

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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1. Independent researcher

Title: *Accreditation Without Evaluation? A Critical Look at HRPP Impact and Accountability*

Reviewer: Bishnu Ram Das

Summary:

This commentary spotlights a critical gap: after 25 years of widespread use, there is still no empirical evidence that Human Research Protection Program (HRPP) accreditation improves human subject protections or the quality of Institutional Review Board (IRB) reviews. Tracing the trajectory from the Jesse Gelsinger case to AAHRPP's dominance, the author calls for evidence-based policy reform.

Strengths

- **Clarity and Focus:** Logical progression from historical background to present-day policy gap; terminology is precise and consistent.
- **Evidence Base:** Relies on credible sources—historical cases, policy documents, and literature. The claim on absent General Accounting Office (GAO)/HHS Inspector General's Office (IGO) evaluations would benefit from explicit documentation of search efforts.
- **Logical Reasoning:** Clear case that accreditation's assumed benefits remain untested; proposals for metrics and comparative designs are timely.
- **Scholarly Contribution:** Opens an unexamined area in research ethics and frames accreditation as a matter of accountability and governance.
- **Writing Quality:** Concise, accessible, and well-organized; minor repetition could be reduced.

Recommendations

1. Add a summary table or timeline of accreditation milestones, stakeholders, and adoption patterns.
2. Include a brief cost-effectiveness estimate to support economic arguments.
3. Note potential indirect benefits (e.g., compliance culture), even if evidence is anecdotal.
4. Outline a concrete evaluation framework with design options, data sources, and controls.
5. Document methods used to confirm the absence of GAO/HHS IGO evaluations.

Final Assessment

Dimension	Rating	Notes
Relevance	High	Significant ethical and operational implications.
Evidence Support	Moderate	Strong history, but lacks new empirical data.
Logical Rigor	Strong	Clear, actionable gap framing.
Influence	Significant	Could prompt policy change and systematic research.

Conclusion:

A timely, well-argued critique of a long-standing policy blind spot. With minor enhancements, it could meaningfully influence accreditation accountability and evidence-based policy in research ethics.

Publication is strongly recommended.

Declarations

Potential competing interests: No potential competing interests to declare.