

Post Approval Monitoring

<https://www.rah.sa.gov.au/research/for-researchers/post-approval-monitoring>

Responsible Party	Report Type	Timeline	To Who	How
Principal Investigator	Annual progress report	Within two weeks of the approval anniversary	The HREC	<p>Approved by CALHN HREC: Complete the CALHN Research Project Annual Progress Report Submit to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>Approved by external HREC: Refer to relevant HREC. Submit a copy of the report and the HREC approval</p>
Principal Investigator	Final report <ul style="list-style-type: none"> > Site Closure – completed at site > Site Closure – termination > Completion of project – completed 	-	The HREC	<p>Approved by CALHN HREC: Complete the CALHN Research Project Final Report Submit to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>Approved by external HREC: Refer to relevant HREC.</p>
Principal Investigator	Amendment <ul style="list-style-type: none"> > Amend protocol > Amend investigator brochure (sponsor) > Amend master participant information sheet and consent form(s) > Amend other supporting document > Add site to existing single-site project (contact CALHN Research Services) > Add site to existing multi-site project (contact CALHN Research Services) > Change investigator or personnel (contact CALHN Research Services) > Reactivate approval (ensure a CALHN Research Annual Progress Report Form is submitted) 	-	The HREC	<p>Approved by CALHN HREC: Complete the CALHN Research Amendment Request and provide updated documents (tracked and clean) Submit to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>Approved by external HREC: Refer to relevant HREC. Submit a copy of documents (tracked and clean) and the HREC approval</p>
Principal Investigator	Site specific participant information sheet and consent form(s) – ensure Master is also provided	-	To the institution	<p>CALHN site: Submit to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>External site: Refer to relevant Research Governance Office</p>
Principal Investigator	Certificate of currency	-	To the institution	<p>CALHN site: Submit to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>External site: Refer to relevant Research Governance Office</p>

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Principal Investigator	All Significant Safety Issues (SSIs)	Within 72 hours of becoming aware of the event	To the institution where the issue occurred	<p>Occurring at a CALHN site, approved by CALHN HREC: The HREC submission by the sponsor will be reviewed by both HREC and the institution. The principal investigator is not required to notify the institution in this instance</p> <p>Occurring at a NALHN site, approved by CALHN HREC: Email notification to HealthNALHNRgo@sa.gov.au</p> <p>Occurring at a CALHN site, approved by external HREC: Email notification to Health.CALHNResearchGovernance@sa.gov.au</p> <p>Occurring at an external site, approved by CALHN HREC: Refer to relevant Research Governance Office</p>
Principal Investigator	Suspected Unexpected Serious Adverse Reactions (SUSARs) and Unanticipated Serious Adverse Device Effects (USADEs)	Within 72 hours of becoming aware of the event	To the institution where the issue occurred	<p>Occurring at a CALHN site, approved by CALHN HREC: Complete the CALHN Research Safety Report</p> <p>Occurring at a CALHN site, approved by external HREC: Email reviewing HREC's form/notification Submit to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>Occurring at a NALHN site, approved by CALHN HREC: Email notification to HealthNALHNRgo@sa.gov.au</p> <p>Occurring at an external site, approved by CALHN HREC: Refer to relevant Research Governance Office</p>
Principal Investigator	Serious breach confirmed by the sponsor as occurring at the site	Within 72 hours of being notified of the serious breach	To the institution where the issue occurred	<p>Occurring at a CALHN site, approved by CALHN HREC: The HREC submission by the sponsor will be reviewed by both HREC and the institution. The principal investigator is not required to notify the institution in this instance</p> <p>Occurring at a NALHN site, approved by CALHN HREC: Email notification to HealthNALHNRgo@sa.gov.au</p> <p>Occurring at a CALHN site, approved by external HREC: Email notification to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>Occurring at an external site, approved by CALHN HREC: Refer to relevant Research Governance Office</p>
Third Parties	Serious breach	-	The HREC	<p>Approved by CALHN HREC:: Complete the CALHN Research Serious Breach Report Form (Third Party) Submit to Health.CALHNResearchMonitoring@sa.gov.au</p> <p>Approved by external HREC: Contact relevant HREC</p>
Sponsor	Significant Safety Issue (SSI) implemented as an Urgent Safety Measure (USM)	Without undue delay and no later than 72 hours of the measure being taken	The HREC	<p>Approved by CALHN HREC: Complete the CALHN Research Safety Report, submit to Health.CALHNResearchEthics@sa.gov.au</p> <p>Approved by external HREC: Refer to relevant HREC</p>
Sponsor	Significant Safety Issues (SSI) not implemented as an urgent safety measure	Within 15 days of the sponsor instigating or being made aware of the issue	The HREC	<p>Approved by CALHN HREC: Complete the CALHN Research Safety Report, submit to Health.CALHNResearchEthics@sa.gov.au</p> <p>Approved by external HREC: Refer to relevant HREC</p>

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Sponsor	Annual safety report The Executive Summary of safety information produced for international regulators, such as a Development Safety Update Report (DSUR), may serve as the annual safety report (a full DSUR is not required)	May be aligned with the reporting cycles of global companies or aligned with the annual progress report sent to the HREC	The HREC	Approved by CALHN HREC: Sponsor to provide written report or DSUR to the principal investigator for submission with the CALHN Research Annual Progress Report to Health.CALHNResearchEthics@sa.gov.au Approved by external HREC: Refer to relevant HREC
Sponsor	Investigator Brochure (IB) updates and interim addenda	When updates are generated	The HREC	Approved by CALHN HREC: Sponsor to provide to the principal investigator. Principal investigator to complete the CALHN Research Amendment Form and submit with the updated documentation to Health.CALHNResearchEthics@sa.gov.au Approved by external HREC: Refer to relevant HREC
Sponsor	Serious breach	Within 7 calendar days of confirming a serious breach has occurred and provide follow-up reports when required	The HREC	Approved by CALHN HREC: Complete the CALHN Research Serious Breach Report Form (Sponsor), submit to Health.CALHNResearchEthics@sa.gov.au Approved by external HREC: Contact relevant HREC
Sponsor	Third party serious breach notification provided to the sponsor by the Human Research Ethics Committee (HREC) determined by the sponsor to meet the definition of a serious breach	Within 7 calendar days of making a decision	The HREC	Approved by CALHN HREC: Complete the CALHN Research Serious Breach Report Form (Sponsor), submit to Health.CALHNResearchEthics@sa.gov.au Approved by external HREC: Contact relevant HREC
Sponsor	Third party serious breach notification provided to the sponsor by the HREC determined by the sponsor to not meet the definition of a serious breach	Within 7 calendar days of confirming a serious breach has not occurred	The HREC	By letter or e-mail, including a justification for the decision