**MEDICAL TECHNOLOGY ASSOCIATION OF AUSTRALIA**
**FORM OF INDEMNITY FOR CLINICAL INVESTIGATIONS**

**HREC REVIEW ONLY**
(For use where the Indemnified Party is providing HREC review ONLY of the Study)

*This Form has been developed by the Medical Technology Association of Australia (MTAA) and is an adaptation of the form developed by Medicines Australia, for use in Australia. It is to be regarded as the basis for agreements between medical technology companies sponsoring clinical investigations and the institution that has oversight of the study to be conducted. Non-members of MTAA are encouraged to use this Form of Indemnity.*

**To:** **[Name and address of the legal entity (hospital, institution or authority) which is providing HREC review only of the Study] ("the Indemnified Party")**
**Only a single legal entity should be named. Where more than one legal entity is to be indemnified, separate Forms of Indemnity should be used for each legal entity to be indemnified.**

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

**Re:** **Clinical Investigation Plan No. [ ], [Clinical Investigation Plan title including name of product]**

1 The Indemnified Party agrees to participate in the above sponsored clinical investigation ("the Study") involving [{patients of [name of hospital, institution or site]} {non-patient volunteers}] ("the Participants") to be conducted by [name of investigator(s)] ("the Investigator") in accordance with the clinical investigation plan annexed, as amended in writing from time to time with the agreement of the Sponsor and the Indemnified Party ("the Clinical Investigation Plan"). The Sponsor confirms that it is a term of its agreement with the Investigator that the Investigator shall obtain all necessary approvals from the applicable Human Research Ethics Committee ("HREC") and the Indemnified Party, where appropriate.

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 (2025 or its replacement)*.

3 In consideration of such participation by the Indemnified Party, subject to paragraph 4 below, 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 dependents and children injured *in utero* through the participation of the child's mother 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 in the Study) arising out of or relating to the use of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Clinical Investigation Plan 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 above:

4.1 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.

4.2 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.

4.3 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 paragraph 4(2) and 4(3) above, the Indemnified Party will use reasonable endeavours 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 endeavours 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 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 Investigation” published by MTAA and will request the Investigator to make clear to the Participants that the Study is being conducted Participant 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

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(Signature)

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(Position)

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

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(Signature)

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(Position)