

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 raises an important and timely ethical and regulatory question regarding the real-world effectiveness of accreditation systems for Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs). The manuscript provides a well-structured historical overview and presents a compelling argument highlighting the lack of formal evaluation of accreditation outcomes despite its widespread adoption and substantial financial investment. The discussion is policy-relevant and contributes meaningfully to debates surrounding accountability and quality assurance in human subject research protections. However, the article would benefit from several enhancements to strengthen its scholarly impact. First, while the commentary effectively identifies the absence of evaluation data, it could be improved by incorporating a more systematic synthesis of available indirect evidence, such as comparative compliance rates, audit findings, or institutional performance reports that may partially reflect accreditation impact. Second, the manuscript would be strengthened by providing clearer methodological proposals for how future evaluations could be conducted, including potential study designs, measurable outcome indicators, and statistical approaches for assessing accreditation effectiveness and cost-benefit outcomes. Third, expanding the discussion to include international accreditation models and ethical oversight frameworks would improve generalizability and contextual depth. Additionally, the manuscript could benefit from a more balanced discussion acknowledging potential non-measurable benefits of accreditation, such as institutional culture improvement and stakeholder confidence. Finally, addressing possible limitations of the proposed performance metrics, including the feasibility of data collection and inter-institutional variability, would enhance analytical

rigor. Addressing these aspects would significantly strengthen the manuscript's contribution to policy development and research ethics governance.

Declarations

Potential competing interests: No potential competing interests to declare.