Government of South Australia | Health Central Adelaide Local Health Network

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Central Adelaide Local Health Network
Research Services

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Central Adelaide Local Health Network Clinical Trial Safety Reporting

The National Health and Medical Research Council *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Products November 2016* and *Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods 2018* define sponsor responsibilities for reporting to Human Research Ethics Committees (HRECs).

Sponsors should no longer submit the following reports to the Central Adelaide Local Health Network (CALHN) HREC:

- Adverse Events (AEs).
- Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs).
- Sudden Unexpected Serious Adverse Reactions (SUSARs). Note, the principal investigator reports SUSARs to the institution via the CALHN HREC.
- Unanticipated Serious Adverse Device Effects (USADEs). Note, the principal investigator reports USADEs to the institution via the CALHN HREC.
- Development, Safety Update Reports (DSURs). Note, the Executive Summary of safety information produced for international regulators, such as the DSUR, may serve as the annual safety report (a full DSUR is not required).
- Line listings
- Protocol deviations and deviation logs. Note, deviations that have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial must be reported as serious breaches.

Any of the outlined reports sent to CALHN HREC will not be reviewed. However, if any of these events result in a Significant Safety Issue (SSI) they must be reported using the CALHN Research Safety Report Form.

Should you require further clarification or advice, please contact CALHN Research Services via email at Health.CALHNResearchEthics@sa.gov.au, or on 08 7117 2229.

Yours sincerely

Bernadette Swart
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Central Adelaide Local Health Network