Faster Study Start-up Starts with the Right IRB Partner

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]

Between managing increasingly complex trials and navigating the evolving regulatory landscape, identifying an IRB partner with decades of expertise that provides defensible, consistent ethical decisions is becoming a non-negotiable.

How Clinical Trials are Increasing in Complexity

37%
Increase in the average number of endpoints in a Phase III clinical trial from 2015 to 2021.[2]

36%
Increase in length of Phase I clinical trials over the past 10 years.[3]

35%
Increase in the number of patients enrolled in Phase III clinical trials for small molecules.[2]

What to Look for in the Right IRB 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** expertise
- **AAHRPP accreditation** and ISO 9001 certification
- **Proven track record** across therapeutic areas
- **Pathways to accelerate review**, without compromising rigor
- **Qualified board members** and a designated support team
- **Transparent timelines** and predictable review processes
- **Proactive, hands-on guidance** to navigate complexity

The Five Most Common IRB Challenges

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

→ Compliance with privacy and other regulatory guidance.

→ Checking for potential financial conflicts of interest.

→ Reviewing methodological soundness and scientific merit.

The combination of multi-center trials, large sample sizes, burdensome 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 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, hands-on guidance, and seamless document handling.

Streamlining the IRB 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]	WCG's IRB Process
The number of days from submission to final IRB approval ranges from **46-295**	The number of days from submission to new protocol review **<6 days**
Collaborative processes decrease the total time from IRB submission to final review by **70%**	Real-time collaboration reduces processing times by **>30%**
Among researchers, administrative reporting was identified as a top burden at **72%**	Smart, automated workflows with eReview Manager reduce submission entry time by **~23%**

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://9468915.fs1.hubspotusercontent-na1.net/hubfs/9468915/May-June%202023%20-%20Protocol%20Scope%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 fo 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. Spellecy, 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/PMC6146014/. 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-jra2/2023/10/13/a-survey-of-research-administrators-identifying-ad. October 13, 2023.
8. https://www.clinicalleader.com/doc/streamlined-clinical-trial-feasibility-the-key-that-unlocks-the-site-sponsor-relationship-0001

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