

1.10.11 SAE report form

ALFRED ETHICS COMMITTEE
ADVERSE EVENTS REPORT FORM

Alfred Project Number:

Project Name:

Principal Researcher:

Event site: ☐ Site under the jurisdiction of The Alfred Hospital Ethics Committee
☐ External site outside the jurisdiction of The Alfred Hospital Ethics Committee

**Please report significant events concerning Alfred Health participant safety
to the Ethics Office within 72 hours.**

Participant reference (eg. code number)	Details of Event	Report type (initial or follow-up)	Relationship to study drug/device/intervention (unrelated, possibly, probably, definitely)

Recommendation by the Principal Researcher:

- Change to the protocol Y/N
- Change to the Participant Information and Consent Form Y/N
- Previously enrolled participants to be notified Y/N
- The study to be stopped Y/N
- No action Y/N

Principal Researcher's comments:

Please comment on (a) the context and significance of the event, (b) the possible impact on participants, and (c) action taken or recommended (add any relevant attachments):

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Principal Researcher's signature:

Date:

Project contact person (please provide name and email address for AE acknowledgment and further communication):

**Please email this form to S 47F Please send this form and the report
in hard copy to the Ethics Manager, Alfred Research & Ethics Unit.**

OFFICE USE ONLY

Action:

Signature: