From: OC GCP Questions
To: [redacted]
Subject: FDA 1572 completed by mexican investigators
Date: Saturday, February 07, 2015 10:34:59 AM

Good morning –

Sorry for the delay in responding. We sent your question to Center for Drugs (CDER) forms office. Please see their response below.

Because both the Ethics Committee and the Research Committee are independent committees but both review and approve the protocol, information for both committees should be provided by using the original 1572 form Item 5 and the "Continuation Page for Item 5."

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

From: [redacted]
Sent: Friday, January 23, 2015 5:55 PM
To: OC GCP Questions
Subject: FDA 1572 completed by mexican investigators

Dear FDA:

I work for a CRO company and some of our sponsors request the completion of FDA 1572. In Mexico we have Ethics Committee and Research Committee but institutions are independent from each other, and both review and eventually approve the protocol . My question is:
We have to complete the point 5 of this FDA 1572 with the name of the Ethics and Research Committee or do you only expect to have the information about the Ethics Committee in this form?

Thank you very much in advance.
[redacted]