From: OC GCP Questions
To: [redacted]
Subject: Amendments to INDs
Date: Wednesday, July 01, 2015 11:57:21 AM

Good afternoon –

The definition and contents of a protocol is outlined in the ICH E- 6 guidance on Good Clinical Practice. http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf
Please see section 6 on page 38.

Also please see 21 CFR Part 312.23(5)(v) CFR - Code of Federal Regulations Title 21 This section gives you a detailed description of a protocol.

If you are referring to a specific amendment to an existing IND, you can contact the regulatory project manager (RPM) of the IND for guidance as to what should be submitted.

If I have not specifically answered your question, please contact the Center for Drugs (CDER) at druginfo@fda.hhs.gov .

Kin regards,

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

From: [redacted]
Sent: Monday, June 29, 2015 4:43 PM
To: OC GCP Questions
Subject: Amendments to INDs

Dear FDA,

In FDA's guidance to Sponsor-Investigators, SIs are instructed to submit a new protocol to the FDA for review and consideration:
If a sponsor intends to conduct a study that is not covered by a protocol already contained in their IND application, the sponsor is expected to submit to FDA a protocol amendment containing a copy of the new protocol and a brief description of the most clinically significant differences between it and the previous protocols

How does the FDA define Protocol? Is that 4 pages of general information or a detailed plan?
We'd like to give our faculty the best advice possible.

Sincerely,

[redacted]