**From:** OC GCP Questions
**To:** [redacted]
**Subject:** Device protocol subject compliance
**Date:** Thursday, November 30, 2017 8:42:00 AM
**Attachments:** [redacted]

---

Good morning -

The updated protocol should be followed as written. Especially if it was updated for subject safety concerns. Please discuss with the sponsor as to how you should handle this particular subject. FDA would expect the revised updated protocol to be followed.

Kind regards,

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




---

**From:** [redacted]
**Sent:** Wednesday, November 29, 2017 2:29 PM
**To:** OC GCP Questions <gcp.questions@fda.hhs.gov>
**Subject:** Device protocol subject compliance

To Whom It May Concern,

I am working on a device trial and have a question concerning documentation of subject compliance in regard to a recent protocol revision by the Sponsor.
The device protocol was required by the agency to be revised due to safety issues noted per recent Sponsor reports.
The revised protocol now provides for additional recommended subject visits to monitor subject safety and all subjects were required to sign a new informed consent form for the revised protocol.
Per the Sponsor, if an investigator confirms and requests additional subject visits as outlined by the revised protocol and the subject does not want to attend an additional visit(s), there is no deviation documented in the database or reported to the IRB even though the subject signed a consent agreeing to the protocol revision changes.

With that said, can you confirm if this would be acceptable and whether a deviation would not apply for the scenario as stated above.

Thank you.

[redacted]