From: OC GCP Questions
To: [redacted]
Subject: Patient safety assessment
Date: Wednesday, November 12, 2014 12:51:28 PM

Good afternoon –

We had a similar question related to whether a PharmD could assess adverse events and document AEs. Please see the message attached above from the Office of Policy that discusses the issue. You can apply this answer to your question.

FDA's regulations are not explicit as to what constitutes adequate training, education and experience, nor do they outline specific qualifications that are required for sponsor personnel. Sponsors have discretion in determining what qualifications are needed in certain positions based on the general recognition that this would include education, training and experience pertinent to the particular clinical study and its design and execution, as well as familiarity with human subject protection (HSP) regulations, recordkeeping, data integrity, and good clinical practice (GCP) standards and requirements. As you can well imagine, the education, qualifications and training of sponsor personnel will vary across the wide range of clinical indications under study.

The sponsor responsibilities to review the safety information of ongoing investigations likely includes the involvement of personnel with medical backgrounds and expertise, but there are no regulations that require such personnel to hold a medical license.

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

Kind regards,

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Office of Good Clinical Practice

Office of the Commissioner, FDA

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: Sunday, November 09, 2014 5:24 AM
To: OC GCP Questions

Subject: Patient safety assessment

Dear GCP Expert,

Can you kindly direct me to specific instructions regarding which clinical investigative staff are authorized to question patients and document AE descriptions?

As I read ICH Topic E6, these activities should be performed by a qualified physician who is an investigator. However we have encountered a situation where a non-medical study coordinator documents AEs, then writes them in an AE log. Investigator signs the AE log and selects severity and relation based on SC description. They are very resistant to our instructions that this must be performed by an investigator, and request the specific GCP clause indicating such.

Many thanks!

[redacted]