

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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Competing interest disclosure: I serve as Chair of the Board of Directors of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which is discussed in this manuscript.

The author provides a thorough review of the origins of the current accreditation environment for IRBs and Human Research Protection Programs (HRPPs). I have two major concerns with their arguments.

First, the GAO conducted an assessment of the state of the IRB “industry” in 2023 (GAO-23-104721) in response to concerns about the consolidation and investor ownership of independent IRBs. Among other conclusions, the report recognized that there were no accepted measures of IRB effectiveness and suggested convening stakeholders to identify approaches to address this need. The Secretary’s Advisory Committee on Human Research Protections (SACHRP) discussed this problem and issued its recommendations to the Secretary of HHS in October of the same year, analyzing extant approaches to assessing the effectiveness of IRB oversight and review. Given the topic of the paper, the GAO report and its analysis should be included in this manuscript.

Second, the metrics suggested by the author are related to research programs in general, not IRBs. Specifically, proposed measures of impact on subjects are measures of research conduct, whereas oversight concentrates on proposed research and response to deviations. Oversight is necessary but should not be the primary mechanism to ensure the responsible conduct of research – that should come from systematic training of researchers in the Belmont Principles, not simply requiring them to take an online course for certification. A well-functioning oversight system could lead to increased

documentation of trespass on the rights and welfare of participants. Similarly, the quality of IRB review cannot be measured by evidence that the IRB has assessed the 8 criteria at 45 CFR 46.111 – such evidence is too easily built into minutes templates and doesn't speak to the quality or substance of the discussion. Again, such quality must be built in by training in ethics, not simply the language of the regulations, which give broad latitude to the judgment of the committee members.

Perhaps the best long-term measure of the impact of accreditation, and of the research oversight system in general, is public trust in the integrity of science, its results, and the institutions where research is conducted. By this measure, we are failing, and the manuscript is a timely contribution to what needs to be a public discussion of how we can do better.

Declarations

Potential competing interests: No potential competing interests to declare.