From: OC GCP Questions
To: [redacted]
Subject: RE: Unanticipated problems/Protocol Deviations
Date: Thursday, December 04, 2014 9:22:00 AM

Good morning,

FDA regulations at 21 CFR 312.66 and 312.53(c)(1)(vii) require that clinical investigators promptly report all changes in the research activity, any unanticipated problems involving risks to subjects or others to the IRB, and will not make any changes in the research without IRB approval, except where necessary to eliminate immediate hazards to human subjects. In addition, 21 CFR 56.108(b) requires that IRBs follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the FDA of (1) any unanticipated problem involving risks to human subjects or others; (2) any instance of serious or continuing noncompliance with the regulations; or (3) any suspension of termination of IRB approval.

FDA has guidance generally related to this question at
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126572.pdf

You may also wish to review the ICH GCP E6 Good Clinical Practice: Consolidated Guidance, (which is recognized as official FDA guidance) available at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

Please also bear in mind that FDA regulations may be considered a minimal standard and that institutions often have requirements over and above those described in the regulations.

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

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Office of Good Clinical Practice
Food and Drug Administration

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather 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.

From: [REDACTED]
Sent: Wednesday, December 03, 2014 4:29 PM
To: OC GCP Questions
Subject: Unanticipated problems/Protocol Deviations

Dear _____
Our IRB requires that we submit all Unanticipated Problems/Protocol Deviations to the IRB either promptly if categorized as Major, or on a cumulative log at renewal if categorized as Minor.
In conducting investigator-initiated IND studies, I do not see a requirement to submit Protocol Deviations or Unanticipated Problems.

Is this required, and how/when should this be done?

Thanks you for your clarification,
[REDACTED]