From: OC GCP Questions
To: [redacted]
Subject: Protocol Amendment
Date: Saturday, January 31, 2015 11:07:47 AM

Good morning –

I don't think that a protocol amendment for a single site of a multicenter trial is acceptable because the potential for bias is high and bias should be minimized in order to ensure the integrity of the research. I recommend the sponsor contact the regulatory project manager of the IND and discuss this situation with this individual.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Thursday, January 29, 2015 4:49 PM
To: OC GCP Questions
Subject: Protocol Amendment

Good Evening,

Can a protocol be amended for a single site in a multicenter trial?

Thank you in advance for your response.
Best Regards,
[redacted]