From: OC GCP Questions
To: [redacted]
Subject: Form FDA 1572/ Use outside of the USA
Date: Monday, July 17, 2017 1:22:00 PM
Attachments: [redacted]

Good afternoon –

Please see FDA's 1572 guidance document. Specifically questions 10-14.
https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf

Kind regards,

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

From: [redacted]
Sent: Monday, July 17, 2017 8:05 AM
To: OC GCP Questions
Subject: Form FDA 1572/ Use outside of the USA

Hello,

May I request a confirmation on whether principal investigators and their site personnel working on a study that is under an IND need to complete the form FDA 1572?

Most of our European sites/ others globally will not complete these forms as they work with the jurisdiction of the national laws and directives of their country (not the US FDA).

Please Note that the information required in the Form FDA 1572 is collected in a document adapted for other countries.

Thank you on advance for looking into my query.

Regards,

[redacted]

[redacted]

[redacted]