Fundamental Trust: Not for Sale

New quality concerns from the U.S. government lay bare the risks of choosing a for-profit IRB.

Executive Summary

The fundamental purpose of an Institutional Review Board (IRB) is to ensure human subjects of biomedical research are protected. With commercial IRBs now overseeing about 70% of all U.S. clinical trials for drugs and medical devices, the United States government has expressed concerns. Does this create an inherent conflict of interest when it comes to human protection in research? Can these for-profit IRBs serve as human subject safety nets, responsible for protecting the hundreds of thousands of people who enroll in clinical trials each year? Or, is their stamp of approval for sale to the highest bidder? Non-profit IRBs, like Salus, represent a compelling alternative for businesses in search of a solution.

State of the Union: For-profit IRBs on the rise, but at whose expense?

Over the past decade, institutional review boards (IRBs) have experienced a wave of commercialization, **with commercial IRBs now overseeing about 70% of all U.S. clinical trials for drugs and medical devices.** Commercialization in the clinical trial sector has been unilateral, with 80% of clinical research now being performed outside the academic medical context in trials set up with independent physician offices or clinics. Each of these studies is overseen by a different commercial IRB, rather than the "old school" process of submitting research to a board within your university or hospital system that would be scrupulously pored over by knowledgeable colleagues. Furthermore, industry conglomerates have begun involving private equity firms in the acquisitions of their smaller competitors. Powerhouses like Advarra and WCG Clinical are held in majority ownership by private equity firms, which are also investors in pharmaceutical and medical device companies. In fact, WCG Clinical was established in 2012 when a private equity firm, Arsenal Capital, acquired and merged Western IRB and Copernicus Group IRB, the two largest IRBs at the time.

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Along with the consolidation efforts, these conglomerates have spent marketing dollars to convince sponsors and researchers that commercial IRBs are more efficient than their academic or nonprofit counterparts. **In 2018 and 2020, the National Institutes of Health (NIH) and the Office of Human Research Protections (OHRP), respectively, began requiring that federally funded trials carried out at multiple research centers must begin using a single IRB, with as few exemptions possible.** Few universities or hospital systems have the capacity to review study protocols and track adverse events for far-flung institutions, so this mandate is expected to drive business for commercial IRBs. Does this create an inherent conflict of interest when it comes to human protection in research? Can these for-profit IRBs serve as human subject safety nets, responsible for protecting the hundreds of thousands of people who enroll in clinical trials each year? Or, is their stamp of approval for sale to the highest bidder?

Under the microscope: Conflicts of interest prompting new government concern

This issue was brought to national attention in late November 2019 when Senators Elizabeth Warren, Bernie Sanders and Sherrod Brown sent a letter to WCG Clinical and Advarra outlining concerns about industry consolidation and inherent conflicts of interest of for-profit investors. The letter states that if managers of private equity "see their primary responsibility as generating returns for their investors, they may emphasize speed over thoroughness in the review process, creating risks for patients." Some experts say these risks are far greater with commercial review boards, which often have harder-to-spot conflicts of interest, a profit motive, and no requirement to provide evidence of their effectiveness at mitigating human research harm. The letter included 27 specific questions for the IRBs regarding their procedures, outcomes and general transparency questions about the approval process. While both companies sent a response to the senators, WCG declined to answer any of the specifically outlined questions posed in the original letter. Advarra provided very specific answers about quality and conflict of interest mitigation; however, they did not provide any specifics about how often or for which studies members with conflicts of interest recused themselves.

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Jennifer Miller, PhD, assistant professor of bioethics at Yale School of Medicine, has studied the impact of private equity investment in commercial IRBs. She thinks the model of private equity investing in scientific review boards, with their practice of buying a company, increasing its value, and reselling within three to five years for a profit, is worrisome. **"Private equity could help an IRB by allowing it to professionalize, better educate, and train its members and handle globalization of research," Miller said. "But it could also put extra emphasis on cutting costs and boosting revenues. The main mission and reason for being an IRB is to protect research subjects."**

Federal regulators at the FDA and the Department of Health and Human Service's (HHS) Office for Human Research Protections are charged with overseeing review boards. Although a statement from an FDA spokeswoman said data from IRB inspections indicate the boards are "generally compliant," **the FDA, HHS, and OHRP do not have sufficient bandwidth to monitor the thousands of IRBs and tens of thousands of studies conducted in the U.S. and internationally.** For example, the FDA inspected WCG Clinical only three times between 2011 and 2016, and in two of those three inspections, found "objectionable conditions or practices" that the company agreed to correct. **Additionally, the FDA reported twice as many violations and problems with commercial IRBs as with nonprofit boards from 2008 to 2014**, according to preliminary findings in a recent study conducted by Gabrielle Goldstein, PhD. Yet in 2015 alone, the company oversaw reviews for 40 out of the 45 drugs that the FDA approved that year. "I think most ethical and other problems with IRBs and human subjects research oversight are not detected by FDA or OHRP," said Michael Carome, MD, a former senior official with the Office for Human Research Protections and now director of Public Citizen's Health Research Group. Mark Schreiner, MD, a medical school professor and vice chairman of the IRB at

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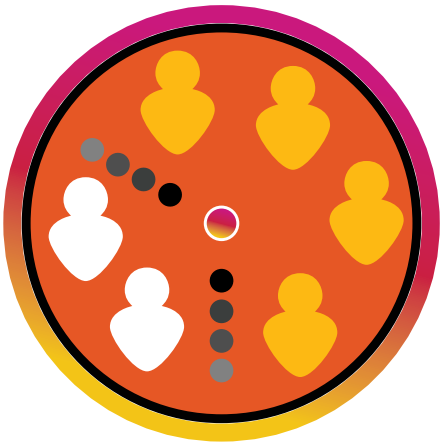

Children's Hospital of Philadelphia, said he is uncomfortable outsourcing the evaluation of pediatric trials to commercial review boards. "IRBs are hired by the sponsor," Schreiner said. "They are paid by them. And so, if they turn down the study, then I think they're unlikely to get repeat business."

A way forward: removing conflict of interest through a non-profit solution

The scientific and business landscapes are changing, and Salus IRB recognizes that you should never have to sacrifice a transparent, ethical review for nimble, customer-focused service. Salus IRB provides industry-leading turnaround times with timely independent review board meetings and efficient administrative operations led by a highly qualified and industry-certified team. Trust in the clinical trial process is fundamental, especially now. As a nonprofit, AAHRRP-accredited IRB with more than 35 years of experience, Salus IRB remains committed to the highest level of human research protection. Because Salus does not owe capital investors, our focus remains on providing the highest quality IRB review services and investing in developing our systems, our team and IRB members, not on lining our pockets.

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