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What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

206. What did you find?

If a study is reviewed by multiple IRBs and one of them finds something significant that needs to be fixed, it should be fixed at all the sites. Don't we have a responsibility to all the study participants? Multiple IRB reviews create a natural experiment. If there is a problem, how many IRBs found it? IRBs should share this information so the ones that missed it can learn (or vice versa). The industry as a whole can identify areas where better training or processes should be implemented. If there are differences on something, they might point to ambiguity in the regulations or protocol, or legitimate differences in judgment that should be recognized. Outstanding IRBs should be recognized, and those at the other end of the spectrum should defer to the ones that are outstanding. Bottom line, as long as we are doing multiple IRB reviews, we should not waste all the extra work that goes into them — we should learn from them.

Do you know a better way? Is something getting under your skin? Please send your ideas for future columns to ngoldfarb@firstclinical.com.

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