A new model for research review aims to address quality challenges

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Holly Fernandez Lynch, JD, MBe, an assistant professor of Medical Ethics and Health Policy. Credit: Perelman School of Medicine at the University of

Senators Elizabeth Warren, Bernie Sanders, and Sherrod Brown recently raised concerns about the increasing use of for-profit Institutional Review Boards (IRBs) to review research proposals, as opposed to boards typically housed at academic medical centers and health care institutions. The senators expressed particular worries about the growing trend of private equity ownership and consolidation of for-profit IRBs.

A new paper published in the *Annals of Internal Medicine*—led by Holly Fernandez Lynch, JD, MBe, an assistant professor of Medical Ethics in the Perelman School of Medicine at the University of Pennsylvania, and Stephen Rosenfeld, MD, MBA, chair of the U.S. Department of Health and Human Services Secretary's Advisory Committee for Human Research Protections (SACHRP) and President at Freeport Research Systems—highlights inherent challenges facing IRBs of all types and especially private equity-owned boards. The article proposes a new model: independent non-profit boards that stand apart from research institutions, take advantage of business approaches to research review, and minimize conflicts of interest.

"There are currently two primary models of IRB oversight—housing boards within research institutions and running boards outside them for a profit—and neither one is perfect," Fernandez Lynch said. "But there are special structural concerns where private equity is involved in running for-profit boards because their goals and interests may diverge in important ways from those of research participants. That's part of what caught the senators' eye—and ours."

The IRB system was created to provide ethical oversight of research in order to promote research participant protection. All IRBs—those at

academic institutions and those that are run for profit—face pressures to move the review process along as quickly as possible to avoid slowing down important science. However, for-profit boards may also face added pressures related to their commercial goals, potentially undercutting the ethical mission of IRBs to protect and promote the rights and welfare of research participants. When these boards are owned by private equity groups, profit interests, responsibilities to investors, and the desire for rapid return on investment can make keeping a focus on ethics even more difficult. As the authors explain, regulatory compliance alone is often inadequate protection against these concerns.

"Human subjects' protection is the primary responsibility of IRBs," said Emma Meagher, MD, senior associate vice provost of Human Subjects Research at Penn. "Ensuring the complete and transparent absence of financial influence in operational principles of IRBs, commercial and academic, is essential to meet our ethical obligations and preserve the trust of the participants we represent."

Today, for-profit boards oversee approximately 70% of U.S. drug and device trials, a number likely to increase given recent regulatory changes. Whether this is problematic is hard to say. For many boards, quality measures include accreditation from the Association for the Accreditation of Human Research Protection Programs, largely based on review of policies and records; confirmation of regulatory compliance; investigator and board member satisfaction; and efficient turnaround of submitted protocols. Yet it is not clear that these industry-standard approaches offer meaningful assessments of ethical quality, nor is it clear what ought to be viewed as satisfactory in this regard. Fernandez Lynch and others created the Consortium to Advance Effective Research Ethics Oversight, or AEREO, in 2018 to help make progress on this issue.

The paper's proposal to create non-profit IRBs offers one path forward. Independent, non-profit IRBs could take advantage of economies of scale that have made for-profit boards so efficient, as well as the professional model of membership that treats protocol review as a full-time, expert position, all while reinvesting resources in structures and processes likely to promote high-quality review. Without the need to constantly grow market share, this type of board also might be positioned to serve as "laboratory," testing different approaches to research ethics oversight and sharing results to inform improved approaches to IRB quality and effectiveness.

"As the Government Accountability Office considers this issue at the senators' urging, we hope that the AEREO Consortium can offer our expertise about which areas and approaches to evaluation will be most enlightening," Fernandez Lynch said. "Although the issues facing private equity-owned boards are front and center, this is a good opportunity to evaluate the IRB system as a whole and to make progress in identifying the strongest models, as well as the most appropriate markers of effectiveness and alternatives to the status quo."

More information: Holly Fernandez Lynch et al. Institutional Review Board Quality, Private Equity, and Promoting Ethical Human Subjects Research, *Annals of Internal Medicine* (2020). DOI: 10.7326/M20-1674

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