# Institutional Review Board (IRB) Accountability and Oversight

## BACKGROUND

Institutional review boards (IRBs) assess the ethics and safety of research studies involving human subjects, such as clinical trials for new drugs or medical devices. Specifically, and as directed by statute, IRBs ensure that: study risks have been minimized by sound research design; the selection of subjects is equitable; and care has been taken to protect vulnerable populations.[1]

Traditionally, IRBs have been based within research institutions, such as universities or nonprofit hospitals, and are comprised of volunteer members. These institutional IRBs are also called "local" IRBs, as they review protocols for research done within the institution.

Medical product sponsors, however, increasingly rely upon commercial or independent IRBs, which promise speedy and efficient reviews. Commercial IRBs must balance the financial incentive to approve research with their legal obligation to protect participants. While local IRBs may face fewer profit pressures, they often struggle with limited resources and competing obligations.[2]

Both commercial and local IRBs can face pressure from medical product sponsors, policy makers, and regulators to allow proposed studies to move forward. In the case of commercial IRBs backed by private equity, these pressures may be heightened. Some experts view these IRBs as beholden to their clients or equity holders.[3]

## THE ISSUES

The Food and Drug Administration (FDA) and HHS's Office of Human Research Protection (OHRP) are tasked with oversight over the 2,300 IRBs based in the U.S. However, FDA and OHRP largely rely upon IRBs to self-report any violations. While FDA and OHRP use audits or inspections to check if IRBs are in compliance with federal regulations, the U.S. Governmental Accountability Office (GAO) found that only a small percentage of IRBs are audited each year due to lack of resources.[4] Additional details on these and other challenges are described below.

### *Lack of Resources Leads to Insufficient Oversight*

Federal government oversight of institutional review boards is piecemeal and limited.[5] Consequently, the government has failed to properly assess whether IRBs conduct rigorous reviews.[6] An IRB's performance is typically evaluated via an audit or inspection, which includes tracking one or more studies that are subject to IRB review and determining whether they conform to current FDA regulations. Functionally, however, this amounts to a box-checking exercise instead of a true evaluation of how well an IRB is doing its job of ensuring patient safety and assessing clinical research. Thus, an IRB could pass an inspection while still approving research studies that unreasonably put patients at risk.

### *Lack of Transparent Standards Can Lead to Inconsistent Protocol Reviews*

While FDA regulations outline concrete procedures for issues such as IRB membership and the keeping of minutes,[7] fewer specifics are provided regarding what criteria IRBs should use in rejecting or approving protocols. For example, the statute stipulates that research procedures must be consistent with "sound research design" and should not "unnecessarily" expose subjects to risks, which must be "reasonable in relation to anticipated benefits." As such, IRBs lack absolute standards for appropriate protocol review, leaving much up to the discretion of the members.[8] Research shows that IRBs approach their reviews inconsistently.[9] In short, when the highest ethical standards are not deployed by IRBs, human research participants are not protected from harm.

### *Involvement of Private Equity Can Create Conflicts of Interest that Can Affect Protocol Reviews*

Commercial IRBs are reviewing an increasing share of investigational drug research. GAO reported that commercial IRBs reviewed 48% of research studies in 2021, up from 25% in 2012. At the same time, the number of commercial IRBs has decreased because of consolidation. Two companies, Advarra and WCG, account for all but a small fraction of U.S. drug trials reviewed by for-profit panels.[10] As the GAO noted in 2023, "an emphasis on speed and profit may result in commercial IRBs with private equity investment being less focused on potential harms of research to human subjects."[11] In other words, these IRBs may be subject to increased pressure from the clients who fund them.

## THE SOLUTIONS

### *Administrative Policy Solutions*

- HHS should create IRB performance standards that include specific criteria for evaluating patient health outcomes, weighing potential harms and benefits, and assessing scientific validity to ensure rigorous trial design.[12] These standards should reflect the foundational premise of human research — balancing potential medical breakthroughs against participant safety.
- HHS should require IRBs to consider data on similar studies that failed before approving another similar study.[13]
- FDA should convene stakeholders to examine and develop approaches for assessing IRB performance and implement the approaches as appropriate.[14]
- As FDA considers reforms to speed up Phase 1 and early clinical research, it should ensure that scientific integrity and human subject protections are not compromised.

### *Legislative Policy Solutions*

- Congress should provide additional resources to HHS to support FDA and OHRP initiatives that aim to promote the quality and effectiveness of IRB review.[15]
- Congress should evaluate the potential for IRB accreditation programs, such as the Association for the Accreditation of Human Research Protection Programs (AAHRPP), to aid in oversight of IRBs.[16]
- Congress should require that IRBs assess the scientific validity of proposed clinical trials to ensure they are meeting their ethical duty to protect trial participants from poor trial designs that put them at risk with no potential benefit.[17]
- Congress should direct HHS to develop specific metrics by which IRBs assess trial quality and include patient protection in its effectiveness standard.

## ENDNOTES

1 45 CFR 46.111; https://pubmed.ncbi.nlm.nih.gov/16514756/; https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html.
2 https://www.gao.gov/assets/gao-23-104721.pdf.
3 Ibid.
4 Ibid.
5 https://www.nytimes.com/2025/10/04/health/drug-trials-ethics-ozempic.html.
6 https://jamanetwork.com/journals/jama/fullarticle/2806686.
7 21 CFR 56.
8 Ethics Review for Sale? Conflict of Interest and Commercial Research Review Boards, Trudo Lemmens and Benjamin Freedman (2000).
9 https://pubmed.ncbi.nlm.nih.gov/25494359/.
10 https://www.gao.gov/assets/gao-23-104721.pdf.
11 Ibid.
12 https://jamanetwork.com/journals/jama/fullarticle/2806686; https://pmc.ncbi.nlm.nih.gov/articles/PMC12686301/#Sec6.
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