Insurance for Clinical Trials

Phase I, II and III Clinical Trials:

As a general rule, from the perspective of providing coverage, the indemnity and insurance arrangements in the public and private sectors treat clinical trials uniformly; in other words, indemnity and insurance arrangements do not distinguish between clinical trials on the basis of the phase of the trial.

For **Phase I, II and III clinical trials**, a HREC Review Only Indemnity and Standard Indemnity (if applicable) must be provided.

To comply with the minimum insurance requirements, sponsored research must provide a copy of the certificate of currency (or insurance certificate) which contains the following information:

- Full Study Title
- The type of insurance – Public and Product Liability – or equivalent such as General Liability or Clinical Trials Insurance
- The full legal name of the Australian entity acting as the sponsor
- The full legal name of the insurer (which must be approved by the Australian Prudential Regulation Authority or a foreign equivalent). All insurers are required to hold Standard & Poor's financial rating of not less than 'A-'.
- The period of insurance
- That the insurance coverage allows for a minimum of AUD$10 million for any one occurrence and in the annual aggregate
- That the insurance coverage contains an excess/deductible, or self-insured retention amount is LESS than AUD$25,000 for each and every claim or series of claims arising out of one original cause.

Post Marketing Study /Phase IV Clinical Trials:

Insurance covering the study for **Post Marketing Study /Phase IV Clinical Trials** is not required however, general insurance covering the Sponsor Company will need to be provided.

Indemnity:

Sponsors Obligations and Responsibilities regarding Indemnity is outlined under section 5.8 of the CTRA Phase 4 Clinical Trial (Medicine) and CTRA Phase 4 Clinical Trial (Medicines – Contract Research Organisation acting as Local Sponsor).

A HREC Review Only Indemnity (not a Standard Form of Indemnity) is required to be provided for all Post marketing studies and Phase IV Clinical Trials.

Authorized by:

Dr Megan Robertson
Director of Research