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Good Clinical Practice Q&A: Focus on Final Reports

According to the regulations in 21 CFR 312.64, an investigator is required to provide a final report to the sponsor after completion of the investigator's participation in the investigation. Do the regulations actually require the investigator to write a study report relative to their participation?

According to an informal response to this question from FDA, all participating clinical investigators are required by FDA's regulations to submit a final report to the sponsor once the associated clinical study site has completed its participation in the investigation. In essence, this final report officially closes out the investigator's participation in the clinical trial and provides the sponsor with the necessary final trial information for their particular site (i.e., final drug/device accountability, subject data) and knowledge that they are no longer an active investigator in the associated study. FDA does not specify what information should be included in this final report or the format for such a report. When the regulations are silent, sponsors and sites have the flexibility to develop their own practices and procedures that make the most sense to them. It is likely that the report used in closing out the study site with the reviewing IRB would suffice; however, one should rely on instructions from the sponsor to determine if there is any additional information that it may request the clinical investigator to include in the final report.

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.