**CABRINI RESEARCH GOVERNANCE**

**CORRECTIVE AND PREVENTATIVE ACTION PLAN**

A Corrective And Preventative Action plan (CAPA) is written to:

* identify the issue(s) or deviation that qualifies as a ***serious breach***\* or clinical incident (or near miss) in the conduct of a research project
* note the root cause of the identified issue(s)
* identify the corrective action to prevent the recurrence of the issue(s), and
* document the resolution of the issue(s).

In general, a CAPA should be forward-looking and not seek to attribute blame for a mistake or error discovered in the conduct of a research project. The focus should be on the systems and processes to find solutions for improving safety.

For a clinical incident involving a clinical trials participant this CAPA should be completed and read in conjunction with the [Clinical Incident Management Policy and Procedure](https://app.prompt.org.au/download/126596?code=2d26acfca8b785293702653da9447c9f). Form may be copied from Riskman entry.

If you have any queries, please contact the Cabrini Research Governance Office via email ResearchGovernance@cabrini.com.au.

 *\** *A* ***serious breach*** *is a breach of, or persistent/systematic non-compliance with, Good Clinical Practice (GCP) or the protocol that is likely to significantly affect the safety or rights of a research participant or the reliability and robustness of the data generated in the research project. Review the* [*Monitoring of Research Policy*](https://outlook.office.com/owa/wopi/files/f6d76e9f-d306-4de7-8dac-4e355619bf97%40cabrini.com.au/AAMkAGY2ZDc2ZTlmLWQzMDYtNGRlNy04ZGFjLTRlMzU1NjE5YmY5NwBGAAAAAABzMhAUxGEjRpmeoDVn9mBaBwDnba..oMlETpBg2qgBnAjsAAAAAAEMAADnba..oMlETpBg2qgBnAjsAAF6VVWYAAABEgAQAKr677.BdghBig5-DVeKvEE%3D_INyyMXak3AgBAQAAAAA%3D/WOPIServiceId_FP_EXCHANGE_ORGID/WOPIUserId_e9c2fa78-8369-41fb-961d-2a622f409386/Monitoring%20of%20Research%20Policy) *for more information on how Cabrini manages serious breaches.*

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| **PROJECT DETAILS****Project title:****Principal Investigator:****HREC number:****RGO number:****Risk Register number:** |
| **Date of completion of this CAPA:** |
| **Person responsible for overall CAPA (if different from PI):***Name, Title, the site/institutional affiliation of the delegated person authoring the CAPA, including their signature* |
| **Issue / Deviation identified:***This section addresses the “What”. Brief description or outline of the topic/process/issue(s) being documented. What is the issue? Who is impacted by the issue? This can be formatted as a paragraph, numbered list, or bulleted items.* |
| **Root Cause:***This section addresses the “Why”. The reason(s) that the issue(s) arose. Root-cause analysis is a class of problem-solving methods used to identify the root causes of issues or events. Why is the issue occurring? (Is it due to training, design, management, documentation etc?) What events led to the issue? Where is it occurring? When did it first occur? How widespread is it? How was the issue identified? Where appropriate discuss with the participant or family member, ensuring open disclosure has occurred.* |
| **Corrective Action Plan:***This section addresses the “How”. Description of the correction action(s) taken or planned by the project team. The corrective action plan should look at rectifying the issue(s) identified above. If the site was instructed to perform these corrective actions (i.e. by the sponsor or monitor), indicate by whom and as of what date. If status of reports, records or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.* |
| **Implementation:***This section addresses the “Who”. Description of the procedures used to document resolution of the issue, the persons who are responsible for the procedures, etc. Include who will provide feedback to patients and their relatives through the open disclosure process. Identify who will inform employees involved in the incident of the recommendations arising from the CAPA,*  |
| **Effective Date of Resolution:** |
| **Preventive Action:***This section addresses the forward looking “How”. Description of the preventive actions taken or planned by the project team. Preventative Actions are to avoid the same or similar issue(s) occurring again in future. They are forward looking and future focussed and complementary to the corrective action plan which is more focussed on rectifying past actions. Preventive actions are taken to eliminate the root-cause of a potential issue, including the detection/identification of issues.* |
| **Evaluation and follow-up:***Describe or list any plan or procedure to monitor and evaluate the implementation and completion, persons who are responsible for the evaluations, timeframe for the evaluation, etc.**Who will ensure local monitoring is in place to evaluate successful improvement* |

**Comments:** *Please add in this section any additional comments, information or relevant observations not noted above.*

Principal Investigator - Signature and Date Principal Investigator - Printed Name

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Delegate completing form - Signature and Date Delegate - Printed Name

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