From: OC GCP Questions
To: [redacted]
Subject: RE: 50.25 C language revisions
Date: Wednesday, December 09, 2015 9:45:00 AM

Good morning.

As described in a previous response to you on this topic, the language included under 21 CFR 50.25(c) must be included in the informed consent document and processes for all applicable clinical trials. The language specified in the regulation may not be altered. FDA's official guidance on this issue can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf .

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

Patrick J. McNeilly, Ph.D., C.I.P.
Office of Good Clinical Practice
Food and Drug Administration

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: Wednesday, December 09, 2015 8:50 AM
To: OC GCP Questions
Subject: 50.25 C language revisions

I was wondering if would acceptable to the FDA if the www. was removed from the Web site address in the required statement, having just http://ClinicalTrials.gov?

Thanks for your guidance.

[redacted]