

Introduction

The following HREC indemnity template has been developed for non-clinical studies, noting the standard HREC indemnity template provided by Medicines Australia may not be suitable. Please note, the source document for this template is the Medicines Australia HREC only form of indemnity template. This template is not a Medicines Australia approved document.

Definitions

Non-clinical research: Social and behavioural sciences, observational and non-interventional/non-therapeutic research.

Instructions for use

Please copy and paste the template (starting on page 2) into your own working document and save the document using an appropriate file name, e.g. "HREC Indemnity [Application ID]". Please ensure the relevant fields are complete (highlighted in yellow – please remove highlighting once complete) and the document is dated and signed. Further guidance can be found in BA G15 Insurance & Indemnity Guidance.

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For use where the Indemnified Party is providing ethical review for a [insert as relevant] where the ethical review will be adopted by [insert as relevant] that are independent from the Indemnified Party, **OR** as a Reviewing HREC for a single center study at an institution that is independent from the Indemnified Party.

To: Bellberry Limited
Level 1, 196 Greenhill Road, Eastwood, SA 5063
ABN: 16 109 019 730
("the Indemnified Party")

From: [Name, registered address and Australian Business Number of the sponsoring company] ("the Sponsor")

Re: Study No. [...], [protocol title including name of product]

1. The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving ("the Participants") to be conducted by ("the Investigators") in accordance with the 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 the Institution participating in the Study that the Investigators shall obtain all necessary approvals from the Indemnified Party's human research and ethics committee ("HREC").
2. The Indemnified Party agrees to participate by making its HREC available to provide review, approval and oversight of the conduct of the Study in accordance with the requirements of the *NHMRC National Statement on Ethical Conduct in Human Research (2023)*.
3. In consideration of such participation by the Indemnified Party, subject to paragraph 4, the Sponsor indemnifies and holds harmless the Indemnified Party and its employees, agents and members of and advisors to its HREC in respect of and against all claims and proceedings (including any settlements or *ex gratia* payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise) by or on behalf of Participants against the Indemnified Party or any of its employees, agents or members of and advisors to its HREC for personal injury (including death) to Participants arising out of or relating to the Protocol to which the Participants would not have been exposed but for the participation of the Participants in the Study.
4. The above indemnity by the Sponsor will not apply to any such claim or proceeding referred to in paragraph 3:
 - (1) to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Indemnified Party or any of its employees, agents or members of or advisors to the HREC;
 - (2) unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Indemnified Party notifies it to the Sponsor in writing and at the Sponsor's request, and cost, has permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing; or
 - (3) if the Indemnified Party, its employees, agents, or members of and advisors to its HREC have made any admission in respect of any such claim or proceeding or taken any action relating to any such claim or proceeding prejudicial to the defence of any such claim or proceeding without the written consent of the Sponsor. Such consent will not be unreasonably withheld. This condition will not be treated as breached by any statement properly made by members of and advisors to the HREC in connection with the operation of the Indemnified Party's internal complaint procedures, accident reporting and quality assurance procedures or disciplinary procedures or where such statement is required by law.

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Bellberry Non-Clinical HREC Indemnity

5. The Sponsor will keep the Indemnified Party and its legal advisers fully informed of the progress of any such claim or proceeding, consult fully with the Indemnified Party on the nature of any defence to be advanced and not settle any such claim or proceeding without the written approval of the Indemnified Party which approval is not to be unreasonably withheld.
6. Without prejudice to the provisions of paragraphs 4(2) and 4(3), the Indemnified Party will use reasonable endeavors to inform the Sponsor promptly of any circumstances of which it has knowledge and which may reasonably be thought likely to give rise to any such claim or proceeding and will keep the Sponsor informed of developments in relation to any such circumstances even where the Indemnified Party decides not to claim indemnity from the Sponsor. Likewise, the Sponsor will use reasonable endeavors to inform the Indemnified Party of any such circumstances and will keep the Indemnified Party informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
7. The Sponsor and the Indemnified Party will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of a Participant.
8. Without prejudice to the foregoing, if injury is suffered by a Participant while participating in the Study, the Sponsor agrees to adhere to the Guidelines relating to the Study, having regard to the protocol and will request the Investigators to make clear to the Participants that the Study is being conducted subject to those Guidelines.
9. For the purpose of this indemnity, the expression "agents" is deemed to include, but is not limited to any health professional providing services to the Indemnified Party under a contract for services or otherwise.
10. This indemnity will be governed by and construed in accordance with the laws applicable in the State or Territory in which the Indemnified Party is established.

DATED the [] day of [] in the year [].

SIGNED by a duly authorised representative of the Sponsor who certifies that they have authority to sign on behalf of the Sponsor

.....
(Signature)

.....
(Name)

.....
(Position)

SIGNED by the Chief Executive or a duly authorised representative of the Indemnified Party

.....
(Signature)

.....
(Name)

.....
(Position)

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