

From: OC GCP Questions
To: [REDACTED]
Subject: Training and delegation question
Date: Thursday, October 22, 2015 12:58:00 PM

Dear [REDACTED],

FDA's regulations do not specifically address site initiation visits. A site initiation visit may be considered part of the sponsor's monitoring plan to ensure that CIs and study staff understand their responsibilities regarding study processes and regulatory requirements. This topic is discussed in FDA's guidance "Oversight of Clinical Investigations —A Risk-Based Approach to Monitoring" which can be found at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf. Your process for providing materials for site initiation visits should be documented in your standard operating procedures (SOPs).

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov.

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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, October 22, 2015 12:05 PM
To: OC GCP Questions
Subject: Training and delegation question

We conduct IVD Clinical Trials, most of which are rated as "exempt" from a risk rating perspective. Prior to the Site Initiation Visit (SIV) which is the official start of the study, we may send limited study materials a couple days in advance of the SIV so they are at the site on time for the actual SIV. We always perform a pre-SIV documented training of the material receipt process so that the study staff know what to do with the materials when they arrive (note: this is only for receiving and storing the materials correctly at this point; no processing of the materials is done until AFTER the SIV is complete). Some of the CRAs in our group will also complete a delegation log only delegating the trained study member(s) to this receive and store the materials received at this point.

Do you see an issue with this or is there a better way you would suggest we document this.

Kind regards,

[REDACTED]