Purpose

This document outlines the minimum requirements for insurance and indemnity as per Chapter 5.1 of the *National Statement on Ethical Conduct in Human Research (2007 incorporating all updates).*

Definitions

Insurance: A policy taken out by an individual or individual organisation to cover their financial liabilities.

Indemnity: An indemnity is a promise by one party to another that it will cover a loss arising from an event that happens to the other party.

Clinical research: research involving human participants for health-related interventions, including drugs, devices, biologicals, surgical techniques, diagnostic and screening tests, therapy, education and care.

Non-clinical research: social and behavioural sciences, and non-interventional/non-therapeutic research

Guidance

Both Insurance and Indemnity are measures taken to guard against financial loss. Insurance is a policy taken out to cover the individual's or institution's risks or liabilities, and the insured pays a premium to transfer financial risk to another party. An indemnity is a contract between two parties in which one party agrees to cover a loss arising from an event that happens to the other party.

There must be insurance and indemnities in place to cover all studies:

All studies must have a local sponsor. The local sponsor of a trial must be an Australian company or entity.

For clinical trials:

- The local sponsor endorses the CTN application. A local sponsor may be:
  - An Australian Pharmaceutical company or an Australian subsidiary of an international pharmaceutical company.
  - A Corporate Research Organisation (CRO) who acts as the local sponsor in the event the entity/company is not an Australian resident.
  - An Australian collaborative research group.
  - An investigator (usually no sponsorship is provided).

For investigator initiated or non-sponsored studies, the investigator or their organisation takes the sponsor responsibilities.

Insurance

Any person or organisation who has involvement in human research and are therefore exposed to potential liabilities should be covered by an adequate insurance policy. Adequate insurance is appropriate for both clinical trials and non-clinical trials.

Both the sponsor of the study and the Principal Investigator need to have adequate insurance cover before the trial can proceed. Co-investigators are also required to have personal insurance cover. The investigator's professional indemnity cover must cover any gaps in any cover. Liabilities may arise from the

initiation or sponsorship of the research. These liabilities may include the development of the research protocol or the conduct of the research.

It is a requirement of all applications to Bellberry for the application form to outline which organisation is taking responsibility for insurance and indemnification. Before approving a study, Bellberry must be satisfied that arrangements exist to ensure adequate compensation to participants for any injury suffered as a result of their participation in a study. The Principal Investigator acknowledges this in the declaration stage of their application.

Sponsors must have a certificate of insurance (certificate of currency) which as a minimum must:

- Name the Australian entity acting as the sponsor as a named insured under the insurance policy.
- Provide evidence that the insurance covers the conduct of the relevant study in Australia.
- Be an insurer with approval by the Australian Prudential Regulatory Authority or a foreign insurer with a minimum credit rating of Standard and Poor's (or equivalent) of A- or higher.
- Provide evidence that the policy will be current throughout the entire period in which the study is conducted, including 6-7 years run-off insurance.
- Contain insurance coverage for a minimum amount of AUD$10 million for any one occurrence and in the annual aggregate. Each jurisdiction has different requirements, and the Sponsor and PI are responsible for ensuring the research has adequate coverage (NS5.1.38-39). Bellberry reserve the right to review the insurance arrangements.
- In the event the trial concerns a registered product then include products liability.
- Ensure that care be taken with medical device trials as ongoing liability may be required to ensure cover is provided for the ongoing treatment risk.
- Cover no-fault liability. When there is no evidence of negligence or product cause for the injury, this recognises that were it not for the participants' participation in the trial there would be no injury.

Indemnities

Sponsors must also have indemnities in place to cover the study. Indemnities are required for all studies, not just clinical trials. There are two types of indemnities;

- the standard indemnity between the sponsor and the Principal Investigator/site, and
- the HREC indemnity between the sponsor and the HREC.

It is the responsibility of the sponsor, or the entity taking on the responsibilities of the sponsor, to provide the HREC indemnity to the HREC (National Statement on Ethical Conduct in Human Research 5.1.9).

Indemnities must be in a form no less favourable than the current Medicines Australia (MA) or the Medical Technology Association of Australia (MTAA) Form of Indemnity.

Bellberry has modelled a non-clinical HREC Indemnity template (BA F15.1.4) on the Medicines Australia template. Parties utilising the Indemnity must note that the document is not a Medicines Australia approved standard template. The indemnity can also be used for social science studies.

Bellberry will consider amendments to the template that are relevant to the research study or an alternative can be provided.

The Standard and HREC indemnities must name the local commercial Sponsor, ensuring the Sponsor is an Australian corporate entity. Please note that if a CRO or local entity is providing the indemnity, it is not acceptable for the indemnity to be from the CRO or local entity as an agent of the overseas company. The CRO or local entity must be providing the indemnity in their own right.

The HREC Indemnity must include:

- Bellberry Limited as the 'Indemnified Party' ensuring the correct address and ABN of Bellberry Limited is stated.

  Bellberry Limited *(not Bellberry HREC)*
  123 Glen Osmond Rd, Eastwood SA 5063
  ABN: 16 109 019 730

- The title of the research to be conducted.
- The name of the investigator(s).
- The ABN of the indemnifying entity.
- The Principal Investigator or their organisation as the indemnifying party if the study is investigator initiated/non sponsored.
- The signature of the duly authorised representatives of both parties.

Please note the following:

Bellberry must view and agree to any changes to the standard clauses within the indemnity templates agreement before execution.

The Bellberry details are completed in the templates relevant to the study type (BA F15.1.2 Clinical, BA F15.1.3 Device and BA F15.1.4 Non-Clinical).

Please do not complete any fields for the Bellberry signatory as there are multiple people delegated this responsibility.

Bellberry accepts both electronic and hard copy indemnities. If you wish to send the indemnity via an electronic platform such as DocuSign or AdobeSign, and the study is multi-centre, please only list the sites that are ready to submit or will submit before lead site approval. Bellberry will return the indemnity to amend the listed additional sites. For paper copies, we will strike and initial these changes before executing the document.

Bellberry does not accept scanned copies of the HREC indemnity with either an electronic signature or wet ink signature. As the indemnity is a legal document, both parties must sign the original document.

Please email electronic indemnities to bellberry@bellberry.com.au.

Please email TrinaODonnell@bellberry.com.au if your company requires the document to be emailed to an individual, and not a generic mailbox. Please ensure that bellberry@bellberry.com.au is cc'd to this email.

Non-sponsored studies

Insurance and indemnities are required for non-sponsored studies. If a study is non-sponsored, the Standard Indemnity is not required. However, the HREC indemnity will be required to be provided by the entity that is taking on sponsor requirements. The sponsor may be the investigator or organisation conducting the study.

The Bellberry Operations Manager or CEO reserve the right to review the insurance and indemnity for any high-risk non-sponsored study. Bellberry may seek insurance advice before any granting any approvals.

Low-risk studies

Insurance and indemnities are required for low risk studies, whether sponsored or non-sponsored. Where necessary, Bellberry may seek insurance advice before granting any approvals.

References

National Statement on Ethical Conduct in Human Research (2007 incorporating all updates)

Medicines Australia (MA) Form of Indemnity

Medical Technology Association of Australian (MTAA) Form of Indemnity

BA F1.1.1 Submission requirements checklist

BA F15.1.1 Insurance and indemnity FAQs

BA F15.1.2 MA Clinical HREC Indemnity 1 October 2012

BA F15.1.3 MTAA Device HREC Indemnity 8 April 2010

BA F15.1.4 Bb Non-Clinical HREC Indemnity