

Submit with Confidence:

Your IRB Readiness Checklist.

Participant safety must be at the heart of any clinical trial. That's why the Institutional Review Board (IRB) process is essential to scientific research.

“

As an IRB, we review and approve research studies before they begin to ensure that they meet ethical standards and minimize risk to participants and patients. Protecting the rights and safety of these individuals is of utmost importance.”

SANA ANSARI
Director, Review Solutions
WCG

The IRB review process requires extensive documentation that can be role dependent. What initially appears as a small submission oversight, from missing attachments to inconsistencies, can lead to costly timeline delays.

Use this checklist to get your submission right:

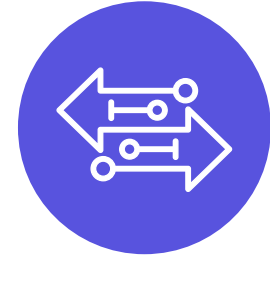
Key documents for study teams, sponsors, and CROs:

- ☒ IRB Initial Review Submission Form
- ☒ Template Consent Form - Submit as a Word File
- ☒ Study Protocol
- ☒ Investigator Brochure (IB) - Current Version
- ☒ Patient-Facing Materials Not Included in the Protocol
- ☒ Funding and Regulatory Documentation (if applicable)
- ☒ Supporting Documents - Including Additional Informed Consent Forms (if applicable)

Key documents for research sites:

- ☒ Site-specific Application Form
- ☒ Adapted Consent Form
- ☒ Investigator Credentials and Training Records
- ☒ Locally Approved Recruitment Materials
- ☒ Institution-required Approvals

Common IRB submission mistakes:

-  Failing to include required attachments.
-  Using outdated templates or using overly technical jargon in informed consent documents.
-  Inconsistencies between the main application and supporting documents.
-  Missing required investigator credentials or training records.

As you prepare your submission, keep in mind that different IRBs have specific requirements for formatting, word count, and supplemental documentation. Be sure to review submission guidelines carefully and double-check all materials before submitting to avoid common pitfalls. Working with an IRB partner who prioritizes consistent communication, transparent submission progress, and defensible, ethical decisions can help you address and even avoid these potential issues

Move through the IRB process with confidence and efficiency.

WCG has served as the trusted partner for 94 percent of all Food and Drug Administration (FDA) approved therapeutic agents over the last five years. With nearly 60 years of independent ethical review experience, our teams keep your study moving without compromising ethical rigor or regulatory compliance.

[Connect with us here](#)