Successful IRB Review Requires a Partner, Not a Vendor

Thoughtful Review. Accelerated Timelines.

wcg™

You want to deliver life-changing therapies to patients quickly and safely. You want to accelerate study-startup activities without compromising excellence. And you want to achieve the highest standard of quality and site support in the IRB review process, becoming the Sponsor of choice for top research sites. To accomplish this, you need a partner, not a vendor. We have the expertise, experience, and insight to be that partner. WCG IRB delivers efficient, high-quality IRB services tailored to the needs of your research studies. An effective partnership begins with communication, accountability, and transparency.

CONSISTENT, MEANINGFUL COMMUNICATION

When you work with us, you have a single point of contact. This ensures both accountability and efficiency. And you can rest assured that you have access to the experience of the entire WCG IRB team; we're available to answer any questions about the IRB process at any stage.

Because we carefully track metrics, we can provide a snapshot of where you stand today and what you can expect tomorrow.

Because we are independent, you work directly with our experts: No red tape. No intermediaries. Formal and informal meetings ensure everything is on track.

The tailored IRB kickoff call gives everyone the opportunity to review the trial and understand the nuances, milestones, and deadlines. The more we understand up front, the better we can help.

Among the topics we may discuss:

1. When is first-patient-in scheduled?
2. Are there certain protocol concerns –such as unique recruitment plans, informed consent considerations or translation issues—that may affect IRB timelines?
3. How many sites require IRB review?
4. Will any of the sites also require institutional biosafety committee review?

Weekly touch-base meetings ensure everyone is on the same page. It's a chance to review the status of reviews. It's also an opportunity to address potential challenges before they turn into problems.

For example, we determined that a sponsor was regularly providing incomplete submissions which created unnecessary delays in board reviews.

We worked with their team to help improve their documents, streamlining their submissions which, in turn, accelerated the process. These weekly meetings also provide an opportunity to make sure we have the right contacts for your team. We understand there are many stakeholders in a clinical trial – for some IRBs, this may present an issue.

WCG IRB strives to keep everything moving forward, and we will ensure we have the correct contacts on the sponsor side. This not only minimizes delays; it also ensures all new team members receive the appropriate training.

These meetings also provide an opportunity to make sure we have the right contacts for your team. This minimizes delays and ensures all new members receive the appropriate onboarding and training. Monthly portfolio meetings include a summary of new studies and sites submitted in the previous month; turnaround times for protocols and sites; and an update on any hold --the time on hold, the reason for the hold and what we're doing to resolve the issues and release the holds.

Quarterly governance meetings include executive level staff as well as key operational stakeholders. Here, we review the progress of our partnership with a focus on objectives and metrics. This not only minimizes delays; it also ensures all new members receive the appropriate training. These meetings also provide an opportunity to make sure we have the right contacts for your team. This minimizes delays and ensures all new members receive the appropriate onboarding and training

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Quarterly governance meetings

include executive level staff as well as key operational stakeholders. Here, we review the progress of our partnership with a focus on objectives and metrics. All of these are supplemented by informal meetings and huddles as needed. One important aspect of these meetings is that it gives us a heads-up – and a head-start — on projects you may have in the pipeline.

ALWAYS PLANNING AHEAD

During our meetings, you can expect us to ask about what's in your pipeline. This benefits both of us. First, it allows us to work with our operations management team to ensure appropriate resources will be in place for your upcoming submissions.

It also helps us to prepare internally for the number and type of informed consent forms you will require. It also puts us on alert for special processing rules that may apply to upcoming studies. Once you have your protocol ready, we'll also request a proposed site list. We'll vet the list, identify the pertinent site-submission requirements, and pass that information on to you. This will help create mutual operational efficiencies as well as streamline the site startup process.

We do this at no additional cost for our clients because, frankly, increases efficiencies for both of us. By taking the initiative upstream, we create downstream efficiencies, including reduced hold times, improved submission quality, and accelerated timelines

AVOIDING COMMON SOURCES OF ERRORS AND DELAYS

Over the years, we've learned how valuable regular communication is in terms of making sure every team is on the same page. For example, it's important to know what can impede a submission's progress. Common issues include: Many of these complications can be avoided if you understand which upstream issues will lead to downstream delays. It's our job to make sure you have the resources you need.

1. Incomplete submission documents
2. Key information missing from protocols
3. Delays in finalizing informed consent forms, including site-specific compensation information or revision requests
4. Delays caused by adding sites in an already-approved protocol

At the same time, your dedicated WCG IRB team closely follows the status of each study. This allows us to identify and prevent potential delays before they affect your schedule. We share your commitment to quality and your sense of urgency.

We recently implemented seven-day-a-week work schedules, so nothing lingers over the weekend. Processing submissions every day leads to faster decisions.

We also believe in checklists-- initial review checklists, change-in-research checklists, customized checklists, etc.

We've seen how, when deployed correctly, these routine checks reduce both human and process errors. With one client—who had not previously been using checklists regularly before working with us—we reduced human errors by roughly 25% and process errors by 75%. Underlying all this is continual, customized training. WCG IRB provides training and guidance to ensure each member of your team is up to speed. This includes step-by-step instructions on using the WCG IRB Connexus platform and access to our extensive library of checklists, SOPs, and training videos. We customize our training to meet the specific needs of your team members. We can reduce error rates p to 50% by identifying and addressing gaps in understanding.

STREAMLINED PROCESSES

The WCG IRB Connexus platform supports your IRB submissions and document management. We designed it with help from our clients, making it intuitive and easy to use.Using it can reduce submission times by 50%. It's not only for submissions: You have on-demand access to documents, forms, templates, etc. Even more important, when you send your studies for review through WCG IRB, you can expect a combined, seamless review for all sites in your study. We coordinate one full board review of the protocol and conduct a concurrent, expedited review of the associated sites.

This means you don't have to manage submissions to multiple IRBs throughout the life of the study. This single review process, as illustrated below, improves IRB review timelines, allowing investigators to begin recruiting earlier.

COMPETITOR MODEL

67 Central Sites

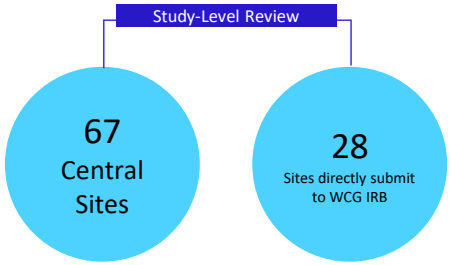
(1 day TAT each)

28 Institutional Sites

Submitting protocol and site application individually to WCG IRB (15 day TAT each - submitted over XX weeks)

Total Time In Review - 487 days

WCG IRB MODEL



(1 day TAT each)

(3 day TAT each - concurrent review)

Total Time In Review - 336 days

151 days could have been saved eliminating redundant protocol review

1 IRB to oversee all of your institutions and private practice sites

A TRUE PARTNER

Our exceptional turnaround times allow you to rapidly move your therapeutic from bench to bedside.

TYPE OF REVIEW	TARGET TAT	ACTUAL* TAT
New Protocol (Full Board)	8.0	5.68
New Protocol (Expedited)	3.7	2.34
New Investigator (Standard)	2.0	1.92
New Investigator (Customized)	5.0	3.43
Translation	3.7	2.34
Change in Research (Expedited - No Consent Forms)	3.7	1.82
Change in Research (Expedited - With Consent Forms)	3.7	2.54
Change in Research (Full Board – No Consent Forms)	8.0	5.97
Change in Research (Full Board – With Consent Forms)	8.0	6.27

TAT is measured from receipt through posting of documents with Connexus

**Average TAT for Q2 2023*