Suspected Serious Breach Report

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| Chief Investigator: Principal Investigator at implicated site: Study Title: REC No: Date Breach Reported to Sponsor:Date of Suspected Serious Breach Review Committee Meeting & Attendees: Breach DetailsImpact AssessmentRoot Cause InvestigationCorrective Actions and Preventative Actions (CAPA) Plan Actual Impact |
| **Completed by: Date:** |