LONG-AWAITED CHANGES TO RESEARCH MISCONDUCT RULES HAVE ARRIVED

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US Policy and Regulatory Alert

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 42 C.F.R. Part 93 (Part 93)—a rule that that has not been amended since it was first codified in 2005.

Part 93 specifically governs alleged research misconduct – i.e. falsification, fabrication or plagiarism -- in research funded by a Public Health Service (PHS) agency, which includes the National Institutes of Health (NIH), the Centers for Medicare & Medicaid Services (CMS), and other HHS grantmaking agencies.

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 forthcoming 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.

Please see our white paper on the research misconduct Final Rule available here for a deeper dive on the changes that ORI did and did not adopt, as well as an analysis of the Rule's anticipated impact on academic medical centers, research institutions, universities and other regulated organizations.

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