From: OC GCP Questions
To: [redacted]
Subject: Documentation of communication between PI and study team
Date: Tuesday, September 23, 2014 9:18:59 AM

Good afternoon --

The expectation is that investigators, sub-investigators, and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. and specific information that needs to be disseminated among study staff. How this information is documented would be up to the site and or institution where the research is being conducted. While not mandatory 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 and 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 and document the training.

Kind regards,

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

From: [redacted]
Sent: Monday, September 22, 2014 6:20 AM
To: OC GCP Questions
Subject: RE: Documentation of communication between PI and study team

Dear Doreen,

Thank you for the letter, but I am afraid that I have not described my question sufficiently.

My question related to the communication process between PI and study team, not to study team and subjects.

I am wondering how the clinically significant information provided to PI should be provided to the rest of the study team (for ex. Sub-Investigators, nurses and etc).

Should minutes of the meeting or updated training log be filed to ISF or it is not mandatory form the FDA's point of view?

Thank you in advance,
[illegible]