From: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Thursday, February 23, 2006 8:15 AM
To: [Redacted]
Subject: RE: Clarification of terminology

Dear [Redacted],

You are absolutely correct when you note that the terms "protocol deviation" and "protocol violation" are synonymous terms. You might also want to note that neither term is mentioned in the regulations that govern good clinical practice (e.g., 21 CFR 312, 812, etc.). These terms are typically used to explain instances when the protocol was not precisely followed. The regulations found at 21 CFR 312.53(c)(1)(vii) and 312.66 don't specifically mention protocol violations or deviations but instead make reference to the phrase "any changes in the research"; the terms you mention have become synonymous with this idea of making changes in the research such that the study protocol was not precisely followed.

The regulation found at 21 CFR 812.150(a)(4) makes mention of deviations from the investigational plan (not protocol); again, these deviations are changes in the research in such a manner that the investigational plan was not precisely followed.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Office of the Commissioner
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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.

-----Original Message-----
From: [Redacted]
Sent: Wednesday, February 15, 2006 11:43 AM
To: OC GCP Questions
Subject: Clarification of terminology

I am looking for a defined difference between protocol deviation and protocol violation. I have never seen anything in writing to differentiate the two and have always thought that the words deviation and violation was one in the same, used synonymously. Is this correct? Does it make a difference? Please clarify.
Thank you,

[Redacted]