

## Long-Awaited Changes to Research Misconduct Rules Have Arrived

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On 12 September 2024, the Office of Research Integrity (ORI) within the US Department of Health and Human Services (HHS) issued a final rule (Final Rule) that significantly modified the standards, procedures, and requirements for research misconduct proceedings housed at Title 42, Part 93 of the Code of Federal Regulations (Part 93)—a rule that has not been amended since it was first codified in 2005.<sup>1</sup> Under Part 93, “research misconduct” is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”<sup>2</sup>

Part 93 specifically governs alleged research misconduct in research funded by a Public Health Service (PHS) agency.<sup>3</sup> PHS is comprised of a number of agencies within HHS, including the National Institutes of Health, the Centers for Medicare & Medicaid Services, and the Agency for Healthcare Research and Quality, thereby covering a large swath of health-related research grants.<sup>4</sup>

Notably, the Final Rule adopted certain clarifications and procedural flexibilities, and it stopped short of finalizing ORI oversight for certain aspects of the process, which enshrined additional discretion and beneficial clarity for grantee institutions who are burdened by extensive requirements to review what seems to be an ever-increasing tide of research misconduct-related allegations.<sup>5</sup> In October 2023, ORI issued a Notice of Proposed Rulemaking (Proposed Rule) that proposed more sweeping modifications to the research misconduct rules than those ultimately adopted.<sup>6</sup> After receiving substantial commentary from research institutions and other interested parties, the Final Rule was issued with some notable differences from the Proposed Rule. For example, the Final Rule declined to adopt: (1) a requirement that institutional assessments would need to be conducted within 30 days or otherwise automatically proceed to inquiry,<sup>7</sup> (2) a requirement that determinations of honest error could only be made at the investigation stage and not at the earlier stages of a proceeding,<sup>8</sup> and (3) a provision that would have permitted ORI to publish information about final institutional actions that did not result in findings of research misconduct or settlements.<sup>9</sup> The Final Rule also provided useful clarifications, for example, of the definition of plagiarism, the standard for recklessness, and who is in scope of the “need to know” for purposes of confidentiality obligations.<sup>10</sup>

This alert will summarize a number of key updates to the research misconduct regulations and, where applicable, will highlight areas of divergence between the Proposed Rule and Final Rule. This alert will

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<sup>1</sup> 89 Fed. Reg. 76,280 (Sept. 17, 2024) [hereinafter, Final Rule].

<sup>2</sup> 42 C.F.R. § 93.103. Note that under the Final Rule, this definition will be re-codified at 42 C.F.R. § 93.234.

<sup>3</sup> *Id.* § 93.102.

<sup>4</sup> *Id.* § 93.220.

<sup>5</sup> The number of research misconduct allegations has steadily risen over the past two decades, with one contributing factor being scientific “sleuths” (many competing scientists) monitoring PubPeer and other repositories of scholarly scientific articles and anonymously raising concerns that may or may not constitute research misconduct on the part of the researcher, but whose institution must nonetheless assess through lengthy and prescribed processes. *See* Angus Chen & Jonathan Wosen, *A flurry of research misconduct cases has universities scrambling to protect themselves*, STAT (Feb. 12, 2024), available at [statnews.com](https://www.statnews.com).

<sup>6</sup> 88 Fed. Reg. 69,583 (Oct. 6, 2023) [hereinafter, Proposed Rule].

<sup>7</sup> *Id.* at 69,596; Final Rule, at 76,285.

<sup>8</sup> Final Rule, at 76,282.

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 76,283–84, 76,298–300.

also provide several key takeaways and practical implications to consider before the revised regulations take effect on 1 January 2026.<sup>11</sup>

## Notable Updates in Final Rule

### Definitional Changes to Key Terms

#### **Meaning of “Intentionally,” “Knowingly,” and “Recklessly”**

The existing regulations have always stipulated that a finding of research misconduct requires that the specific misconduct at issue “be committed intentionally, knowingly, or recklessly;”<sup>12</sup> however, the regulations did not provide any definitions for those scienter standards.

“Intentionally” is now defined as to: “act with the aim of carrying out the act.”<sup>13</sup>

“Knowingly” is now defined as to: “act with awareness of the act.”<sup>14</sup>

“Recklessly” is now defined as to: “propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.”<sup>15</sup>

The new definition of “recklessly,” in particular, will hopefully bring additional clarity when it comes to assessing the responsibility of principal investigators, lab directors and other supervisors for the misconduct of researchers they supervise. The final definition is resonant of a 2018 research misconduct case in which the administrative law judge (ALJ) said that “even if [the respondent] did not insert the false material and he did not intentionally or knowingly use false material proposing, performing, reviewing, or reporting PHS funded research, he is still liable as a PI, author, editor, or contributor for recklessly permitting false material to appear in grant proposals, an article, and posters.”<sup>16</sup> The ALJ further explained that “under the [then current] broadly drafted 42 C.F.R. pt. 93, one listed as having responsibility for the action such as a PI or author may be found liable for the research misconduct, *even if he or she committed no act other than “recklessly” permitting the inclusion of false, fabricated, or plagiarized material in proposing, performing, or reviewing research, or in reporting research results.*”<sup>17</sup>

It will be important to monitor for additional guidance from ORI and new findings under this standard once the Final Rule takes effect to determine the impact on liability for principal investigators and others with oversight duties.

#### **Scope of “Plagiarism”**

Part 93 currently defines plagiarism (one of the types of potential research misconduct) as “the appropriation of another person’s ideas, processes, results or words without giving appropriate credit.”<sup>18</sup> In the Proposed

<sup>11</sup> *Id.* at 76,289, 76,296.

<sup>12</sup> 42 C.F.R. § 93.104(b).

<sup>13</sup> Final Rule, at 76,299.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 76,300.

<sup>16</sup> ORI v. Kreipke, No. C-16-402, at 80 (DAB May 31, 2018), <https://www.hhs.gov/about/agencies/dab/decisions/alj-decisions/2018/alj-cr5109/index.html>.

<sup>17</sup> *Id.* at 81 (emphasis added).

<sup>18</sup> 42 C.F.R. § 93.103(c).

and Final Rules, ORI revised the definition of plagiarism to *exclude*: self-plagiarism, authorship or credit disputes; and limited use of identical or nearly identical phrases describing a commonly used methodology.<sup>19</sup>

### ***Expanded Reporting Requirement: Entire Institutional Record***

The existing regulations require an institution to provide the investigation report to ORI following the conclusion of a research misconduct investigation.<sup>20</sup> The Proposed and Final Rules revised the regulations to expand this reporting requirement by requiring an institution to transmit the “institutional record” to ORI after a final determination is made on research misconduct findings.<sup>21</sup> The institutional record includes:

- Documentation of the assessment;
- The inquiry report and investigation report, and all records considered or relied on during the inquiry and investigation stages (if applicable);
- All transcripts;
- Decision(s) of the Institutional Deciding Official;
- Complete record of any institutional appeal;
- Index of all research records and evidence compiled during the proceeding, except records not considered or relied on; and
- General descriptions of records that were sequestered but not considered or relied on.<sup>22</sup>

The Final Rule contains an important carveout that the Proposed Rule did not—specifically, an institution will not be required to provide information to ORI where it was **not “considered or relied on”** at any stage of the research misconduct proceeding.<sup>23</sup> Still, this expanded reporting requirement will require institutions to review and modify their current record-keeping procedures for research misconduct matters.

### **Procedural Changes**

The Final Rule also provides some noteworthy modifications to general procedures that institutions must be aware of, including changes to time periods for the various stages of a research misconduct proceeding, and necessary items in reports.

### ***Time Periods for Assessment, Inquiry, and Investigation Stages***

The existing regulations create a three-stage process for research misconduct proceedings, including (1) an *assessment* of allegations to determine whether allegations are “sufficiently credible and specific so that potential evidence of research misconduct may be identified;”<sup>24</sup> (2) an *inquiry* involving “[p]reliminary information-gathering and fact-finding” to determine whether there is a “reasonable basis” for concluding the research misconduct allegation has substance;<sup>25</sup> and (3) an *investigation* involving “formal

<sup>19</sup> Proposed Rule, at 69,593; Final Rule, at 76,299–300. Of note, in doing so, ORI codified guidance it had issued in 1994 that self-plagiarism and authorship disputes do not constitute research misconduct. See ORI, *Policy on Plagiarism* (Dec. 1994), <https://ori.hhs.gov/ori-policy-plagiarism>.

<sup>20</sup> 42 C.F.R. § 93.315.

<sup>21</sup> Proposed Rule, at 69,599; Final Rule, at 76,304–05.

<sup>22</sup> Proposed Rule, at 69,592–93; Final Rule, at 76,299.

<sup>23</sup> Compare Proposed Rule, at 69,592–93, with Final Rule, at 76,299.

<sup>24</sup> 42 C.F.R. § 93.307(a)(3).

<sup>25</sup> *Id.* § 93.307(d).

development of a factual record and examination of that record,” which allows for a determination on whether research misconduct has occurred.<sup>26</sup> These stages have varying applicable time periods, which were modified by the Proposed and Final Rules:

### **Assessment Stage**

The Proposed Rule had included a requirement that institutional assessments needed to be conducted within 30 days, or they would proceed automatically to the inquiry stage.<sup>27</sup> After receiving comments that this requirement was unrealistic and overly burdensome, the Final Rule relented and also simplified the assessment stage by requiring institutions to merely document the assessment process rather than prepare a formal report.<sup>28</sup>

### **Inquiry Stage**

The Proposed Rule had left the time for an institution to complete an inquiry at “60 days” after initiation but the Final Rule extended the time period to “90 days” unless circumstances warrant an extension.<sup>29</sup>

### **Investigation Stage**

The Proposed Rule and Final Rule extended the time period to complete an investigation from “120 days” to “180 days” unless circumstances warrant an extension.<sup>30</sup>

### ***Required Contents of Inquiry and Investigation Reports***

The existing regulations require that an institution generate an inquiry report and an investigation report during those stages of the proceeding and provide them to ORI.<sup>31</sup> The Proposed and Final Rules augmented the required contents of these reports, newly requiring in the inquiry report, for example: an inventory of sequestered research records and other evidence, a description of how sequestration was conducted, any scientific or forensic analyses conducted, and the basis on which any allegations do not merit an investigation.<sup>32</sup>

Reporting requirements for the investigation report were also expanded to specify, for example: any additional allegation(s) addressed during the research misconduct proceeding, the composition of the investigation committee, transcripts of all interviews conducted, identification of the research records that allegedly contained the falsified, fabricated, or plagiarized material, and a description of the investigation committee’s consideration of comments made by the respondent and complainant on the draft report.<sup>33</sup>

### ***Who Can Conduct an Inquiry***

Although the existing regulations are silent on whether a committee is required to conduct an inquiry, most institutions have a practice of empaneling a committee at the inquiry stage. The Final Rule clarifies that a committee is not required to conduct the inquiry, and an institution may instead designate the Research Integrity Officer or another official to conduct the inquiry if desired.<sup>34</sup> This clarification allows

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<sup>26</sup> *Id.* § 93.215.

<sup>27</sup> Proposed Rule, at 69,596.

<sup>28</sup> Final Rule, at 76,285.

<sup>29</sup> Proposed Rule, at 69,597; Final Rule, at 76,282, 76,302.

<sup>30</sup> Proposed Rule, at 69,598; Final Rule, at 76,289, 76,303–04.

<sup>31</sup> 42 C.F.R. §§ 93.309, 93.313.

<sup>32</sup> *Id.* § 93.309; Final Rule, at 76,303.

<sup>33</sup> 42 C.F.R. § 93.313; Final Rule, at 76,304.

<sup>34</sup> Final Rule, at 76,302.

flexibility for institutions and may serve to streamline the inquiry stage and conserve resources for investigations.

### ***Sharing Interview Transcripts With Respondent***

The existing regulations require creation of transcripts for witness, respondent, and complainant interviews and that copies be provided to the specific interviewee.<sup>35</sup> The regulations do not currently require that copies of all transcripts be shared with the respondent. The Proposed Rule created a requirement that transcripts be shared with the respondent, and the Final Rule officially codified the requirement (though the Final Rule did remove the requirement that interviews be transcribed at the assessment and inquiry stages).<sup>36</sup> Notably, ORI considered, but did not specifically act on, requests from commenters that institutions be required to redact the transcripts before forwarding to the respondent, to protect interviewee identities.<sup>37</sup> While this new rule allows for greater transparency to the respondent, it may have the unintended consequence of disincentivizing testimony or candor in testimony for fear of respondent retaliation. Institutions may want to consider providing transcripts in a redacted or anonymized fashion to avoid such issues.

### ***Multiple Respondents***

The Final Rule allows an institution to add respondents to an ongoing research misconduct case without conducting a separate inquiry for each new respondent.<sup>38</sup> To address commenters' concerns that this provision could set a precedent that infringes on respondents' rights, the Final Rule specifies that each additional respondent must be provided notice of the allegations and an opportunity to respond.<sup>39</sup> In a departure from the Proposed Rule, ORI removed an exemplary list of potential co-respondents, as it concurred with commenters' concerns that listing the types of researchers to be considered as potential respondents created a confusing standard and could be detrimental to those individuals.<sup>40</sup> Notably, the scope of these types of potentially additional respondents (e.g. principal investigators, co-authors, collaborators and lab members involved in conducting the research or generating the research records) may still be swept up in the more generalized scope of the new standard for "recklessness," which includes reviewing or reporting research results (as discussed above).<sup>41</sup>

### ***Multiple Institutions***

The Final Rule specifies that when allegations involve research conducted at multiple institutions, one institution must be designated as the "lead institution" if a joint research misconduct proceeding is conducted.<sup>42</sup> The "lead institution" should obtain research records and other pertinent evidence, including witness testimony, from the other relevant institutions.<sup>43</sup> ORI notes that there has been an increase in complex cases involving more than one institution and indicated it will provide further guidance on how to handle such cases, including how to determine a lead institution.<sup>44</sup>

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<sup>35</sup> 42 C.F.R. § 93.310(g).

<sup>36</sup> Final Rule, at 76,281–82, 76,284, 76,303.

<sup>37</sup> *Id.* at 76,289.

<sup>38</sup> *Id.* at 76,284–85, 76,301.

<sup>39</sup> *Id.* at 76,285.

<sup>40</sup> *Id.*

<sup>41</sup> *See id.* at 76,300.

<sup>42</sup> *Id.* at 76,301–02.

<sup>43</sup> *Id.* at 76,302.

<sup>44</sup> *Id.* at 76,288.

## Additional Changes of Note

### ***Sequestration***

Under the Final Rule, ORI moves away from the use of the term “custody” and focuses on the institution’s obligation to obtain and sequester all research records and other evidence that it will need to conduct the research misconduct proceeding.<sup>45</sup> As ORI recognized in the Proposed Rule, with the use of cloud-based storage, it may not be possible to obtain “custody” of the original research records and other evidence that will be needed to conduct a research misconduct proceeding.<sup>46</sup> Thus, institutions may sequester copies of records needed to conduct a research misconduct proceeding if they are substantially equivalent in evidentiary value to the original records.<sup>47</sup> Whenever possible, the institution must obtain the research records or other evidence (1) before or at the time the institution notifies the respondent of the allegation(s); and (2) whenever additional items become known or relevant to the inquiry or investigation.<sup>48</sup>

### ***Subsequent Use Exception***

Although Part 93 generally applies only to research misconduct occurring within six years of the date HHS or an institution receives an allegation of research misconduct, it provides for a “subsequent use” exception if the respondent cites, republishes or otherwise uses for his/her potential benefit the research record that is alleged to have been fabricated, falsified, or plagiarized.<sup>49</sup> Given researchers’ practices, for example, of attaching their curriculum vitae with a running list of all publications to each relevant grant application, the exception functionally nullified in many cases any meaningful statute of limitations. The Final Rule clarifies that the subsequent use exception applies only to the respondent’s use, republication, or citation to “*the portion(s)* of the research record” that is/are alleged to have been fabricated, falsified, or plagiarized (e.g., processed data, journal articles, funding proposals, data repositories) when used, republished, or cited in submitted or published manuscripts, submitted PHS grant applications, progress reports submitted to PHS funding components, posters, presentations, or other research records within six years of when the allegations were received by HHS or an institution.<sup>50</sup> ORI agreed with commenters that institutions (not ORI) should be able to make a final determination of whether the subsequent use exception applies to a given case, provided such determination is documented.<sup>51</sup>

Although this narrowed scope for the exception seems promising to give some practical meaning to the intended six-year lookback period, it may be difficult in practice to delineate when a “portion” of a research record has been cited. ORI may address the application of the subsequent use exception for institutional reporting requirements through future guidance or policymaking.

### ***Confidentiality Issues***

The Final Rule clarifies institutional confidentiality obligations regarding the identity of respondents, complainants, and witnesses while conducting research misconduct proceedings. Specifically, disclosure

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<sup>45</sup> *Id.* at 76,301.

<sup>46</sup> Proposed Rule, at 69,586.

<sup>47</sup> *Id.* at 76,301.

<sup>48</sup> *Id.*

<sup>49</sup> 42 C.F.R. § 93.105(a), (b)(1).

<sup>50</sup> Final Rule, at 76,297.

<sup>51</sup> *Id.* at 76,281.

must be limited, to the extent possible, to “those who need to know”, as determined by the institution. Such individuals now illustratively include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions.<sup>52</sup> Additionally, the limitation on disclosure of the identity of respondents, complainants, and witnesses no longer applies once an institution has made a final determination of research misconduct findings.<sup>53</sup> Coupled with ORI clarifying the finality of institution actions (discussed below), these clarifications may aid institutions that previously felt caught between a rock and a hard place when wanting to initiate corrective action plans, such as urging journal retractions, following an institutional finding of research misconduct while ORI’s review is still pending.

### ***ORI Findings***

The Final Rule (1) confirms the finality of an institutional decision, stating that ORI findings are not required for institutional decisions regarding research misconduct to be considered final and actionable by the institution,<sup>54</sup> and conversely (2) states that the lack of an ORI finding of research misconduct does not overturn an institution’s determination that conduct constituted professional or research misconduct warranting remediation under the institution’s policy.<sup>55</sup>

### **Key Takeaways and Practical Implications**

1. While the Final Rule adopts many of the proposed changes from the Proposed Rule, it appears that ORI heard the concerns of institutions and other stakeholders by removing certain proposed changes that could have been overly burdensome or otherwise problematic, such as the 30-day assessment timeline requirement and ORI’s ability to publish information about final institutional actions that did not result in findings of research misconduct or settlements.
2. The Final Rule provides clarity to many of the processes and procedures governing research misconduct proceedings; however, there are grey areas that remain, including how the new definition of “recklessly” will impact principal investigators and others with oversight duties, and how the narrowed “subsequent use” exception will operate in practice. Institutions and other stakeholders should look for additional ORI guidance on these topics.
3. Though the Final Rule also codified additional requirements, for example to the scope of what must be included in inquiry and investigation reports, on balance, research institutions retained or gained some beneficial discretion in carrying out their responsibilities under the research misconduct rules.
4. Overall, the Final Rule includes significant changes to the standards and procedures that institutions must follow in conducting research misconduct proceedings. Institutions should begin evaluating necessary revisions to their policies and procedures in the near term to prepare for the 1 January 2026 effective date.

K&L Gates’ Health Care and FDA practice regularly advises academic medical centers and universities on research compliance and related regulatory matters and is able to assist in this regard.

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<sup>52</sup> *Id.* at 76,283–84, 76,298.

<sup>53</sup> *Id.* at 76,298.

<sup>54</sup> *Id.* at 76,306.

<sup>55</sup> *Id.*

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