From: OC GCP Questions
To: [redacted]
Subject: Completion of 1572 by foreign investigators
Date: Thursday, May 07, 2015 11:08:54 AM

Good afternoon –

If the study is FDA-regulated and under an IND, the 1572 form (original form) must be signed by the clinical investigator. Additionally you may wish to contact the Center for Drugs (CDER) directly as the form originates from this Center. 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, May 06, 2015 4:18 PM
To: OC GCP Questions
Subject: Completion of 1572 by foreign investigators

In the May 2010 Guidance on Statement of Investigator (Form FDA 1572), application of the 21 CFR 312.53(c) regulation and the "must" language in FAQ #3 places some non-US investigators in a bind. They claim they cannot sign the US-based FDA form as an investigator under the US-based IND, but they would be happy to sign an equivalent prepared agreement (i.e., Statement of Investigator by that title or another) that provides for all the elements in 21 CFR 312.53(c)(1).

For example, the sponsor could prepare a virtually identical form or an agreement document to be signed whose contents collect the listed elements like name & address, laboratory facilities, IRB/Ethics Committee, and recites the list of commitments, etc. We note that FDA/CDRH, which does not have such a form as the 1572, has always used this approach for required Investigator Agreements, and this would also meet the GCP requirements under E6 Sections 4.5.1 and 5.6.3.

We already have ascertained that some non-US forms, like the Health Canada Qualified Investigator Undertaking form, would not be an adequate substitute. In cases like that, a more robust agreement would be needed since so many important elements would have been missing relative to the list in 21 CFR 312.53(c)(1).

But we do consider that a properly constructed signed agreement prepared by the sponsor—not using the Form FDA 1572 itself—would satisfy the "alternate approach if it satisfies the requirements of the applicable statutes and regulations" in meeting the requirement for a "signed

investigator agreement" from investigators.

Would you agree this alternative approach can be done for those foreign investigators who feel compelled to not use the US Form FDA 1572?

Please advise. Your prompt reply will be greatly appreciated.

Best regards,

[redacted]