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It's About Time to Stop Using the IRB as a Regulatory Compliance Committee

Scott Lipkin, Managing Director at FTI Consulting, talks with Norman Goldfarb, Editor of the Journal

Scott, what do you think it's about time for the clinical research enterprise to start doing?

It's about time we stop relying on the IRB to serve as a research compliance oversight committee ("RCOC"). The IRB's essential function is to protect the rights, safety and welfare of human research participants.

IRBs are, of course, always reviewing compliance with human subjects protection regulations. However, few, if any, IRBs have the expertise, time or administrative resources to properly investigate and provide a determination of serious or continuing noncompliance, craft a management plan, and perhaps monitor corrective actions. Plus, if a research site has multiple IRBs, it becomes even less practical to give them research compliance oversight responsibilities.

Who at a research institution should be on the RCOC?

Membership on the RCOC usually includes at least one compliance professional (e.g., the Research Compliance Officer or the Chief Compliance Officer), the Human Research Protection Program ("HRPP") Administrator, an IRB Chair, representation from the legal department, representation from the investigator community (i.e., a physician investigator, a department head, or a dean), and perhaps others.

Do IRBs have any role related to the RCOC's oversight of regulatory noncompliance?

Yes, the RCOC must inform the IRB of anything that the IRB needs to know to do its job. The IRB should be a *consumer* of the information provided by the RCOC. The IRB considers determinations and management plans within the context of protecting the rights, safety and welfare of research participants under the overarching ethical principles of autonomy, beneficence, justice and the regulatory criteria for approval of human research. For example, the IRB needs to know if the RCOC has determined that an investigator has been noncompliant on informed consent. The institution should establish a policy as to when the RCOC informs the IRB. Is it when noncompliance is reported? When substantial evidence of noncompliance has been found? Or, when the RCOC has found actual noncompliance? Judgment will probably be required.

What effect will single-IRB review have on this situation?

Central IRBs are not set up for regulatory compliance oversight. Neither can a research site expect the IRB or RCOC at another institution to handle this responsibility for them.

So, why do so many research sites still give their IRBs responsibility for regulatory compliance oversight?

Most IRBs correctly self-identify as the definitive protector and advocate of research participants. They don't want to give up any part of that responsibility. Nevertheless, an IRB should look at the RCOC as another ancillary committee, like scientific review, COI or IBC that supports the IRB's mission. If the IRB is represented on the RCOC and there is good communication between the two committees, the IRB will still see itself as the ultimate human research participant oversight body and accept the RCOC as a vital member of the HRPP. However, the IRB would need to get comfortable with the idea that any alleged noncompliance by the IRB itself or its staff would be subject to review by the RCOC.

How common are RCOCs?

They are beginning to gain traction in major research institutions with well-developed HRPP programs. We are also starting to see them in in hospitals and health systems that want to develop a more robust HRPP program. IRB outsourcing and single-IRB review help drive this trend.

Well, Scott, I'm not usually one to recommend yet another committee, but it makes a lot of sense to offload the regulatory compliance oversight responsibility from IRBs, which already have plenty to do and probably aren't that good at it anyway.

Interviewer

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.