PRATT'S GOVERNMENT CONTRACTING LAW REPORT

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U.S. Department of Health and Human Services Announces Updates to Policies on Research Misconduct

By Summer H. Martin, Rebecca J. Merrill and Dan M. Silverboard*

In this article, the authors report on the 2024 Public Health Service (PHS) Policies on Research Misconduct involving PHS-funded research that were released recently by the U.S. Department of Health and Human Services through the Office of Research Integrity.

The 2024 Public Health Service (PHS) Policies on Research Misconduct involving PHS-funded research have been released by the U.S. Department of Health and Human Services (HHS) through the Office of Research Integrity (ORI).

The final rule¹ updates the 2005 regulation and is intended to respond to technological changes and clarify requirements for addressing research misconduct in PHS-funded research "to provide clarity, transparency, and a better streamlined process."

POLICY UPDATES

Notably, the updates are intended to, among other things:

- Clarify institutional confidentiality obligations;
- Identify areas of institutional discretion (e.g., notification to publications of corrections);
- Better describe research misconduct investigation requirements, including with regard to investigating leads;
- Clarify permissible areas for institutional discretion;
- Extend the timeline for institutional inquiries from 60 days to 90 days;
 and
- Provide a clearer appeal process.

EFFECTIVE DATE

The final rule takes effect on January 1, 2025, and becomes applicable on January 1, 2026.

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https://www.federalregister.gov/documents/2024/09/17/2024-20814/public-health-service-policies-on-research-misconduct.

CONCLUSION

In addition, ORI plans to release sample policies and guidance in the coming months to help prepare PHS-funded entities.²

² ORI's website, at https://ori.hhs.gov/blog/ori-final-rule, provides further details.