

## Many Capabilities Need to Be Evaluated by the Sponsor or CRO When it Chooses a Central IRB

# How to Choose a Central IRB

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**R**ecent events have focused increased scrutiny by sponsors and CROs on the capabilities of the IRB providing study oversight. The selection of an IRB should be considered carefully. A quality IRB potentially enhances a study, both before startup and throughout the process. The wrong choice, however, could cause delays, or in the case of the recent closure of an IRB, the need for re-review of the study. Both can be very costly.

The new era will view the IRB as a trusted consultant that can prevent costly errors, and works with the sponsor/CRO to support decisions made if they are ever questioned.

Accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) provides assurance that an independent entity has reviewed the board and administrative processes.

However, additional criteria should be considered. First and foremost, IRB selection should be based on the membership of its board. Considerations include the members' scientific or non-scientific backgrounds, ability to evaluate and validate the scientific basis of the study, longevity with the IRB, years of IRB experience, training in regulatory requirements, continuity as a group, access to outside experts, willingness and availability to convey rationale supporting decisions, frequency of meetings, ability/willingness to convene ad hoc meetings on short notice, and financial relationship to the commercial entity.

**BACKGROUNDS.** Look at the IRB's membership roster and request CVs of the members. Does the group provide breadth and depth of experience in not only medical/scientific areas but regulatory, statistics, ethics, legal, and non-scientific areas to adequately review your protocol? A simple screen might include checking the IRB Web site. Is its membership posted? Will they stand behind their reviews if they are not willing to publicly acknowledge their memberships?

Is the IRB willing to validate the scientific basis as well as the project design as a whole? Developing a project entails a broad range of decisions before it is even presented to an IRB. These decisions include the type of patient to be studied, drug dosage, the use of a wash-out period and/or placebo, testing procedures, and statistics. In order for a study to be validated by the IRB, its members must be capable of analyzing all of the study's complex components. The questions the board asks after reviewing a protocol represent indicators of this capability.

**EXPERIENCE AND CONTINUITY.** As in other roles, members of an IRB grow through experience and training. Ask for information regarding the members' years of experience on the IRB being considered, as well as other IRB experience. Board turnover speaks to the continuity of the team. Rapid turnover could signal problems with the IRB itself, or with the administrative team. Are the board members provided regular training in new ethical considerations and regulatory requirements? Does the board request and have

a means to access outside assistance if deemed beneficial? Will the same board review amendments?

**COMMUNICATION.** Does the board routinely object to certain aspects of a protocol, or does it provide suggested changes to enhance the project? This provides insight as to whether the board views its role as limited to human subject protection, or if its membership also considers research a societal good. In most cases both objectives may be achieved through open discussion of the thought processes regarding decisions, and creative suggestions that both protect human subjects and advance science.

**FREQUENCY OF MEETINGS.** Frequency can impact a study significantly. All IRBs require adequate time for review of materials by the board before a meeting. Sponsors and CROs should ask for the standard review time allotted to the board and determine if it is adequate for a thoughtful review. Frequent meetings allow for a review more rapidly. Once a study is started, unpredictable things occur and may require a more rapid review. How quickly can an ad hoc IRB meeting be convened? If board members are employees, some sponsors/CROs might consider them conflicted. The IRB function and capability is significantly linked to the administrative team.

**REGULATORY EXPERIENCE.** Although board members should be cognizant of the applicable regulations, the administrative team is frequently responsible for knowing, researching, and informing the board of guidance updates and suggesting avenues that traverse the maze to a successful conclusion. Do staff members have regulatory experience in both sponsor/CRO and IRB environments?

**CONTINUITY.** While each project is unique, sponsors/CROs frequently have “usual practices” that distinguish its work.

Having an administrative liaison that is company-specific (or at least project-specific) reduces frustration and contributes to quality outcomes.

**DOCUMENT MANAGEMENT.** The electronic environment can provide instant access to all documentation as well as tracking of the submission process. Systems must be validated. IRBs that distribute documentation to their board via paper will have a longer turnaround time unless they shorten the time for review by the board. Again, the primary emphasis should be on a sound board review. Allowing adequate time for review by the board is critical.

**QUALITY.** Ask for samples of documentation. Is the documentation detailed enough to provide your staff with the information they need? Documentation in the

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research environment requires meticulous attention to detail. Ask for quality metrics.

**SUPPORT.** Does the IRB provide support for investigators? When an investigator or site staff call with a question, is a response provided within a reasonable time frame? Does the IRB provide initial and ongoing training?

The choice of an IRB should be an important decision in the research process. The right IRB engenders the confidence of the C-suite and legal department of a sponsor/CRO. The IRB you choose should be the one you want sitting next to them in a Congressional hearing, if something is questioned.

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