Clinical Trial Research Agreement

New Zealand Association of Clinical Research:
Contract Research Organisation acting as the Local Sponsor

Important Notice

Clauses 5.8 to 5.10 of the Clinical Trial Research Agreement (CTA) for a Clinical Research Organisation (CRO) acting as local sponsor, state that:

5.8 The CRO (defined as the Local Sponsor) or sponsor (defined as the Organisation) are to provide an indemnity to the Institution on the standard terms as set out in Schedule 3.
5.10 The CRO is to maintain insurance, or ensure that it is a named insured under the Organisation's insurance policy, with respect to its activities and indemnity obligations.

These clauses are adapted from the Medicines Australia Clinical Trial Research Agreements. However, underpinning the Australian version of the Agreements are the Clinical Trial Insurance and Risk Management Guidelines mandated by the statutory insurers now established in Australia to cover hospitals and state employed clinicians for medical risk, including within clinical trials. These Guidelines are very specific. They require that the counter party to the CTA must be an Australian corporate and the insurance provided must be with an Australian insurer and for a minimum level of AUD10 million for any commercially sponsored trial.

These requirements have not been transferred to New Zealand. While there is a requirement for compensation to be available to at least ACC-equivalent standard (Standard Operating Procedures for Health and Disability Committees, May 2012, Clauses 145-150), there is no equivalent requirements to those mandated in Australia. We have therefore become aware of situations where a shell company has been set up in New Zealand to be the Local Sponsor. Such a company provides no comfort commercially as to its ability to meet the sponsor's obligations in the CTA. As in Australia, this makes it critical that in these circumstances the insurance arrangements are robust and it is confirmed that the policy will indemnify the local sponsor where the indemnity crystallises. It is vital, therefore in the case of contracts with a CRO,that the site satisfies itself that the Local Sponsor/CRO has adequate insurance cover in its own name for that study or is expressly covered by the sponsor's insurance. Note: It is the responsibility of the site to check this - clause 147, Health and Disability Ethics Committees, Standard Operating Procedures for Health and Disability Ethics Committees)

An alternative, favoured by Auckland DHB, is that the I&CA is provided by the sponsor where the sponsor's insurance is being offered as this ensures a direct contractual claim against that policy.

29 July 2014

Bruce Northey
Auckland District Health Board
Phone: +64 9 630 9943, ext: 26876
Mobile: 021 938 104