

INDEMNITY

Date: _____

PARTIES

- (1) Waikato District Health Board ("WDHB")
- (2) _____ ("Investigator")
- (3) _____ ("Sponsor")

BACKGROUND

- A WDHB and the Sponsor have entered into a Clinical Study Agreement ("Clinical Study Agreement") under which WDHB has appointed the Investigator as the principal investigator for [] (the "Clinical Study").
- B The Sponsor has agreed to indemnify, and keep indemnified, the Investigator, WDHB and its employees and agents in respect of the Clinical Study.

The parties agree as follows:

1 DEFINITIONS

1.1 In this agreement:

"Protocol" means the protocol attached to or referred to in the Clinical Study Agreement;

"Subjects" means a patient of WDHB (and where relevant that patient's in utero child or children except for the purposes of clause 3.1(b) where an in utero child or children will not be a Subject) who is participating in the Clinical Study;

2 INDEMNITY

2.1 In consideration of WDHB's and the Investigator's participation in the Clinical Study, the Sponsor indemnifies WDHB, the Investigator, and WDHB's employees and agents (together *Indemnitees*):

- (a) against all losses, costs, expenses and liability arising directly or indirectly from any claims, proceedings or demands (including any reasonable legal and expert costs and expenses on a solicitor and own client basis) threatened, made or brought, whether successfully or otherwise, by or on behalf of a Subject (or that Subject's dependants or parents) or any third party against the Indemnitees (or any of them) arising out of or relating to the Clinical Study (*Loss*); and
- (b) for any losses, costs, expenses or liability the Indemnitees (or any of them) have suffered as a result of their participation in the Clinical Study.

3 **LIMITATIONS ON INDEMNITY**

3.1 The indemnity by the Sponsor set out in clause 2 will not apply to a claim, proceeding or demand:

- (a) to the extent that the Loss has been materially caused by the intentionally wrongful acts or omissions of the Indemnitees;
- (b) if solely in respect of the circumstances giving rise to the claim, proceeding or demand, the Indemnitees did not strictly comply with laws and regulations applicable to the Clinical Study, or failed to secure written informed consent from the relevant Subject;
- (c) if the Indemnitees have, without the Sponsor's consent, made an admission in respect of such claim, proceeding or demand which materially and adversely affects the grounds available to defend the claim, proceeding or demand (except where such admission is in connection with WDHB's internal complaint procedures, accident reporting procedures, disciplinary procedures or any other similar internal procedure or where such statement is required by law).

3.2 Notwithstanding anything in clause 3.1, no Indemnitee will lose the right of indemnity set out in clause 2 solely by reason of another Indemnitee's action or inaction pursuant to any of the provisions of clause 3.1(a) to (c).

4 **CLAIMS ARISING FROM THE CLINICAL STUDY**

WDHB will use reasonable endeavours to inform the Sponsor promptly of any circumstances thought likely to give rise to any claim, proceeding or demand relating to the Clinical Study.

5 **ASSISTANCE**

The Sponsor and WDHB will give each other such assistance as may be reasonably required by the other for the efficient conduct and prompt handling of any claim, proceeding or demand relating to the Clinical Study.

6 **CARE AND CONTROL**

At the Sponsor's written request and subject to the Sponsor having first confirmed to WDHB in writing that it will meet any Loss or other liability of the Indemnitees arising from the claim, proceeding or demand, WDHB will permit, and WDHB will use reasonable endeavours to procure its employees and agents to permit, the Sponsor (at the Sponsor's cost) to have full care and control of any claim, proceeding or demand relating to the Clinical Study.

7 **SPONSOR TO INFORM WDHB**

The Sponsor will inform WDHB of any circumstances thought likely to give rise to any claim, proceeding or demand relating to the Clinical Study or any similar study being conducted elsewhere in the world. The Sponsor will keep WDHB and its legal advisers fully informed of any developments in relation to any claim, proceeding or demand relating to the Clinical Study (or other similar study), and will consult with WDHB on the nature of any defence to be advanced in respect of the Clinical Study.

8 **SETTLEMENT**

The Sponsor will not settle any claim, proceeding or demand relating to the Clinical Study without the prior written approval of WDHB. The Sponsor will

ensure that any settlement will be in full and final settlement and preclude any further claim, proceeding or demand against the Indemnitees.

9 **INSURANCE**

The Sponsor will effect and maintain, for the duration of the Clinical Study and thereafter for a period agreed in writing with WDHB, (and failing agreement for a period of at least five (5) years) insurance to cover the risks and liabilities that it will be called upon to make payments in respect of the Indemnitees described in clause 2. At WDHB's request and at such times as WDHB may require, the Sponsor will provide WDHB with a certificate from its insurers certifying that the insurance is in full force and effect.

10 **COMPENSATION**

Without prejudice to the above, the Sponsor will follow the principles of, and will provide compensation to, Subjects in accordance with the guidelines published by the Researched Medicines Industry Association of New Zealand Inc. (the "RMIANZ Guidelines"), except where compensation is provided for under the Injury Prevention, Rehabilitation and Compensation Act 2001.

11 **AGENTS**

For the purpose of this agreement, the expression "agents" will be deemed to include, without limitation, any nurse, other health professional or any other person providing services to or for or on behalf of WDHB under a contract for services or otherwise.

12 **CONTRACTS PRIVACY ACT 1982**

The parties acknowledge, for the purpose of the Contracts (Privity) Act 1982, that this Indemnity contains provisions that confer benefits on, and are intended to be enforceable by, Subjects and Indemnitees.

13 **APPLICATION OF NEW ZEALAND LAW**

This Indemnity will be governed by and construed in accordance with New Zealand law and the courts of New Zealand will have non-exclusive jurisdiction in any proceedings relating to it.

Signed for and on behalf of
**WAIKATO DISTRICT HEALTH
 BOARD**

in the presence of:

Name:

Occupation:

Address:

Signed by DR [_____]

in the presence of:

Name:

Occupation:

Address:

Signed for and on behalf of
[_____]

Name:

Position:

in the presence of:

Name & occupation:

Address: