with respect to data integrity concerns, including the responsibility to coordinate amongst the other authors and retaining, or ensuring the retention of, the original data;
  - an agreement not to bring defamation actions or other legal action against the journal or its editors if the journal proceeding regarding the data reliability issues has been conducted in good faith.
- Institutions should ensure each researcher as part of his or her employment terms and conditions is bound by a policy that establishes the roles and responsibilities of researchers with respect to data integrity, including compliance with institutional data retention and research misconduct policies, and specifies that the institution has the right to intervene with publishers with respect to concerns about unreliable or inaccurate published or submitted data.[25]
- Corrective action should occur independently of the research misconduct proceeding while keeping all misconduct-related information confidential.[26] Institutions should communicate with journal editors regarding published data as soon as the institution determines that there are serious questions about their accuracy or reliability, which most often occurs well before the research misconduct process is complete.[27] When an institution conducting a research misconduct proceeding decides to advance

(*Continued*)

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allegations to an investigation, the inquiry committee and the institution itself should use that event as a reminder to consider whether notifying the relevant journal is indicated (for example, to encourage a posting of a notice of concern or even a retraction).
• Journal editors should promptly acknowledge and review each corrective action request made by institutions at which the relevant research was conducted and communicate with such institutions about the journal's findings and actions.[28]
• The biomedical research community should adopt a default rule that an expression of concern will be posted for data integrity concerns that cannot be resolved within a specific deadline (e.g., 90 days after the journal becoming aware of such concerns). Such notice should alert readers to an ongoing evaluation of the data that may affect the reliability of the published findings, which should deter other researchers working to replicate or expand upon the research in question from relying on unreliable data. The notice of concern should be followed by an exoneration, correction, or retraction, after sufficient facts have been found to resolve the issue.[29] This rule would incentivize journals, authors, and institutions to investigate promptly, including in part by changing the incentive alignment around corrections — if notices of concern are posted routinely during the pendency of reviews, the publication of a notice of concern would be destigmatized, and authors would be incentivized to review concerns, collaborate with journals, and seek corrections as quickly as possible.
• Journal editors and publishers should post corrective actions on the electronic page of the posted paper and on their websites as soon as possible, followed by print publication when applicable.[30] The notice of the corrective action should also be published in the relevant table of contents.[31]
• Journal editors and publishers should frame the text of each corrective action as a statement of fact without implying any impropriety or culpability on the part of any individual author.
• Journal editors and publishers should inform all authors of the corrective action as soon as they determine that corrective action is necessary. The journal editors should permit authors to agree or disagree with the editors' determination and then publish the authors' opinion along with the corrective action. The journal should not wait for all authors' concurrence before issuing corrective action.

guidelines, in order to offer recommendations to editors of biomedical research journals and administrators of academic institutions for when and how to take corrective action when inaccurate or unreliable data have been identified in published research (Table 1). In our estimation, a clear and prescriptive framework is particularly needed for journal review, processing, and implementation of corrective actions to ensure that journals take prompt and consistent actions and not idiosyncratic positions responsive to the various self-interested pressures applied by authors and editors.

Conclusion

Maintaining an accurate public biomedical research record is integral for protecting human health, preserving the integrity of subsequent research, and restoring public confidence in the scientific enterprise. Researchers, academic institutions, and journals have an ethical obligation to correct the research record expeditiously and publicly so that unreliable data are identified and, when possible, replaced by accurate and verifiable data. The current situation in which many institutions hesitate or decline to recommend corrections or retractions, authors resist needed corrections or retractions, and journals fear offending someone in the research ecosystem, is unproductive and unsustainable. A new direction is needed — one in which the primary objective of all the participants in the research enterprise is to ensure the reliability of published data and the integrity of science.

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