Government of South Australia | Health Southern Adelaide Local Health Network

SALHN Monitoring and Reporting Guidelines

Purpose:

To provide 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.

Instructions:

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

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

SAC HREC is the lead HREC			
Submission type	**Documents to be submitted to OFR**	**OFR Response**	**Overview**
Protocol Amendment	Project Amendment Form Any documents that have been amended (both clean and tracked)	Approval email 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. Sub studies cannot be submitted via amendment.
PICF Amendment	Project Amendment Form A tracked and clean version of the PICF	Approval email 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
Investigator's Brochure	Project Amendment Form A tracked and clean version of the new Investigator's Brochure and a summary of changes	Acknowledgement email on behalf of SAC HREC and SALHN RGO	The Investigator's Brochure must be acknowledged by the PI. The submission must include a summary of changes
Serious Adverse Event (SAE) not related to study	n/a	n/a	Unrelated SAEs do not need to be submitted to the HREC
Serious Adverse Event (SAE) related to the study and unexpected	Safety Monitoring Report	Notation email on behalf of SAC HREC and SALHN RGO	Submit to the HREC within 7 days. The CPI or PI must have acknowledged the event

SAC HREC is the lead HREC + SALHN Governance			
Submission type	**Documents to be submitted to OFR**	**OFR Response**	**Overview**
Urgent Safety Measures (USM)	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO	A USM is any measure taken by either the sponsor or investigators to eliminate an immediate hazard to participant health/safety
Significant Safety Issue Amendment	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO	Should be reported no later than 15 calendar days of sponsor awareness and include any relevant changed documents such as IB and Protocol
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	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 halt the trial
Early Termination of a trial for safety reasons	Safety Monitoring Report	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
Protocol/GCP deviation reporting Reporting of Serious Breaches of good Clinical Practice or the Protocol	**Protocol-GCP Suspected or Serious Breach Report** **Definitions:** **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 **Minor Deviation** – not required to be reported	Notation email sent on behalf of SAC HREC and SALHN RGO The SAC 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.
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
Annual Reports	Annual Review / Extension Request form	Notation email sent on behalf of SAC HREC and SALHN RGO	Annual Reports can include Development Safety Update Report Executive Summaries and Safety monitoring outcomes.

Extension Request	Annual Review / Extension Request form For all applications received before governance was introduced, a SALHN site specific assessment form needs to be submitted to the for authorisation	Approval email sent on behalf of SAC HREC and SALHN RGO	Extension requests should be submitted 30 days before approval expires. If the ethics approval has expired, a letter from the PI is required explaining why the ethics approval was allowed to expire, if participants were recruited during this time and what will be done to prevent this from occurring again.
Study Complaints	Any documentation relating to the complaint to the SAC HREC and Site RGO	SAC HREC acknowledgement email + SALHN RGO acknowledgement if applicable	All complaints should be reported to the SAC HREC and the Site and recorded in the study file
Final Study Report	Final Report Form	Notation email 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.

SALHN governance only (not SAC HREC approved)			
Submission type	**Documents to be submitted to OFR**	**OFR Response**	**Overview**
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.
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.
Serious Adverse Event (SAE) **NOT** related to study	Does not need to be reported to RGO or HREC	Not applicable	Unrelated SAEs do not need to be submitted to the HREC or RGO
Serious Adverse Event (SAE) related to the study and unexpected See NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (Nov. 2016)	Safety Monitoring Report Please include any relevant supporting documents such as: ➢ Lead HREC submission or acknowledgement letter (the lead HREC should be notified of all SAE's related to the study and unexpected) ➢ 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 When the Site is also the Local Sponsor, the SALHN RGO will notify the TGA	SAEs only need to be reported to the RGO when they are serious, related to the Site, study intervention, and unexpected. They should be reported no later than 15 calendar days of sponsor awareness and include any relevant changed documents such as IB and Protocol. The TGA should be notified by the sponsor if SAE related to the study drug or device
Suspected Unexpected Serious Adverse Reaction (SUSAR)	No need to submit to RGO	Not applicable	SUSAR Line Listings should not be submitted independently but should be included in the Annual Safety Monitoring Report
Urgent Safety Measures (USM)	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO	A USM is any measure taken by either the sponsor or investigators to eliminate an immediate hazard to participant health/safety
Significant Safety Issue Amendment	Safety Monitoring Report	Notation email sent on behalf of SAC HREC and SALHN RGO	Should be reported no later than 15 calendar days of sponsor awareness and include any relevant changed documents such as IB and Protocol

Temporary Halt of a trial for safety reasons	Safety Monitoring Report	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 halt the trial
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
Protocol/GCP Deviations 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. **Suspected Breach** reported to HREC when sponsor needs advice regarding whether it meets serious breach **Minor Deviation** – not required to be reported	Auto response email from OFR	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. 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. Governance need only be aware of Site Serious Breaches
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.
Site Complaints	Any documentation relating to the complaint	RGO notation email	Complaints made to investigators should be sent to the RGO for acknowledgement and recorded in the study file.
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.
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.