From: OC GCP Questions
To: [redacted]
Subject: Site Initiation
Date: Monday, May 14, 2018 8:24:00 AM
Attachments: [redacted]

Good morning –

Conducting a site initiation visit prior to IRB/IEC approval and is not contrary to regulations. The site needs to be aware, however, that they cannot initiate any study activities prior to approval. This means they cannot actively recruit potential study subjects until IRB approval is in writing. As long as you follow good clinical practices and inform the site of the restrictions in this regard, there is nothing else you need to do. If your company needs/wants something in writing from the sponsor to document this is their specific request that again is a business decision and not something governed by FDA regulations.

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

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: Monday, May 14, 2018 1:19 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Site Initiation

Dear Sir,

For one of my studies we have not received a local regulatory approval. Can we still conduct a Site Initiation Visit? We will enroll patients only on receipt of the valid approval. Please advice.

Regards,

[redacted]