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Peer Review

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

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This is an interesting article and update to “Assessing the Quality and Performance of Institutional Review Boards: Impact of the Revised Common Rule” DOI: 10.1177/1556264,6221094407, which assessed human research protections performance metrics for VA institutions from 2016 to 2021. The current article extends the period of analysis to 2024, which allows for a broader assessment of trends in the performance metrics created by the author outside of just the scope of the pandemic. Any research into human research protections program (HRPP) performance is welcome, as there just isn't enough out there.

The author's comment about not knowing how to assess metrics prior to 2018 may need to be reworded or better cited. The current citation references the author's paper about identifying the performance metrics assessed in the current article but does not address why 2018 was stated as the birth moment for performance assessment for HRPPs.

Outside of the author's own writing, it is unclear to me how widely the 5 performance metrics identified by the author have been adopted as the key performance metrics for HRPPs. I would love to see more about whether these metrics are considered key outside of the VA. If more widely accepted, expanding the research to other types of institutions would be interesting. Alternatively, the article could benefit from a comparison of the five performance metrics against other widely accepted HRPP metrics outside of VA institutions.

In regard to the assertion that the revised Common Rule has achieved the goal of reducing researcher burden, different HRPPs/Institutional Review Boards have implemented alternatives to continuing

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review that may indicate the revised Common Rule's intended burden reduction has not occurred. If there has been research into researcher satisfaction with burden reduction post-2019, discussing the research findings in the context of assessing burden reduction would be great here. There is a possibility that the burden has actually increased, as the author indicated when discussing single IRB review. Incorporating the section about single IRB review into the earlier discussion of the reduction of burden may be advisable; as currently placed, it seems like it could actually be an entirely different article--one I would happily read.

The article would be well served by a deeper discussion of what may be causing the noncompliance regarding lack of consent/HIPAA authorization. Is the author suggesting that the noncompliance is occurring due to the reduction in researcher reporting requirements? Some of the administrators I have spoken with at other institutions give this possibility as a reason for regular check-ins (our institution implemented an annual check-in to keep track of enrollment and remind researchers that they need to report any problems, withdrawals, amendment requirements, etc.), but I am not aware of any research into whether regular check-ins do decrease noncompliance. Assessing what is driving noncompliance would likely require considering educational initiatives, types of research with greater noncompliance, participant populations, and other aspects that may affect compliance.

I'd also like to see more about next steps for the research. Where do we go from here?

Declarations

Potential competing interests: No potential competing interests to declare.