From: OC GCP Questions
To: [redacted]
Subject: RE: Clinical Trials.gov text question
Date: Thursday, September 04, 2014 7:55:00 AM

Good morning,

As is noted in FDA's guidance related to 21 CFR 50.25(c) (see http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf), FDA expects the statement to be reproduced word-for-word. This requirement provides a standardized format for all applicable clinical trials and avoids the need for interpretation of what must be included. FDA would expect that the statement be reproduced as it appears in the regulation.

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

From: [REDACTED]
Sent: Wednesday, September 03, 2014 5:16 PM
To: OC GCP Questions
Subject: Clinical Trials.gov text question

Dear Sir/Madame,

I am emailing to inquire about the clinical.trials.gov text, which is required to be included on informed consents.

Per the FDA guidance, this language must be included 'word for word' on the site ICF's. Over the past couple years, I have noticed the following changes to this text:

website – instead of Web Site
clinicaltrials.gov – instead of ClinicalTrials.gov
The removal of the comma, after ClinicalTrials.gov

Are changes like this acceptable, or must capitalization, punctuation and formatting all be identical to the FDA released text?

Thanks for your guidance.

Best,

[REDACTED]