From: OC GCP Questions
To: [redacted]
Subject: Documentation of communication between PI and study team
Date: Monday, September 15, 2014 11:27:49 AM

Good afternoon ---

FDA regulations do not specifically address your question therefore sponsors, institutions and others may develop their own standard operating procedures (SOPs) to address specific situations or issues. Companies are free to set-up their own internal infrastructures to ensure the integrity of a clinical trial.

While FDA regulations do not specially state how communication between study staff and subjects should be documented, the two guidance below mention communication and safety of research subjects.

Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf

ICH E-6 – Good Clinical Practice Consolidated Guidance

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

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

Kind regards,

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

From: [redacted]
Sent: Friday, September 12, 2014 3:26 AM
To: OC GCP Questions
Subject: Documentation of communication between PI and study team

Dear Sir or Madam,

I would like to ask you the following question concerning the documentation of communication process between PI and study team.

Would you please advise the appropriate way of the documentation of communication of the information for example related to Safety of subjects because in almost all cases such letters provided only to PI and filed to Investigator Site File but SIs make the assessments of subjects too.

In case of questions please let me know.

Looking forward for your answer.

Thank you very much in advance,
[redacted]