**From:** OC GCP Questions
**To:** [redacted]
**Subject:** adverse drug reaction reporting to IRB for post-approval KAB study
**Date:** Wednesday, February 11, 2015 11:11:11 AM

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Good morning –

I forwarded your email to the Center for Drugs (CDER) Office of Medical Policy. Please see their answer below.

Kind regards,

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

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

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If this study is conducted under an IND with an approved drug product, the sponsor must follow the safety reporting requirements described in both 21 CFR 312 32 and 21 CFR 314 80 Since you are an IRB representative inquiring about sponsor safety reporting requirements, our understanding is that the IRB has an agreement with the investigator and the sponsor for the sponsor to report directly to the IRB, per FDA's *Adverse Event Reporting to IRBs – Improving Human Subject Protection* guidance (pages 5-6)

21 CFR 312 32 and FDA's Safety Reporting Requirements for INDs and BA/BE Studies guidance describe the types of adverse events that sponsors must report to FDA for their IND application and to participating investigators in an expedited fashion 21 CFR 314 80(c)(1) and FDA's March 2001 Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines draft guidance describe the types of adverse events that sponsors must submit to FDA as 15-day Alert reports for their approved NDA

Link to the *Adverse Event Reporting to IRBs – Improving Human Subject Protection* guidance:
http://www fda gov/downloads/RegulatoryInformation/Guidances/UCM126572 pdf

Link to the Safety Reporting Requirements for INDs and BA/BE Studies guidance:
http://www fda gov/downloads/Drugs/ /Guidances/UCM227351 pdf

Link to the Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines draft guidance:
http://www fda gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm092257 pdf

The information provided in response to this inquiry does not address any specific product or trial Follow up questions regarding specific products or trials should be directed to the appropriate FDA review division by the sponsor

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**From:** [redacted]
**Sent:** Wednesday, January 28, 2015 2:24 PM
**To:** OC GCP Questions
**Subject:** RE: adverse drug reaction reporting to IRB for post-approval KAB study

Hello,

Yes. In particular, KAB studies conducted pursuant to an FDA post-marketing requirement.

Thank you,
[redacted]

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**From:** OC GCP Questions [mailto:gcp.questions@fda.hhs.gov]
**Sent:** Wednesday, January 28, 2015 1:44 PM
**To:** [redacted]
**Subject:** adverse drug reaction reporting to IRB for post-approval KAB study

Good afternoon –

Are the KAB studies FDA-regulated?

Thank you,

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

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**From:** [redacted]
**Sent:** Wednesday, January 28, 2015 1:19 PM
**To:** OC GCP Questions
**Subject:** adverse drug reaction reporting to IRB for post-approval KAB study

Good afternoon,

This question pertains to post-approval Knowledge-Attitude-Behavior ("KAB") studies for drug products.

It is expected that adverse reactions occurring with these approved drugs will be reported to FDA via the MedWatch program. Should a KAB sponsor also report the reactions to the reviewing IRB, given that such reactions are not "related" to the sole study procedure of questionnaire completion?

Thank you for your consideration of this matter.

Regards,
[redacted]