

Insurance Cover Guidelines and Checklist

Insurance for Clinical Research

All research projects hosted by a South Australian Local Health Network site involving SA Health and/or external staff must have appropriate insurance and indemnity prior to the project commencing.

Please Note: Throughout the term of the study, any updates or changes to the insurance and indemnity cover must be sent to the SA Health Legal Governance and Insurance Services (LGIS) office for review and approval.

For additional information, project indemnity queries or clarification please contact LGIS at the following email: Health.LGISResearchTrials@sa.gov.au

General Insurance Advice

- The Principal Investigator (PI) is responsible for confirming the insurance and indemnity arrangement for the research project. The PI must provide all required supporting documentation to the Central Adelaide Local Health Network (CALHN) Research Office.
- SA Health employees conducting a research project in the capacity of their employment with SA Health are covered by SA Health insurance where approval from a SA Health HREC or National Mutual Acceptance (NMA) HREC has been obtained.
- LGIS is not required to review each individual research trial/project if it can be satisfied that the HREC, who has approved the trial/project, has given consideration to any risks associated with the trial/project and ensured they have been identified.
- If the researcher is an SA Health Employee, but has dual employment with a University or South Australian Health and Medical Research Institute (SAHMRI) or another organisation, or is also a university student, and is conducting a research trial/project in the capacity of their non SA Health employment, or as part of their private studies, indemnity must be provided by the University or SAHMRI and/or third party sponsor.
- For research projects conducted by non SA Health employees at a SA Health organisation that involve SA Health patients, staff, resources or data to support the project, the PI must provide appropriate insurance documentation from the non SA Health organisation. Appropriate insurance documentation includes current insurance certificate/s and written insurance approval from the organisation. These requirements include research projects conducted by staff and students of academic institutions, such as Universities.
- Important: For clinical research trials with third party sponsors it is a requirement that the Sponsor indemnifies the trial and provides evidence of indemnity, by way of Certificate of Currency (this is in addition to SA Health and/or non SA Health insurance cover).
- For research projects sponsored by a third party, including commercially sponsored clinical trials, the sponsor must supply evidence of its insurance cover. A sponsor's insurance cover must as a minimum identify the local site, investigator and research staff, and participants involved in the research project. For all commercially sponsored clinical trials, the 'Medicines Australia Form of Indemnity for Clinical Trials – Standard' must also be submitted.

Please review the Insurance certificate against the following checklist prior to submission

Checklist for Insurance Certificate	Please check
<p>Is the Insurance certificate from a reputable insurer?</p> <ul style="list-style-type: none"> Be wary of certificates from unusual places or from an insurer with an unusual name. 	Yes <input type="checkbox"/>
Does the certificate quote a policy number?	Yes <input type="checkbox"/>
Does the certificate specifically name the Australian entity (Sponsor / Local Sponsor) as the name insured?	Yes <input type="checkbox"/>
<p>Does the certificate show evidence that the policy will be current throughout the period of the clinical trial?</p> <ul style="list-style-type: none"> Insurance certificates are generally only for a 12 month period. If a trial straddles more than one period, the sponsor will need to be approached for an updated certificate prior to the expiry of the cover. 	Yes <input type="checkbox"/>
<p>Does the certificate specify the study name?</p> <ul style="list-style-type: none"> Where a certificate is for a specific trial, the Protocol/CTN number is not always shown (ie only the name of the trial is given). This is acceptable. Some certificates are not specifically for one trial, but for multiple clinical trials which are sponsored by a company. This is acceptable only if the risk of the trials is low. 	Yes <input type="checkbox"/>
Does the certificate contain insurance coverage for a minimum amount AUD\$10 million for any one occurrence and in the annual aggregate.	Yes <input type="checkbox"/>
A sponsor's insurance certificate will generally only cover the sponsor's responsibility in a trial (eg provision of drugs, confidentiality of information).	
Be aware of any restrictions (eg the cover excludes a trial in Australia)	

If the checklist highlights any of the details as incorrect, please inform the Sponsor and correct prior to submitting to SA Health for approval.