From:
To: [redacted]
Subject: Adverse Event review
Date: Friday, September 12, 2014 2:08:51 PM

Good afternoon [redacted] –

This is a follow-up email to address the issue of delegation of study tasks.

The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)). FDA's guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) states that, "The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task."

It also states --It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study. The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task.

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The delegation of certain study-related tasks to employees would include sub-investigators, research coordinators, and other study staff.

The expectation is that investigators and sub-investigators and well as study staff (research coordinators) will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Note that sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required frequency of GCP training, in which case the investigator, sub-investigators and study staff would be expected to meet that frequency of training in order to comply with the sponsors requirements. Every effort should be made to train the investigational sites.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
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: Friday, September 12, 2014 10:23 AM
To: OC GCP Questions

Subject: Adverse Event review

To Whom It May Concern:

I am monitoring an IDE study and, during an initial monitor visit, observed that a study coordinator who is not medically degreed has been completing the adverse event (AE) source documentation including the assessment of causality and providing this documentation to the investigator for his signature; there is no signature by her attributing her entries on this form so, it appears that the form was solely completed by the Investigator. During my visit, I found numerous AE source worksheets that had been "pre-filled" by the study coordinator that were unsigned; I also found several AE source worksheets that were pre-signed by the Investigator without the causality assessment(s) and other info completed. The protocol does state that the Investigator is to determine all adverse events, report them , and complete the adverse event case report form. The Delegation Log being used is not very specific and only has a choice for "observe adverse events."

Given the information and scenario above, under what circumstances would the FDA find it acceptable for a non-medically degreed study coordinator to be determining the causality for adverse events in a clinical research study? The case where a source form has been pre-signed by the investigator and to be filled in later by the study coordinator is obviously not GCP standard?