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Ethics, Integrity and Policy

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/gacr20

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To cite this article: Minal M. Caron, Carolyn T. Lye, Barbara E. Bierer & Mark Barnes (13 Aug 2024): The PubPeer conundrum: Administrative challenges in research misconduct proceedings, Accountability in Research, DOI: 10.1080/08989621.2024.2390007

To link to this article: https://doi.org/10.1080/08989621.2024.2390007

Published online: 13 Aug 2024.

ACCOUNTABILITY IN RESEARCH, 2024
https://doi.org/10.1080/08989621.2024.2390007

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The PubPeer conundrum: Administrative challenges in research misconduct proceedings

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ABSTRACT

The founders of PubPeer envisioned their website as an online form of a "journal club" that would facilitate post-publication peer review. Recently, PubPeer comments have led to a significant number of research misconduct proceedings – a development that could not have been anticipated when the current federal research misconduct regulations were developed two decades ago. Yet the number, frequency, and velocity of PubPeer comments identifying data integrity concerns, and institutional and government practices that treat all such comments as potential research misconduct allegations, have overwhelmed institutions and threaten to divert attention and resources away from other research integrity initiatives. Recent, high profile research misconduct cases accentuate the increasing public interest in research integrity and make it inevitable that the use of platforms such as PubPeer to challenge research findings will intensify. This article examines the origins of PubPeer and its central role in the modern era of online-based scouring of scientific publications for potential problems and outlines the challenges that institutions must manage in addressing issues identified on PubPeer. In conclusion, we discuss some potential enhancements to the investigatory process specified under federal regulations that could, if implemented, allow institutions to manage some of these challenges more efficiently.

ARTICLE HISTORY
Received 28 May 2024
Accepted 5 August 2024

KEYWORDS
PubPeer; research misconduct; research integrity; ORI

Introduction

PubPeer, an online platform established to allow users to discuss scientific research after publication, is now well known across segments of the scientific community, most notably in cellular and molecular biology and related fields that are heavily reliant on image data, such as Western blots. The volume of PubPeer comments that identify possible concerns with scientific

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research is immense, and there are many recent high-profile examples of research misconduct allegations involving the published work of prominent researchers having been initiated through PubPeer. The use of artificial intelligence tools by the research integrity community to detect potential research misconduct has also contributed to the rise in PubPeer allegations (Hosseini and Resnick 2024).

PubPeer assists the research community by identifying problematic research but also can create significant burden on research compliance operations within universities, academic medical centers, research institutes, and other recipients of federal research funding. These institutions often receive e-mails – frequently anonymous – that link to concerns posted on PubPeer about a researcher's work, and research integrity officers ("RIOs") and other research compliance officials within the institutions must then evaluate how and whether to process these concerns as allegations of "research misconduct." Federal requirements for reviewing allegations of misconduct involving federally funded work are onerous, requiring a highly prescriptive process for gathering and securing evidence, conducting interviews and preparing interview transcripts, and completing detailed written reports for transmission to the federal government. These procedural requirements are meant to ensure a careful evaluation of allegations, as well as multiple opportunities for respondents to offer evidence in their defense. In our experience, research compliance staff can be overwhelmed by the volume of PubPeer issues relating to research published from their institution, and significant institutional resources are needed to review PubPeer allegations under the standards set forth under 42 C.F.R. Part 93 ("Part 93") and other applicable federal agency requirements.

This article (i) provides background on PubPeer and its use by the scientific and research compliance community, (ii) discusses the impact of PubPeer on research institutions, (iii) describes the institutional challenges of handling PubPeer comments within the existing regulatory framework for review of allegations of research misconduct relating to federally funded research, and (iv) proposes avenues for change to ensure that specific and credible allegations are rigorously assessed while reducing some of the burden on institutions tasked with investigating multiple speculative comments that appear on PubPeer or other widely available internet sources.

Background on PubPeer

Founding and initial aims

In October 2012, PubPeer launched as an online platform available to the entire scientific community, allowing any individual an opportunity to discuss any research publication ever published, in any field, independent of the

journals in which the papers have been published. PubPeer provides a form of post-publication peer review ("PPPR") – review carried out after a manuscript has been published. PPPR can take on several other forms, including submitting a formal letter to the editor, publicly commenting on a journal website, writing directly to the author or the author's institution, or writing about the research publication in some other public forum. PubPeer is a unique platform because it allows commenting regardless of where a research article is published and encourages commenters and authors to respond and interact with one another in real time.

The founders of PubPeer were initially anonymous, but in connection with the launch of a nonprofit arm (the PubPeer Foundation) in 2016, they revealed their identities (Callaway 2015). Dr. Brandon Stell, one of the co-founders, completed his scientific training at academic institutions in the United States and is currently a neuroscientist at the Centre national de la recherche scientifique in Paris, France. Dr. Stell has become the most public-facing individual of the three founders, speaking regularly about the benefits to the scientific community of a platform like PubPeer (Stell 2016). Dr. Stell has indicated that the purpose in creating PubPeer was to form an online version of "journal clubs" – "to capture discussions of the scientific literature that … scientists typically have in the lab and share them publicly to help other scientists evaluate the scientific literature" (Stell 2022). Specifically, Dr. Stell wanted PubPeer to be a platform that "facilitate[s] public, on-the-record discussions about the finer points of experimental design and interpretation" (Peer 0 2014) and allows the authors to participate in those discussions (Stell 2016).

Dr. Stell has pointed out that by promoting the critical assessment of research, PubPeer serves as a centralized platform that informs the scientific community of flaws in research and of instances in which research is not reproducible (Stell 2016). If such flaws are not shared widely, there can be "significant costs – financial costs, because … of wasted money trying to reproduce research that … [cannot be] reproduced … and human costs, … because if you spend time … trying to reproduce research that [cannot] be reproduced, [that] can be devastating for your career" (Stell 2016). Thus, in Dr. Stell's view, PubPeer may help to redirect researchers and funding entities from spending research funding on unreproducible research and pursuing research questions that may not be fruitful. Identifying errors in research publicly may also facilitate more accurate clinical decision-making, pharmaceutical development, and governmental policymaking (Stell 2016).

Anonymity

At its inception, comments on PubPeer could not be posted anonymously. However, researchers contacted the PubPeer founders with messages stating

that they were "afraid to comment in the open view of their senior peers" (Torney 2018). In March 2013, when PubPeer implemented the option of commenting anonymously, comments on the website increased substantially (Peer 0 2015). In a series of articles and blog posts written in 2015 and 2016, the PubPeer founders responded to criticism about anonymous posting. The founders explained that when commenters are completely anonymous (i.e., they have not registered as a user on PubPeer and therefore have not provided any identifying information to PubPeer), their comments are moderated by PubPeer personnel who confirm that each comment is based on (1) "publicly verifiable information," such as a figure in a research publication, and (2) the research itself, not the researcher (Stell 2016). According to Dr. Stell, when these two criteria are applied, PubPeer does not observe the types of problematic comments appearing on other platforms such as YouTube where anonymous commenting is allowed; instead, the vast majority of commentary is "specific to the data" (Stell 2016). The founders have also pointed out that when comments are made about a specific research publication, the authors of that paper are alerted to the comments and encouraged to respond to them (Stell 2016).

Critics of PubPeer often focus on the same anonymity. Some researchers have voiced concerns that anonymity "will enable unfounded denigration of researchers" (Barbour and Stell 2020). Others have pointed out that the anonymous comments are "non-constructive" for science in general; some argue that "commentators seem to be obsessed to find image manipulation in seemingly every figure of any published paper" (Torney 2018), as the majority of comments on PubPeer tend to involve image-based data (Stell 2016). A related criticism is that while scientists should be (and most often are) willing to participate in debates about their scientific research, they would prefer that the parties to the debate be known to one another to ensure discourse is "critical but fair," particularly if misconduct allegations are raised (Parak et al. 2013). More recently, one scientist submitted a letter to PubPeer requesting that certain comments made in "bad faith" be removed from PubPeer that the scientist claims have been made to harass him and his colleagues (Joelving 2023). Such use of PubPeer for pure harassment may not be an experience unique to this one scientist, and the functioning of PubPeer would certainly seem to allow for such malicious use of its platform.

In response, Dr. Stell has argued that PubPeer's "critics are rarely able to produce even a single example of a career that has been unjustly harmed by criticism on PubPeer, despite the large number of comments now in the PubPeer database" (Barbour and Stell 2020). Dr. Stell has maintained that "in all of the high-profile cases that we are aware of, the criticisms have been found to be accurate and justified" (Barbour and Stell 2020). Furthermore, Dr. Stell has stated that the risk of "ruffl[ing a few] academic feathers pales into insignificance when patients' lives, taxpayer billions, and young

researchers' careers are at stake" (Barbour and Stell 2020). The benefit of pointing out potentially faulty research, to Dr. Stell, is much greater than the "surprisingly slight 'defamatory' risk" (Barbour and Stell 2020). Finally, Dr. Stell points out that authors cannot and should not be immune from post-publication criticism by peers altogether, that publishing scientific findings in the public domain constitutes tacit acceptance that one's research may be criticized for a variety of reasons, and that researchers must bear responsibility when such criticisms are substantiated. Dr. Stell has commented that "authors who don't wish their work to be criticized or questioned are always free not to publish" (Barbour and Stell 2020).

Use of PubPeer by scientific community

There is little publicly available data informing the research community about PubPeer's impact on the scientific community and on how institutions and companies have investigated concerns raised on PubPeer. In 2022, Dr. Snell stated that PubPeer receives 3,500 comments and over 700,000 page views per month (Stell 2022). A 2021 study conducted by a researcher at the Institute for Advanced Social Sciences (Cordoba, Spain) classified a sample of PubPeer comments posted in 2019 and 2020 and analyzed those comments for purposes of determining what types of issues are discussed on PubPeer, the disciplines that are the most frequent subject of comments, and characteristics common to the most active commenters on PubPeer (Ortega 2021). The study found that most articles that are the subject of comments receive only a small number of comments: 50% of articles were the subject of only a single comment; 35% were the subject of only two comments; and only seven articles (out of 24,016 articles in the sample) were the subject of more than 100 comments. The study further found that publications relating to health sciences and life sciences received the vast majority of comments appearing on PubPeer, and that 77% and 79% of the comments relating to articles in these fields, respectively, were related to suspected fraud (Ortega 2021). The study also found that 85.6% of comments are anonymous, and while most PubPeer users have commented only once or twice, 17.1% of comments can be traced back to a small group of 25 users (Ortega 2021). Finally, of the five most active PubPeer commenters, two are not anonymous – Drs. Elisabeth Bik and Lydia Maniatis. Although there appears to be little publicly known about Dr. Maniatis, Dr. Bik is now widely recognized for her scholarship on research integrity issues, her contributions to PubPeer, and her comments on research misconduct issues in the national and international media.

Impact of PubPeer on research institutions

Overview

As discussed, PubPeer was originally created as an "online journal club" – not a whistleblower platform serving as a launch pad for institutional reviews of alleged falsification, fabrication, and plagiarism. However, comments on PubPeer increasingly lead to research misconduct proceedings as well as to other fact-finding processes that are not subject to direct oversight by the federal government (e.g., research that is not funded or proposed to be supported by the federal government and research conducted by pharmaceutical manufacturers that are not subject to research misconduct regulations, but that pharmaceutical manufacturers may nevertheless investigate through internal company processes for legal, reputational, and ethical reasons). While it is difficult to quantify how often PubPeer comments give rise to institutional and company investigations of falsification, fabrication, or plagiarism, a 2023 study conducted by researchers from the Instituto de Estudios Sociales Avanzados in Spain found that of a sample of 17,244 articles published after the year 2000 that received comments on PubPeer, 63.7% of the articles (10,989 articles) received comments reporting potential data or image manipulation. Of these articles, 2,256 articles (20.5%) received an editorial notice of some kind, most often either an erratum or retraction notice (Ortega and Delgado-Quirós 2023).

Given the increasing notoriety and frequency of research integrity concerns that have arisen out of concerns posted to PubPeer, PubPeer is increasingly discussed in national fora. In 2022, Dr. Stell testified before the Subcommittee on Investigations and Oversight of the U.S. House of Representatives Committee on Science, Space, and Technology, in which he discussed the role of PubPeer in the context of assessing grant applications and applications for research positions, as well as the power of PubPeer as an avenue for post-publication peer review given that the number of regular PubPeer users surpasses the number of experts at most scientific journals (Stell 2022). On 29 October 2022, the *New York Times* published an opinion piece written by Elisabeth Bik, in which she stated that after "report[ing] 2,500 [problems in research papers] to … journals' editors and – after learning the hard way that journals often do not respond to these cases – I posted many of these papers along with 3,500 more to PubPeer" (Bik 2022).

Intersection of PubPeer and research misconduct regulatory requirements

Federal regulations require institutions to review and investigate allegations of research misconduct relating to federally funded work. Many institutions have become overwhelmed by the volume of allegations of research misconduct that are derived from PubPeer posts, frequently brought to the

institution's attention by anonymous individuals or by the federal Office of Research Integrity ("ORI"), which with some frequency contacts institutions to advise that a research misconduct inquiry should be initiated regarding the data problems identified on PubPeer. Yet, as described in this paper, review of concerns appearing on PubPeer often fits poorly into the federally mandated process for investigation of research misconduct.

Overview of research misconduct regulatory requirements

Federal requirements regarding institutional review of research misconduct allegations involving federally supported work are derived from the Federal Research Misconduct Policy, issued by the White House's Office of Science and Technology Policy ("OSTP") on 6 December 2000 (the "Federal Research Misconduct Policy") (OSTP 2000). The OSTP Policy "applies to federally-funded research and proposals submitted to [f]ederal agencies for research funding" and required that all "federal agencies that conduct or support research … implement this policy" within one year of the publication of the policy (OSTP (2000), 76263). A primary goal of the policy was to "help achieve uniformity across the [f]ederal agencies in implementation of the research misconduct policy" (OSTP (2000), 76260). Most, if not all, federal agencies that provide extramural funding for research have adopted the standards and other requirements under the OSTP Policy, including ORI (ORI, HHS (2005)).[1]

In developing institutional policies and procedures for addressing allegations of research misconduct, many institutions apply one uniform policy regardless of the source of research funding. Such policy is generally designed to ensure compliance with Part 93, which applies only to research for which PHS funds have been provided or requested. PHS funding includes that from the National Institutes of Health ("NIH"), the largest public funder of biomedical and behavioral research in the United States.

Under Part 93, upon receipt of allegations of research misconduct, institutions (typically through their RIOs) must first assess the allegations to determine whether an inquiry process is warranted. Under 42 C.F.R. § 93.307(a), an inquiry is warranted if the allegation meets the following criteria: (1) the allegation falls under the definition of research misconduct under [Part 93]; (2) the allegation involves PHS-supported work; and (3) the allegation is "sufficiently credible and specific so that potential evidence of research misconduct may be identified." Research misconduct is defined at 42 C.F.R. § 93.103 as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

The institutional inquiry process, which is initiated only if the allegation is determined to be a cognizable claim of potential falsification, fabrication, or plagiarism, entails an initial review of the evidence to determine whether a more in-depth investigation is warranted. Specifically, pursuant to 42 C.F.

R. § 93.307(d), the inquiry process addresses whether, with respect to each allegation, there is (1) a reasonable basis for concluding that the allegation falls within the definition of research misconduct under Part 93 and involves PHS funding; and (2) a preliminary review of evidence from the inquiry indicates that the allegation may have substance. If an allegation is deemed to meet these criteria, a full investigation of the allegation must be undertaken.

The criteria for sending an allegation from inquiry to full investigation constitute a low bar, and in its 2005 preamble accompanying the issuance of Part 93, ORI emphasized that determinations of "honest error" should not be made at the inquiry stage, but rather only at the investigation stage after a full review of all relevant evidence (ORI, HHS (2005), 28378). ORI issued guidance in 2021 that further emphasizes the low threshold to move from inquiry to investigation, advising institutions to perform a "cursory review of other papers and grant applications within [six years of the date on which the allegation is received by the institution or ORI]" before determining that an investigation is not warranted, so as to ensure that other instances of potential misconduct are not missed (ORI 2021). In effect, the existing guidance stands for the proposition that ORI believes that most "close calls" at the inquiry stage must proceed to investigation under the existing regulatory framework. In the proposed changes to Part 93 issued by ORI in October 2023, ORI seeks to codify this "low bar," by revising Part 93 to expressly state that determinations of honest error must be made at the investigation stage (ORI, HHS (2023), 69597). During the public comment period, ORI received substantial pushback on this provision, with many institutions and individuals arguing that it is unduly rigid and burdensome to prohibit institutions from reaching a finding of honest error at the inquiry stage (Ropes & Gray LLP and MRCT Center 2024; COGR 2023; ARIO 2023).

If the inquiry process results in a decision that one or more allegations should advance to investigation, a time-intensive and detailed review results. Under federal regulation at 42 C.F.R. § 93.310(d)–(h), the investigation requires institutions to obtain "all the research records and evidence needed to conduct the research misconduct proceeding," document the investigation thoroughly, "interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation," and "pursue diligently all significant issues and leads discovered."

Incompatibility with existing regulatory framework

The first iteration of the research misconduct regulations applicable to PHS-funded work was issued in 1989 (Caron et al. 2023; Public Health Service 1989). OSTP issued the Federal Research Misconduct Policy in 2000, and ORI then revised its existing research misconduct policies to be consistent with this policy, promulgating a final rule in 2005. These developments long

predated PubPeer. In particular, while the regulations do not expressly require that a complainant be a known person, many provisions in the regulations suggest that the complainant is a person who has specific knowledge of the research in question and who may be approached to provide additional detail regarding the allegations in the course of a research misconduct proceeding.

In several passages, Part 93 contemplates *one* complainant making allegations, not several, unidentified complainants posting various complaints about the same published work on a public electronic website like PubPeer with a velocity, frequency, and number that were unanticipated – even inconceivable – at the time Part 93 was adopted. For example, under Part 93, a "complainant" is defined as "a person who in good faith makes an allegation of research misconduct," and an "allegation" is defined as "a disclosure of possible research misconduct through any means of communication[;] the disclosure may be by written or oral statement or other communication to an institutional or HHS official." Under 42 C.F.R. § 93.210, "good faith" is defined as "having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time." The preamble to the Federal Register publication of Part 93 in 2005 further states that ORI accepts "oral allegations, including oral, anonymous allegations," but again, Part 93 contemplates that oral, anonymous allegations are made to an institutional or HHS official, not on a website that has no affiliation with the institution or HHS.

Relevant provisions of Part 93 that govern the inquiry and investigation processes also suggest that ORI anticipated that allegations of research misconduct would typically be made by an identifiable complainant. For example, under 42 C.F.R. § 93.300(b), "in respond[ing] to each allegation of research misconduct … [institutions must ensure that there are no] unresolved … conflicts of interest with the complainant, respondent or witnesses." At the investigation phase, under 42 C.F.R. § 93.310(g), institutions must also "[i]nterview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation." Part 93 further contemplates notifying the complainant as to whether the institution has found that an investigation is warranted, providing the complainant with a copy of the draft investigation report, and notifying the complainant of the final HHS action taken in relation to the allegations of research misconduct – all of which are not readily achievable when the "complainant" has been one or more anonymous sources on a public platform.

Taken together, Part 93 suggests that there is typically an identifiable complainant, and in particular a single complainant making a complaint with whom the institution and ORI may communicate at several junctures

of a research misconduct proceeding to gain a greater understanding of the allegation and its context. ORI did not, at the time Part 93 was promulgated, anticipate that there would be a public medium through which numerous anonymous complainants could express multiple, frequent challenges to scientific publications that would require significant time and effort from RIOs to review, even when some of the complaints might quickly and demonstrably be determined to be false or may represent simple misunderstandings. In practice, institutions frequently receive anonymous e-mails containing a link to PubPeer comments – leaving institutions in the position of deciding whether to construe such e-mails or the PubPeer link contained within the e-mails as allegations of misconduct. ORI itself often sends institutions letters instructing them to review comments posted to PubPeer as allegations of research misconduct.[2]

Potential improvements to research misconduct regulatory requirements to permit more efficient management of PubPeer-derived concerns

Two important provisions within Part 93 play a large role in determining the volume of data integrity concerns that institutions must review under Part 93 as allegations of research misconduct, and thus are important in regard to how institutions handle PubPeer allegations. The first provision is the "subsequent use" exception to the six-year statute of limitations. The second provision is the standard used at the preliminary assessment to assess if an allegation of research misconduct merits a formal inquiry. Both provisions are open to interpretation, as neither the regulations nor written guidance from ORI provides clarity as to how these provisions should be interpreted by institutional recipients of federal funding. In this section, we discuss various interpretations of these key provisions and explain how certain interpretations and/or changes to the existing regulations could allow for more efficient management of PubPeer concerns under Part 93.

Statute of limitations and subsequent use exception

The regulations at 42.C.F.R. § 93.105(a) specify a six-year lookback period: Part 93 requirements apply only to potential instances of research misconduct "occurring within six years of the date HHS or an institution receives an allegation." However, there are two "exceptions" under which institutions must review allegations involving any research that predates the six-year lookback period.[3] First, under the "subsequent use exception" provided at 42 C.F.R. § 93.105(b)(1), an instance of alleged research misconduct must be reviewed in accordance with Part 93 requirements if the respondent "renews any incident of alleged research misconduct that occurred before the six-year

limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized."

While the second exception – the "health or safety of the public exception" – is rarely invoked, the subsequent use exception is frequently triggered, requiring institutions to initiate many research misconduct proceedings that assess allegations relating to articles published well outside of the standard six-year lookback period. PubPeer comments are not structurally limited to conform to this statute of limitations, and often make allegations regarding published papers of some vintage. Because of the "subsequent use exception," therefore, PubPeer comments regarding papers published ten years ago, twenty years ago, or even further back in time can often give rise to research misconduct proceedings (ORI, HHS (2022), 73007).

Most common interpretation

In our experience, the most common interpretation of the subsequent use exception in its current form is that allegations falling outside the six-year lookback period must be reviewed if the research in question has been re-cited or otherwise reused in any capacity in a separate publication or other research record prepared by the potential respondent within the six years preceding the receipt of the allegation. Institutions that adopt this interpretation need only conduct a routine literature search to determine whether any recent articles or grant applications have cited the work in question, a process that may be time-consuming but is easy to understand and implement with consistency across cases. Importantly, ORI appears to utilize this interpretation of the subsequent use exception when deciding whether to refer a set of allegations to an institution for review by the institution in accordance with such institution's research misconduct policy.[4]

This interpretation has the benefit of relative simplicity, since it requires no scientific assessment of the recent articles that contain a reference to the earlier work. However, this interpretation results in a significant number of research misconduct proceedings being undertaken by institutions that involve articles published long ago, particularly as PubPeer is increasingly used as a forum to bring to light potential issues with papers published far beyond the six-year lookback period.

Narrower reading of subsequent use exception

Under a second possible (and we believe, reasonable) interpretation of the subsequent use exception, a recent citation to the research published outside the six-year lookback period is not sufficient to trigger the subsequent use exception. Instead, in this alternate view, the subsequent use exception would only be triggered if the recent citation or other reference to the older work is

clearly related to the portion of the older work about which questions have been raised.

In our experience, this interpretation of the subsequent use exception is not commonly used but does characterize the research misconduct process utilized by at least a few specific institutions. For example, in The Ohio State University's "Six-Year Time Limitation & the Subsequent Use Exception – Standard Operating Procedures" policy, "in order to be considered subsequent use, the questioned data, or the conclusions or results derived from the questioned data, or the allegedly plagiarized text, must be cited, republished, or used as a direct reference in some manner to support the respondent's ideas, claims, theories, or conclusions" (The Ohio State University 2020). Additionally, the proposed changes to Part 93 issued by ORI in October 2023 include a revision to the subsequent use exception that appears to contemplate a related version of this interpretation. Specifically, the proposed changes include that the reuse of the earlier work must relate to "the portion(s) of the research record … that is alleged to have been fabricated, falsified, or plagiarized" (ORI, HHS (2023), 69591–69592).

Based on our experience working on a wide range of research misconduct proceedings, we believe that the effect of a universal change to this narrower interpretation of the exception would be substantial – that is, many more allegations would be deemed time-barred if the narrower interpretation of the subsequent use exception were adopted on a widespread basis. This would effectively reduce the number of allegations that would be cognizable and, as applied to allegations made through PubPeer, would reduce the number of those allegations that might trigger research misconduct proceedings about older publications.

Many members of the research community, in our experience, believe it unfair that a colleague's career could be permanently damaged or ruined by findings of misconduct resulting from PubPeer comments when the work in question is decades old, the techniques used today to interrogate figures and detect manipulation are far better than they were, and no primary data are available to permit a respondent to defend himself or herself, particularly when there is (and was) no federal requirement or institutional policy requiring the researcher to have retained such primary data for such an extended period of time. Therefore, this narrowing of the scope of the "subsequent use exception" would likely increase the regulated community's perception of the fairness of the misconduct process, even though it would allow some research misconduct to be left unidentified.

"Sufficiently credible and specific" standard at preliminary assessment stage

The first stage of a research misconduct proceeding under Part 93 is a preliminary assessment, the purpose of which is to evaluate whether each allegation is "sufficiently credible and specific so that potential evidence of research misconduct may be identified," as described at 42 C.F.R. §93.307(a). Institutions typically view this standard as a very low bar to clear – if the allegation is cognizable (i.e., the RIO can understand what is being alleged) and not clearly erroneous on its face, then an inquiry must be undertaken, regardless of where the allegation may have originated. In many cases, the low bar leads institutions to conclude that an inquiry must be undertaken even if the RIO is highly confident that no findings of research misconduct will result from the ultimate inquiry (and, if deemed necessary, investigation). In these cases, RIOs tasked with reviewing allegations at the preliminary assessment stage may be confident that a concern, such as a single instance of image duplication in a published paper, is an honest error and that the allegation of intentional, knowing, or reckless falsification or fabrication of data could be quickly resolved by a prompt review of the primary data, but under Part 93, determinations of honest error cannot be made until the investigation stage.

Currently, these types of issues, many of which have originated from an online source like PubPeer, often proceed to inquiry, which in turn requires the institution to sequester evidence in a formal manner, identify and empanel one or more expert fact-finders (frequently, a faculty committee), and prepare a detailed written report memorializing the inquiry. For all these reasons, the administrative burden associated with conducting an inquiry can be significant, even for simple cases involving only a small number of concerns that could potentially be resolved by a quick review of the primary data.

One alternative, particularly in connection with review of PubPeer concerns, might be to allow institutions and RIOs greater latitude in their evaluation of "allegations" not brought by an identifiable individual. Whether the concern is brought to the attention of the institution or RIO as an anonymous e-mail or other method flagging a PubPeer post or similar source, RIOs should have discretion to evaluate the concerns expressed, and either dismiss the concerns, resolve them through a streamlined process as discussed below, or send the concerns to inquiry and/or investigation if deemed necessary, without ORI second-guessing reasoned decisions by RIOs in this category. In an enhanced assessment process, determinations by RIOs should be well-documented, to ensure that the assessment is fair, reasonable, and auditable.

Consider the scenario of an anonymous individual emailing the RIO a link to a PubPeer post and stating that the post raises a concern of potential research

misconduct, with the PubPeer post itself simply stating that two images "look unexpectedly similar." In this common situation, if the two images do indeed look highly similar (as many Western blots often do) but the allegation of exact (and inappropriate) duplication is equivocal without access to the primary data, an institution arguably should be permitted to conduct a detailed review of the assertion during the preliminary assessment stage prior to any certification for inquiry in order to substantiate whether the allegation is "sufficiently credible" to proceed. The most efficient way of accomplishing such a detailed review would be to provide the potential respondent (typically, the first, senior, and/or corresponding authors) with notice of the concern and an immediate opportunity to respond with source data.

A detailed review at the preliminary assessment stage of concerns originating on PubPeer (and other allegations not brought by an identifiable complainant), provided that the RIOs are afforded the discretion and authority to conduct such a detailed review, would have several advantages. First, the detailed review would equip RIOs with more scientific information about the work in question at this early, preliminary stage, thereby allowing institutions and respondents to avoid some (and perhaps many) unnecessary inquiries and all the research integrity efforts and formal processes that must be applied at the inquiry stage. Additionally, the detailed review would more closely align the initial stages of a research misconduct proceeding with the manner in which authors of challenged works typically respond to comments on PubPeer and/or queries from the journals in which the work was published: rapid, informal responses in real-time, outside the formal confines of a research misconduct proceeding and the formalities of sequestration and adjudication by an inquiry committee. Further, a robust preliminary assessment may reveal that certain PubPeer comments have no scientific credibility and may have been placed on PubPeer with malicious intent or inadequate knowledge. In these cases, an institution is better able to support and protect the reputation of its researchers if it has the latitude to conclude that patently false allegations lack merit and dispose of those without needing to refer them to an inquiry. Many researchers whose work has been challenged would benefit from a more efficient adjudication as well, as fewer cases would proceed to the inquiry and investigation processes, sparing innocent respondents from long periods of significant stress and relieving operational pressure on research misconduct offices, allowing them to focus on the more egregious instances of data falsification, fabrication, and plagiarism.

However, under Part 93 in its current form, it would be challenging to implement an approach under which a more thorough review can be conducted, and a cognizable allegation resolved, at the preliminary assessment stage. Specifically, the existing regulations at 42 C.F.R. § 93.305(a) are clear that the identification and gathering of relevant research records (which Part 93 refers to as "sequestration") must occur prior to or concurrent with

the institution's providing a respondent with notice of the allegation. Sequestration is typically done at the commencement of inquiry and is an onerous process requiring institutions to partner with their IT departments or outside vendors to secure electronic data and, despite interruptions, secure hard copy data, such as lab notebooks and slides. The sequestration obligations under Part 93 help minimize the possibility that, given notice of the allegations, a respondent might destroy or manipulate research records to cover up or cloud the evidence of misconduct. Notwithstanding this public policy rationale, PubPeer comments are available for the public to see as soon as they are posted, and as such, it is not clear whether the benefit of the existing sequestration requirements adds much value as compared to the likely value of streamlining the process by providing potential respondents with an initial opportunity to respond and avoid unnecessary investigatory steps.

That being said, we also acknowledge an important qualification to our argument that empowering institutions with greater discretion to close out cases at the preliminary assessment and inquiry stages would be beneficial to institutions. Specifically, this argument assumes institutions would capitalize on these changes industriously, by exercising good judgment and thereby taking advantage of greater efficiencies to process other research misconduct proceedings and research integrity initiatives more quickly. In reality, if ORI were to give institutions greater latitude in their institutional decision-making at the early stages of a research misconduct proceeding, there would probably be a wide variety of outcomes. Institutions with strong research integrity functions – in particular, experienced RIOs and other research compliance personnel, adequate funding for research integrity efforts, and an institutional culture allowing RIOs and institutions to scrutinize the work of senior faculty without fear of retaliation or other negative ramifications – would likely experience an improvement in the quality and timeliness of research misconduct proceedings, resulting in a more favorable opinion of research misconduct proceedings by all constituencies (respondents, committee members, researchers, and faculty of the institution more generally). However, institutions lacking these elements could actually experience a degradation of their research misconduct function, as RIOs may be unconsciously incentivized to use this exception to dismiss cases, particularly those involving "allegations" not brought by identifiable individuals, at early stages when additional probing might have revealed significant problems with the research in question.

Conclusion

PubPeer has played a preeminent role in the elevation of research integrity concerns to the national consciousness. However, the influx of PubPeer

comments received by institutions and triaged by RIOs and other research compliance personnel has placed a significant burden on research institutions already stretched thin by ongoing research misconduct proceedings and other research integrity and research compliance obligations. On the one hand, institutions and RIOs cannot spend every waking hour reviewing PubPeer comments and other potential concerns of research misconduct originating on blogs, social media, and other online sources. On the other hand, when serious concerns are raised to the attention of an institution that may have originated from PubPeer and brought forward without an identified "complainant," then there is a need to evaluate the concerns, although with a realization that there is no identifiable complainant to assist in giving context and details. As detailed in this article, modifications to the subsequent use exception within Part 93, and more streamlined case management at the preliminary assessment stage, would allow institutions and RIOs to review and address significant PubPeer comments in a more efficient and effective way.

While there is no magic policy solution to balance the high volume of research misconduct concerns originating on PubPeer with institutions' responsibility to ensure that serious concerns, regardless of origin, are reviewed carefully, clear guidance from ORI that empowers institutions to utilize greater discretion in their review of PubPeer-based allegations would improve the research misconduct investigatory function, allowing for quicker and more practical case management. In particular, all research stakeholders – not only accused researchers but also their collaborators, journals, institutions, funding agencies, and the larger scientific community – would benefit from more efficient processing of allegations and rapid resolution of concerns that can be disposed of within a reasonable margin of certainty. Mistakes could occur as a result of allowing such an exception, but in an academic and scientific world of limited resources, there must be a way of taking advantage of crowd-sourced data analysis like PubPeer, while avoiding the paralytic burden of addressing every such crowd-sourced issue as though it merits an inquiry and, perhaps, an investigation.

Notes

1. On October 6, 2023, ORI issued a Notice of Proposed Rulemaking, which includes proposed amendments to Part 93, such as changes to the multi-part structure of research misconduct proceedings, the subsequent use exception, and definitions applicable to the research misconduct process (ORI, HHS 2023). In the authors' view, however, none of the proposed changes would alleviate the institutional challenges described in this article – the proposed changes, if adopted, would only exacerbate these challenges.
2. In the authors' experience assisting institutions with research misconduct proceedings and as RIOs and acting RIOs, ORI "forwards" PubPeer comments to institutions, in

some cases requesting that the institution conduct an assessment as to whether a formal inquiry is necessary and in other cases instructing that an inquiry should be conducted. Our experience with such communications is corroborated by a recent news article about alleged research misconduct at Central Michigan University, which provides a copy of a letter sent from ORI to the university with PubPeer "allegations" that were not otherwise brought to ORI's attention by an identifiable complainant (McMurray 2024).

3. In addition to the two exceptions described herein, Part 93 includes a third exception: the "'grandfather' exception." This exception only applies to allegations received by HHS or the institution before the effective date of Part 93 (i.e., June 16, 2005) and therefore is not relevant today.
4. This statement is derived from the personal knowledge of the authors, based on their participation in specific cases that are subject to ORI oversight.

Disclosure statement

Mark Barnes, J.D. LL.M., Minal M. Caron, J.D., and Carolyn T. Lye, M.D., J.D. are attorneys at Ropes and Gray LLP, an international law firm that represents multiple entities in the health care and academic sectors, including by advising academic medical centers and institutions of higher education on research misconduct matters. Barbara E. Bierer, MD, formerly served as senior vice president of research and the Research Integrity Officer at the Brigham and Women's Hospital and often serves as a committee member in research misconduct proceedings.

Funding

The author(s) reported there is no funding associated with the work featured in this article.

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