Questions in the form below are mirrored in the eProtocol PVR report form. As such, a serious breach can be reported to the Bellberry HREC via completion of the below form, or via submission of a PVR form in eProtocol.

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| **SERIOUS BREACH REPORT FORM (SPONSOR)** | | | |
| This form should be completed when the trial sponsor is reporting a serious breach to the Human Research Ethics Committee (HREC) or when a sponsor is providing additional/follow-up information following a third-party report of a confirmed serious breach | | | |
| HREC reference number: |  | Date of this report: |  |
| Project title: |  | | |
| HREC: |  | Coordinating Principal Investigator: |  |
| Sponsor: |  | Sponsor Contact (Aus): |  |
| Initial Report  Follow up Report | | | |
| Details of the organisation/individual committing the serious breach: | | | |
| **Details of the serious breach** | | | |
| Indicate the impact of the serious breach on any of the following: | | | |
| Participant safety: |  | | |
| Participant rights: |  | | |
| Reliability and robustness of data: |  | | |
| Provide: 1) An explanation of where, how and when the serious breach occurred and how it was identified 2) Any other relevant information (e.g. project status) | | | |
| **Details of any action taken to date\*** | | | |
| Include:   1. Any investigations you/others are conducting 2. The outcome of those investigations if completed (or details of when they will be available/reported) 3. How the serious breach will be reported in the final report/publication 4. Any corrective and preventative action implemented to ensure the serious breach does not occur again   \*If the investigation or the corrective/preventative action is ongoing at the time of this report, please indicate your plans with projected timelines for completion and provide any further information in a follow-up report. | | | |