

CLINICAL STUDY AGREEMENT

Dated this _____ day of _____ 20____

BETWEEN: Waikato District Health Board having its principal address at _____ ("Institution").

AND: _____ having its principal address at _____ ("Sponsor").

RE: * 1. Enter RE line* (the "Clinical Study")

PROTOCOL NUMBER:

PROTOCOL DATE:

BACKGROUND:-

- A. The Sponsor wishes the Institution to conduct the Clinical Study in accordance with this agreement and the protocol attached at Schedule 3 (the "Protocol").
- B. At the Sponsor's request, the Institution has appointed _____ to conduct and supervise the Clinical Study ("Investigator").
- C. The Sponsor engages the Institution to perform the Clinical Study on behalf of Sponsor on the terms and conditions in this agreement.

AGREEMENT:-

The parties agree as follows:

1 DEFINITIONS AND INTERPRETATION

1.1 In this agreement:

"IEC" means the Independent Ethics Committee;

"GST" or "goods and services tax" means a tax, duty, levy, charge or deduction imposed by or under GST law, together with any related additional tax, interest, penalty, fine or other amount imposed in respect of the above;

"GST law" means the *Goods and Services Tax Act 1985*;

"Monitor" means a representative appointed by Sponsor to monitor the Clinical Study;

1.2 In this agreement:

- (a) headings are included for convenience only and do not affect interpretation;
- (b) unless the context otherwise requires:
 - (i) the singular includes the plural and vice versa;
 - (ii) words importing one gender will import all other genders; and
 - (iii) a reference to an enactment is a reference to that enactment as amended, or to any enactment that has been substituted for that enactment;

- (c) including means including, without limitation to the generality of the surrounding terms;
 - (d) references to parties include their employees, servants, agents, successors and assigns.
- 1.3 If there is a conflict between any parts of this agreement when compared by treating each part as an entire agreement, then for the purposes of interpretation, the parts of this agreement rank in the following descending order of priority with each lower part to be disregarded to the extent that it conflicts with a higher ranking part, that higher ranking part, for these purposes, to be treated as an entire agreement:
- (a) the Indemnity;
 - (b) the body of this agreement;
 - (c) the Protocol;
 - (d) Schedule 1.

2 THE INVESTIGATOR

2.1 The Institution will procure the Investigator to:-

- (a) personally conduct or supervise the Clinical Study at the Institution's premises;
- (b) comply with all conditions specified in the Protocol, Protocol amendments and/or addenda;
- (c) comply with the applicable requirements of the most recent version of the Declaration of Helsinki ;
- (d) comply with all the applicable New Zealand laws or standards;
- (e) comply with the applicable Good Clinical Practice Guidelines and/or other nationally established guidelines;
- (f) comply with the terms of approval of the IEC;
- (g) only use an informed consent document, which has been reviewed and approved by the IEC;
- (h) keep the Monitor informed of the progress of the Clinical Study, be available for periodic visits by the Monitor, and accept reasonable directions of the Monitor;
- (i) use his/her best endeavours to randomise at least **2. number of eligible patients** eligible patients to the Clinical Study; and
- (j) ensure that patient data is entered into the Case Record Form (CRF) in a timely manner.

If, for any reason:

- (k) the Investigator is unwilling or unable to continue to conduct and supervise the Clinical Study; and

(l) the Sponsor and the Institution cannot agree on a replacement,
then this agreement will be terminated in accordance with clause 12.

*Note: Further patient recruitment above *3. number of patients* patients will be discussed and agreed by the parties and will depend on overall numbers of patients recruited.*

3 **CLINICAL STUDY DURATION**

This agreement will commence on _____ and will continue for a period of _____, unless earlier terminated under clause 12 or at law.

4 **AUDIT BY SPONSOR**

4.1 The Sponsor may audit the Clinical Study provided that the Sponsor:

- (a) gives the Institution reasonable notice of such audit, and the audit is conducted at times and locations approved in advance by the Institution; and
- (b) complies with all reasonable conditions outlined by the Institution.

4.2 During audits a designated representative of the Sponsor may inspect the procedures, facilities or Clinical Study records (including portions of other pertinent records for all patients in the Clinical Study) and those procedures, facilities or Clinical Study records of any contractor, agent or Clinical Study site that are used in conducting the Clinical Study.

4.3 If, during the course of an audit, the Sponsor discovers a material lack of compliance by the Institution with this agreement, the Sponsor may give the Institution written notice of the non-compliance. If the non-compliance is not rectified within 20 days of the date of the Institution's receipt of the Sponsor's notice, the Sponsor may terminate this agreement on 20 days' prior written notice. Upon receipt of notice of termination under this clause, the Institution will promptly terminate conduct of the Clinical Study to the extent medically permissible for all patients.

5 **CLINICAL STUDY DRUG USE AND RECORD RETENTION**

5.1 The Institution will use the drugs furnished for the Clinical Study solely in accordance with the terms of the Protocol, and must not use them for any other purpose. Unless otherwise stated in the Protocol, the Sponsor will (at its own expense) supply to the Institution all necessary quantities of Clinical Study drug(s) to be used in the Clinical Study, packed and labelled as described in the Protocol.

5.2 The Institution will (at the Sponsor's cost) follow the Sponsor's reasonable instructions relating to the destruction and disposal of the Clinical Study drug(s). The Institution will not destroy or dispose of used/unused Clinical Study drug(s) without express written instructions from the Sponsor.

5.3 Following completion of the Study, the Institution will procure the Investigator to give the Sponsor all documentation relating directly to the Clinical Study, other than that documentation which the Institution wishes to retain in the normal course of its business.

6 PAYMENT

6.1 The maximum budget for the Clinical Study is \$*4. \$* being the total of the amounts set out in Schedule 1. If applicable, the exchange rate will be set at the current rate at time of payment.

*NOTE: Should further patients be recruited above *3. number of patients* patients (as discussed and agreed by the parties) the maximum study budget will be increased accordingly*

6.2 In consideration for the work carried out by the Investigator and the Institution, the Sponsor will pay to the Institution (by way of cheque or direct credit to the Institution's account set out in Schedule 1) the fees set out in Schedule 1 on the basis set out in that Schedule ("Fees"). The Sponsor will pay:

- (a) any per patient payments on a quarterly basis, once it has received completed the Case Report Forms for that quarter; and
- (b) Pro-rata payments according to Schedule 1 for patients prematurely withdrawn from the Clinical Study.

Nothing in the Case Report Forms will be deemed to imply any warranty by the Investigator or the Institution that the Clinical Study drug(s) is fit for the purpose intended by the Sponsor or any other purpose, or that the Clinical Study drug(s) has no side effects other than those disclosed in the Case Report Forms.

6.3 The Fees include an amount for unscheduled patient visits as defined in the Protocol and local laboratory costs. However, the Sponsor will separately pay any IEC fees, pharmacy set-up and/or dispensing fees, and patient transport costs.

6.4 In the event that fewer patients are recruited than are covered by the amount of any advance, the Institution will refund to the Sponsor the excess payment upon termination of this agreement.

6.5 The Sponsor will not make any payment for ineligible patients who are randomised to the Clinical Study. Eligibility criteria are set out in the Protocol.

7 GOODS AND SERVICES TAX

Unless stated otherwise, all amounts payable under this agreement are exclusive of GST which must be paid by the Sponsor at the same time that the Sponsor pays the Fees to the Institution.

8 PROPERTY

The Protocol, the Investigator's brochure and the results of the Clinical Study will remain the exclusive property of the Sponsor. The Sponsor may transmit the results of the Clinical Study without restriction to any health authority in charge of drug registration.

9 DATA AND PUBLICATIONS

9.1 The fact and results of the Clinical Study will be published once the Clinical Study and final analysis have been completed. Publication of the Clinical Study

results from a single centre is not permitted. The Sponsor will ensure that the Institution's and Investigator's participation in the Study is acknowledged in the publication.

- 9.2 If the Investigator or the Institution desires to publish or present the results of the Clinical Study, a copy of the manuscript or abstract will be provided to the Sponsor at least 60 days prior to the expected date of submission to the intended publisher or planned presentation. The Sponsor will promptly review the manuscript to prevent forfeiture of patent rights to data not in the public domain. Where the manuscript or abstract will not forfeit the Sponsor's patent rights to data not in the public domain, the Sponsor will promptly give its consent to the publishing or presentation of the results of this Clinical Study by the Investigator or the Institution (as the case may be).

10 PUBLICITY

- 10.1 The Institution will not place any communication (including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements and newsletters) soliciting patients for the Clinical Study until the Sponsor and the IEC have approved (in writing) the text of that communication. Such communications must comply with applicable laws and guidelines.
- 10.2 The Sponsor must approve (in writing) any press statement regarding the Clinical Study or the Clinical Study drug(s) before the statement can be released. The Institution must approve (in writing) any press statement regarding the Clinical Study or the Clinical Study drug(s) which specifically refers to the Institution (or any of its personnel) before the statements can be released.
- 10.3 All inquiries received by the Institution from reporters or financial analysts are to be directly referred to the Sponsor both during and after the Clinical Study.
- 10.4 The Institution agrees not to use the Sponsor's name or the names of any of the Sponsor's employees in any advertising or sales promotional material or in any publication without the prior written consent of the Sponsor. The Sponsor agrees not to use the Investigator's name, the Institution's name, or the names of any of the Institution's personnel in any advertising or sales promotional material or in any publication without the prior written consent of the Institution.
- 10.5 Nothing in this agreement will prevent the Institution or the Investigator from disclosing information regarding the Study where it is legally required to do so.

11 EQUIPMENT

- 11.1 If the Sponsor provides the Institution with equipment for use in the Clinical Study ("Equipment"):
- (a) the Equipment must be in good working order, and must be accompanied by proper instructions on use and safety precautions; and
 - (b) the Institution will maintain, and bear the risk of loss of or damage to the Equipment during the term of this agreement.
- 11.2 The Institution will ensure that the Equipment remains in the same condition during the Clinical Study (ordinary wear and tear excepted) and the Institution will (at the Sponsor's cost) follow the Sponsor's reasonable instructions for

disposition of the Equipment at the completion or termination of the Clinical Study. The Equipment will remain the property of the Sponsor at all times.

- 11.3 The Sponsor warrants that the use by the Institution, the Investigator or the Institution's employees or agents of any Equipment will not breach the intellectual property rights of any third party.

12 TERMINATION

- 12.1 The Sponsor may terminate this agreement if the Investigator is unwilling or unable to recruit or to continue to serve and no successor who is acceptable to both the Sponsor and the Institution is available.
- 12.2 The Sponsor may terminate any patient's participation in the Clinical Study, or the Clinical Study itself, at any time for any reason. In the event that the Sponsor terminates a patient's participation in the Clinical Study under this clause, the Sponsor will promptly pay to the Institution a pro-rata payment according to Schedule 1.
- 12.3 The Institution may terminate any patient's participation in the Clinical Study, or the Clinical Study itself, at anytime for any reason (including, without limitation, if the Institution believes that the Clinical Study should cease in the interest of its patients).
- 12.4 If this agreement is terminated for any reason whatsoever, the Institution will (at the Sponsor's cost) subject to clause 12.5 return or dispose of all Clinical Study drug(s) in accordance with the Sponsor's reasonable instructions and regulatory requirements. The Sponsor will promptly pay to the Institution an amount to reflect the work that has been performed up to the date of termination which has not previously been paid. If any advance or other payments previously made by the Sponsor exceed the amount owed for work performed as at the date of termination, the Institution will return the excess balance to the Sponsor.
- 12.5 Upon receipt or giving of notice of termination under this clause, as the case may be, the Institution will promptly terminate conduct of the Clinical Study to the extent medically permissible for all patients.

13 INDEMNIFICATION

- 13.1 The details of indemnity cover provided by the Sponsor are described in the indemnity agreement attached to this agreement at Schedule 2 (*Indemnity*).

14 LIMITATION OF LIABILITY

- 14.1 The liability of the Institution to the Sponsor is limited to direct loss or damage caused to the Sponsor up to an amount not exceeding the amounts paid by the Sponsor to the Institution under this agreement during the 12 month period immediately prior to the event giving rise to the loss or damage.
- 14.2 Except as provided in clause 14.1, the Institution's liability to the Sponsor whether in tort (including negligence), contract, breach of statutory duty, equity or otherwise arising from the relationship between the Institution and the Sponsor is excluded to the fullest extent permitted by law.
- 14.3 For the purposes of clause 14.1, direct loss or damage will not include:

- (a) any loss of profit, loss of revenue, loss of use, loss of contract or loss of goodwill of any person;
- (b) any indirect, consequential or special loss; or
- (c) any loss resulting from liability to any third party.
- (d) any payment made to an Indemnitee under clause 2.1 of the Indemnity referred to in Schedule 2.

15 DISPUTES

- 15.1 The parties will try to resolve any disputes in relation to the Clinical Study or this agreement on a friendly basis. However, if the dispute cannot be resolved within 21 days, then any party may require the dispute to be referred to mediation by giving written notice to the other parties. The mediation must be conducted in terms of the Arbitrators' and Mediators' Institute of New Zealand Inc. Standard Mediation Agreement. The mediation must be conducted by a mediator (and at a fee) agreed by the parties. If the parties are unable to agree upon a mediator within fourteen (14) days of the written notice then the mediator will be appointed by the then president of the Arbitrators' and Mediators' Institute of New Zealand Inc.
- 15.2 The parties must maintain the confidentiality of any documents or other information made available to, or coming to the knowledge of, any party in the course of negotiations and any mediation. The parties may use this information in settling the dispute, but not for any other purpose. The parties may not rely on, or introduce as evidence in any arbitral, judicial or other proceeding:
- (a) views expressed or suggestions made by another party on a possible settlement of the dispute;
 - (b) admissions or concessions made by another party in the course of negotiations or any other agreed process to resolve the dispute;
 - (c) proposals made or views expressed by a neutral person employed by the parties to the dispute; or
 - (d) the fact that another party had or had not indicated willingness to accept a proposal for settlement.
- 15.3 The mediation will be terminated by:
- (a) the signing of a settlement agreement by the parties; or
 - (b) notice to the parties by the mediator, after consultation with the parties, to the effect that further efforts at mediation are no longer justified; or
 - (c) notice by one of the parties to the mediator to the effect that further efforts at mediation are no longer justified; or
 - (d) the expiry of sixty (60) days from the mediator's appointment, unless the parties expressly consent to an extension of this period.
- 15.4 If the mediation is terminated other than under clause 15.3(a), any party may refer the dispute to arbitration in accordance with the Arbitration Act 1996 (excluding clauses 1,4 and 5 of the Second Schedule), such arbitration to be conducted by a single arbitrator agreed by the parties (or if the parties cannot

agree within 7 days of the referral to arbitration, as appointed by the then President of the New Zealand Law Society, or the President's nominee).

15.5 Nothing in this clause will preclude a party from taking immediate steps to seek urgent equitable relief before an appropriate court.

16 GENERAL

16.1 This agreement is governed by and will be construed in accordance with the laws of New Zealand. The courts of New Zealand will have non-exclusive jurisdiction to hear and determine all claims under or in connection with this agreement.

16.2 The Sponsor must keep confidential all:

- (a) information belonging to the Investigator;
- (b) information belonging to the Institution; and
- (c) personal health information identifying a subject, patient or client of Institution,

unless the Institution has given its prior written approval for the release of such information.

16.3 The Sponsor must ensure that all persons entering onto the Institution's site for any purpose relating to this agreement comply with the Institution's health and safety and emergency management policies.

16.4 Reference in this agreement to a party to this agreement also refers to all that party's employees, servants, agents, successors, representatives and assigns.

16.5 This agreement constitutes the entire understanding between the parties and supersedes any prior arrangements, understandings, promises or agreements made or existing between the parties relative to the subject matter of this agreement. Except as otherwise provided herein, no addition, variation, amendment to or modification of this agreement will be effective unless it is in writing and signed by all parties.

16.6 Failure by a party to enforce any of the provisions contained in this agreement will not:

- (a) be deemed to be a waiver of that party's rights;
- (b) in any way affect the validity of the whole or any part of this agreement; or
- (c) prejudice the right of that party to take subsequent action.

16.7 A waiver of any breach of this agreement will not be effective unless that waiver is in writing and signed by the party against whom that waiver is claimed. A waiver of any breach will not be, or be deemed to be, a waiver of any other or subsequent breach.

16.8 The Sponsor warrants that it has disclosed and provided to the Institution all information relevant to the Clinical Study drug(s) and the Clinical Study which is known by the Sponsor at the commencement of the Clinical Study. The Sponsor undertakes to immediately disclose and provide to the Institution any additional information which subsequently becomes known to the Sponsor and is relevant to the Clinical Study drug(s) and/or the Clinical Study.

16.9 The Sponsor must ensure that it at all times maintains adequate insurance to cover any liability in respect of the Clinical Study.

16.10 Nothing in this agreement should be interpreted as constituting either the Institution or the Sponsor as an agent or partner of the other.

16.11 The Sponsor warrants that:

- a. it has all requisite power and authority to enter into the agreement and the Indemnity;
- b. any person who executes the agreement and/or the Indemnity as attorney for the Sponsor has all requisite power and authority to execute the agreement and/or the Indemnity;
- c. this agreement and the Indemnity are validly executed in accordance with the laws of **6. insert jurisdiction in which entity is incorporated/created**; and
- d. the agreement and the Indemnity each constitutes a valid and binding agreement of the Sponsor enforceable in accordance with its terms.

17 **FORCE MAJEURE**

The Institution will not be liable for failure to perform its obligations herein if the failure results from an event beyond the Institution's reasonable control.

EXECUTED AS AN AGREEMENT

On behalf of **7. Sponsor**

Date:

Name

Title

On behalf of Waikato District
Health Board

Date:

Name

Title

Account details for payment:

Bank: _____

Account Name: _____

Bank address: _____

Bank Account no: _____

SCHEDULE 2 – INDEMNITY

SCHEDULE 3 – PROTOCOL