Qeios

Peer Review

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

Stephen J. Rosenfeld[1]

1. Independent researcher

This article is a fascinating and well-presented analysis of data on human research protection metrics within the US VA system and documents the impact of the revised Common Rule on the volume and type of study under IRB oversight. The quality of human research protections and the effectiveness of oversight have historically been difficult to measure; as the author notes, there remain no commonly accepted direct measures of such protection.

The findings of the analysis on research volumes (a very significant decrease in the number of studies undergoing continuing review) and study types (a similarly significant increase in the number of studies classified as "exempt" from the further requirements of the Common Rule) are not surprising, given the changes in the Rule.

The conclusion that the quality of protections has suffered is based on increases in three of five metrics, each of which measures a discrete failure of an aspect of the system, and is less convincing. While the percentage increases are impressive (+300%, +52% in two measures of "dignitary harms," informed consent or HIPAA authorization not obtained), these percentage increases are derived from a very small number of incidents. For example, the highest number of informed consents not obtained was 84 out of a total of 71,724 forms audited. Further, while the trends are statistically significant, the year-to-year variations are high and include the years of the COVID-19 pandemic. In interpreting these numbers, it would be helpful to see a line or bar graph of the yearly changes to better appreciate the variability.

doi.org/10.32388/5S8L3K

It would also be very helpful if the author would share his thoughts on what mechanism drove the observed increases in dignitary harms. In my experience, the single IRB mandate may have shifted burdens rather than reducing them. The shift of study oversight responsibilities away from human research protection professionals to study teams may be responsible for some of the observed changes. I expect it will also be argued that these changes, even if real and significant, are offset by the relatively dramatic decrease in burden. It would be interesting to know how burden is perceived by investigators, especially those whose research falls under the single IRB mandate.

Overall, the article is a welcome and all-too-rare attempt to quantify human research protections and regulatory burden. I believe the conclusion - that burden was reduced but protections not enhanced - may be too strong (in both regards). Given the difficulty of quantifying both burden and protection, I would like to see more discussion about the limitations of the methodology and perhaps some ideas of how we could expand this area of inquiry. I believe, and I expect the author does as well, that assertions like those used to justify the changes to the Common Rule must be tested. If regulation fails to achieve its stated goals, it should be re-examined.

Declarations

Potential competing interests: No potential competing interests to declare.