From: OC GCP Questions
To: [redacted]
Subject: RE: Site closure in clinical trial
Date: Thursday, December 03, 2015 9:28:00 AM

Dear [redacted]
From the limited information provided in your email, it is difficult to determine whether an information amendment under 21 CFR 312.31 or notification per 312.56 should be submitted to FDA, or if there is another mechanism of notification that should be used (e.g., a report). We recommend that you contact the FDA Project Manager assigned to your IND for information specific to your submission.

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: Tuesday, December 01, 2015 9:55 AM
To: OC GCP Questions
Subject: Site closure in clinical trial

Dear Sir, Dear Madam,

We are the sponsor of a clinical trial which is conducted under an IND. One of our US sites will be closed for a reason not linked to a non compliance (no patient randomized). Could you please clarify if the sponsor should send a site closure notification to the FDA?
Many thanks for your support.

Best regards,

[redacted]