From: OC GCP Questions
To: [redacted]
Subject: RE: ClinicalTrials.gov Language
Date: Friday, January 24, 2014 1:40:00 PM

Good afternoon,

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: Friday, January 24, 2014 11:01 AM
To: OC GCP Questions
Subject: ClinicalTrials.gov Language

Hello,

I hope this email finds you well. I work with a CRO and wanted to reach out and confirm if the FDA's requirement on 'verbatim' includes spacing, capitalization, and punctuation. For example, does the FDA consider "website" and "Web site" to mean the same thing, or is "Web site" the only acceptable option under FDA guidance? This would also apply to things like "US" vs. "U.S." or "clinicaltrials.gov" vs. "ClinicalTrials.gov." Thank you so much for your guidance!

Kind regards,

[REDACTED]