From: OC GCP Questions
To: [redacted]
Subject: GCP question about
Date: Wednesday, March 29, 2017 9:36:00 AM
Attachments: [redacted]
Importance: High

Good morning –

If a sponsor voluntarily commits to conduct a non-U.S. study (or the operation of non-U.S. sites in a multi-national study) under a U.S. IND and its provisions, then the 1572 must be collected from all investigators under the IND (including non-U.S. investigators), and the commitments on the 1572 are expected by FDA to be followed by all clinical investigators so covered.

I suggest the sponsor conduct the FDA regulatory project manager for the IND for guidance.

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

From: [redacted]
Sent: Monday, March 27, 2017 3:33 PM
To: OC GCP Questions
Subject: GCP question about
Importance: High

How do you suggest that a company handles a situation where a foreign country, in which they are conducting clinical studies for a drug included in an IND, passes a law that prohibits Investigators from signing Form 1572.

Best Regards,

[redacted]