

## Queensland Health Indemnity

### A PRO FORMA MEDICINES AUSTRALIA (formerly known as APMA) FORM OF INDEMNITY FOR CLINICAL TRIALS

*This Form has been developed by Medicines Australia (formerly the Australian Pharmaceutical Manufacturers Association (APMA)) 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 Queensland Health institution or authority in which the study is to be conducted, and may be incorporated in a more general agreement and/or modified to suit particular circumstances.*

**FROM:** *(Name and address of Sponsor or Contract Research Organisation) ("the Sponsor")*

**TO:** The State of Queensland acting through Queensland Health (Via the Princess Alexandra Hospital) ("The Authority")

**RE:** *(Full title of clinical trial/research study in question, including all Sponsor codes/numbers, protocol numbers etc.)*

1. The Authority agrees to participate in the above sponsored study ("the Study") involving (patients of the Authority)/(non-patient volunteers) ("the Subjects") to be conducted on behalf of the Authority by (name of principal investigator) ("the Investigator") in accordance with the protocol annexed, as amended in writing from time to time with the agreement of the Sponsor and the Authority ("the Protocol"). The Sponsor confirms that it is a term of its agreement with the Authority that the Principal Investigator shall obtain all necessary approvals from the applicable Ethics Committee and the Authority, where appropriate. The Authority confirms that it is a term of its agreement with the Sponsor that the Authority accepts the revenue arrangements specified in [insert name of document which specifies cost-payment issues] and confirms that the Authority will liaise with the Investigator on any revenue issues.
2. The Authority agrees to participate by allowing the Study to be undertaken on its premises or as otherwise agreed, utilising such facilities, personnel and equipment as may reasonably be required for the Study.
3. In consideration of such participation by the Authority, subject to paragraph 4 below, the Sponsor indemnifies and holds harmless the Authority and its employees and agents (see paragraph 9) 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 Subjects taking part in the Study (or their dependants) against the Authority or any of its employees or agents for personal injury (including death) to Subjects arising out of or relating to the administration of the product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Subjects would not have been exposed but for the participation of the Subjects in the Study.
4. The above indemnity by the Sponsor shall 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 Authority, its employees or agents.
  - 4.2 to the extent that such personal injury (including death) is caused by the failure of the Authority, its employees, or agents to conduct the Study strictly in accordance with the Protocol.
  - 4.3 unless, as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Authority notifies it to the Sponsor in writing and at the Sponsor's request, and cost, have permitted the Sponsor to have full care and control of the claim or proceeding using legal representation of its own choosing.
  - 4.4 If the Authority, its employees, or agents shall have made any admission in respect of such claim or proceeding, or taken any action relating to such claim or proceeding prejudicial to its defence, without the written consent of the Sponsor. Such consent shall not be unreasonably withheld. This condition shall not be treated as breached by any statement properly made by the Authority, its employees or agents in connection with the operation of the Authority's internal complaint procedures, accident reporting procedures or disciplinary procedures or where such statement is required by law.
5. The Sponsor shall keep the Authority and its legal advisers fully informed of the progress of any such claim or proceeding, consult fully with the Authority on the nature of any defence to be advanced and not settle any such claim or proceeding without the written approval of the Authority, which approval is not to be unreasonably withheld.
  6. Without prejudice to the provisions of paragraph 4.3 and 4.4 above, the Authority shall 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 shall keep the Sponsor informed of developments in relation to any such circumstances even where the Authority decides not to claim indemnity from the Sponsor. Likewise, the Sponsor shall use reasonable endeavours to inform the Authority of any such circumstances and shall keep the Authority informed of developments in relation to any such claim or proceeding made or brought against the Sponsor alone.
  7. The Authority and the Sponsor shall 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 Subjects (or their dependants).
  8. Without prejudice to the foregoing, if injury is suffered by a Subject 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 (formerly APMA) and shall request the Investigator to make clear to the subjects that the study is being conducted subject to these 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 Authority under a contract for services or otherwise, any member of or adviser to the Ethics Committee reviewing the Study on behalf of the Authority, and any person carrying out activities for the Authority under a contract connected with such of the Authority's facilities and equipment as are made available for the Study under paragraph 2 above.
  10. This indemnity shall be governed by and construed in accordance with the law of the State of Queensland.

**DATED** the \_\_\_\_\_ day of \_\_\_\_\_ 2004

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**SIGNED** by a duly authorised representative of the Sponsor

.....  
(Signature)

.....  
(Name and Position)

**In the presence of:**

.....  
(Witness signature)

.....  
(Witness name)

.....  
Date

**SIGNED** for and on behalf of The state of Queensland through Queensland Health (via the Princess Alexandra Hospital) by a duly authorised representative

.....  
(Signature)

.....  
Deb Podbury, District Manager

**In the presence of:**

.....  
(Witness signature)

.....  
(Witness name)

.....  
Date