

Peer Review

Review of: "Does Accreditation Improve the Protection of Human Research Subjects and the Quality of Institutional Review Board Reviews?"

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This commentary addresses an important and underexplored question regarding the real-world effectiveness of accreditation in improving human research subject protection and the quality of institutional review board (IRB) oversight. The manuscript's primary strength lies in its historical and policy-oriented analysis, effectively tracing the development of human research protection program (HRPP) accreditation following major regulatory failures and institutional reforms. The author appropriately highlights a critical evidence gap by questioning whether accreditation processes, despite their widespread adoption and financial investment, have demonstrably improved participant safety or review quality. The proposed use of quantitative performance metrics for evaluating human research subject protection and IRB review quality represents a valuable and pragmatic contribution to research governance discussions. Additionally, the manuscript raises relevant concerns regarding potential conflicts of interest, particularly in the context of for-profit independent IRBs. However, several limitations should be addressed to strengthen the manuscript. The commentary would benefit from a broader international perspective, as the analysis is largely centered on the United States regulatory environment and the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The argument would also be strengthened by incorporating available empirical or comparative literature examining accreditation outcomes in related healthcare quality assurance systems. Furthermore, the proposed evaluation metrics, while innovative, would benefit from additional discussion regarding feasibility, data availability, and potential measurement bias. The manuscript could also include a more balanced discussion acknowledging potential indirect benefits of accreditation, such as the standardization of governance processes and the institutional quality culture. Overall, the article

provides a thought-provoking and policy-relevant perspective on accreditation effectiveness and contributes meaningfully to ongoing discussions about accountability and evidence-based research governance, though expanded empirical contextualization and broader comparative analysis would further enhance its scholarly impact.

Declarations

Potential competing interests: No potential competing interests to declare.