

## IRBs Can Provide Education and Facilitate Better Relationships to Improve Research Compliance

# Compliance Through Partnership

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A question was asked recently at an IRB Congressional hearing, “How many studies did you disapprove?” In the opinion of the Ethical Review Committee (ERC) an independent institutional review board (IRB), the question did not take aim at the real concern of potential IRB failure to protect the human participant in research. It is not the objective of the IRB to disapprove research. Our purpose is to help facilitate potentially valuable research in a manner that safeguards the human participant, promotes compliance with the FDA regulations, and takes into consideration the ethics and scientific design of the protocol.

The ERC views this objective with serious intention and attempts to achieve it through partner relationships and education rather than a “roadblock” mentality. At times a “cloak of mystery” seems to surround the IRB process. Even among experienced investigators and sponsors a lack of real understanding of what the IRB does and how determinations are made may exist. Asking questions of the IRB has been described as “asking your dad for the car keys as a teenager.” Most investigators in private research, as well as many of the staff representing the sponsors and contract research organizations (CROs), have never observed or participated in an IRB review meeting. They often do not understand the purpose for the information requested by the IRB committee or administrative staff.

In an alliance of partnership with the sponsor and investigator, the IRB can

help accomplish the desired outcome of a higher level of compliance through education rather than from an enforcement perspective. This compliance helps protect the study participant’s safety and well-being. It also facilitates a more controlled research environment resulting in accurate data collection, which in turn supports the ultimate goal of a successfully conducted research project.

Noncompliance, or the failure to comply with the regulations, ranges in scale from inattention to details to intentional scientific misconduct. Serious noncompliance can result in the suspension or termination of IRB approval. The costs of noncompliance can have considerable impact on the research trial.

### What are potential outcomes of scientific misconduct and questionable research practices?

#### Increased risk to research participants:

- May result in an increase of participant complaints and concerns.

#### Inaccurate data collection:

- Jeopardizes the reliability and validity of a clinical trial. Misconduct by a single investigator can have a broad impact on projects initiated by several sponsors.
- May result in the exclusion of data collected at that site, which wastes time, money, and the resource of participants.
- Potentially skews data that could affect the worldwide population such as drug recalls, lawsuits, and need for additional data collection.

- May result in the FDA's refusal to accept data from the research in support of a marketing application. This can increase drug development costs and postpone product approval, leaving some patients without effective treatments for longer periods of time.

#### **Budget and management increases:**

- Additional monitoring and reporting requirements.
- Increased involvement of Senior Management, Quality Assurance, and Legal departments for sponsor, CRO, and IRB.
- Potential FDA investigation.
- Potential damage to relationships between sponsor, CRO, and IRB.

#### **Negative impact to research image:**

- Decreases public confidence in clinical research and raises questions about the effectiveness of trial monitoring and the responsiveness of the FDA.
- Significant noncompliance can place the sponsor, CRO, investigator, and the IRB in the "headlines" of public scrutiny and unfavorable publicity.

No IRB can be the "research participant's protector" at each step of the research process. The philosophy of the ERC has always been that the most effective way to protect the participants in a research trial is to carefully review the qualifications of the investigators conducting the study. The investigator and research staff carries much of the responsibility for the protection of the participant. It is at the investigator level where the research decisions are made that has the greatest opportunity to affect the participant's safety.

No one would choose to be on the opposite side of education, would they? The question is more to the issue of how to provide the education in an effective and efficient manner. Time is critical in the

environment of research. Most investigators have demanding schedules and are heavily reliant upon their study coordinators, especially in late stage research that is often conducted in the primary care physician's practice.

Training before research initiation can be the most effective tool in preventing noncompliance. This helps guard against errors that increase risk. Ineffective research, at the minimum, wastes the valuable resource of the human participant. As the IRB for many multi-site studies, the ERC attempts to find ways to educate the investigator and research staff in all communications. The communication contains regulatory explanation, which can help point the investigator to informed decisions leading to better compliance.

Opportunities for IRB to provide education include presentations at investigator meetings; information booklets with IRB and regulatory language in a "user friendly" format; on-line Web-based training; and more.

Within a climate of relationship and education, the IRB should be approachable and knowledgeable, supportive to the research objectives, flexible within the constraints of the regulations, and continually striving to raise the educational level in order to improve compliance and efficiency. In replacing the "cloak of mystery" that

### **In an alliance of partnership, the IRB can help accomplish a higher level of compliance through education.**

seems to exist regarding IRBs with understanding and cooperation, the objective to promote valuable research while protecting the human participant will be much better served.

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