

This Confidentiality Agreement is dated

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between

[insert full corporate name, ABN and address of Sponsor] ("the 1st Party")

and

The Minister for Health is incorporated as the board of Royal Perth Hospital (ABN 13 993 250 709) of Wellington Street, Perth, WA 6000, under s7 of the *Hospitals and Health Services Act 1927* (WA) and has delegated all the powers and duties as such to the Director General of Health ("**the 2nd Party**")

1. INTERPRETATION

(a) In this Agreement:

Agreement means this Agreement,

Confidential Information means:

- A. information which is by its nature confidential;
- B. information which is specified by a party to be confidential;
- C. information which a party knows or ought to know is confidential;
- D. patient information;
- E. Personal Information;
- F. the Protocol and information relating to the Protocol and Investigational Product;
- G. information, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Institution or the Sponsor as the case requires; and
- H. know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study;

Institution means Royal Perth Hospital

Investigational Product is the medicine, device or technique being tested in the Study.

Personal Information has the same meaning as in the *Privacy Act 1988 (Cth)*.

Personnel means officers, employees, contractors, agents and/or authorised representatives and includes in the case of the 2nd Party, the principal investigator and sub-investigator proposed for the Study

Protocol means the document describing the objective(s), design, methodology, statistical considerations and organisation of the Study.

Recipient means the party receiving Confidential Information

Study means the investigation to be conducted in accordance with the Protocol.

- (b) Except where the context otherwise requires:
 - (i) clause headings are for convenient reference only and are not intended to affect the interpretation of this Agreement;
 - (ii) where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;
 - (iii) any reference to a person or body includes a partnership and a body corporate or body politic;
 - (iv) words in the singular include the plural and vice versa;
- (c) This Agreement may be executed in any number of counterparts. All of such counterparts taken together are deemed to constitute one and the same Agreement.

2. CONFIDENTIALITY

- (a) Subject to sub-clauses (b) and (c), a party must not disclose any Confidential Information given to it by the other party, other than where and only to the extent disclosure is strictly necessary for the performance of the Study.
- (b) The 2nd Party may disclose the Confidential Information in any of the following circumstances:
 - (i) for the purposes of complying with the requirements of any regulatory authority;
 - (ii) for the purposes of the monitoring of the Study by the Responsible HREC;
 - (iii) where the 1st Party consents in writing to the disclosure;
 - (iv) where the Confidential Information has been independently received from a third party who is free to disclose it;
 - (v) where the Confidential Information has entered the public domain other than as a result of a breach of this Agreement;
 - (vi) as part of an a publication approved by the 1st Party;
 - (vii) where release of the Confidential Information is required by law or pursuant to an order of a Court or Tribunal;
 - (viii) for the purpose of obtaining legal and other professional advice where such advisors are bound by obligations of confidentiality;
 - (ix) to the Institution's insurer; and
 - (x) to Parliament (including committees of it), and Ministers of the Crown.
- (c) The 1st Party may disclose the 2nd Party's Confidential Information in any of the following circumstances:

- (i) subject to 2(c)(ii), to the Investigational Product manufacturer and any study related vendors.
 - (ii) where the Institution consents in writing to the disclosure;
 - (iii) where the Confidential Information has been independently received from a third party who is free to disclose it;
 - (iv) where the Confidential Information has entered the public domain other than as a result of a breach of this Agreement;
 - (v) subject to 2(c)(ii), for the purpose of obtaining legal and other professional advice where such advisors are bound by obligations of confidentiality; and
 - (vi) to the 1st Party's insurer.
- (d) Both parties may disclose Confidential Information of the other party to the extent required by applicable laws or regulations or as ordered by a court or other regulatory or government authority; provided however, that receiving party shall:
- (i) provide prior written notice to the 1st Party, provided that it is lawful to do so
 - (ii) only disclose the minimum amount of Confidential Information required to be disclosed in order to comply, and
 - (iii) use best endeavours to make any applicable claim of confidentiality in respect thereof to the extent commercially reasonable.
- (e) The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of this Agreement.

3. PRIVACY

The 1st Party must ensure that any Personal Information arising from the Study regarding Study subjects, is collected, stored, used and disclosed in accordance with the *Privacy Act 1988 (Cth.)* or such other legislation, code or guideline which applies in Western Australia and which relates to the protection of personal information

4. APPLICABLE LAW

This Agreement is governed by the laws of the State of Western Australia. The parties irrevocably submit to the exclusive jurisdiction of the courts of Western Australia.

5. MISCELLANEOUS

- (a) Both parties agree that a breach of this Agreement may cause irreparable harm to the other party for which monetary damages would not adequately compensate and that, in addition to other remedies it may have available at law or equity, the disclosing party shall be entitled to injunctive relief for such breach.
- (b) Upon termination of this Agreement or at any other time the disclosing party requests, the 2nd Party will, subject to compliance with any legal requirements,

transmit to the 1st Party any written, printed or other materials embodying such information, including all copies, excerpts thereof, and samples given to the 2nd Party or prepared by the 2nd Party in connection with the 2nd Party's evaluation and participation under this Agreement.

- (c) Acceptance of this Agreement shall not carry with it any express or implied grant of any right or license to Recipient of any trademark, invention, copyright or patent of either party.

6. TERM

- (a) **Effective Date.** The Effective Date of this Agreement shall be the last date on which a party executes this Agreement.
- (b) **Expiration of Agreement.** The ability to exchange Confidential Information under this Agreement shall terminate five (5) years after the Effective Date, and the Agreement will pertain to any and all Confidential Information disclosed to the Receiving Party by or on behalf of the Disclosing Party during the term of this Agreement.

Executed as an agreement:

Signed on behalf of the **1st Party**

Signed:

Name:

Position:

Date:

Signed on behalf of the **2nd party**
by

Signed:

Name:

Position:

Date:

for and on behalf of the Director General of Health as delegate of the Minister for Health