

**CABRINI RSEARCH GOVERNANCE**

**REQUEST FOR EVENT(S) TO BE NOTED**

Applicable events include protocol deviations and violations, serious breaches\* (e.g. data and privacy), breaches of conditions of ethics or governance approval, SOP or policy non-compliance and research integrity issues.

***Complaints and compliments are recorded in RiskMan® Feedback module. \*Any serious breach where Cabrini systems or processes have contributed to unexpected harm or a near miss to a clinical trial participant should be reported in RiskMan™ Incident Management System.***

This form should not be used for reportable safety events (SAEs, SUSARs/SUSADEs, USMs, SSIs).

Do not report events which have no impact on participant safety, ongoing conduct of the study or data integrity.

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| **Cabrini project number**: |
| **Title**: |

**Event/s to be presented:**

| **Report number** | **Date** | **Description of event and Investigator’s comments**  **Please state:**   * **impact on participant safety, ongoing conduct of the study or data integrity** * **what action has been taken to prevent re-occurrence** |
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| **Principal Investigator name**: | |
| **Principal Investigator signature**: | **Date**: |