MEDICINES AUSTRALIA FORM OF INDEMNITY FOR CLINICAL TRIALS

HREC REVIEW ONLY

For use where the Indemnified Party is providing ethical review for a multicentre clinical Study where the ethical review will be adopted by hospitals, institutions or sites that are independent from the Indemnified Party, **OR** as a Reviewing HREC for a single centre study at a hospital or institution that is independent from the Indemnified Party.

NOTE there is a different Form of Indemnity for use where the Indemnified Party is providing premises for the conduct of the Study and HREC Review, **or** is providing premises only [The STANDARD Form of Indemnity]

This Form has been developed by Medicines Australia and is an adaptation of the form used by The Association of the British Pharmaceutical Industry (ABPI), for use in Australia. It is to be regarded as the basis for agreements between pharmaceutical companies sponsoring clinical studies and the institution that has oversight of the study to be conducted. Non-members of Medicines Australia are encouraged to use this Form of Indemnity.

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 sponsoring company] ("the Sponsor")**

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

1. The Indemnified Party agrees to participate in the above sponsored study ("the Study") involving [{patients of [name of hospital(s), institution(s) or site(s)]} {non-patient volunteers}] ("the Participants") to be conducted by [name of investigator(s)] ("the Investigator") 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").

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.*

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 (including their dependants and children injured *in utero* through the participation of the child's mother or father in the Study) 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 (and children injured *in utero* through the participation of the child's mother or father in the Study) arising out of or relating to the administration and/or use of the product(s) under investigation or any clinical intervention or procedure provided for or required by 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.

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 Participants (including their dependants and children injured in utero through the participation of the child's mother or father in the Study).

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 for Compensation for Injury Resulting From Participation in a Company-sponsored Clinical Trial" published by Medicines Australia and will request the Investigator 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)