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,

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

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]