

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: IND Safety Report policy
Date: Tuesday, November 17, 2015 1:44:55 PM

Good afternoon –

My office generally does not review outside stakeholders' policies. You might want to contact someone in the FDA's Office of Medical Policy(OMP) at CDEROMP@fda.hhs.gov as they are the experts on safety reporting and wrote the guidance that you reference in your email.

Kind regards,

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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.

From: [REDACTED]
Sent: Monday, November 16, 2015 5:07 PM
To: OC GCP Questions
Subject: IND Safety Report policy

Hi-

Our research center receives thousands of IND safety reports as part of our clinical research programs. I am hoping that the FDA would review the attached policy to confirm it is in compliance with FDA regulations and in accordance with the 2009 Guidance for Clinical Investigators, Sponsors, and IRBs: Adverse Event Reporting to IRBs – Improving Human Subject Protection.

Thank you for your consideration.

[REDACTED]