From: OC GCP Questions
To: [redacted]
Cc: [redacted]
Subject: RE: Web site vs. website
Date: Tuesday, May 19, 2015 10:25:00 AM

Dear [redacted] -

Thank you for your question. I have consulted other colleagues and have been informed that 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.

If you need further information and/or have additional questions, please feel free to contact us once again at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of the Commissioner, Food and Drug Administration

From: [redacted]
Sent: Wednesday, May 13, 2015 2:11 PM
To: OC GCP Questions
Cc: [redacted]
Subject: Web site vs. website

Dear FDA,

My IRB recently requested that I change the spelling of website to Web site in my new informed consent forms due to the issuance of your guidelines related to the clinicaltrials gov website. They will not approve the consents unless I "correct" the spelling, citing the following statement contained in the document http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf

"6. What is the exact statement required to be included in informed consent documents?
Under new 21 CFR 50.25(c), the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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."

I note, however, that WITHIN THIS SAME DOCUMENT, the author spells the word in question as "website" (See: 2. Why is it necessary to include this new statement in informed consent documents? The requirement for this provision was included in section 801 of FDAAA. This law also provided for mandatory registration and results reporting of certain applicable clinical trials on www.ClinicalTrials.gov. The statement is the means by which the statute provided for investigators/sponsors to inform applicable clinical trial participants of the availability of the clinical trial information on the public ***website*** located at www.ClinicalTrials.gov.)

Furthermore, I refer the author to the following resource regarding current prevailing preferred spelling: http://grammarist.com/spelling/web-site-website/

I *would appreciate clarification on whether it is required that I spell the term the way it is phrased in the boilerplate form, or if it is still considered accpetable by FDA and GCP guidelines to include it with the current preferred spelling.*

Regards,
[redacted]