Submitting to an IRB?

Start with this 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 of Business Development, Review Solutions
> WCG

Because the IRB process requires extensive documentation, small submission mistakes — from omitted attachments to inconsistencies — can lead to delays.

Use this checklist to stay organized:

Key documents for study teams, sponsors, and CROs:

- ☑ IRB Application Form
- ☑ Template Consent Form
- ☑ Study Protocol
- ☑ Investigator Brochure (IB) and Study Manuals
- ☑ Recruitment Materials
- ☑ Funding and Regulatory Documentation (if applicable)
- ☑ Supporting Documents

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- Using outdated templates or using overly technical jargon in informed consent documents.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.

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.

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