From: OC GCP Questions
To: [redacted]
Subject: BA/BE study need FDA 1572
Date: Monday, August 22, 2016 10:35:00 AM

Good morning –

Please see the answer below from the Center for Drugs (CDER).

It depends. Per the Guidance for Industry and Investigators Safety Reporting Requirements for INDs and BA/BE Studies:

The IND safety reporting requirements under 21 CFR 312.32 apply to BA and BE studies that are conducted under an IND. However, BA and BE studies that meet the conditions for exemption under 21 CFR 320.31 are not conducted under an IND and are not subject to the IND safety reporting requirements. The rule contains safety reporting requirements under 21 CFR 320.31(d)(3) that apply to persons conducting BA or BE studies that are exempt from the IND requirements.

Kind regards,

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

From: [redacted]
Sent: Saturday, August 20, 2016 2:02 AM
To: OC GCP Questions
Subject: BA/BE study need FDA 1572

Dear mam,

kindly clear my question for BA/BE study FDA form need to be update or it only applicable for IND.

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[redacted]

[redacted]