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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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Bureaucracy vs Ethics

As a European, the impression one gets of the Institutional Review Board (IRB) system in the United States is that of a large, inconsistent, but often overly bureaucratic system focused on risk and profit rather than ethics. And yet, research and innovation in the United States routinely outstrip similar activities conducted elsewhere. The interesting question is whether the uniquely US way of doing research ethics through its IRB system is actually better at supporting research compared to equivalent processes elsewhere.

To determine this, it is necessary to work out what we mean by "supporting research." It is widely accepted that the "ends do not justify the means," and therefore research success in terms of invention, innovation, and the academic *lingua franca* of peer-reviewed publications might not represent the whole picture if research participants (or maybe even researchers) are being sacrificed for this success. This is where research ethics is supposed to play a role, protecting the participants of research and ensuring that alongside technical innovation, research and researchers are also supported to take into account the dignity and rights of those involved. But at the same time, overzealous research governance can be a significant source of research waste, so supporting research also means gaining the balance of enabling researchers to press ahead without unnecessary hurdles - after all, it would not be "ethical" to stop groundbreaking research due to essentially arbitrary administrative barriers.

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In "*Impact of the Revised Common Rule on Enhancing Human Research Subject Protections and Reducing Researcher Burdens*," Min Fu Tsan looks at two specific aspects of the 2019 implemented update of the US "Common Rule": changes in the inclusion criteria for IRB review (presumably aimed at reducing bureaucracy) and performance metric data on research harms, in response to the 2019 update being marketed as "*enhancing protections for human research subjects.*" Min Fu Tsan concludes that "*At five and a half years after the implementation of the revised Common Rule... there was an increase of 259% in the number of exempt protocols... (t)hus, the revised Common Rule has achieved its objective of markedly reducing the burden of low-risk studies on researchers... (o)n the other hand, analysis of human research subject protection performance metric data during the same period revealed that there was no enhancement in human research subject protections.*" The implication of the paper is that the 2019 changes were successful in their aim of reducing bureaucracy and presumably research burden/waste, but not providing better protection for participants. In particular, provisions for improving consent processes did not seem to be working. The data came from audits on research projects conducted by the Department of Veterans Affairs (VA) health care system from 2016 through 2024, looking at the number of exempted protocols alongside performance metrics such as adverse events and protocol deviations regarding obtaining consent and/or other permissions. The paper's conclusion is broadly based on the observation that many more projects were exempt from reviews, but there was a decrease in the various performance metrics used as proxies for monitoring research harms, with an increase in "dignitary harms" (violations of autonomy and privacy rights) being particularly concerning.

While this is interesting information in the context of the 2019 changes to the Common Rule, it is perhaps not particularly surprising. Inclusion criteria for ethics reviews are constantly evolving [1] as technology and research methods evolve, and also to a certain extent in response to global emergencies such as the COVID pandemic where a lot of research type activities were conducted under the banner of public health response/surveillance. Similarly performance metric data will always fluctuate to a certain extent based on research priorities, the types of studies that may be running at any one time, and again subject to global emergencies that may dictate the types of studies that are conducted - indeed Min Fu Tsan does acknowledge the pandemic as being a potentially confounding factor in the analysis. But taken in context, this paper does not present any earth shattering conclusions, or give any particular guide as to future directions.

The value of this paper is that it is indeed an analysis of the changes to the Common Rule, and to be charitable highlights a common theme within policy change wherein updates are often neither

disastrous nor revolutionary. However, I would not consider this the last word on the matter, and indeed feel that significantly more could be done to analyse the Common Rule update. Ideally research would perhaps look specifically at the experience of IRB members and researchers, gathering before and after data that reflected individuals' experience, and critically opinion, as to whether the system is now working better than it was. Critically such an analysis should seek to answer whether more research was being conducted to higher ethical standards, and if considering the now increased number of studies excluded from IRB review, whether any ethically problematic studies are now being missed.

But more importantly, this paper continues the tradition of US centred myopia within research ethics. While the US is indeed a research superpower, from a research ethics policy perspective it can be considered more than twenty years behind countries such as the UK, that successfully moved to a system of coordinated national research ethics committees around 2005 (for instance). If US based researchers and ethicists do indeed want to see improvements in their systems and processes, rather than focussing only on their own systems, they could benefit from also looking abroad and considering whether there might be any precedence that they could borrow. In research ethics context is everything, and this includes research ethics policy.

References

1. ^*Simon E. Kolstoe, Erman Sözüdoğru, Janet Messer, Elizabeth Coates, et al. (2025). Is my project research? Determining which projects require review by a research ethics committee. Accountability in Research. doi:10.1080/08989621.2025.2460521.*

Declarations

Potential competing interests: No potential competing interests to declare.