

Good Clinical Practice Q&A: Focus on IRBs

Some clinical research professionals have the idea that sponsors should not communicate directly with IRBs, but rather that they should pursue such communications through clinical investigators. Some even claim that the FDA has discouraged sponsors from communicating directly with IRBs. What is the situation?

The idea that sponsors should refrain from communicating directly with IRBs is an artifact from the early 1980s. In a 2010 draft guidance, for instance, the FDA even recommends direct communication between sponsors and IRBs as part of the continuing review process for multi-site studies.

"The notion that IRBs should not communicate directly with sponsors is a holdover from about 1982, when the current IND regulations were written," says Paul Goebel, president of Paul W. Goebel Consulting, Inc., a clinical research consulting firm, and a former chief of CDER's Institutional Review Branch. "When the regs were first written, some FDA officials said the communications should go through the principal investigator to keep the sponsors from bullying the IRBs and to keep IRBs safe from undue influence by the sponsors. Nothing was ever included in the regulations on this, but such comments were made in meetings. The FDA thought better of this in about 1984, and has consistently stated since then that it is perfectly acceptable for the sponsor and the IRB to communicate directly with each other. The basic reason [for the change] was that it became apparent that three-way communication is a long, inefficient and error-prone process. This new position developed about the same time as the first independent IRBs were established. Since they often review multi-site studies, protection of the study subjects was not enhanced by requiring each investigator to submit the study documents separately and repeatedly to the same IRB, when the sponsor could do so with one submission."

In its IRB Information Sheets, the FDA acknowledges that it "does not prohibit direct communication between the sponsor and the IRB, and recognizes that doing so could result in more efficient resolution of some problems. FDA does require direct communication between the sponsor and the IRBs for certain studies of medical devices and when the 21 CFR 50.24 informed consent waiver has been invoked."¹

Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2011, #8.31 p. 290

Source

"Good Clinical Practice: A Question & Answer Reference Guide 2011," is available for \$45.95 at <http://www.barnettinternational.com> in electronic and paper form.