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| Serious Breach Report Form (Sponsor) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| The definition of a **Serious Breach** is:  “*A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness of the data generated in the research project.”*  Serious breaches must be notified to the reviewing Human Research Ethics Committee (HREC).  This form must be completed by the **sponsor** when reporting a serious breach to the Human Research Ethics Committee (HREC) or when a sponsor is providing additional/follow-up information following notification by an individual / institution of a confirmed serious breach.  Serious breaches at a site should also be reported by the site Principal Investigator (PI) to their site Research Governance Officer (RGO) using this form. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Research Project | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| HREC reference number | | e.g. HREC/17/Abc/123 | |  | | HREC approval date | | | | | | | | | | | Select date | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Local reference number | | Enter text | |  | | Date of this report | | | | | | | | | | | Select date | | | | | | | | | | | | |
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| Project title | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Sponsor | | Enter text | |  | | Sponsor telephone | | | | | | | | | | | Enter text | | | | | | | | | | | | |
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| Sponsor contact (Aus) | | Enter text | |  | | Sponsor email | | | | | | | | | | | Enter text | | | | | | | | | | | | |
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| Coordinating Principal Investigator (CPI) for project | | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Study coordinator name | | Enter text | |  | | Study coordinator email | | | | | | | | | | | Enter text | | | | | | | | | | | | |
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| Is the project a clinical trial? | | | | Select one | | | | | | | | | | | | | | | | | | | | | | | | | |
| Organisation/individual committing the serious breach | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name | | Enter text | |  | | Principal Investigator (PI) | | | | | | | | | | | Enter text | | | | | | | | | | | | |
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| State/Territory | | Enter text | |  | |  |  |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  |  |  |  |  | | |
| Details of the serious breach Has the serious breach had any impact on any of the following: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Participant safety | | Select one | |  | | Participant rights | | | | | | | | | | | Select one | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Reliability and robustness of data | | Select one | |  | |
| P | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Record date of breach**   |  | | --- | | Select date |   **Number of participants directly affected as a proportion of total number of enrolled participants (e.g. 10/20)**     |  | | --- | | Enter number | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Brief explanation of the serious breach and other relevant information | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  | | --- | --- | | Explain where, how and when the serious breach occurred and how it was identified | Enter text |   **Details of any action taken to date\***  **Explain any investigations you/others are conducting relating to the breach**   |  | | --- | | Enter text |   **Document the outcome of those investigations if completed or details of when they will be available/reported**   |  | | --- | | Enter text |   **Explain how the serious breach will be reported in the final report/publication**   |  | | --- | | Enter text |   **What corrective and preventative action was implemented to ensure the serious breach does not occur again?**   |  | | --- | | Enter text |   **\*** *If the investigation or the corrective/preventative action is ongoing at the time of this report, please indicate your plans with the projected timelines for completion and provide any further information in a follow-up report.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Actions recommended by the sponsor (on advice of Principal Investigator) | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Action 1 | | Select one | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Action 2 *(if applicable)* | | Select one | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Action 3 *(if applicable)* | | Select one | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **Specify other action** | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Action(s) to prevent recurrence of the incident | | | | Enter text | | | | | | | | | | | | | | | | | | | | | | | | |
| *If changes are made to the Protocol, Participant Information Sheet and Consent Form(s), or any other documents approved by the HREC, submit the amended document(s) together with an Amendment Request Form (available from* [*www2.health.vic.gov.au/about/clinical-trials-and-research*](https://www2.health.vic.gov.au/about/clinical-trials-and-research)*) for review by the HREC.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Declaration | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| *To be completed by the Sponsor/CRO for a multi-site project, or the Principal Investigator (PI) for a single-site project.* | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016), or as amended. | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Name | Enter text | |  | | Email | | | | | | | | | | | Enter text | | | | | | | | | | | | |
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| Organisation | Enter text | |  | | Telephone | | | | | | | | | | | Enter number | | | | | | | | | | | | |

**Signature**

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**Date** Select date

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| *Office use only* | | | | | | |
| Research office acknowledgement – HREC | | | | | | |
| Name | | Enter text |  | Position | | Enter text |
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**Signature**

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