Serious Adverse Events Guidelines

These guidelines are designed to give researchers the information to complete a serious adverse events (SAE) report. The SAE report is required by the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) within 72 hours of the event occurring.

How to use this document:

To maintain SAC HREC approval, researchers have a significant responsibility to monitor and report on current research. This includes reporting on all serious adverse events. Below is a link to the report template. Email the completed report and any supporting documentation, ensuring they are not password protected, to the Office for Research: Health.SALHNOfficeforResearch@sa.gov.au

Background:

Please refer to the National Statement on Ethical Conduct in Human Research, Sections 5.5 (covering all research) and 3.3.19 (for clinical research) for advice on the monitoring and reporting of approved research. Researchers are responsible for verifying, to the SAC HREC that the conduct of the research conforms to the approved proposal.

> Serious Adverse Event report template

> SAEs relating to local patients at any SA Health site (where the SAC HREC is the lead HREC) to be reported to the committee via the Office for Research within 72 hours of the event becoming known to the local investigator.

> SAEs from interstate public health sites (where the SAC HREC is the lead HREC) to be reported within 72 hours of the event occurring unless the PI considers immediate notification is necessary.

> If there is no material impact from an interstate SAE on the continued ethical acceptability of the study, the following is required:

  ○ After the completed Serious Adverse Event report has been noted by the SAC HREC you will receive an acknowledgment email from the committee. Forward a copy of this acknowledgment email and the report to the relevant interstate RGO and CPI.

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For more information

Office for Research
SAHLN
Telephone: (08) 8204 6453
www.sahealth.sa.gov.au/SALHNresearch

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If there is a material impact from an interstate SAE on the continued ethical acceptability of the study the following is required:

- After the completed Serious Adverse Event report has been noted by the SAC HREC you will receive an acknowledgment email from the committee. Forward a copy of this acknowledgment email and the report to the relevant interstate RGO and CPI.
- It is the CPIs responsibility to communicate all changes to the trial protocol or safety monitoring to the SAC HREC.
- It is the CPIs responsibility to action any urgent safety related modifications to the SAC HREC.

For SAEs that have occurred after recruitment has ceased (once follow up is complete at local or multiple sites) no further SAE reports are required unless the investigator believes the SAE has implications for local participants that were involved in the research.

Data Safety Monitoring (DSM); Data Safety Monitoring Board (DSMB); Quarterly Line Listings; other safety documents:

- These documents should be submitted upon receipt by the local investigator to the SAC HREC, using the Declaration of Safety Documents Form for the life of the project. Once the study is complete at the local sites and multi-sites, the SAC HREC does not require submission of these documents unless the investigator believes the matters raised have ongoing implications for local participants involved in the research.