Guidance and Checklist – Forms of Indemnity

Overview

Medicines Australia (MA) and the Medical Technology Association of Australia (MTAA) have two standard forms of indemnity in relation to clinical trials.

a) Where the Study is to be conducted at the site, whether or not the Reviewing HREC is CALHN HREC, the commercial sponsor must provide an indemnity in the form of 'Form of Indemnity for Clinical Trials: Standard' in favour of CALHN.
b) Where CALHN HREC is the Reviewing HREC under National Mutual Agreement (NMA), the commercial sponsor must provide an indemnity in the form of 'Form of Indemnity for Clinical Trials: HREC review only' in favour of CALHN.

These forms are available for download on the respective websites located here for Medicines Australia (MA), and here for Medical Technology Association of Australia (MTAA).

The indemnities referred to above must be given by an Australian corporate entity. This may be:
a) an Australian company;
b) an Australian company that is subsidiary of an overseas parent company; or
c) an Australian contract research organisation (CRO) that has been engaged by an overseas or Australian company to conduct the trial in Australia.

It is not acceptable for an indemnity to be provided by any company as an agent of an overseas entity; that is, the commercial sponsor must provide the indemnity in its own right.

Checklist

<table>
<tr><th>For both "Standard" and "HREC Review Only" agreements</th><th>Yes</th><th>No</th></tr>
<tr><td>Is the Indemnified Party details as below?
Central Adelaide Local Health Network Incorporated
ABN 96 269 526 412
Royal Adelaide Hospital
Port Road, Adelaide, SA 5000</td><td>☐</td><td>☐</td></tr>
<tr><td>Has the full legal name and ABN of the Sponsor been provided?</td><td>☐</td><td>☐</td></tr>
<tr><td>Are the Study title and Protocol number correct?</td><td>☐</td><td>☐</td></tr>
<tr><td>Clause 1: Has the correct patient group (patients of the Indemnified Party or non-patient volunteers) been selected?</td><td>☐</td><td>☐</td></tr>
<tr><td>Clause 1: Has the correct Principal Investigator name been inserted for "the Investigator" with the correct title?</td><td>☐</td><td>☐</td></tr>
<tr><td>For HREC Review Only under NMA:
1. The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving study participants from the following sites ("the Participants") to be conducted by the named Principal Investigators ("the Investigators")
<table><tr><th>Participants</th><th>Investigators</th></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table>in accordance with the above referenced protocol, as amended in writing from time to time with the agreement of the Sponsor and the Indemnified Party ("the Protocol"). The Sponsor confirms that it is a term of its agreement(s) with each hospital or institution participating in the Study that the Investigator shall obtain all necessary approvals from the Indemnified Party's human research and ethics committee ("HREC").</td><td>☐</td><td>☐</td></tr>
<tr><td>For HREC Review Only under NMA
Have you checked that all sites have been approved by the Reviewing HREC?
Any private sites will require an External Entities Agreement.</td><td>☐</td><td>☐</td></tr>
<tr><td>Have you checked clauses 2 to 10 have not been altered from the MA or MTAA template?</td><td>☐</td><td>☐</td></tr>
</table>