

E. 21 CFR 312.64(b)

Effective Prior to March 28, 2011	Effective March 28, 2011	Description of Significant Change(s)
<p>Safety Reports. An investigator <i>shall promptly</i> report to the sponsor any <i>adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately.</i></p>	<p>Safety reports. An investigator <i>must immediately</i> report to the sponsor any <i>serious adverse event, whether or not considered drug related, including those listed in the protocol or investigator brochure</i> and must include an assessment of whether there is a reasonable possibility that the drug caused the event. Study endpoints that are serious adverse events (e.g., all-cause mortality) must be reported in accordance with the protocol unless there is evidence suggesting a causal relationship between the drug and the event (e.g., death from anaphylaxis). In that case, the investigator must immediately report the event to the sponsor. The investigator must record nonserious adverse events and report them to the sponsor according to the timetable for reporting specified in the protocol.</p>	<ul style="list-style-type: none"> • Investigators must report all serious adverse events, whether or not drug related • Investigator must include assessment of causality with serious adverse events