From: OC GCP Questions
To: [redacted]
Subject: RE: clinicaltrials.gov language
Date: Tuesday, January 13, 2015 2:07:00 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: Tuesday, January 13, 2015 1:12 PM
To: OC GCP Questions
Subject: clinicaltrials.gov language

This is an issue that has come up, and it seems like no one can agree on an answer.

In informed consent documents, is

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by United States law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

the same as

"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by United States law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Sincerely,

[redacted]