Tracking and Reporting

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Adverse Event Tracking

At every study visit, the subject should be observed for adverse events and should be asked about any adverse event that might have happened since the previous visit. Most of these adverse events might not meet the definition of an Unanticipated Problem Involving Risks to Subjects or Others. All study events need to be tracked meticulously in an Adverse Event Tracking Log. See IRB Post-Approval Reporting for additional guidance.

Protocol Deviation Information

Although it is important to follow the protocol very strictly, deviations do sometimes occur due to various reasons. Some protocol deviations might meet the definition of an Unanticipated Problem Involving Risks to Subjects or Others. The Protocol Deviation Tracking Log tracks all the protocol deviations and serves as documentation of the determination of whether or not a particular deviation should be submitted to the IRB. See the OHRPP Violation Incident Guidelines for additional guidance.

Note to File

A Note-to-File may be written by any member of the study team to provide additional information or clarification.

Need assistance or have clinical study management questions? Please contact ResearchGo.

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