From: OC GCP Questions
To: [redacted]
Subject: Question: eDiary Training
Date: Thursday, April 05, 2018 11:13:00 AM
Attachments: [redacted]

Good morning –

Since this office does not know the specifics of the study, it is best to have the sponsor speak directly to the FDA regulatory project manager of the IND so that they can advise you on how to handle this matter. The decision that is made that addresses this issue should be documented by the sponsor.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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: Thursday, April 05, 2018 10:59 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Question: eDiary Training

Dear FDA-

We are working with a client who is running a Phase 2 study in which an eDiary application is being utilized to record the subject's data. The sponsor has provided multiple eDiary training to all of the sites, but subjects are still having difficulty using the eDiary.

My question is whether or not a sponsor can have direct contact with the subject for only training purposes of a tool because they would like to observe how the sites are actually conducting the training. This training would occur prior to the subject receiving drug or any data collection. I acknowledge this is not typical, however, I cannot find any documentation stating it is not allowed.

Any guidance you can provide is greatly appreciated.

Kind Regards,

[redacted]

[redacted]