From: OC GCP Questions
To: [redacted]
Subject: Safety reporting requirements for IND exempt studies
Date: Friday, January 30, 2015 1:25:10 PM

Good afternoon --

If a study is exempt from the IND requirements per 21 CFR 312.2(b), the study is also exempt from the IND safety reporting requirements (21 CFR 312.32). However, if you are conducting an IND exempt bioavailability or bioequivalence study, you must notify FDA and all participating investigators of any serious adverse event, as defined in 21 CFR 312.32(a), observed during the conduct of the study within 15 days (21 CFR 320.31(d)(3)).

I hope this answer is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Thursday, January 29, 2015 3:51 PM
To: OC GCP Questions
Subject: Safety reporting requirements for IND exempt studies

Are there any requirements to report serious, unexpected and suspected events when studying an approved drug under an IND exempt study?
entirety, whether electronic or hard copy. Thank you.