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 Details  Impact Assessment  Root Cause Investigation  Corrective Actions and Preventative Actions (CAPA) Plan  Actual Impact |
| **Completed by: Date:** |