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| --- | --- | --- | --- |
| **Date:** |  | **Project Reference Number:** |  |
| **Project Title:** |  | | |
| **Principal Investigator:** |  | **Email:** |  |
| **Study Contact Person:** |  | **Contact email:** |  |

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| --- | --- | --- | --- | --- |
| **Date of breach**  *dd mmm yy* | **WH Site**  *e.g. Sunshine Hospital, Footscray Hospital* | **Number of participants impacted** | **Description of Breach**  *Please include details of any changes to medication, dose interruptions, changes to visit schedule and activities, use of external services (i.e. pathology, imaging) and any missing data.* | **Actions**  *Any actions recommended by the sponsor* |
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*Add more rows if required*

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| **DECLARATION** | | |
| 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 ethics committee/panel (and subject to any changes subsequently approved). The project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (2007 and updates), ICH Guideline for Good Clinical Practice E6 (R2) (2016) and the Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (NHMRC, 2016), or as amended. | | |
| **Principal Investigator (or delegate):** |  | |
| **Signature:** | | **Date:** |