

## Accreditation, Previous Audits, Capacity, and Research Community Support All Factor Into Deciding on an Ethics Board

# What Should Sponsors Ask Their IRB?

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Is there anything a sponsor can do to prevent the chaos and cost of a shutdown of its ethics board? By asking a few key questions, a sponsor should be able to minimize the risk of a suspended study and the cost of a re-review. Many independent and institutionally-based ethics boards provide excellent and reliable services. A sponsor can identify a reliable board by asking questions about the board's documented processes, accreditation status, quality systems, and resources to handle the proposed project.

These questions can be asked of both independent review boards and institutionally-based review boards. The term "independent" review board describes a freestanding organization that focuses on providing ethics review services. An institutionally-based review board (also called a "local" review board) is often a committee or department of the university, hospital or research organization that will be doing the research. Through a quirk in the federal regulations, all of these types of ethics review boards are called "institutional review boards" (IRBs) in the United States.

### **What should a sponsor look for?**

First, it is important for the IRB to have written procedures. The FDA has published a checklist of processes that an IRB should document (see <http://www.fda.gov/oc/ohrt/irbs/irbchecklist.html>). If the sponsor has the resources to conduct a pre-qualification audit, the FDA checklist provides a road map for the processes and documentation to review. Even if the

sponsor is not able to visit the IRB on-site, most IRBs will provide a table of contents of their processes upon request to allow the sponsor to obtain an overview of the IRB's written processes.

The sponsor also should insist on accreditation of the IRB. Earlier this year, Pfizer became the first pharmaceutical company to state publicly that it would use only accredited IRBs for its clinical research. Other major sponsors may soon follow suit. Many major universities, institutions, and independent IRBs are accredited. A number of accredited ethics review board organizations are available in Canada.

### **Why is accreditation important?**

Through accreditation, an independent third party verifies that an organization has an adequate set of written processes and follows those processes. Until 2005 there were two accrediting organizations, but since 2005 there has been only one: the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

AAHRPP maintains a number of categories of accreditation, such as full accreditation, qualified accreditation, and probation. The accreditation status of an IRB can be confirmed on the AAHRPP Web site at [www.aahrpp.org](http://www.aahrpp.org). Accreditation is a rigorous process that includes a review of written procedures, a review of IRB member abilities and training, and interviews of sponsors, staff, board members, and investigators. A sponsor that chooses an accredited IRB knows that the IRB has built extensive safeguards

into its operations and adheres to the highest standards for research.

### **Is there any regulatory action against the IRB?**

Another important question to ask is whether a government agency has taken regulatory action against the IRB. A sponsor should ask an IRB for all documentation of all of its FDA audits. This documentation might include inspectional observations as reported on a FDA Form 483 or, of greater significance, warning letters (which are issued for violations of regulatory significance). A sponsor also can confirm whether an IRB has received a warning letter by searching under the FDA's Web site at <http://www.fda.gov/foi/warning.htm>.

The other government agency most involved in IRB oversight is the DHHS Office of Human Research Protections, or OHRP (see <http://www.hhs.gov/ohrp>). OHRP has jurisdiction over many federally funded studies and a sponsor should ask for documentation of any adverse regulatory action by OHRP.

### **Does the IRB support the research community?**

A sponsor also might want to ask about the IRB's participation in organizations that support the research community. Many independent IRBs, for example, belong to the Consortium of Independent Review Boards, or CIRB, a non-profit organization with a central mission of assuring the protection and rights of human research subjects, while promoting the integrity, high quality, and effectiveness of the independent IRB process (see <http://www.consortiumofirb.org>).

IRBs also are active in national organizations such as Public Responsibility in Medicine and Research, or PRIM&R (see <http://www.primr.org>), or in regional nonprofit organizations that belong to the States United for Biomedical Research (<http://www.statesforbiomed.org>).

### **How many studies does the IRB handle annually?**

Sponsors should inquire into whether the IRB has the capacity to handle the proposed project within the desired time frame. Both independent and local IRBs can become overwhelmed by one large study or by the demands of multiple studies. A sponsor should ask how many studies and sites the IRB handles

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annually. The sponsor also should make sure the IRB's timelines for reviewing the study and generating approval documents are consistent with the researchers' expectations.

### **Does the IRB have a quality system in place?**

Finally, a sponsor should ask whether the IRB has a quality system to help minimize error. The usual elements of a quality system include process change control, an employee training program, quality control checks on approval documents, a "CAPA" (corrective and preventive action) program, and an audit program. Don't hesitate to ask the IRB for details on how it approaches any one of these elements.

This year's events have left many members of the research community worried about the reliability of their ethics review boards. By asking a few key questions, however, sponsors should be able to identify those organizations that are capable of maintaining the integrity and quality of their ethics review processes.

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