From: OC GCP Questions
To: [redacted]
Subject: Best Practice Question Regarding Protocol Versioning Error at a Site
Date: [redacted]
[redacted]

Good morning –

Protocol changes/amendments -- During the course of a study, a protocol may be formally changed by the sponsor. Such a change is usually prospectively planned and implemented in a systematic fashion through a protocol amendment. Protocol amendments must be reviewed and approved by the IRB, prior to implementation, and submitted to FDA.

Since I don't know the specifics of the study and don't know if subjects were enrolled under the wrong protocol version, I recommend you contact the reviewing IRB at that site and also the FDA regulatory project manager of the IND for advice. It is best to document all correspondence regarding this issue.

For further specific advisement concerning protocol submissions, again, I would recommend that you contact the assigned review Division. Contact information is available on the following web page: www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134493.htm.

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: Tuesday, April 17, 2018 10:53 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Best Practice Question Regarding Protocol Versioning Error at a Site

To whom it may concern,

If a qualified site has just unknowingly submitted a protocol version that has not yet been submitted to the FDA. What is the best practice to correct this?

Do we ask the site to pull the IRB submission, and have them wait until the newest protocol has been submitted, which is set to occur within one to two weeks?

A prior version was submitted to the FDA, but the site had a version that was still being circulated

and not yet ready for a new FDA submission.

Thank you for your help.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]