BRANY

Critical Questions to Ask Your IRB

Think the IRB review process can't be easier? Think again.

Before you submit your study protocol, ask your potential IRB partner these 8 questions.

Table of Contents

Introduction

Submitting your protocol to an IRB is the first of many steps in a successful clinical trial. Get it right the first time, and you keep your pace in the drug development race. But any problem at this stage — whether it's slow responses, multiple review cycles, or difficult submission systems — can get in the way of you and your study's start line.

What if the IRB experience was smoother?

The good news: With the right IRB, it can be. **Keep reading for helpful criteria and questions to ask about your potential IRB partners!**

6 Qualities to Consider When Choosing an IRB

As you research potential IRBs for your clinical trial, there are six key differences to remember. These distinctions can impact your study's timelines and overall success, so carefully evaluate each IRB's capabilities

Depth of Experience

An experienced IRB is well-versed in the regulations governing research, which helps to navigate potential challenges and prevent delays in the approval process.

IRB experience can vary, so choosing a committee with a proven track record is essential for success.

Review Frequency

The frequency of IRB meetings can impact how quickly research protocols are reviewed and approved.

Some IRBs meet daily, weekly, or bi-weekly, offering more opportunities for timely reviews, while others may meet less frequently, leading to longer review times.

Accreditation

AAHRPP accreditation is the gold standard of quality for IRBs.

IRB Committee Diversity

The IRB committee should include members from diverse backgrounds to ensure representation for various populations, including but not limited to the economically or educationally disadvantaged, children, and those who are cognitively impaired.

The membership must also include both scientific and non-scientific representatives to ensure scientific and ethical considerations are addressed from multiple viewpoints.

Strong Communication

Clear communication ensures your ClinOps team is fully informed and aligned throughout the IRB review process.

Consistent communication also helps to address potential issues early and streamline approvals.

In contrast, an IRB with weak communication can cause delays that impact timelines.

Customer Support

Effective customer support ensures your inquiries are addressed promptly. When you need guidance or have a concern, you should be able to count on your IRB to assist.

Quality support fosters a positive working relationship between the IRB and the ClinOps team, helping to avoid delays and keep the study on schedule.

A poor customer support experience can create frustration and delays.

There are many factors to consider, which can make the IRB selection process feel overwhelming.

So, how do you know if an IRB is a good fit? Ask these questions. >>

8 Questions to Ask When Considering a New IRB

When you talk to a potential IRB for your clinical study, ask the following questions to ensure they meet your needs and standards:

1. **Can I call my IRB representative with questions? Will I have the same primary contact throughout the study?**
2. **Is the IRB submission system user-friendly?**
3. **Does the IRB have frequent meetings, and are expedited reviews processed daily?**
4. **Does the IRB provide rapid feedback when I make a submission?**
5. **Can the IRB meet my timelines?**
6. **Are the fees transparent?**
7. **Does the IRB have sufficient experience (e.g., more than 20 years of experience or a broad range of therapeutic areas)?**
8. **Are IBC services available for research involving recombinant or synthetic nucleic acid molecules, or human gene transfer?**

Read on to understand why each question is important — and the kind of answers you should expect from a great IRB.

1. *Can I Call My IRB Representative with Questions? Will I Have the Same Primary Contact throughout the Study?*

Why This Is Important

Resources and support should be readily available to sponsors, CROs, and ClinOps teams so they can ask questions and receive assistance with submissions.

The IRB process can be complex, and having an initial call before document submission can lay the groundwork for a successful and smooth submission.

When the clinical operations team and IRB define the expectations and timelines for IRB submission and review, the goals are known and achievable.

The Ideal Answer

Your IRB should be available for support calls. While email and chatbots can be helpful for general questions, talking to an IRB representative over the phone allows you to ask more specific questions and receive personalized support.

View your IRB as a partner that facilitates the ethical and compliant progression of research so your study can have the smoothest pathway to enrollment. The IRB ensures clinical trials meet the regulatory requirements that protect the individuals who agree to participate in them.

Thinking Ahead

With an IRB like BRANY, you will work with the same knowledgeable representative every time you call. Our helpful and approachable manner gives you the confidence to reach out whenever you need assistance. For example, if you are concerned about compliance or have questions, you can count on your representative to provide support that keeps your project on track.

2. *Is the IRB Submission System User-Friendly?*

Why This Is Important

If your team is hesitant to change their go-to IRB because they don't want to learn another system, you want to ensure the new submission system is easy to navigate.

This will help reduce resistance to change and improve overall adoption rates.

Staff turnover on clinical operations teams has also increased significantly in recent years. With frequent changes in personnel, repeatedly training new staff on how to use a cumbersome IRB submission system can take time and effort.

The Ideal Answer

An IRB should offer a user-friendly submission system that requires minimal training. This eases the burden of constantly retraining team members and allows your coordinators and researchers to focus on their primary tasks.

Additionally, having a system that's available 24/7 is beneficial since clinical operations teams and researchers often work outside of typical business hours.

If your clinical operations team, the researchers, and the research staff can navigate the system independently without needing support, it ensures a smoother submission process.

Thinking Ahead

The next era of drug and device development requires the next era of IRB submission technology. BRANY's proprietary submission management system is easy to learn and supported by real people. Our technology:

- Gets continuous improvements based on customer feedback.
- Helps to centralize training certificates, conflicts of interest, and other approvals as needed.
- Allows for multiple related items in one IRB submission.

3. *Does the IRB Have Frequent Meetings, and Are Expedited Reviews Processed Daily?*

Why This Is Important

Frequent IRB meetings and expedited reviews allow for timely approvals that help you meet timelines. This efficiency is vital for maintaining momentum in research, particularly in areas requiring rapid response, such as clinical trials for new drugs or devices.

The Ideal Answer

An IRB should hold multiple meetings per week and carry out expedited reviews on a daily basis to allow sponsors and CROs to meet industry deadlines more efficiently.

Frequent meetings also provide flexibility and minimize delays, ensuring that if you miss a submission deadline, you have another opportunity in a matter of days instead of weeks.

Thinking Ahead

BRANY holds IRB meetings twice a week and screens new submissions within one business day. Our commitment to efficiency helps to keep your study moving forward.

4. *Does the IRB Provide Rapid Feedback When I Make a Submission?*

Why This Is Important

Knowing that your IRB partner will ask questions in advance or provide prompt feedback before and after meetings assures that your submissions are being handled effectively. Proactive communication keeps you up-to-date on the status of your review and gives you confidence that your submission is in good hands.

The Ideal Answer

A forward-thinking IRB will have a dedicated project manager pre-screen submissions to:

- Review the protocol and consent documents for completeness.
- Anticipate potential questions.
- Ensure all necessary information is available for the IRB committee review.

As a result, the IRB can conduct a high-quality review without causing delays due to missing information or unanticipated issues.

Timely feedback also means that if there are any conditions for approval or required changes, you can address them quickly and minimize delays.

For instance, if a study is approved pending minor consent form changes, knowing that these changes can be reviewed promptly through an expedited review process ensures that the final approval will not be unduly delayed.

Thinking Ahead

An IRB's efficiency and reliability are essential for meeting tight timelines and ensuring studies can proceed without unnecessary delays. BRANY takes pride in pre-screening documents and promptly notifying clinical operations teams of outcomes to facilitate a smooth and swift review process.

5. *Can the IRB Meet My Timelines?*

Why This Is Important

When you are notified soon after the meeting, you immediately know if your study was approved and can understand the next steps. This timely communication reduces anxiety about the submission's status and ensures you are well-informed.

The Ideal Answer

An IRB with an electronic system can automate notifications to all related parties, ensuring everyone stays informed. While initial review notifications are critical, continuing review is also a significant part of the IRB process.

An electronic system can alert you several weeks before your continuing review is due, helping you stay on track with your compliance requirements.

Electronic systems facilitate strong communication with key stakeholders, including sponsors, CROs, and participating study sites. This capability ensures everyone is on the same page and facilitates faster resolutions.

Thinking Ahead

BRANY's IRBManager™ system allows for tailored notifications and information flow management. Customized workflows and automated notifications streamline communication and enhance the overall reliability of the IRB process.

6. *Are the Fees Transparent?*

Why This Is Important

A readily available fee schedule ensures transparency and ease of budget planning for sponsors and CROs. It can also demonstrate an IRB's commitment to openness and collaboration. For example, you want to know if:

- You will be charged for re-reviews.
- Documents are charged on a per-page basis.
- There are separate charges for conflict-of-interest review.

The Ideal Answer

You should know what you will be charged from the start. That way, you can avoid unexpected costs down the line.

Thinking Ahead

When you request a fee schedule from BRANY IRB, **you will be contacted by a team member who will talk you through the fees and gain an understanding of your project needs.** This approach allows BRANY to provide a tailored budget that considers:

- The study's duration.
- The number of anticipated study sites.
- The number of Informed Consent Documents.
- Translation needs.
- The overall volume of IRB activity during the course of the trial.

While some IRBs charge separately for each item in a submission, BRANY IRB will often bundle related items to offer a more cost-effective solution.

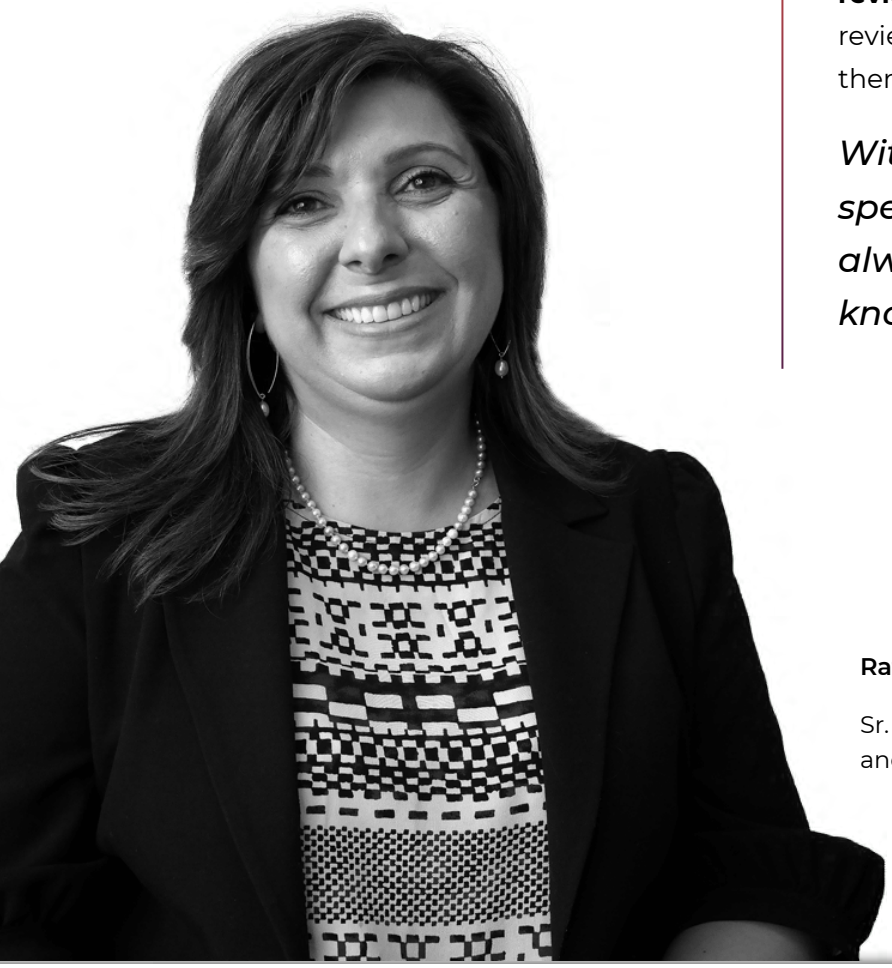
7. *Does the IRB Have Sufficient Experience (e.g., More Than 20 Years of Experience or a Broad Range of Therapeutic Areas)?*

Why This Is Important

An IRB with a 20+ year history and extensive experience in diverse therapeutic areas ensures they have the necessary expertise to review and understand various drugs and devices. This breadth of knowledge prevents unnecessary delays from an inexperienced IRB asking unexpected or irrelevant questions.

The Ideal Answer

An experienced IRB will be able to work in various therapeutic areas, which ensures a detailed and thorough review.



Thinking Ahead

Choosing an IRB with a wide range of therapeutic experience ensures a smoother, more efficient review process that reduces delays and enhances the quality of the review. Over the last 25 years, BRANY has reviewed thousands of studies across many therapeutic areas.

With access to consultants with specialized expertise, BRANY can always provide a thorough and knowledgeable review.

Raffaella Hart, MS, CIP

Sr. Vice President, IRB
and IBC Services

8. *Are IBC Services Available for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or Human Gene Transfer?*

Why This Is Important

An IBC review is needed for NIH-funded research involving human gene transfer or the use of recombinant or synthetic nucleic acid molecules.

Working with an organization that provides IRB and IBC services means these reviews can be conducted in parallel.

This helps streamline the setup of research sites by ensuring that both the IRB and IBC aspects are handled efficiently and cohesively.

The Ideal Answer

An organization with extensive experience in setting up and managing IBCs can handle the complexities involved. This includes adhering to federal biosafety regulations and assembling committees with the appropriate expertise.

For instance, committee members must be located within a certain distance from the research site, and experienced experts are adept at managing these details.

Thinking Ahead

BRANY's IBC services can help expedite the review process while providing rigorous biosafety oversight. Their experts can help your team navigate NIH guidelines and focus on the risk assessment for the following areas:

- Study agent.
- Containment levels and procedures required to conduct the research safely.
- Preparedness of the facility and its personnel.
- Potential impact on the environment.

BRANY can also support adding the required nonaffiliated members to represent the interests of the surrounding community and local environment.

Conclusion

A successful clinical trial starts with a successful IRB review.

Are you starting your study on the right foot? Rethink where you send your study protocol for approval by asking these helpful questions. The answers will reveal what it really should be like to work with an IRB:

- Support calls.
- User-friendly submission system.
- Frequent meetings.
- Rapid feedback.
- No hidden fees or surprises in the fee schedule.
- Well-rounded therapeutic area expertise.
- IBC services for research involving recombinant or synthetic nucleic acid molecules, or human gene transfer.

BRANY is a fully AAHRPP-accredited, independent IRB that puts participants' safety and the future of your study first. Contact BRANY to get started.