

Peer Review

Review of: "Impact of the Revised Common Rule on Enhancing Human Research Subject Protections and Reducing Researcher Burdens"

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This study provides a comprehensive and methodologically sound evaluation of the 2018 revision of the U.S. Common Rule using longitudinal audit data from 107–109 Veterans Affairs research facilities between 2016 and 2024. The article is well-structured and presents strong empirical evidence demonstrating that the revised regulation successfully reduced administrative burden by substantially increasing exempt protocols and decreasing IRB continuing review requirements. Importantly, the author introduces measurable performance indicators for human subject protection, which represents a valuable contribution to research ethics evaluation. However, the conclusion that the revised Common Rule impaired participant protections may be somewhat overstated, as the observed deterioration in certain compliance metrics is based on relatively low absolute event rates and may be influenced by confounding factors such as the COVID-19 pandemic, evolving research complexity, or implementation variability across institutions. Additionally, the study would benefit from broader generalizability beyond the VA system, incorporation of investigator or IRB stakeholder perspectives, and clearer exploration of causal mechanisms underlying noncompliance trends. Overall, the article offers an important policy-relevant analysis and advances the discussion on balancing regulatory efficiency with ethical oversight, though further multi-institutional and qualitative research is needed to confirm and contextualize its conclusions.

Declarations

Potential competing interests: No potential competing interests to declare.