Qeios

Peer Review

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

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Thank you for this excellent analysis of the impact of the revised Common Rule on the protection of human research participants in the U.S., particularly within the VA. Tsan has been a leading advocate for performance metrics in assessing IRB effectiveness, making this contribution especially valuable. The breakdown of exempt protocols and the resulting reduction in researcher burden is particularly noteworthy.

One point of consideration, which I hesitantly describe as minor circularity, relates to the statement by Tsan that the revised Common Rule:

“included no specific provisions that were designed to enhance human research protections. This was in part because there were no procedures or interventions that had been shown to improve human research subject protections, as prior to 2018, we didn’t know how to measure human research subject protections.”

If there were no established procedures or metrics to measure human research protections before 2018, it becomes difficult to assert that the revised Common Rule failed to enhance protections. A more precise characterization might be that the revised Common Rule set an objective that has yet to be fully developed and measured. If there was no prior assessment framework, then failure is a premature judgment.

Unless the argument is that increasing the number of exempt protocols was expected to result in greater adherence to informed consent and HIPAA requirements—yet this does not appear to be the case. The observed non-compliance seems to be independent of the rule change. If researchers were

 doi.org/10.32388/WTQTP8

already failing to meet ethical expectations, it is reasonable to assume they would have done so under the previous rule as well.

Tsan does acknowledge the COVID-19 pandemic as a potential confounding factor, but ultimately rejects it as the cause of continued non-compliance post-2022—a fair point. However, I would argue that closer scrutiny of researcher behavior and IRB oversight could yield better insights into why human research protections appear to have been reduced.

Ultimately, I agree with Tsan that the revised Common Rule should clearly define how this objective should be achieved. Establishing clear guidelines would allow for a meaningful study on whether these protections have, in fact, improved. Or, in my opinion, remove the claim that the changes were intended to enhance human research protections and instead simply state that reducing IRB workload and promoting exempt research with less risk were the intended measurable objectives.

Transparency statement: I am not an expert in statistics, and as such, my review is limited to research ethics, which is my area of expertise.

Declarations

Potential competing interests: No potential competing interests to declare.