From: OC GCP Questions
To: [redacted]
Subject: 1572 Question regarding NON-US Investigators
Date: Saturday, February 07, 2015 10:38:26 AM

Good morning –

We sent your question to the Center for Drugs (CDER) for a response. Please see their answer below.

The question is very general and missing context it is difficult to provide an answer the question. Please provide URLs below for two guidances that may answer the question. The first guidance below, especially guidance questions 10-13 with the associated answers may answer the question for the person.

"Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572)" http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm214282.pdf

"Guidance for Industry and FDA Staff: FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions" http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf

Kind regards,

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

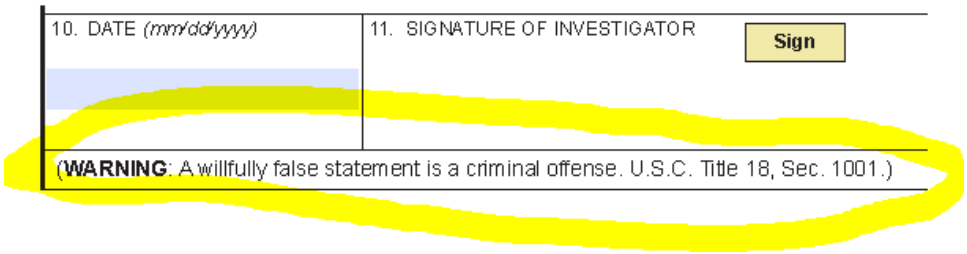
From: [redacted]
Sent: Wednesday, January 14, 2015 5:19 AM
To: OC GCP Questions
Cc: [redacted]
Subject: 1572 Question regarding NON-US Investigators

Dear FDA,

I would like some guidance regarding 1572 and non US investigators.
The study is filed under US IND and we will collect 1572 globally.

Investigators in Europe are not familiar with 1572 and some questions have been raised. I have read the FAQ- very helpful.

1,Please help me with the WARNING below. The investigators would like to know the meaning of this legally outside of US?



2, As I understand the Investigators have to be trained in Code of Federal Regulations Title 21. Can you recommend any training material suitable for investigators signing 1572?

Thank you for your time ,

Kind Regards
[redacted]