Clinical Trial Research Agreement

Investigator-Initiated, Company Supported Studies

The body of the Agreement is not to be amended. Revisions are to be detailed in Schedule 3 with appropriate cross-referencing to the relevant section of the Agreement.

DETAILS OF THE PARTIES

INSTITUTION	
Name	
Address	
ABN	
Contact for Notices	
Fax for Notices	
Phone Number	
COMPANY	
Name	
Address	
ABN	
Contact for Notices	
Fax for Notices	
Phone Number	
STUDY NAME	
PROTOCOL NUMBER	
DATE OF AGREEMENT	

THIS AGREEMENT IS MADE BETWEEN THE INSTITUTION AND THE COMPANY

PURPOSE OF THE AGREEMENT

A The Institution wishes to conduct the Study as an investigator initiated study. The Company is supporting the Study by either providing quantities of Investigational Product and/or funding for the Study. The Institution, through the Principal Investigator, is responsible for the conduct of the Study at the Study Site which is under the control of the Institution.

OPERATIVE PROVISIONS

1. INTERPRETATION

1.1 In this Agreement:

Adverse Event has the meaning given in the TGA document "Access to Unapproved Therapeutic Goods – Clinical Trials in Australia" (October 2004) or replacement.

Agreement means this Agreement, including all the Schedules hereto.

Background Intellectual Property means information, techniques, know-how, software and materials (regardless of the form or medium in which they are disclosed or stored) that are provided by one party to the other for use in the Study (whether before or after the date of this Agreement), except any Study Materials.

Biological Samples means any physical samples obtained from Study Subjects in accordance with the Protocol.

Case Report Form means a printed, optical or electronic document or database designed to record all of the information, required by the Protocol on each Study Subject.

Company means the pharmaceutical company so described on the first page of this Agreement.

Confidential Information means:

(1) in respect of the Institution:

(a) all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere;

(b) the Protocol, the Investigator's Brochure, information relating to the Protocol and Study Materials;

(c) 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;

(d) Know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study; and

(e) Information concerning the business affairs or clients of the Institution;

(2) in respect of the Company:

(a) Investigational Product(s);

(b) Information, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Company;

(c) Know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study; and

(d) Information concerning the business affairs or clients of the Company.

(3) in respect of the Institution, information in relation to the Institution's business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors;

but Confidential Information does not include Personal Information.

Essential Documents means documents which individually and collectively permit evaluation of the conduct of the Study and the quality of the data produced.

GCP Guideline means the Committee for Proprietary Medicinal Products (CPMP)/International Conference on Harmonisation (ICH) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) as adopted with annotation by the TGA, as amended from time to time.

GST means the Goods and Services Tax payable under a GST Law.

GST Law means the same as in *A New Tax System (Goods and Services Tax) Act 1999 (Cth)* as amended from time to time, and any regulations made pursuant to that Act.

Institution means the body so described on the first page of this Agreement.

Investigational Product means the medicine(s) or device(s) being trialled or tested in the Study and includes where relevant any placebo.

Investigator's Brochure is a compilation of the clinical and non-clinical data on the Investigational Product(s) which are relevant to the study of the Investigational Product in humans.

Intellectual Property means all industrial and intellectual property rights, including without limitation:

(1) patents, copyright, future copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trade marks, know how, trade secrets and the right to have confidential information kept confidential, any and all other rights to intellectual property which may subsist anywhere in the world; and

(2) any application or right to apply for registration of any of those rights.

Multi-centre Study is a Study conducted by several investigators according to a single protocol at more than one study site.

NHMRC means the National Health and Medical Research Council of the Commonwealth of Australia.

Personnel means employees, agents and/or authorised representatives, and includes in the case of the Institution, the Principal Investigator.

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

Principal Investigator is the person responsible for the conduct of the Study at the Study Site as described in **Schedule 1**.

Protocol means the document identified in Schedule 1which document describes the objective(s), design, methodology, statistical considerations and organisation of the Study, as such document may be amended from time to time and most recently approved by the Responsible HREC.

Publish means to publish by way of a paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video, instruction material or other disclosure of Study Materials, in printed, electronic, oral or other form. **Publication** has a corresponding meaning.

Regulatory Authority means any government body which has jurisdiction over the conduct of the Study at the Study Site and includes the TGA and any overseas regulatory authorities who may require to audit any part of the Study or Study Materials.

Responsible HREC means the Human Research Ethics Committee reviewing the Study on behalf of the Institution as described in **Schedule 1**.

Relevant Privacy Laws means the *Privacy Act 1988 (Cth)* and any other legislation, code or guideline which applies in the jurisdiction in which the Study Site is located and which relates to the protection of personal information.

Serious Adverse Event has the meaning given in the TGA document "Access to Unapproved Therapeutic Goods – Clinical Trials in Australia" (October 2004) or replacement.

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

Study Materials means all the materials and information created for the Study including all data, results, Biological Samples, Case Report Forms, (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not relating to the Study which are discovered or developed as a result of the Study.

Study Subject means a person recruited to participate in the Study.

Study Site means the location(s) under the control of the Institution where the Study is actually conducted.

TGA means the Therapeutic Goods Administration of the Commonwealth of Australia or any successor body.

1.2 Except where the context otherwise requires:

(1) clause headings are for convenient reference only and are not intended to affect the interpretation of this Agreement;

(2) where any word or phrase has a defined meaning, any other form of that word or phrase has a corresponding meaning;

(3) any reference to a person or body includes a partnership and a body corporate or body politic;

(4) words in the singular include the plural and vice versa;

(5) all the provisions in any schedule to this Agreement are incorporated in, and form part of, this Agreement and bind the parties;

(6) if a period of time is specified and dates from a given day or the day of an act or event, it is to be calculated inclusive of that day;

(7) a reference to a monetary amount means that amount in Australian currency; and

(8) references to a party includes its Personnel.

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. STUDY

2.1 Obligations and responsibilities of the Institution

2.1.1 The Study is initiated by the Institution who also own the protocol. The Institution will act as sponsor of the Study for the purposes of the TGA's CTN Scheme (or any successor scheme). The Institution is responsible for preparing and submitting all documents required by the TGA to file an application for initiating and conducting the Study.

2.1.2 The Institution must comply with, and conduct the Study:

(1) in accordance with the Protocol and any condition of the Responsible HREC.

(2) any requirements of relevant Commonwealth or State or Territory laws or of Regulatory Authorities;

(3) the GCP Guideline; and

(4) the NHMRC National Statement on Ethical Conduct in Human Research (2007) or replacement, and any other relevant NHMRC publication or guideline that relates or may relate to clinical trials.

2.2 Obligations and responsibilities of the Company

2.2.1 In consideration of the Institution conducting the Study, Company agrees to:

(1) supply at no cost to the Institution to the Institution such quantities of the Investigational Product in accordance with the protocol that are required for the Study; and

(2) provide funding for the Study as specified in Schedule 2. Other than its obligation to provide the amount of funding specified in Schedule 2, the Company is under no obligation to finance, fund or support the Study.

2.1.1 Company will monitor the application of the Investigational Product in other places (both within and outside Australia) and advise the Institution, and TGA of the cessation elsewhere of any relevant trial, or the withdrawal of the Investigational Product from any other market for safety reasons.

2.1.2 Company will notify the Institution of any Adverse Events (including Serious Adverse Events) that occur during the course of the Study (either at the Study Site or other study sites, including overseas sites) which may require alteration of the conduct of the Study, or which may affect the rights, interests, safety or well-being of Study Subjects.

2.1.3 Company will cooperate with the Institution and its respective HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Study

3 FUNDING

3.1 The amounts set out in Schedule 2 do not include GST. At the time of providing the funding, Company will also provide to the Institution any amount of GST that the Institution is required to pay in accordance with GST Law.

3.2 The Institution must use the funding paid to it under this Agreement exclusively for the conduct of the Study. The Institution is liable for any tax payable on the research grant, other than GST.

3.3 Payments will be made by Company upon either receipt of a valid tax invoice or a "Recipient Created Tax Invoice" issued by Company.

3.4 Company and the Institution warrant that they are registered under GST Law. Tax invoices must identify supplies for which GST is payable.

4 INVESTIGATIONAL PRODUCT

4.1 Company must ensure that all Investigational Product is

4.1.1 manufactured under all relevant manufacturing standards, including those specified in the *Therapeutic Goods Act 1989* as Manufacturing Principles,

4.1.2 packaged in a safe and appropriate manner; and

4.1.3 labelled in accordance with all requirements of the TGA and relevant laws.

4.2 The Institution must:

4.2.1 ensure that all Investigational Product is used strictly according to the Protocol and is not used for any other purpose.

4.2.2 not charge a Study Subject or third party payer for Investigational Product; and

4.2.3 keep all Investigational Product under appropriate storage conditions as specified in the Protocol in a secured area accessible only to authorised Personnel, and that complete and current records are maintained for all received, dispensed and returned Investigational Product.

4.3 In the event of termination, the Institution must promptly return (or destroy if requested by Company, and provide evidence of such destruction) to Company any unused Investigational Product.

5 CONFIDENTIALITY

5.1 Subject to **clause 5.2**, the Parties must not, and must ensure their Personnel do not, use or disclose any Confidential Information, other than

where and only to the extent such use or disclosure is necessary for the performance of the Study.

5.2 The Institution may use or disclose Confidential Information in any of the following circumstances:

5.2.1 for the purposes of complying with the requirements of any Regulatory Authority;

5.2.2 for the purposes of the monitoring of the Study by the Responsible HREC;

5.2.3 where the Company consents in writing to the disclosure;

5.2.4 where the Confidential Information has been independently received from a third party who is free to disclose it;

5.2.5 where the Confidential Information has entered the public domain other than as a result of a breach of this Agreement;

5.2.6 where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the Comapny;

5.2.7 for the purposes of legal advice; and

5.2.8 disclosure to the Institution's insurer.

5.3 Where Confidential Information is disclosed in accordance with **clause 5.2.2**, the Confidential Information must only be used in connection with the legitimate purposes of the Institution, and only disclosed to those who have a need to know it for such purposes and are obligated to keep the information confidential.

5.4 The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in this **clause 5**, and are bound in similar terms to keep such information confidential, but are not responsible if those Personnel deliberately and intentionally fail to observe those restrictions.

6 PRIVACY

6.1 The parties must ensure that any Personal Information arising from the Study regarding Study Subjects or Personnel, is collected, stored, used and disclosed in accordance with the Relevant Privacy Laws.

7 LIABILITY AND INSURANCE

7.1 Each party is liable for its acts and omissions in relation to the conduct of the Study.

7.2 Each party must maintain such insurances as are reasonably available and necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Study or performing its obligations under this Agreement.

7.3 The Institution satisfies the requirements of clause 10.2 if it is entitled to indemnity under a program or scheme of insurance or indemnity that is arranged by a department or agency of a State or Territory of the Commonwealth of Australia.

8 PUBLICATIONS

8.1 The Institution, Principal Investigator and other investigators ("Discloser") involved in the Study have the right to Publish the methods, results of, and conclusions from, the Study, subject to this clause and in accordance with copyright law.

8.2 The Institution must ensure that the Discloser gives notice of any proposed Publication drafted by them and/or other Personnel involved in the conduct of the Study to Company at least 40 days before any forwarding to a party that is not bound by the confidentiality obligations set out in **clause 5**.

8.3 Company may, within that 40-day period do any one or more of the following:

8.3.1 provide comments on the proposed Publication to the Institution, in which case the Institution must consider such comments but will not be bound to follow them;

8.3.2 request delay of Publication for no more than 120 days to allow Company to file patent applications or take other measures to preserve its proprietary rights, in which case the Institution must abide by that request;

8.3.3 request that the Discloser remove specified Confidential Information (other than the results of the Study) from the Publication, in which case the Institution must remove such specified Confidential Information as is reasonably required to protect the Intellectual Property of the Sponsor.

8.4 If the Institution has not received any comments from Company on the proposed Publication within 40 days of giving notice to Company under **clause 11.3**, the Discloser may proceed to make the Publication.

8.5 Where Company intends to Publish the method, results or conclusions from the Study, any person named as an author on that Publication or otherwise noted as the Principal Investigator or an investigator of the Study in the Publication, will be given a reasonable opportunity to review the Publication and request the removal of his or her name from the Publication and the Sponsor shall comply with any such request.

8.6 In all Publications Company's support of the Study shall be acknowledged.

8.7 Company may Publish a summary of the Study Results and conclusions on the Company's on-line Clinical Trial Register before or after Publication by another method.

8.8 Company may freely use, copy and disseminate any manuscript following its Publication in a journal without further obligation to the Institution or Discloser.

9 STUDY RESULTS AND INTELLECTUAL PROPERTY

9.1 The data and results of the Study, including the Case Report Forms are the property of the Institution. If requested by the Company, the Institution must provide a copy of the data and results of the Study and the Case Report Forms to the Company. The Institution agrees that a Company may use such information for any commercial, scientific or regulatory purpose.

9.2 This Agreement does not affect the rights of any party to its respective Background Intellectual Property. The Company grants to the Institution a non-exclusive, non-transferable, royalty-free licence under the Company Background IP to conduct the Study in Australia for the term of this

Agreement. The Institution grants to the Company a non-exclusive, non-transferable, royalty-free licence under the Institution Background IP for the purpose of conducting the Study in Australia for the term of this Agreement.

9.3 All Intellectual Property created or developed as a result of the use of or developed in relation to any Company Background IP or the Investigational Product, (**Company Study IP**) vests in the Company immediately upon its creation.

9.4 All Intellectual Property created, developed or arising from the use of the Institution Background IP other than the Company Study IP (**Institution Study IP**) vests in the Institution immediately upon its creation.

9.5 The Company grants to the Institution a non-exclusive, non-transferable, royalty-free licence under the Company Study IP to conduct the Study in Australia for the term of this Agreement.

10 TERM AND TERMINATION

10.1 This Agreement commences from the date specified on the first page of this Agreement, or if such date is not included on the date this Agreement is last signed by either the Institution or the Company.

10.2 In the ordinary course of events this Agreement terminates when the Institution receives all amounts owing to it under this Agreement, or when the Institution publishes the final report of the Study, whichever occurs later.

10.3 Either the Institution or the Company may terminate this Agreement with 30 days prior written notice or such shorter time period as is reasonably required in the circumstances if the other party:

10.3.1 is in breach of any obligations under the Agreement or the Protocol (including without just cause to meet a timeframe) and fails to remedy such breach where it is capable of remedy within 30 days of a written notice from the terminating party specifying the breach and requiring its remedy;

10.3.2 is declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business; or

10.3.3 assigns this Agreement to a person considered unsuitable to perform the Agreement as set out in **clause 16.2**.

10.4 In addition to **clause 10.2**, a party may terminate this Agreement immediately by written notice to the other party if it believes on reasonable grounds that:

10.4.1 continuing the Study poses an unacceptable risk to the rights, interests, safety or well-being of Study Subjects; and

10.4.2 terminating this Agreement is the most appropriate way to respond to that risk.

10.5 In the event of termination the Institution must take all appropriate action to close out the Study Site in a timely manner.

10.6 The following provisions survive termination of this Agreement, **clauses 1.1**, **1.2**, **5**, **6**, **7**, **8.1**, **10**, **11**, **12**, **13**, **15** and **17**.

11 DISPUTES

11.1 No party may commence legal proceedings against another in respect of a dispute arising in relation to this Agreement (except for urgent interlocutory relief) unless the parties have complied with this clause and that party has first notified the other party in writing of the dispute and has used all reasonable endeavours to resolve the dispute with the other party within 28 days of the giving of that notice ("**Initial Period**").

11.2 If the dispute is not resolved within the Initial Period, then the dispute shall be referred within a further 28 days to the Australian Commercial Disputes Centre for mediation or any other agreed venue which conducts mediation. The parties will by agreement appoint a mediator to mediate the dispute in this forum. If the parties cannot agree to a mediator, then the mediator will be nominated by the then current President of the Law Society of the State or Territory in which the Institution is located. Any documents produced for the mediation are to be kept confidential and cannot be used except for the purpose of settling the dispute.

11.3 Each party must bear its own costs of resolving a dispute under this clause, and unless the parties otherwise agree, the parties to the dispute must bear equally the costs of the mediator.

11.4 In the event that the dispute is not settled at mediation within 28 days (or such other period as the parties agree in writing) after the appointment of the mediator, or if no mediator is appointed, then within 28 days of the referral of the dispute to mediation, then the parties are free to pursue any other procedures available at law for the resolution of the dispute.

12 APPLICABLE LAW

This Agreement will be governed by, and construed in accordance with, the law for the time being in force in the State or Territory in which the Institution is located and the parties submit to the jurisdiction of that State or Territory and courts entitled to hear appeals from those courts.

13 NOTICES

13.1 A notice, consent, approval or other communication (each a **notice**) under this Agreement must be:

13.1.1 delivered to the party's address;

13.1.2 sent by pre-paid mail to the party's address; or

13.1.3 transmitted by facsimile to the party's address.

13.2 A notice given by a party in accordance with this clause is treated as having been given and received:

13.2.1 if delivered to a person's address, on the day of delivery if a business day, otherwise on the next business day;

13.2.2 if sent by pre-paid mail, on the third business day after posting;

13.2.3 if transmitted by facsimile to a person's address and a correct and complete transmission report is received, on the day of transmission if a business day, otherwise on the next business day.

13.3 The addresses of the parties for the purposes of giving any notice are set out on the front page of this Agreement.

14 WAIVER

14.1 No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the party waiving the right. A waiver by any party in respect of any breach of a condition or provision of this Agreement will not be deemed to be a waiver in respect of any other breach.

14.2 Failure or delay by any party to enforce any provision of this Agreement will not be deemed to be a waiver by that party of any right in respect of any other such breach.

15 VARIATIONS

No variations of this Agreement are legally binding on any party unless evidenced in writing signed by all parties.

16 ASSIGNMENT

16.1 Subject to **clause 16.2**, a party may not assign its rights or obligations under this Agreement without the prior written consent of the other party, such consent not to be unreasonably withheld.

16.2 A party may assign the benefit of this Agreement necessitated by the merger or sale of all or substantially all off its assets, provided it obtains from the relevant assignee a written undertaking in favour of the other party to be bound by the terms of this Agreement.

16.3 If a party assigns this Agreement under **clause 16.2,** and the relevant assignee is determined by the non-assigning party, in its discretion, as unsuitable to perform its obligations under this Agreement, that party may terminate the Agreement in accordance with **clause 10.3.3**.

17 ENTIRE AGREEMENT

17.1 This Agreement constitutes the entire agreement between the parties and supersedes all prior representations, agreements, statements and understandings, whether verbal or in writing.

17.2 The body of this Agreement (that is from the second page of this Agreement to the execution clauses) is intended to be identical to the standard form 'CTRA for investigated initiated studies – Alfred Health', a copy of which is located at http://www.alfredresearch.org/ethics/legal.htm. Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 3 by way of Special Conditions

18 SEVERANCE

If any part of this Agreement is prohibited, void, voidable, illegal or unenforceable, then that part is severed from this Agreement but without affecting the continued operation of the Agreement.

19 RELATIONSHIP OF THE PARTIES

Nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the parties and no party will hold itself out as an agent for another.

20 FORCE MAJEURE

If any party is delayed or prevented from the performance of any act required under the Agreement by reason of any act of god, act of nature, including any epidemic or outbreak of pandemic disease, fire, act of government or state, war, civil commotion, insurrection, embargo, prevention from or hindrance in obtaining raw material, energy or other supplies, labour disputes of whatever nature or whatever reason beyond the control of the party, performance of such act shall be excused for the period of such event provided that if such interference lasts for any period in excess of 30 days each party may, by written notice to the others, terminate this Agreement.

21 CONFLICT

In the event of any inconsistency between this Agreement and the Protocol, this Agreement prevails.

In witness hereof, the parties have caused this Agreement to be executed as of respective dates written below.

Signed on behalf of the **INSTITUTION**

Signed: …….

Name: ……..

Position: ……

Date: …….

Signed on behalf of the **COMPANY**

Signed: …….

Name: ……..

Position: ……

Date: …….

Schedule 1
Key Information

Study Name: _____

Study Site/s: _____

Protocol Number:

_____

Principal Investigator
Name: _____

Address: _____

State: P/code:

_____

Responsible HREC: _____

_____

_____

_____

Study Protocol Identification _____

Full Title:

Version Number:

Date:

List of Key attachments:

_____

Schedule 2
Funding

Please enter funding details

Schedule 3
Special Conditions

Please enter text below