

Responsibility Reminder

2009

SUBMITTING PROTOCOL DEVIATION REPORTS

Compass IRB requires that *all significant deviations should be reported no later than ten (10) working days* from the day the Sponsor or Investigator becomes aware of the event.

Compass IRB refers to deviations/violations from the approved study design collectively as Protocol Deviations. A protocol deviation is considered to be significant when the safety or confidentiality of the study subject or the scientific integrity of the study is compromised by any instance where the protocol was not followed.

It is imperative that the aforementioned events are reported to us promptly. In this interest, the following are recommended reporting guidelines. A brief description of our reporting guidelines is listed on our Compass IRB Protocol Deviation Reporting Form and within the Investigator Resource Tool you were supplied with at the time of initial approval.

In order to satisfy Sponsor/CRO mandates and/or investigator/site preferences, Compass IRB will accept all protocol deviation reports that are submitted, but will only mandate those that are as previously stated (significant).

When submitting protocol deviations to us, please use the Compass IRB Protocol Deviation Reporting Form.

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For your reference

If you have additional questions regarding reporting of protocol deviations, please visit our FAQ section at www.compassirb.com or feel free to contact us directly.