From: OC GCP Questions
To: [redacted]
Subject: RE: Informed Consent Outside the US and 50.25C
Date: Thursday, August 13, 2015 7:59:00 AM

Good morning,

If the trial you are referring to meets the definition of an applicable clinical trial, the statement at 21 CFR 50.25(c) would be required. FDA has issued a guidance document related to the required statement entitled "Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c)" which can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf .

Questions 6., 21., and 22. directly relate to your inquiry and state:

> **"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" (emphasis added)
>
> **"21. Do informed consent documents for studies conducted outside of the United States have to comply with the new regulations?**
>
> Yes, any applicable clinical trial, including 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. The statute defines applicable clinical trials as trials of drugs and devices that are subject to FDA regulation. If the clinical trial is not of a drug or device subject to FDA regulation, and, thus, not an applicable clinical trial, at the time of the initiation of the trial, then the statement is not required. See the response to questions 3 and 4 concerning the definition of an applicable clinical trial."
>
> **"22. What if the new statement conflicts with foreign informed consent requirements?**
>
> Congress did not provide an exemption from the statutory requirement. If the clinical trial is an applicable clinical trial, then it must include the new statement."

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

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: [redacted]
Sent: Wednesday, August 12, 2015 3:23 PM
To: OC GCP Questions
Subject: Informed Consent Outside the US and 50.25C

Hi,

I am working with a sponsor who wants to revise the required statement concerning clinicaltrials.gov

It's their contention that this is an FDA rule and applies only to what we do in the US and that the FDA has no jurisdiction over other countries. Based on that reasoning, they are editing the statement.

Would that be acceptable to the FDA?

Thanks for your help,
[redacted]