From: OC GCP Questions

To: Subject:

RE: Brief Name for clinical trial

**Date:** Wednesday, October 14, 2015 9:44:00 AM

## Good morning,

I am not aware of any particular issue related to the use of the same or similar names between trials. The ClinicalTrials.gov staff does conduct a quality control review of information that is submitted to the databank. Whether their review would identify a trial with a similar name is a question that should be addressed by the NIH/National Library of Medicine. Questions for the ClinicalTrials.gov staff may be addressed to the <a href="NLM Helpdesk">NLM Helpdesk</a>. Please bear in mind that each new clinical trial submitted to ClinicalTrials.gov should receive a unique NCT Number which should help in differentiating between trials which may have similar names.

I hope this information is helpful. Please contact us again at <a href="mailto:gcp.questions@fda.hhs.gov">gcp.questions@fda.hhs.gov</a> 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:

Sent: Tuesday, October 13, 2015 3:48 PM

**To:** OC GCP Questions

**Subject:** Brief Name for clinical trial

I have a question regarding the designation of a brief name for a clinical trial. While recognizing that the name must be truthful and accurate and not false or misleading, does FDA review brief names of clinical trials before the trials may be posted on clintrials.gov? For example, Women's Health Initiative, or WHI, is listed as an example on the clintrials.gov website. Would there be a problem if another clinical trial used the same brief name, such as WHI with a different name? Clintrials.gov appears to have a number of trials that have the same or similar names. Is that sameness or similarity been an issue to the agency's knowledge?