From: OC GCP Questions
To: [redacted]
Subject: Question about Form 1572 for other countries
Date: Thursday, September 24, 2015 5:45:47 AM

Good morning –

It is best to send your question to the Center for Drugs (CDER) at druginfo@fda.hhs.gov

Kind regards,

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

From: [redacted]
Sent: Wednesday, September 23, 2015 7:50 PM
To: OC GCP Questions
Subject: Question about Form 1572 for other countries

Dear Sir or Maddam,

Hello. I am [redacted], director of regulatory affaris of [redacted].

We are conducting global clinical studies in Europe, Asia and Latin countires for our products.

Since the clinical studies are not conducted in US the IND was not submitted, however we are conducting studies in compliance with global GCP guidelines.

We have a plan to submit the 351(k) application after completion of the studies.

Regarding FDA FormWith best regards, 1572, according to FDA's Q&A, I understood that it is only required for the studies under the IND in US.

However we are requesting to the investigators to sign on the form for our future 351(k) application to the FDA, although it is not necessary to the investigators in other countries.

It would be appreciated if we can have your answer whether the Form 1572 is deemed necessary during GCP inspection of FDA during 351(k) review.

With best regards,

[redacted]