

## Good Clinical Practice Q&A: Focus on Protocol Exceptions

**Assume that a clinical investigator obtains FDA clearance, through what some call a "protocol deviation" or "protocol exception," to enroll a subject who did not otherwise meet a study's inclusion/exclusion criteria. If the clinical investigator also has the sponsor's approval, must this deviation be approved by the IRB as well?**

Previous FDA advice on such cases suggests that IRB review and approval would not be necessary. "I do not view this type of rare, approved exception to the protocol as a protocol modification that would require IRB approval," then-director of the FDA's Good Clinical Practice Program David Lepay, M.D., wrote in 2002. "The protocol itself is not being modified. Also, FDA would not generally grant such an exception without review of potential impact on subject safety. The subject should be informed of the protocol's eligibility conditions and the nature of the exception that has been granted. I would expect such exceptions to be very rare. If they become more frequent, the protocol clearly needs to be modified to reflect the realities of inclusion/exclusion; such modification would require IRB (and FDA) approval. One suggestion to avoid confusion or ambiguity may be to incorporate some provision for notification to the IRB of such protocol exceptions as part of the IRB's (and institution's) SOPs." <sup>1</sup>

### Reference

1. "Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2009, #7.18 p. 264

### Source

"Good Clinical Practice: A Question & Answer Reference Guide 2009," is available for \$45.95 at <http://www.barnettinternational.com/>.