



BRANY

**Initial IRB Submission:  
7 Fundamentals  
of Success**

## Introduction

*IRB review and approval are required before a clinical trial can begin. How can you work to get the initial IRB submission right the first time?*



*The faster your protocol is approved, the faster you can get to your trial's starting line.*

**Depending on your study, the initial IRB submission process can involve these common challenges**

### **Incomplete Submissions**

- ▶ Missing or incomplete documents—especially when FDA-regulated drugs or devices are involved—cause delays. The IRB may require additional information or revisions before proceeding with the review.

### **Protocol Amendments**

- ▶ Delays may occur if a protocol amendment is introduced during the initial IRB review.

***To help you overcome these obstacles, here are seven fundamentals you should know about a successful initial IRB submission.***

## **1: Seek Pre-Screening Support Before IRB Submission**

**You can work with an IRB that offers pre-screening support before you begin your IRB submission process to ensure your submission contains all the information the IRB needs and your study protocol is as complete as possible.**

Choose an IRB that will pre-screen new submissions and communicate any questions or concerns early so you can address potential issues before the review. By collaborating closely with the IRB and incorporating its feedback, you can submit a well-prepared IRB submission that meets its requirements and leads to a smoother review process.

*Make use of resources available on the IRB's website and seek guidance from its support teams so you can adhere to the IRB's submission requirements.*

## **2: The Informed Consent Form Should Be Easily Understandable**

**Write your informed consent form at a sixth- to eighth-grade reading level to ensure it's easily understandable by all participants.**

The form must include all required elements specified by regulations, including but not limited to:

- ▶ The purpose of the research
- ▶ Foreseeable risks
- ▶ Any benefits
- ▶ Alternatives that might be available
- ▶ The voluntary nature of participation
- ▶ Information about research participants' rights and whom to contact in the event of a research-related injury

To achieve this, follow guidelines around readability standards for informed consent and ensure the informed consent form (ICF) meets all regulatory standards. IRBs often provide comprehensive ICF templates. If you need help, consider reaching out to your IRB for resources and guidance.

*BRANY IRB's experienced team is very adept at editing consent forms to ensure clarity and compliance.*

### **3: Avoid Piecemeal Submissions to Minimize Revisions & Resubmissions**

**Gather all necessary documents and submit them together in a single, comprehensive package.**

Submitting everything at once allows the IRB to conduct a thorough and cohesive review of your entire submission instead of evaluating pieces of it over multiple rounds.

*A complete, well-organized submission speeds up the review process and fosters a smoother pathway to approval.*

### **4: Open Communication Keeps Stakeholders Aligned**

**Clearly communicate submission requirements and provide all documents to study sites to ensure all study sites experience a smooth IRB submission process.**

Effective communication helps eliminate confusion and ensures all parties are aligned on what is needed for the IRB submission.

*Everyone involved—the sponsor, CRO, study sites, and the IRB—should know what documents are required, the deadlines to meet, and the specific details that need to be addressed.*

Miscommunication or a lack of clarity can lead to discrepancies in the information submitted to the IRB, incomplete submissions, or unnecessary delays.

Providing study sites with comprehensive and detailed instructions, including a summary of all required documents, is beneficial. This helps expedite the IRB submission and ensures everyone is working toward the same goal with a shared understanding of the project's requirements.

## **5: Responsiveness** *Maintains Submission Momentum*

**Respond to emails promptly to keep your initial IRB submission on track.**

Delays in communication, such as the IRB waiting a week for a response after sending a consent form to a liaison, can significantly slow down the entire submission process. Each delay can create a ripple effect that causes subsequent steps to be postponed and potentially pushes back the overall timeline of the study.

*Small delays can lead to larger setbacks, risking critical milestones and jeopardizing the study's start date.*

Set clear expectations for timely responses to prevent these delays. For example, establish a standard response time of 24-48 hours with your IRB to address any issues, questions, or requests for additional information.

## **6: A User-Friendly IRB Submission System Can Improve Efficiency**

**Look for an IRB partner with a submission platform that has a short learning curve and a dedicated support team.**

This enables your team to focus on the submission content rather than dealing with the system's mechanics. However, it's important to remember that everyone's ability to adapt to a new system differs.

*Your IRB should offer training and support to accommodate your ClinOps team and the study sites' understanding of the IRB submission platform.*

An easy-to-use submission tool also facilitates better collaboration among team members. When everyone can easily access and navigate the system, it promotes seamless communication and ensures all documents are submitted on time.

## **7: A Flexible IRB Supports Your Submission Process**

**Working with an IRB that is willing to understand and adapt to your clinical trial's unique needs ensures an efficient submission process.**

Every clinical trial has distinct requirements based on its design, scope, and the specific needs of the study sites. A one-size-fits-all approach to IRB review doesn't account for the particular nuances of your specific trial.

An IRB should accommodate each trial's submission formats, timelines, and documentation requirements. This will make the process more efficient and less prone to delays caused by misalignment or rigid procedures.

*BRANY IRB works the way you do. We meet your expectations by embedding ourselves into your process while upholding quality and regulatory compliance.*

## Conclusion

Getting your initial IRB submission approved sets your clinical study on the path to success.

Refer to these seven fundamentals before you start your next study:

1. Seek pre-screening support before IRB submission.
2. The informed consent form should be easily understandable.
3. Avoid piecemeal submissions to minimize revisions and resubmissions.
4. Open communication keeps stakeholders aligned.
5. Responsiveness maintains submission momentum.
6. A user-friendly IRB submission system can improve efficiency.
7. A flexible IRB supports your submission process.

*Need an IRB for your upcoming study? BRANY IRB operates by this playbook. As a fully AAHRPP-accredited, independent IRB with more than 25 years of experience, we help ClinOps teams, CROs, and sponsors start their studies on a solid foundation. [Contact BRANY](#) to get started.*