From: OC GCP Questions
To: [redacted]
Subject: FDA Statement Clinical Trials
Date: Wednesday, August 16, 2017 6:03:00 AM
Attachments: [redacted]

Good morning –

Please see the guidance link below.

https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf

Please see question 21 of the guidance.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, August 15, 2017 1:17 PM
To: OC GCP Questions
Subject: Message for Mrs Doreen M. Kezer, MSN, Senior Health Policy Analyst - FDA Statement Clinical Trials

Dear Mrs Kezer,

I hope this email finds you well.

in an email dated October 17, 2012, you wrote the following, as regard to the FDA Statement on Clinical Trials and the possibility for the wording to be slightly altered (not to include “required by US law”) for REB's outside of the U.S.:

«The guidance is saying that the wording needs to be used verbatim as it appears in the final rule except for outside of the U.S. where it may be altered.

Applicable clinical trials conducted outside the United States, must comply with the new regulation (21 CFR § 50.25(c)) and include the statement regarding www.ClinicalTrials.gov in informed consent forms however as “required by US law” would not apply given that you are from Canada.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA»

It would be greatly appreciated if you could please provide us with the reference of this FDA guidance for the Statement regarding www.ClinicalTrials.gov in informed consent forms and if you could indicate if this guidance still applies.

We thank you in advance for your attention.

Best regards,

[redacted]