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Good Clinical Practice Q&A: Focus on Consent Observers

Is it ever acceptable for a member of the IRB to observe the informed consent process at a site?

Yes. The FDA regulations authorize the IRB to observe or have a third party observe the consent process, as well as the research (21 CFR 56.109(f)). According to the informed consent guidance, IRBs should consider using this authority when it believes it is appropriate and will enhance the protection provided to subjects (e.g., when the investigator is also the treating physician for a potential subject, when the person conducting the consent interview is relatively inexperienced, or when the clinical investigation involves vulnerable subjects). In addition to observing a sample of consent interviews, the IRS could interview subjects to assess the consent process and evaluate the subjects' understanding of the clinical investigation.

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International. The Guide is available at http://www.barnettinternational.com in electronic and paper form.