

The Seven Hats of an IRB (and which Members Wear Them)

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In simple terms, Institutional Review Boards (IRBs) are responsible for looking out for the interests of study subjects. To accomplish this objective, an IRB may perform the following seven reviews (among others):

- Compliance of the protocol with good clinical practice (GCP)
- The biology of the experiment
- The statistical design of the experiment
- Measures to protect the subjects' private health information
- Qualifications of the site and investigator
- Compliance with local considerations
- Adverse event and safety reports

IRB members may be qualified to participate in some of these reviews, but probably not all of them. Table 1 shows the ability of various experts to perform these reviews compared to a member of the general population.

Table 1. Review Capabilities of IRB Members with IRB Experience Compared to Members of the General Population

Expertise	Clinical Research Professional	Physician	Medical Scientist	Pharmacist	Regulatory Expert	Statistician	Local Layperson	Total "+"s
GCP	++				+++	+	+	7
Biology	+	++	+++	++				8
Statistics	+	+	++	+	+	+++		9
Privacy	+				+++	+	+	6
Qualifications	++	+	+	+	++			7
Local*	+	+	+	+	+	+	++	8
Safety	+	++	+++	+++		+++		12

* Assumes that all IRB members are local.

Table 1 demonstrates that a local IRB board with the complete range of expertise is well-qualified to perform its review functions. (The FDA has published a draft guidance document that permits written submission of local considerations to central IRBs.¹ In either case, local considerations seldom play a significant role in IRB reviews.)

In the absence of seven separate specialists, one member may play multiple roles, e.g., clinical research professional, physician and medical scientist. An IRB can outsource some of these functions to non-members. For example, few IRBs have biostatisticians on staff and a review of the medical science requires a specialist in the relevant therapeutic area.

Success at these tasks requires expertise plus data plus tools to manage and analyze the data. Protocols and investigator brochures stand on their own merits. Members of a local IRB are more likely to have access to site qualification data than members of a central IRB. Few IRBs have effective tools for managing and analyzing safety reports; at small scale, manual review works fine, but it is a challenge for busy IRBs to separate the wheat from the chaff. The author is not aware of any research that identifies and weighs the importance of local considerations.

IRBs face a formidable challenge. By having members with or access to a complete range of expertises, they can do a better job looking out for the interests of study subjects.

Reference

1. "Guidance for Industry: Using a Centralized IRB Review Process in Multicenter Clinical Trials", 3/05, last accessed 11/18/05 at <http://www.fda.gov/cder/guidance/OC273.htm>.

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