

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,

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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.

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]