

What Am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

150. The winner's curse

In auctions, the "winner's curse" refers to the fact that every potential buyer but the winner thinks the item auctioned was overpriced, and maybe they're right. In clinical research, there is a similar mechanism operating with local IRBs. Imagine a protocol has problems that 40 IRBs notice and 10 IRBs miss. The 10 inattentive IRBs approve the protocol and research proceeds. Perhaps 25 of the rest work with the investigator and sponsor to resolve the issues. Research proceeds, albeit delayed. The other 15 IRBs reject the protocol. How has this process protected the subjects' rights? Perhaps study sponsors should inform all the IRBs of the issues raised and how they were resolved. It sounds like a potential nightmare, but not if sponsors were to get protocols and informed consent forms right in the first place, perhaps with some IRB consultation. What am I missing here?

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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