Qeios

Peer Review

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

Leon Marković[1]

1. University Eye Department, Klinička bolnica "Sveti Duh", Zagreb, Croatia

Strengths:

1. Comprehensive Overview:

- The introduction effectively summarizes the background and objectives of the revised Common Rule, including its intended goals and specific changes.

2. Methodological Detail:

- The methodology section provides a clear description of data collection and analysis, referencing prior studies and established statistical methods.

3. Use of Data:

- The text presents detailed data from 2016-2024, providing a strong empirical basis for evaluating the impact of the revised Common Rule.

4. Clear Organization:

- The structure of the document, with separate sections for the introduction, methods, results, discussion, and conclusion, follows a logical and coherent flow.

5. Addition of Discussion Section:

- The discussion section effectively contextualizes findings, examines possible reasons for trends, and incorporates references to past research.

doi.org/10.32388/O1BX1F

Areas for Improvement:

1. Lack of Critical Analysis in Introduction:

- The introduction focuses on summarizing regulatory changes but does not critically assess potential shortcomings or unintended consequences. Adding a brief discussion of any known criticisms or limitations of the revised Common Rule would provide a more balanced perspective.

2. Ambiguous Impact on Human Research Subject Protections:

- The text states that no procedures were in place to measure human subject protections prior to 2018 but then later analyzes data from 2016-2024. Clarify how meaningful conclusions about human research subject protections can be drawn despite the lack of prior measurement tools.

3. Overuse of Technical Jargon:

- The document uses many regulatory and statistical terms without sufficient explanation for a general audience. Providing brief explanations or examples for complex terms such as "ordinal contingency table analysis" and "serious, unanticipated, and related adverse events" would be helpful.

4. Results Section Could Be More Concise:

- Some information is repeated or could be summarized more effectively (e.g., the discussion of IRB continuing review requirements appears multiple times). Consider using tables or bullet points to present key trends in the data more succinctly.

5. Discussion Section Could Provide More Concrete Policy Recommendations:

- The discussion section identifies problems resulting from the revised Common Rule but does not propose actionable solutions. Suggest potential regulatory amendments, additional guidance, or institutional policies to mitigate unintended negative consequences.

6. Conclusion Could Be Strengthened:

- The text does not clearly state whether the revised Common Rule achieved its intended goals beyond reducing administrative burden. Summarize key findings and explicitly state whether the policy changes effectively balanced human subject protection and reduced administrative burden.

Final Thoughts:

The document provides a strong foundation for evaluating the impact of the revised Common Rule. However, a more critical introduction, clarification of data limitations, improved accessibility of

technical terms, and concrete policy recommendations would enhance its ability to inform policymakers and researchers about the effectiveness of these regulatory changes.

Declarations

Potential competing interests: No potential competing interests to declare.