Insurance Services Guide

Indemnity Insurance for Research Projects/Clinical Trials

Review of Indemnity

Role and Responsibility of Human Research Ethics Committee

The relevant Human Research Ethics Committee (HREC) will consider any risks associated with the research project/clinical trial, and ensure that they are identified in the participant information sheet as appropriate, and appropriately acknowledged by the participant as part of the consent form.

In order for indemnity to be provided the consent form must include a statement that the participant acknowledges any risks outlined in the participant information sheet. The preferred format which researchers should be encouraged to use are the Standardised Participant Information and Consent Forms which can be found at: https://hrep.nhmrc.gov.au/toolbox/standardised-forms

Examples of acceptable clauses to be included in consent forms are:

- I understand the purposes, procedures and risks of the evaluation described in the research project/clinical trial.
- I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks as described within it.
- I have had the opportunity to ask questions, and the details of procedures and any risks have been explained to my satisfaction.

Role and Responsibility of Research Governance Officers

Research Governance Officers (RGOs) will collate the documents in relation to the research projects/clinical trials as part of the Site Specific Assessment (SSA) submissions. For Ethics approved research projects/clinical trials in which the Principal Investigator is an SA Health employee and conducting the research in the capacity of their employment, and there is no third party sponsor, the RGO can confirm the indemnity with the Principal Investigator.

It is the responsibility of the Principal Investigator/Researcher to identify in their application whether the research project/clinical trial is being conducted in the capacity of the SA Health employment, or outside their SA Health employment (e.g. as part of their employment with a University or SAHMRI, or for private studies). In the event that the research project/clinical trial is not undertaken as part of their SA Health employment they must provide external confirmation of indemnity for the research project/clinical trial, to the RGO. The RGO will ensure that acceptable confirmation of indemnity has been provided by the University or SAHMRI. Once this confirmation has been received the RGO can confirm indemnity for the Principal Investigator.

Third Party Sponsor Insurance Certificates

If a third party sponsor (e.g. pharmaceutical company) is involved, evidence of the third party's indemnity (certificate of currency) must also be submitted by the Principal Investigator to the RGO. The RGO will review the certificate of currency to confirm whether the indemnity provided by the Sponsor is acceptable.

It should be noted that evidence of indemnity (certificate of currency) is only required if a third party sponsor is involved. This is not a requirement for trial/projects with Grant Funding.

Please refer to attached Guideline regarding reviewing insurance certificates.

SA Health's Corporate Affairs is available to assist RGOs where necessary in complex cases, or where it is not clear if the insurance certificate meets the requirements.

Additional Information

SA Health Employment and Indemnity

Indemnity does not extend to research which an SA Health employee undertakes in their own time without the approval/support of SA Health, even if conducting the research on SA Health premises.

It is the responsibility of the principal investigator to determine and clarify if they are conducting the research 'within the capacity' of their SA Health employment. This is not based on what percentage of their employment is with SA Health or what percentage is with a University, or where the research is being undertaken, but whether conducting research is within the scope of their employment contract with SA Health and the research project/clinical trial is being conducted with the approval of SA Health.

For example, if a principal investigator is employed with a university 80% and SA Health 20%, and conducting research within their SA Health employment contract which is approved/supported by SA Health management, then they will be covered by SA Health indemnity arrangements.

Offsite Research

SA Heath employees will be indemnified for research projects/clinical trials conducted offsite at non SA Health premises (eg. at the university). It is important to note that the work being undertaken must be directly related to the SA Health research project/clinical trial, and being conducted in their role as the principal investigator under SA Health employment arrangements, for it to be covered offsite at non SA Health premises.

Sub-studies

Sub-studies which form part of a larger study will be indemnified (assuming all requirements for indemnity as outlined in this document have been met) if:

- The sub-study has been considered and approved by the HREC as part of the approval process; and
- The context of the study and supporting documentation does not vary from the initial study.

In the event that the sub-study has not been considered by the HREC as part of the approval process, ethics approval will be required together with a further review of indemnity.

Additional Sites

If a new site is being added to a previously HREC approved research project/clinical trial and the context of the study and supporting documentation is not altered, a further review of indemnity is not required. Indemnity will be extended to include the additional SA Health site.

Extensions and Exclusions to Indemnity Arrangements

- SA Health employees will be indemnified if:
    - They are involved in a HREC approved research project/clinical trial; and
    - Their involvement is approved as part of their SA Health employment.

  SA Health employees will also be indemnified if they are participating, as part of their SA Health employment, in a HREC approved research project/clinical trial which is being conducted by a University or SAHMRI (provided the University or SAHMRI has confirmed their indemnity for the trial).

- SA Health will indemnify university students for their involvement in SA Health initiated research project/clinical trials. This indemnity only applies in relation to any activity carried out directly in relation to the SA Health indemnified research project/clinical trial where:
    - the principal investigator is an SA Health employee conducting the research within the capacity of their employment; and
    - the university student is acting under the direct supervision of the SA Health employed principal investigator. This does not require the Principal Investigator to be present to monitor all tasks, but they are responsible for overseeing the trial/project and directing the university student in the research. It is expected the university student will report to the principal investigator and in conducing the research will comply with any SA Health guidelines and policies.
- SA Health indemnity does not extend to private organisations, and their employees.
- SA Health's indemnity and insurance arrangements will cover staff involved in research projects/clinical trials in the event of injury or death being caused by their negligence, but does not include cover for deliberate breaches of confidentiality, wilful misconduct, or the misuse of information, fraud or similar risks.
- SA Health indemnity does not extend to research projects/clinical trials conducted in an employee's private practice, unless they have a Rights of Private Practice (ROPP) Agreement in place, and the research project/clinical trial is within the scope of their ROPP Agreement. The indemnity applies to the SA Health employed principal investigator conducting the research in line with their approved ROPP only, and does not extend to employees of the private practice.
- SA Health indemnity only applies to the activities and procedures directly relating to the approved research project/clinical trial, and any standard of care procedures which would be provided to the patient/participant regardless of their involvement in the trial, are not covered by the research project/clinical trial indemnity. Therefore normal standard of care procedures performed outside of the public health system (eg. at a private hospital or practice) must be covered under the private organisation's insurance arrangements. If a private hospital or company is being paid to provide services in relation to a research project/clinical trial a Services Agreement should be in place between the Local Health Network and that organisation. If further clarification is required regarding the terms of a Services Agreement, a formal request for Legal Advice can be submitted to Legal Governance and Insurance Services at HealthLegalRequests@sa.gov.au

Any queries in relation to research projects/clinical trials should be directed to Corporate Affairs by the RGO at the following email:

Health.LGISResearchTrials@sa.gov.au

Guidelines for Reviewing Insurance Certificate/Certificate of Currency

- Name of Insured – This should be the name of the trial sponsor. Check details of the sponsor against SSA or NEAF. If the certificate identifies a different name of insured, then you should request a revised certificate be provided with the correct entity named. Alternatively, if the sponsor's name is correct on the certificate, the SSA may need to be updated.

- Level of Cover – Should be for an amount of not less than $10m, or if certificate of insurance is issued in another currency, then equivalent to $10m AUD.

  Sometimes a sponsor may hold more than one policy with different insurers, or a 'top up' policy. If the policies have a combined total limit of $10m AUD, this would be considered acceptable.

- There are different types of insurance policies and certificates which may be provided and considered acceptable. The certificate may vary depending on the type of trial.

  - Clinical Trials

    This may be general insurance certificate which covers clinical trials, or a certificate which has been issued for the specific trial and will list the trial name. If the insurance policy is specific to the trial, ensure the name of the study title on the insurance certificate correctly matches the name of the trial/study.

  - Products Liability

    "Products" includes goods sold, supplied and repaired. A products liability certificate may be provided if the trial involves trial for a type of equipment being supplied by the sponsor. Sometimes products liability will be a combined policy with public liability and this is considered acceptable.

  - Professional Indemnity/Medical Malpractice

    Provides cover for loss or injury arising from errors or omissions in the provision of health care services. Some medical malpractice policies will include cover for clinical trials.

  - Public Liability

    A general insurance which provides cover for bodily injury/property damage. Unless specifically listed as an inclusion, this would unlikely include cover for clinical trials, unless specifically listed as an inclusion to the policy

  - Other additional or top up policies

    Sometimes a sponsor may have more than one policy to provide the cover.

    An 'excess liability' policy provides additional limits above a primary liability policy. It provides the same level of cover as the primary policy, but where the limit of other

policies has been exhausted, this policy will pick up. For example a sponsor may have a products liability policy for $5m, and a further excess liability policy which includes products liability for $5m providing total cover of $10m cover.

An ‘umbrella liability’ is usually a policy which provides additional cover for claims that might not be covered under an existing policy. An example of this may be the addition of cover for clinical trials, to an existing medical malpractice policy which doesn’t already include this type of cover.

- Check the dates of the certificate of currency to ensure that it is current and valid.

There are some exceptions regarding dates which may be acceptable for insurance certificates which are for a specific trial:

- The trigger for the cover to commence is the starting date of the trial. If the starting date of the trial falls within the period of insurance listed on the insurance certificate, the insurance is considered acceptable.
- The certificate covers the life of the study and will usually state duration of the study; and certificate period.
- Whilst a certificate is issued within an underwriting year, that certificate may remain as valid proof of insurance for claims arising through the duration of the study.

Any queries in relation to insurance certificates provided for research projects/clinical trials should be directed to Corporate Affairs by the RGO at the following email:

Health.LGISResearchTrials@sa.gov.au