JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 9, No. 5, May 2013 "Happy Trials to You"

Assessing Efficiency in Working with an IRB

By Jonathan Nelson

The institutional review board (IRB) "industry" is undergoing major changes:

- Economic pressures require improvements in the quality, timeliness and cost of IRB reviews.
- Workflow and portal technologies are streamlining submission and review processes.
- Increasing numbers of local and central IRBs are gaining accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP).
- Increasing numbers of research institutions are outsourcing part or all of their IRB responsibilities to central IRBs.
- The Office for Human Research Protections (OHRP), in its Advanced Notice of Proposed Rule Making (ANPRM), has recommended a single IRB review for all domestic sites participating in multi-site studies.

This article will discuss important questions that sponsors, CROs and research institutions can ask potential IRB service providers to evaluate whether they are equipped for the new environment. Research institutions should also ask their own IRBs the same questions.

The Basics

The following attributes provide a foundation for efficiency. Regulatory compliance, for example, may not seem to relate to efficiency, but it would if noncompliance requires rework, leads to an audit or inspection, or contributes to a failed study.

Questions to ask the IRB:

- **What is your history with FDA Inspections?** Ask for documentation describing any 483 findings received in the past few years, and their resolution. If the IRB has received a warning letter, make doubly sure that any problems have been resolved and the IRB has a robust culture of regulatory compliance.
- **Are you AAHRPP-accredited?** AAHRPP accreditation confirms that the IRB follows rigorous standards for human research subject protection.
- **Do you have relevant experience?** The IRB should have expertise in your therapeutic area, medical treatment (e.g., drug or device), and type of trials (e.g., phase and design).
- **What is your review culture and philosophy?** The IRB should share your attitudes about matters such as timeliness, meticulousness, flexibility and responsibility. The IRB's policies and forms provide insights into these attitudes.

Organizational Interactions

An IRB may provide a single point of contact or offer direct access to multiple people in their organization. With direct access, you can (in theory) talk directly to the right person. On the other hand, it is easier to develop a relationship with a single, dedicated contact person who understands your situation and can (in theory) expeditiously track down the information or facilitate the action you need.

Questions to ask the IRB:

- **Do you provide a dedicated, single point of contact?** The IRB may also offer a hybrid model with a primary point of contact, with direct access to other personnel under certain circumstances.
- **If not, who will be the points of contact and how accessible are they?** Find out who is responsible for what and who you can talk to if that person is not available.
- **If so, what relevant experience does he or she have?** It helps if he or she understands the peculiarities of your type of organization, therapeutic area, medical treatment, and trials.
- **If so, what operational expertise and influence does this person have?** Is your contact just a message carrier or can he or she effectively advocate for you?
- **If so, does he or she typically attend IRB meetings?** By attending board meetings, your contact will be better equipped to help you interpret Board feedback, thereby reducing time to approval.
- **Can we arrange introductions and a study start-up call?** A brief start-up teleconference call can set the tone for the life of the study and help both parties understand the other's timelines, expectations and operational processes.

Turnaround Times

Ask about average actual turnaround times and also how long it takes to process, say, 80% of instances.

Questions to ask the IRB:

- **How long does it take from submission to Board review?** Some IRBs have more boards than others, and the frequency of meetings varies. Also, the time required for pre-Board meeting activities varies. Most IRBs have standard deadlines for submission prior to a meeting; some allow exceptions.
- **Following a Board meeting, how quickly will we receive the Board's response?** Some IRBs offer 24-hour turnaround.
- **How long will it take to receive comments on the informed consent form following a Board meeting?** Some IRBs offer 24- or 48-hour turnaround, absent major problems with the form.
- **How long after the Board meeting can we expect final approval of a study?** This metric varies substantially from study to study and depends on your turnaround times as well, so frame this question for your situation.
- **How long does it take for expedited review?** Some IRBs offer 24-hour turnaround.
- **What is the turnaround time for amendments?** A reasonable range is 2-5 business days, depending on whether an amendment qualifies for expedited review.
- **What is the turnaround time for recruitment materials?** A reasonable range is 2-3 business days.
- **How long does it take to obtain translations?** A reasonable range is 4-7 business days, depending on how the time is measured. (Does the IRB have preferred relationships with translation companies?)
- **Do you offer "draft review"?** You can avoid delays by obtaining preliminary feedback on your application before board review.

- **How quickly can we expect a meaningful response to different types of inquiries?** If the IRB cannot provide a meaningful response within the expected time, will it immediately set a time for the response?
- **Can you provide metrics to support your stated turnaround times?** IRBs that measure, and do not just estimate, their turnaround times are more likely to provide accurate numbers and better manage their operational processes. How have the metrics changed over time?

Electronic Submission

IRB submission technology ranges from paper, to fillable .doc or .pdf forms, to intelligent online form completion and document upload. Online submission systems can be complex and expensive to implement but are much more efficient to operate, more secure, easier to keep current, and less prone to the frequent delays caused by incomplete data. Well-designed web-based, smart forms guide the user through the application process, preventing errors and avoiding detours through irrelevancies. A modern system should also save appropriate data from one study to the next and make custom templates available to each organization.

Questions to ask the IRB:

- **What technology do you employ for submissions?** Within a class of technology, implementations can vary.
- **How "smart" are the forms?** Ask to see any paper, .doc and .pdf forms. Ask for a demonstration of any electronic submission forms. If possible, test the forms with actual data to evaluate their ease of use.
- **Does the system support collaboration between sites and sponsors/CROs?** If sites and sponsors/CROs are involved in the process of preparing submissions, shared access to the system facilitates the process.
- **Does the system store submission data for use in future submissions?** Repeatedly entering the same data is time-consuming and prone to error.
- **Can we upload data in bulk, e.g., a list of investigators or sites?** Bulk upload saves time.

Web Portal

Online IRB portals provide easy access to IRB approval documents and other pertinent data. Effective portals should offer an intuitive interface, real-time interactions, and a transparent view of what is happening at the IRB. Technologies and implementations vary, so a demonstration and also, preferably, a test drive of the portal are a must. Ask current users of the system about their experience and how the web portal is evolving over time.

Questions to ask the IRB:

- **Can I use the portal to track all relevant IRB activity and download all relevant documents?** The web portal should be useful for the entire IRB interaction, from submission to close-out.
- **How intuitive is the portal?** The amount of recommended training indicates ease of use.
- **If there is an issue, can we track its status and resolution on the portal?** Portals can provide a single, unified source for this information, which can otherwise be difficult to monitor.

- **How long does it take before information is entered and documents are uploaded for access through the portal?** If the IRB's internal system is integrated with the portal, access should be instantaneous.
- **What reporting capabilities does the portal offer?** What reports do you want, with what content, and in what format? Reports should be available in both Acrobat and Excel.
- **How many of our people can use the portal?** A limited number might be problematic. Your authorized personnel should be able to add or remove users without going through the IRB.
- **What notifications will the portal send me, e.g., upon approval of a submission?** You should not have to keep checking the portal for the status of important developments.
- (If you are a sponsor or CRO) **Can I use the web portal to monitor research sites interactions with the IRB?** It is very useful to know site status and progress with respect to submission and later IRB interactions.

Conclusion

Every IRB — and every IRB client — is different. Different organizations will place different priorities on different issues. The above questions focus on the efficiency of working with an IRB. Other aspects of selecting an IRB require asking other questions. You should not ask questions for the sake of asking questions, but you want to enter into any IRB relationship with your eyes wide open. The questions you ask an IRB — and your reactions — will help the IRB understand your concerns so any relationship can proceed on solid footing.

Author

Jonathan Nelson is Director of Biopharma Services at Schulman Associates IRB. Contact him at 1.360.259.5008 or jnelson@sairb.com.