From: OC GCP Questions
To: [redacted]
Subject: Question on unanticipated problems
Date: Monday, April 17, 2017 9:19:00 AM
Attachments: [redacted]

Good morning –

If your study is exempt from the need for an IND, then the reporting requirements specified for IND studies do not apply. However, studies that are IND exempt - studies meeting the specifications of 21 CFR 312.2(b) - are still required to follow 21 CFR Parts 50 and 56, informed consent of study subjects and institutional review board (IRB) approval (21 CFR 312.2(b)(iv)).The requirements in Part 312 are a GCP standard, though reports to FDA are obviously not required if the study is IND exempt.

Kind regards,

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

From: [redacted]
Sent: Monday, April 17, 2017 8:51 AM
To: OC GCP Questions; [redacted]
Subject: Question on unanticipated problems

Hi,

I am writing as the [redacted] My office is listed as the CRO and sponsor representative for the PI on many roles. The PI does keep overall responsibility. We manage phase I and II IST cancer trials for PIs and all responsibilities from initial protocol concept writing, creation of CRFs and databases, data querying, review of data for deviations, reporting of SAEs, amendment creation, overall study maintenance and publication (this is a very short list of all responsibilities).

I have a question about unanticipated problems. One of my office's responsibilities is to audit in real-time and to assess each cycle of data submitted by the treating site to us, to ensure all required cycle elements were done per protocol and are transcribed on the CRFs correctly. My office has SOPs and processes so that there are Reviewers who will make determinations, for instance, if there is something that was not done or which was done incorrectly on a study, to review it as being a minor or major deviation (as per our SOP definitions).

When there is a deviation that is ruled by one of our Reviewers as being a major deviation, we also ask the Reviewer to confirm if he feels the deviation also meets the unanticipated problem definition. Post review of a major deviation, my office submits the review to the site and w require submission to their local IRB. We also track their acknowledgement of the deviation. Per the IRB's responsibility with OHRP they would handle their own reporting of an unanticipated problem as well. If the trial has an IND than our process is also such that we submit, as an IND amendment, a memo outlining the deviation and ruling as an unanticipated problem to the FDA. However, my question is for an IND exempt trial, I wanted to obtain confirmation that with an IND exempt trial, my office is not required to submit a memo or Medwatch outlining the reviewed unanticipated problem and that this responsibility for reporting the unanticipated problem is with the IRB of the hospital. Please if someone can confirm that is great.

Thank you

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