SALHN Monitoring and Reporting Guidelines

Purpose:

To guidance on post approval submission reporting requirements for applications approved by the Southern Adelaide Clinical Health Research Ethics Committee (SAC HREC) and/or authorised by the SALHN CEO through the Office for Research (OFR) Research Governance Officer (RGO).

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. If the study is commercially sponsored, please ensure their reporting requirements are also adhered to.
- NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (Nov. 2016) for more information.

Instructions:

All relevant documents can be found on the Office for Research website or are available on the Research GEMS portal.

ll documents should be submitted by the Principal Investigator or to Health.SALHNOfficeforResearch@sa.gov.au. The SAC HREC will not communicate directly with sponsors.

All local site and/or patient unexpected study related safety issues must be reported to either the SAC HREC or Site/s RGO.

SALHN uses the Safety Learning System (SLS) which is a mechanism by which clinical data is collected and reported. It is expected that the reporting and management of clinical incidents at SALHN will lead to improvements to the safety and quality of clinical services delivered across the region. This SALHN Safety Learning System (SLS) is used by SALHN staff only.

SAC HREC is the lead HREC + SALHN Governance or SAC HREC Lead HREC only			
Submission type	**Documents to be submitted to OFR**	**OFR Response**	**Overview**
Progress reports	Progress report, publications, any supporting documentation	Notation email sent on behalf of SAC HREC and SALHN RGO	Progress reports can include Development Safety Update Report Executive Summaries and Safety monitoring outcomes. Progress must be submitted annually on the ethics approval date stated on the approval letter. Failure to submit the report will result in the ethics approval being suspended until the report is provided.
Data Safety Monitoring Board or Independent Data Monitoring Committee minutes	Correspondence from DSMB/IDMC or equivalent	Notation email sent on behalf of SAC HREC and SALHN RGO	DSMB/IDMC meeting minutes should be reported to the HREC even if no change to trial protocol is recommended
Development Safety Update Reports (DSURs)	Safety Monitoring Report any supporting documentation	Notation email sent on behalf of SAC HREC and SALHN RGO	Development Safety Update Reports can be submitted with the Annual Report
Early Termination of a trial for safety reasons	Safety Monitoring Report any supporting documentation	Notation email sent on behalf of SAC HREC and SALHN RGO	Must be notified without undue delay and no later than 15 calendar days of the sponsor's decision to terminate the trial
Extension Request	Progress report, publications, any supporting documentation	Approval email sent on behalf of SAC HREC and SALHN RGO	Extension requests should be submitted 30 days before approval expires on the progress report form. If the ethics approval has expired the study will be suspended until the progress report has been provided.
Final Study report	Final Report Form, publications, and any supporting documentation	Notification email sent on behalf of SAC HREC and SALHN RGO	Final Reports should be submitted with copies of any publications. If results are not available at the time of the report submission, they can be provided at a later date. Completion of the project is defined as the time point where all participants have completed any study related activity and all access to medical records has ceased.

Protocol Amendments	Project Amendment Form, with any amended documentation (both clean & tracked) i.e., Protocol, PICF, Investigator Brochure, patient facing documents.	Approval email sent on behalf of SAC HREC and SALHN RGO	Provide a summary of the changes in the project amendment form and include the rationale for each amendment
Reporting of Serious Breaches of good Clinical Practice or the Protocol	**Serious Breach** A deviation from Good Clinical Practice or the protocol that is likely to affect to a significant degree: ➢ The safety or rights of a trial participant, or ➢ The reliability and robustness of the data generated in the clinical trial. **Suspected Breach** reported to HREC when sponsor needs advice regarding whether it meets serious breach	Notation email sent on behalf of SAC HREC and SALHN RGO (if SALHN specific) Where the sponsor has notified the HREC of the serious breach, the HREC will: ➢ Assess the report, including any corrective and preventative actions implemented, and provide any necessary feedback to the sponsor ➢ For trials conducted under the CTX/CTN Scheme, inform the TGA and the sponsor if the ➢ notification of a serious breach leads to the suspension or withdrawal of the ethics approval for the trial	HRECs need only be made aware of suspected/serious breaches 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. Minor protocol deviations do not need to be reported to the HREC. The sponsor must report serious breaches to the Site PI and reviewing HREC within 7 calendar days of confirming a serious breach has occurred and provide follow-up reports when required. Must also be reported on the SALHN Safety Learning System (SLS)

	Minor Deviation – not required to be reported	Not reportable to OFR	
Study Complaints	Any documentation relating to the complaint to the SAC HREC and Site RGO	Notation email sent on behalf of SAC HREC and SALHN RGO (if SALHN specific	All complaints should be reported to the SAC HREC and the Site and recorded in the study file
Suspected Unexpected Serious Adverse Reaction (SUSAR) All significant safety issues at local site and/or involving a participant that are study related	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO (if SALHN specific.	They should be reported within 72 hours of the PI becoming aware of the event. Must also be reported on the SAHLN Safety Learning System (SLS)
Suspected Unexpected Serious Adverse Reaction (SUSAR) Line Listing	Do not need to be reported	Not applicable	SUSAR Line Listings do not need to be submitted to the SAC HREC but may be included with Annual Safety Monitoring Report
Serious Adverse Event (SAE) related to the study and unexpected All significant safety issues at local site and/or involving a participant that are study related	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO (if SALHN specific)	Should be reported no later than 15 calendar days of sponsor awareness and include any relevant changed documents such as IB and Protocol A SSI is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. TGA report - The TGA should be notified by the Sponsor if SAE related to the site and study drug or device Must also be reported on the SALHN Safety Learning System (SLS) if SALHN specific

Temporary Halt of a trial for safety reasons	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO (if SALHN specific)	Must be notified without undue delay and no later than 15 calendar days of the sponsor's decision to halt the trial. Must also be reported on the SALHN Safety Learning System (SLS) if SALHN specific
Serious Adverse Event reported related to the study and unexpected as an Urgent Safety Measures (USM) All significant safety issues at local site and/or involving a participant that are study related	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO (if SALHN specific)	To be reported without undue delay and no later than 72 hours of the measure being taken. A USM is any measure taken by either the sponsor or investigators to eliminate an immediate hazard to participant health/safety TGA report - The TGA should be notified by the Sponsor if SAE related to the site and study drug or device Must also be reported on the SALHN Safety Learning System (SLS) if SALHN specific

SALHN governance only (not SAC HREC approved)			
Submission type	**Documents to be submitted to OFR**	**OFR Response**	**Overview**
Annual Reports	Annual Report Form – must contain SALHN activity details If Sponsor report – HREC acknowledgement letter must be included	Filed in study file - No notation will be sent	Annual Reports can include Development Safety Update Report Executive Summaries and Safety monitoring outcomes.
Certificate of Currency	Certificate of Currency / Insurance Certificate	Filed in Study file - No notation will be sent	Submit the Certificate itself. No supporting documentation is required.
Early Termination of a trial for safety reasons	Safety Monitoring Report HREC acknowledgement email	Notation email sent on behalf of SAC HREC and SALHN RGO	Must be notified without undue delay and no later than 15 calendar days of the sponsor's decision to terminate the trial
Final Study Report	Lead HREC acknowledgement email of Final Report Final Report form – must contain Site activity and any publications	RGO notation email	Final Reports should be submitted as soon as lead HREC acknowledgement has been received.
Investigator's Brochure	Project Amendment Form, a copy of the HREC approval letter, a tracked and clean version of the new Investigator's Brochure and a summary of changes Or Safety Monitoring Report If IB change is related to serious safety issue.	RGO notation email acknowledging HREC approval letter	The Investigator's Brochure must be acknowledged by the PI. The submission must include a summary of changes.

Protocol Amendment	Project Amendment Form, a copy of the HREC approval letter along with any amended documentation (both clean & tracked)	RGO notation email acknowledging HREC approval letter	Provide a summary of the changes in the project amendment form and include the rationale for each amendment and a copy of the lead HREC approval
PICF Amendment	Project Amendment Form, a copy of the HREC approval letter, a copy of the master PICF approved by the HREC and the site specific PICF	RGO notation email acknowledging HREC approval letter + site specific PICF	The PICF changes should be tracked. The clean site-specific version should be representative of what SALHN participation involves.
Reporting of Serious Breaches of good Clinical Practice or the Protocol	**Serious suspected breach of GCP-Protocol form (if site related)** **Types of Breaches:** **Serious Breach** A deviation from Good Clinical Practice or the protocol that is likely to affect to a significant degree: ➢ The safety or rights of a trial participant, or ➢ The reliability and robustness of the data generated in the clinical trial.	Notation email sent on behalf of SAC HREC and SALHN RGO	HRECs need only be made aware of suspected/serious breaches 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. Minor protocol deviations do not need to be reported to the HREC. . The sponsor must report serious breaches to the Site PI and reviewing HREC within 7 calendar days of confirming a serious breach has occurred and provide follow-up reports when required.
	Suspected Breach reported to HREC when sponsor needs advice regarding whether it meets serious breach		
	Minor Deviation – not required to be reported	Not reportable to OFR	

Serious Adverse Event reported related to the study and unexpected as an Urgent Safety Measures (USM) All significant safety issues at SALHN and/or involving a participant that are study related	Safety Monitoring Report Report to the SALHN RGO first and then to the lead HREC once RGO acknowledgement received TGA report - The TGA should be notified by the Sponsor if SAE related to the site and study drug or device	Notation email sent on behalf of SAC HREC and SALHN RGO	To be reported without undue delay and no later than 72 hours of the measure being taken. A USM is any measure taken by either the sponsor or investigators to eliminate an immediate hazard to participant health/safety Must also be reported on the SALHN Safety Learning System (SLS)
Serious Adverse Event (SAE) related to the study and unexpected – reported as a SSI All significant safety issues at SALHN and/or involving a participant that are study related.	Safety Monitoring Report Report to the SALHN RGO first and then to the lead HREC once RGO acknowledgement received TGA report - The TGA should be notified by the Sponsor if SAE related to the site and study drug or device.	Filed in study file – no notation will be sent	They should be reported no later than 15 calendar days of sponsor awareness and include any relevant changed documents such as IB and Protocol. A SSI is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. A SSI only needs to be reported to the RGO when they are serious, related to the Site, study intervention, and unexpected. Must also be reported on the SALHN Safety Learning System (SLS)

Suspected Unexpected Serious Adverse Reaction (SUSAR) All significant safety issues at SALHN and/or involving a participant that are study related.	Safety Monitoring Report Report to the SALHN RGO first and then to the lead HREC once RGO acknowledgement received.	SALHN RGO acknowledgement	They should be reported within 72 hours of the PI becoming aware of the event. Must also be reported on the SALHN Safety Learning System (SLS)
Suspected Unexpected Serious Adverse Reaction (SUSAR) Line Listing	Do not need to be reported	Not applicable	SUSAR Line Listings do not need to be submitted to the SAC HREC but may be included with Annual Safety Monitoring Report
Temporary Halt of a trial for safety reasons	Safety Monitoring Report Report to the SALHN RGO first and then to the lead HREC once RGO acknowledgement received.	SALHN RGO acknowledgement	Must be notified without undue delay and no later than 15 calendar days of the sponsor's decision to halt the trial. Must also be reported on the SALHN Safety Learning System (SLS)