

Review of: "How Well Are We Protecting Human Research Subjects?"

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Potential competing interests: No potential competing interests to declare.

The abstract provides a comprehensive overview of the evolution of human research subject protections. It effectively highlights the shift from solely relying on IRBs to a more comprehensive approach involving multiple stakeholders. The discussion of human research protection programs and their accreditation is relevant and timely.

Here are some suggestions to further strengthen the abstract:

1. Clarity and Conciseness:

Consider shortening the first sentence to improve clarity and conciseness. For example: "Protecting human research subjects is an ethical imperative for all contemporary research."

The second sentence could be rephrased to focus on the key point: "While IRBs and the Common Rule were established to protect human subjects, it became clear that a more comprehensive approach was needed."

2. Highlighting the Key Contribution:

The core contribution of the abstract is the introduction of human research subject protection performance metrics. This should be emphasized more prominently. For example, you could add a sentence like: "The recent development of human research subject protection performance metrics offers a novel opportunity to quantify the effectiveness of these efforts."

3. Future Implications:

While the abstract outlines potential applications of these metrics, it could delve deeper into the broader implications. For instance, you could mention how these metrics can inform policy decisions, improve research practices, and enhance public trust in research.

Potential Areas for Improvement of the text:

- Deeper Dive into the Role of Institutional Official: While the article mentions the increasing role of institutional officials
 in human research protection programs, it could benefit from a more in-depth exploration of their specific
 responsibilities and authority.
- 2. International Perspective: While the focus is on the U.S. system, a brief discussion of international standards and regulations could provide valuable context.



3. Future Directions: The article could conclude with a forward-looking perspective, discussing potential challenges and opportunities in the field of human research subject protection. For example, the impact of emerging technologies like AI and big data on ethical considerations could be explored.