**From:** OC GCP Questions
**To:** [redacted]
**Subject:** GCP question
**Date:** Wednesday, February 04, 2015 11:19:12 AM

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Good morning --

FDA regulations do require the sponsor to ensure clinical investigator (CI) compliance and to take measures to bring sites into compliance when deviations are noted. If compliance cannot be secured, the sponsor is directed to terminate the study at the problematic site. (See Title 21, Code of Federal Regulations (21 CFR) 312.56(b), 56.113rep and 812.46.

If there are human subject protection (HSP) issues for a given FDA-regulated study, the CI will be the one held responsible for the conduct of the study at his/her site. Since the sponsor is responsible for monitoring their studies and ensuring CI compliance, the sponsor will also be held responsible if there is evidence the noncompliance was not identified by study monitors or not remedied if identified. (Sponsors are responsible for bring CIs into compliance or terminating the study at that site if compliance cannot be attained.) If the reviewing IRB was aware of CI noncompliance, the IRB would also be held responsible if they did not appropriately report it and/or take action to attain compliance or terminate their approval of the study is compliance could not be attained.

The regulations state –
*Sec. 312.56 Review of ongoing investigations.--*
*(b) A sponsor who discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or the requirements of this part or other applicable parts shall promptly either secure compliance or discontinue shipments of the investigational new drug to the investigator and end the investigator's participation in the investigation. If the investigator's participation in the investigation is ended, the sponsor shall require that the investigator dispose of or return the investigational drug in accordance with the requirements of 312.59 and shall notify FDA.*

*Subpart C--IRB Functions and Operations Sec. 56.113 Suspension or termination of IRB approval of research.*
*An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Food and Drug Administration.*

The sponsor should notify the reviewing IRB as well as FDA. Please see the link below.

Report Problems to FDA > Suspension or Termination of IRB Approval

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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**From:** [redacted]
**Sent:** Tuesday, February 03, 2015 2:26 PM
**To:** OC GCP Questions
**Cc:** [redacted]
**Subject:** GCP question

Good afternoon,

I have a GCP issue that I would like to request some guidance on. We have an investigator who is non-compliant. After several attempts to bring into compliance, a study team has decided to remove him from the study. Is there a requirement for us to notify the IRB of the site that we have closed the site and terminated the investigator due to non-compliance?

Thank you

Kind regards,
[redacted]