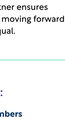
Streamlining IRB in Clinical Research

Institutional Review Boards (IRBs) are critical in the oversight of clinical research and the protection of participants, and with the right expertise, ethical review can result in more efficient, higher quality, more consistent research outcomes.[1] With managing highly complex trials and navigating the changing regulatory landscape, it is increasingly crucial for research professionals to partner with an expert IRB partner.

Clinical Trial Complexities

Increase in the average number of endpoints in a Phase III clinical trial from 2015 to 2021.[2]

Increase in length of Phase I clinical trials over the past 10 years.[3]



Increase in the number of patients enrolled in Phase III clinical trials for small molecules.[2]

What to Look for in the Right Partner

Complex trial designs, evolving regulations, and multi-site studies make IRB review more challenging. The right partner ensures compliance, protects participants, and keeps studies moving forward — but not every IRB partner is created equal.

Look for an IRB partner with:

- History of regulatory compliance
- Accreditation
- Proven track record
- Qualified members
- Experience with similar studies
- Clear review process
- Trust and transparency

Top 5 IRB Challenges

The scope of IRB responsibilities has expanded as clinical research has become more complex and demanding and has grown to include:[4]

- Compliance with privacy regulations.
- Checking for potential financial conflicts of interest.
- Reviewing methodological soundness and scientific merit.

The combination of multi-center trials, large sample sizes, administrative requirements, and operational inefficiencies makes research complex, and these common challenges with IRBs can complicate the process.[5]

1. Lack of transparency and visibility into submission status.
2. Excessive back-and-forth email communication instead of a unified portal.
3. Delays due to managing separate ethical and biosafety review partners.
4. Administrative burden on clinical staff who would rather focus on research than forms.
5. Delays because of missing information, inefficient workflows, and document versioning issues.

One potential solution that has emerged is the need for sponsors to use a single, central IRB for multi-center research. The right partner can improve the IRB process through accelerated submissions, real-time collaboration, and seamless document handling.

Streamlining the Process

Streamlining the IRB process can reduce administrative burden and deliver quicker turnaround times while ensuring the safety, welfare, and privacy of human research participants in accordance with Good Clinical Practice Guidelines.[4]

Standard IRB Process[6,7]

The number of days from submission to final IRB approval ranges from

46 to 295

Collaborative processes decrease the total time from IRB submission to final review by

70%

Among researchers, administrative reporting was identified as a top burden at

72%

ClinSphere® eReview Manager

Use smart, automated workflows to reduce submission entry time by

~23%

Real-time collaboration reduces processing times by

>30%

Intuitive modern interface reduces administrative burden by

15%

For nearly six decades, WCG has set the standard for ethical reviews. Today, WCG continues this legacy as the leading review partner to the top 50 sponsors, top 20 CROs, 3,600+ institutions, and 300,000+ research sites. Backed by ISO 9001 certified IRB and IBC and strong relationships, WCG helps you protect participants and reduce delays.

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Sources:

1. "Single IRB Review for All Multicenter Clinical Trials." Applied Clinical Trials. https://www.wcgclinical.com/wp-content/uploads/2022/03/single-irb-review-for-all-multicenter-clinical-trials.pdf. September 20, 2017.
2. Tufts Center for Drug Development. "Impact Report." https://7f468915.fs1.hubspotusercontent-na1.net/hubfs/7468915/May-June%2020231%20-%20Protocol%20Science%20and%20Execution_Page_1.jpg. May/June 2023.
3. Markey, N., Howitt, B., El-Mansouri, I. et al. "Clinical trials are becoming more complex: a machine learning analysis of data from over 16,000 trials," Scientific Reports. https://www.nature.com/articles/s41598-024-53211-z. February 12, 2024.
4. Getz, K. "Frustration with IRB Bureaucracy and Despotism." Applied Clinical Trials. https://www.appliedclinicaltrialsonline.com/view/frustration-irb-bureaucracy-despotism. January 1, 2011.
5. Marquis-Gravel, G., Robertson, H., Jones, W.S., et al. "Streamlining the institutional review board process in pragmatic randomized clinical trials: challenges and lessons learned from the Aspirin Dosing: A Patient-centric Trial Assessing the Benefits and Long-Term Effectiveness (ADAPTABLE) trial. BMC. https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-021-05026-w. January 25, 2021.
6. Spetsieg, R., Eve, A., Connors, E.R. et al. "The Real-Time IRB: A Collaborative Innovation to Decrease IRB Review Time." Journal of Empirical Research in Human Research Ethics. https://pmc.ncbi.nlm.nih.gov/articles/PMC6144014/. June 14, 2018.
7. Schiller, J.L., LeMire, S.D. "A Survey of Research Administrators: Identifying Administrative Burden in Post-Award Federal Research Grant Management," SRAI. https://www.srainternational.org/blogs/srai-jrsa2/2023/10/13/a-survey-of-research-administrators-identifying-ad. October 13, 2023.
8. https://www.clinicaleader.com/doc/streamlined-clinical-trial-feasibility-the-key-that-unlocks-the-site-sponsor-relationship-0001

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