



Clinical Trial Agreement

Collaborative or Cooperative Research Group (CRG) Studies – Standard Form

The body of this Standard Form Agreement should not be amended. Any proposed changes to this Agreement must be incorporated into **Schedule 4** by way of Special Conditions.

Details of the parties

Institution:	The Minister for Health is incorporated as the board of Royal Perth Hospital under s7 of the <i>Hospitals and Health Services Act 1927</i> (WA) and has delegated all the powers and duties as such to the Director General of Health
Address:	Wellington Street, Perth, Western Australia, 6000, Australia
ABN:	13 993 250 709
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Name of CRG:	
Address:	
ABN:	
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Study name:	
Protocol Number:	
Date of Agreement:	

THIS AGREEMENT IS MADE BETWEEN THE CRG AND INSTITUTION

PURPOSE OF THE AGREEMENT

According to this Agreement:

- A. The CRG is an academic and/or non-commercial collaborative research group responsible for sponsoring, initiating, managing, developing and coordinating the Study.
- B. The Institution, through the Principal Investigator, is responsible for the conduct of the Study at the Study Site(s).
- C. The Study will be conducted on the terms and conditions set out below.
- D. The parties acknowledge that they are not for profit organisations and the Study will be conducted in the spirit of cooperation and collaboration.

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.

Affiliate means any company which (directly or indirectly) controls, is controlled by or is under common control with the CRG.

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, to be reported to the CRG on each Study Subject.

Confidential Information means:

- (1) in respect of the CRG:
 - (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, Study Materials and Investigational Product;
 - (c) Information, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques owned by the CRG or its Affiliates;
 - (d) Know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study; and
 - (e) Information concerning the business affairs of the CRG or its Affiliates;

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- (2) 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.

CRG means the collaborative or cooperative research group so described on the first page of this Agreement.

Date of Agreement means the date of last signature by the parties

Equipment means, where relevant, the equipment supplied to the Institution by CRG as set out in Schedule 1 for the purposes of the Study.

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.

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.

Investigational Product means, where relevant, the medicine(s), trial interventions or device(s) being trialled or tested in the Study and includes any placebo as identified in Schedule 1.

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.

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)*.

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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 3** which describes the objective(s), design, methodology, statistical considerations and organisation of the Study, as 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.

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.

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

Serious Adverse Event has the meaning given in the GCP Guideline.

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

Study Completion means:

- (1) the final study database lock has occurred; or
- (2) all study follow-up requirements have been met, and a copy of the letter from responsible HREC acknowledging receipt of the final report and/or closure letter from the PI has been received by the CRG; or
- (3) as otherwise determined by the CRG and notified to the Institution in writing

Study Materials means all the materials and information created for the Study or required to be submitted to the CRG 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) where the Study is actually conducted as set out in Schedule 1.

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;

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- (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 unless specified otherwise in Schedule 2; and
- (8) references to the CRG include 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 The parties must comply with, and conduct the Study in accordance with the Protocol and any condition of the Responsible HREC. In addition the Parties must comply with the following, as applicable:
- (1) any requirements of relevant Commonwealth or State or Territory laws or of Regulatory Authorities;
 - (2) the requirements of the TGA in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or replacement and any other TGA publication or guideline that relates or may relate to clinical trials, or other such regulations or guidances governing the conduct of clinical research in the jurisdiction of the Study;
 - (3) the GCP Guideline;
 - (4) the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996;
 - (5) 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 trial;
 - (6) any Study specific and standard operating procedures provided by the CRG prior to the commencement of the Study; and
 - (7) any reasonable direction given by the CRG in order to ensure the safe conduct of the trial and compliance with applicable regulatory requirements.
- 2.2 If any issue relating to the safety of Study Subjects arises which requires a deviation from the Protocol, the Institution through the Principal Investigator may immediately make such a deviation without breaking any obligations under this Agreement. If there is a need for such a deviation the Institution must notify the CRG and the responsible HREC, according to HREC guidelines, of the facts and circumstance causing the deviation as soon as is reasonably practical, but in any event no later than 5 working days after the change is implemented.

3. PRINCIPAL INVESTIGATOR

3.1 Role of Principal Investigator

The Institution has authorised the Principal Investigator as the person responsible on a day to day basis for the conduct of the Study at the Study site. The Principal Investigator does not have authority on behalf of the Institution to amend this Agreement or the Protocol.

3.2 Liability for Principal Investigator

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As between the CRG and the Institution only, the Institution agrees to be responsible for the acts and omissions of the Principal Investigator in relation to the conduct of the Study, to the extent that such responsibility would attach to the Institution in accordance with its obligations under this Agreement or under the common law on the basis that the Principal Investigator is acting as an employee of the Institution.. Nothing in this clause or Agreement affects any pre-existing contractual or other arrangement which may be in place between the Institution and the Principal Investigator.

3.3 Obligations and responsibilities

Without limiting any other obligations the Institution has under this agreement or at law, the Institution is responsible for ensuring that the Principal Investigator:

- (1) ensures written approval has been obtained to conduct the Study from the Responsible HREC and the Institution prior to Study initiation. Written documentation of approval by the Responsible HREC and the Institution must be provided to the CRG;
- (2) conducts the Study according to the Protocol without changes except as provided in **clause 2.2**, or as agreed to in writing by the CRG and the Institution and approved in accordance with **clause 3.3(4)**;
- (3) thoroughly familiarises himself or herself with the appropriate use of the Investigational Product(s), as described in the Protocol, Investigator's Brochure, information relating to the Investigational Product and any other information sources provided by the CRG;
- (4) ensures that any amendments to the Protocol are approved by the Responsible HREC and CRG prior to implementation of the amendment;
- (5) as soon as is practical advises the CRG if the Responsible HREC alters its approval of the Study;
- (6) obtains prior written approval from the CRG and the Responsible HREC of any proposed advertisements to be used for the purpose of Subject recruitment in the Study;
- (7) provides the CRG with evidence of the Principal Investigator's qualifications through a current curriculum vitae and/or other relevant documentation and a list of appropriately qualified persons to whom they have delegated significant Study-related duties, if required;
- (8) uses his or her best endeavours to recruit the target number of Study Subjects, within the recruitment period, specified in **Schedule 1**, provided that if the overall target number of Study Subjects for the Study is reached, the CRG may direct the Institution to cease recruitment;
- (9) is available when a clinical research representative of the CRG visits the Study Site, as mutually agreed prior to the visit, and is contactable by telephone or electronic mail as frequently as is reasonably required;
- (10) notifies the CRG, the Institution and the Responsible HREC of any Adverse Events (including Serious Adverse Events) that occur during the course of the Study in accordance with the Protocol, and relevant ethical and regulatory guidelines, and in the case of the Institution and the Responsible HREC with their policies and procedures;
- (11) completes Case Report Forms within the agreed time period. The Principal Investigator will ensure that Study Subjects' identifying information are removed from all records being transferred to the CRG;
- (12) provides regular written progress reports to the CRG in relation to the Study as required by the Protocol;

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- (13) completes and returns to the CRG as required any Study related materials within a reasonable time period;
- (14) is not subject to any obligations, either contractually or in any other way, which would unreasonably interfere with or prohibit the performance of work related to this Study;
- (15) ensures that informed consent to participate in the Study is obtained from each Study Subject prior to their enrolment in the Study and documented using an information and consent document which has been reviewed and approved by the CRG, the Institution and the Responsible HREC.

4. INSTITUTION

4.1 Obligations and responsibilities

- (1) If the Principal Investigator leaves the Institution or otherwise ceases to be available then:
 - (a) The institution must notify the CRG as soon as is practical;
 - (b) the Institution must consult with the CRG and use reasonable endeavours to nominate as soon as practicable a replacement acceptable to both Parties; and
 - (c) if a replacement cannot be found who is acceptable to both parties, the CRG may require recruitment into the Study by the Institution to cease, and the CRG may terminate this agreement in accordance with **clause 13.4**.
- (2) If the Principal Investigator fails to carry out those obligations specified in **clauses 3.3(1), (2), (4), (8), (10), (11), (13), (15)**, then the Institution must itself perform those obligations and rectify and make good any breach. The Institution will ensure that any Personnel who assist in the conduct of the Study are informed of and agree to abide by all terms of this Agreement relevant to the activities they perform.
- (3) The Institution warrants that to the best of its knowledge, it, its affiliates and any person involved in the conduct of the Study, including the Principal Investigator, are properly registered with appropriate professional registration bodies, have not been disqualified from practice or disbarred or banned from conducting clinical trials by any Regulatory Authority for debarment. Furthermore, the Institution shall notify the CRG as soon as practical after it becomes aware of any such disqualification, disbarment or ban.
- (4) The Institution will not engage in any conduct on the CRG's behalf which is in violation of, or potentially in violation of, any applicable local or foreign laws or regulations.
- (5) The Institution must have adequate security measures to ensure the safety and integrity of the Investigational Product(s), Essential Documents and Study records and reports, Equipment and any Study related materials held or located at the Study Site.
- (6) Subject to **clause 9**, the Institution will allow regular monitoring and scheduled audit visits in accordance with the GCP Guideline and as required by Regulatory Authorities or as specified in the Protocol and permit access to the Essential Documents (including original records), Study records, reports, other Study related materials and its Personnel as soon as is reasonably possible upon request by the CRG, Regulatory Authority, Responsible HREC or any third party designated by the CRG. Any such access is to take place at times mutually agreed during business hours and subject to such

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reasonable conditions relating to occupational health and safety, security, and confidentiality as the Institution may require.

- (7) The Institution will make available adequate facilities, equipment and any other resource of the Institution reasonably required to safely follow the Protocol, provided that any amendments to the Protocol which take place after the execution of this Agreement and requiring any additional use of facilities, equipment, staff or resources, have been approved in writing by the Institution and the Responsible HREC.
- (8) The Institution will have an adequate number of appropriately qualified Personnel for the foreseen duration of the Study and ensure that such Personnel are adequately informed about the Protocol, the Investigational Product(s), and their Study related duties and functions. The Personnel appointed by the Institution to assess Study Subjects will attend an investigator meeting or a pre-study/initiation meeting, where appropriate.
- (9) The Institution must retain and preserve a copy of all Study Materials, including copies of signed consent forms, Case Report Forms, Protocol, information relating to the Investigational Product, correspondence and investigator files for at least 15 years from Study Completion and must ensure that no Study related materials are destroyed before the expiration of this time period without the written approval of CRG. The Institution agrees to notify the CRG before destroying any Study Materials.
- (10) The Institution will ensure that the Study is subject to the continuing oversight of the Responsible HREC throughout its conduct.
- (11) If the Institution is contacted by any Regulatory Authority in connection with the conduct of the Study, the Institution shall immediately notify the CRG, unless prevented from doing so by law.
- (12) The Institution will provide the CRG with all reasonable assistance and cooperation to rectify any matter raised by a Regulatory Authority or as the result of an audit of the Institution or Study Site. This includes execution of any documents reasonably requested by the CRG in connection with the requirements of a Regulatory Authority or the CRG as a result of such an audit. Any costs resulting from such audit shall be borne equally by the parties, unless the cost has resulted solely from an act or omission of a party, in which case that party will bear the total costs.

5. CRG

5.1 Obligations and responsibilities

- (1) Prior to the Agreement being executed, the CRG or its designate will provide the Principal Investigator, and through the Principal Investigator the Institution and the Responsible HREC, with all current and relevant information regarding the Investigational Product that is reasonably available to the CRG and required to justify the nature, scope and duration of the Study.
- (2) The CRG will act as sponsor of the Study for the purposes of the TGA's CTN Scheme or CTX Scheme (or any successor scheme). The CRG is responsible for preparing and submitting all documents required by the TGA to file an application for initiating and conducting the Study.
- (3) The CRG will implement and maintain quality assurance and quality control systems to ensure that the Study can be conducted and data generated, documented, recorded and reported in compliance with all of the documents referred to in **clause 2**.
- (4) The CRG will register the Study on the appropriate clinical trials registry.

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- (5) The CRG will designate appropriately qualified personnel to advise on Study-related medical questions or problems.
- (6) The CRG will, as soon as it becomes aware, advise the Institution, through the Principal Investigator and TGA of the cessation elsewhere of any relevant trial, or the withdrawal of the Investigational Product from any other market for safety reasons.
- (7) The CRG 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.
- (8) The CRG will cooperate with the Institution and/or the Responsible HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Study.
- (9) To assist the Institution to comply with **clause 8**, the CRG will provide the Institution with adequate information and all necessary product accountability forms.

6. PAYMENTS

- 6.1 In consideration of the Institution conducting the Study, the CRG will pay to the Institution as nominated in **Schedule 2** in the manner and on the basis of the amounts and at the times set out in **Schedule 2**. The amounts set out in **Schedule 2** do not include GST. At the time of payment, the CRG must pay to the Institution any amount of GST that the Institution is required to pay in addition to the amounts set out in **Schedule 2**, and in accordance with GST Law.
- 6.2 The CRG reserves the right to refuse to pay to the Institution payments specific to Study Subjects entered into the Study who do not meet the entry criteria specified in the Protocol.
- 6.3 If a Study Subject discontinues their participation in the Study or if the Study is terminated as a whole, only those costs incurred up until the date of discontinuation or termination, including costs of final visit and completion of all Case Report Forms, will be paid.
- 6.4 Payments will be made by the CRG upon either receipt of a valid tax invoice or a "Recipient Created Tax Invoice" issued by the CRG.
- 6.5 The CRG and the Institution warrant that they are registered under GST Law. Tax invoices must identify supplies for which GST is payable.

7. PROVISION OF EQUIPMENT

- 7.1 The CRG will facilitate the supply of the Equipment by the manufacturer to the Institution and Principal Investigator with the Equipment at no cost to the Institution.
- 7.2 Unless otherwise agreed by the parties in writing, the Institution must ensure that the Equipment is used only by the Principal Investigator and Personnel involved in the conduct of the Study and only for the purposes of the Study.
- 7.3 If proper usage of the Equipment requires training, the Institution agrees that:
 - (1) the Principal Investigator and Institution's Personnel will make themselves available for training in using the Equipment, at no cost to the Institution; and
 - (2) the Equipment will only be used as described in written directions provided by the CRG.

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- 7.4 The Institution must take all reasonable steps in the use and security of the Equipment to ensure that it is not lost or damaged.
- 7.5 Subject to clause 7.6, at any time after Study Completion, the Institution must comply with any request from the CRG:
- (1) on behalf of the manufacturer, to return to the manufacturer the Equipment and all related training materials and documentation provided by the manufacturer
 - (2) to return all related training materials and documentation provided by the CRG to the CRG at no cost to the Institute.
- 7.6 If the CRG does not request the return of the Equipment or any related training materials and documentation after the Study Completion, the Institution may retain, at no cost to it, or destroy same.
- 7.7 The CRG will comply with any reasonable request from the Institution to assist in maintaining the Equipment in good working order, and ensuring that it is in a safe condition and compliant with the requirements of the relevant licensing and safety authorities at all times.

8. INVESTIGATIONAL PRODUCT & PRODUCT LIABILITY

- 8.1 The CRG will facilitate the supply of such quantities of the Investigational Product as will be required for the purpose of the Study.
- 8.2 The Institution must:
- (1) ensure that all Investigational Product is used strictly according to the Protocol and is not used for any other purposes, unless agreed in writing by the CRG;
 - (2) provide a written explanation accounting for any missing Investigational Product;
 - (3) not charge a Study Subject or third party payer for Investigational Product; and
 - (4) 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.
- 8.3 In the event of termination, the Institution must promptly return (or destroy if requested by the CRG, and provide evidence of such destruction) to the CRG or its designate any unused Investigational Product(s).

9. CONFIDENTIALITY AND PRIVACY

- 9.1 Subject to **clause 9.2**, 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.
- 9.2 The Institution may use or disclose Confidential Information in any of the following circumstances:
- (1) for the purposes of complying with the Institution's internal complaint procedures, accident reporting procedures, quality assurance activities, disciplinary procedures or any applicable policy in relation to patient safety, Adverse Events and/or reportable incidents;

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- (2) for the purposes of disclosing any material risks identified during the Study or subsequent to it, to Study Subjects, Principal Investigators, medical practitioners administering treatment to Study Subjects, Responsible HRECs and Regulatory Authorities;
 - (3) for the purposes of complying with the requirements of any Regulatory Authority;
 - (4) for the purposes of the monitoring of the Study by the Responsible HREC;
 - (5) where the CRG consents in writing to the disclosure;
 - (6) where the Confidential Information has been independently received from a third party who is free to disclose it;
 - (7) where the Confidential Information has entered the public domain other than as a result of a breach of this Agreement;
 - (8) as part of a publication issued under the provisions of **clause 11**;
 - (9) where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the CRG;
 - (10) for the purposes of legal advice; and
 - (11) disclosure to the Institution's insurer.
- 9.3 Where Confidential Information is disclosed in accordance with **clause 9.2(1)** or **9.2(4)**, 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.
- 9.4 The parties are responsible for ensuring that their Personnel are aware of the obligations in respect of Confidential Information in this **clause 9**, 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.
- 9.5 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.

10. LIABILITY AND INSURANCE

- 10.1 Each party is liable for its acts and omissions in relation to the conduct of the Study.
- 10.2 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.
- 10.3 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 State or Territory of the Commonwealth of Australia.

11. PUBLICATIONS

- 11.1 The Institution, its personnel and the Principal Investigator must not Publish or present any aspect of the Study without the prior written approval of the CRG such approval not to be unreasonably withheld. However, the Institution may use and present any information concerning the Study for the purposes of internal training, education, evaluation or discussion without the consent of the CRG.
- 11.2 The CRG acknowledges that the Institution may periodically wish to distribute information releases and announcements regarding the progress of research, including this Study. The Institution agrees that they will not release such written or

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oral material regarding the Study to the news media or a third party without the prior written approval of the CRG, such approval not to be unreasonably withheld.

- 11.3 The parties agree that publications or presentations of any of the results from the Study will take into account the co-operative nature of the conduct of the Study and the overall objective of increasing public knowledge and shall be in accordance with accepted scientific practice, academic standards and customs and in accordance with the Protocol and with any more specific publication/presentation guidelines developed during the course of the Study, including but not limited to the following:
- (1) If the Study is a Multi-centre Study, the results from a single centre must not be Published before the Publication of results from all centres.
 - (2) Individuals making a substantial contribution to the Study will be recognised with co-authorship in the publication of results from the Study, unless they elect not to be recognised.

12. STUDY RESULTS AND INTELLECTUAL PROPERTY

- 12.1 All Intellectual Property created and provided by the CRG remains the sole property of the CRG or its designate.
- 12.2 In order to carry out the Study, the Institution may use Intellectual Property which is part of the Institution's Background Intellectual Property. Any such Background Intellectual Property remains the sole property of the Institution. The Institution grants to the CRG a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) the Institution's Background Intellectual Property for the commercialisation of the Study Materials.
- 12.3 Subject to **clause 12.2**, all Intellectual Property in the Study Materials will vest automatically upon its creation in the CRG, and the Institution presently assigns the CRG all existing and future Intellectual Property rights (including all future copyright) contained in the Study Materials. The Institution agrees to execute or procure the execution by its Personnel of any documents reasonably necessary to give effect to this assignment, at the CRG's expense.
- 12.4 As a general principle, any Intellectual Property specifically relating to any Investigational Product or Equipment shall be the sole property of the company owning the Investigational Product or Equipment. Nothing in this agreement transfers any Intellectual Property rights (other than a right to use where expressly stated in this agreement) in the Equipment and the Investigational Product to the Institution or the Principal Investigator.

13. TERM AND TERMINATION

- 13.1 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 CRG or Institution. In the ordinary course of events this Agreement terminates on Study Completion.
- 13.2 Either the CRG or the Institution 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:
- (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;

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- (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
 - (3) assigns this Agreement to a person considered unsuitable to perform the Agreement as set out in **clause 19.3**.
- 13.3 In addition to **clause 13.2**, a party may terminate this Agreement immediately by written notice to the other party if it believes on reasonable grounds that:
 - (1) continuing the Study poses an unacceptable risk to the rights, interests, safety or well-being of Study Subjects; and
 - (2) terminating this Agreement is the most appropriate way to respond to that risk.
- 13.4 The CRG may terminate this agreement immediately by giving notice if the Principal Investigator leaves the institution and an acceptable replacement cannot be found in accordance with clause 4.1(1)(c).
- 13.5 The CRG may terminate this Agreement with 30 days prior written notice to the Institution. In the event of such early termination, the CRG will pay the reasonable costs of the Institution relating to the Study calculated in accordance with Schedule 2.
- 13.6 In the event of termination, the Institution must promptly initiate all appropriate action to close the Study and, subject to any applicable retention requirements imposed by law, return to the CRG (or destroy if requested by the CRG, and provide evidence of such destruction) any completed Case Report Forms and other materials received from the CRG before Study Completion.
- 13.7 In the event of termination the CRG must take all appropriate action to close out the Study Site in a timely manner.
- 13.8 In the event of early termination, the CRG will cooperate with the Institution to ensure that Study Subjects who may be affected by termination receive adequate medical care. This may include facilitating the provision of Investigational Product in certain circumstances at no cost to the Institution.
- 13.9 The following provisions survive termination of this Agreement, **clauses 1.1, 1.2, 4.1(6), 4.1(7), 4.1(9), 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 and 20**.

14. DISPUTES

- 14.1 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**").
- 14.2 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.
- 14.3 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.

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- 14.4 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.
- 14.5 Nothing in **clause 14** will prevent a party from seeking injunctive relief where damages may be an inadequate or inappropriate remedy.

15. 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.

16. NOTICES

- 16.1 A notice, consent, approval or other communication (each a **notice**) under this Agreement must be:
- (1) delivered to the party's address;
 - (2) sent by pre-paid mail to the party's address; or
 - (3) transmitted by facsimile to the party's address.
- 16.2 A notice given by a party in accordance with this clause is treated as having been given and received:
- (1) if delivered to a person's address, on the day of delivery if a business day, otherwise on the next business day;
 - (2) if sent by pre-paid mail, on the third business day after posting;
 - (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.
- 16.3 The addresses of the parties for the purposes of giving any notice are set out on the front page of this Agreement.

17. WAIVER

- 17.1 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.
- 17.2 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.

18. VARIATIONS

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

19. ASSIGNMENT

- 19.1 Subject to **clause 19.2**, 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.
- 19.2 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.
- 19.3 If a party assigns this Agreement under **clause 19.2**, 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 13.2(3)**.

20. ENTIRE AGREEMENT

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

21. 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.

22. 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.

23. 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.

24. 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 the Agreement Date below.

Signed on behalf of the **CRG**

Signed: _____

Name: _____

Position: _____

Date: _____

Signed on behalf of the **INSTITUTION**

Signed: _____

Name: _____

Position: _____

Date: _____

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

The Principal Investigator acknowledges this Agreement and understands the obligations it imposes.

Acknowledged by the **PRINCIPAL INVESTIGATOR**

Signed: _____

Name: _____

Position: _____

Date: _____

Schedule 1: Key Information

(to be inserted by CRG)

Study Name: _____

Study Site/s: _____

Protocol Number: _____

Target number of Study Subjects: Minimum: Maximum:

Recruitment Period: Start: / /

End: / /

Principal Investigator
Name: _____

Address: _____

State: P/code:

Responsible HREC: _____

Equipment: _____

Investigational Product: _____

Schedule 2: Payments

Please Paste/Enter Text In Field Below

Schedule 3: Study Protocol Identification

Full Title: _____

Version Number: _____
Date: / /

List of Key attachments: _____

Schedule 4: Special Conditions

Please Paste/Enter Text In Field Below

Amendment to Clauses in the Body of the Agreement

1. The definition of "Confidential Information" in clause 1.1 is amended:
 - i) by inserting the following words "which is provided by the CRG (and if owned by an Affiliate of the CRG is identified as such at the time of provision)" at the end of the paragraph (1)(c)
 - ii) by inserting the following words "provided by the CRG (and if owned by an Affiliate of the CRG is identified as such at the time of provision)" after the word "Information" in paragraph (1)(e)
2. The definition of "Intellectual Property" in clause 1.1 is amended to replace the words "which may subsist anywhere in the world" with the words "as recognised by the law in force in Australia".
3. The definition of "Personnel" in clause 1.1 is amended to insert the word "officers" after the words "Personnel means" and inserting the word "contractors" after the word "employees,"
4. The definition of "Relevant Privacy Law" in clause 1.1 is amended:
 - i) by replacing the word "and" after the words "Privacy Act 1988 (Cth)" with the word "or"
 - ii) by replacing the words "in the jurisdiction in which the Study Site is located" with the words "in Western Australia".
5. The following definition is inserted in clause 1.1 between "Study Materials" and "Study Subject":

"Study Related Materials means the Study Materials, and other documentation provided to the Institution which embodies Confidential Information of the CRG and is related to the Study".

All references to "Study related materials" are changed to references to "Study Related Materials."
6. Clause 2.1 is amended to:
 - i) replace the words "... the Protocol and any condition of the responsible HREC. In addition the Parties must comply with the following, as applicable:" with the words "the following, in the following order of precedence"
 - ii) replace the following words:
 - (2) "the requirements of the TGA in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or replacement and any other TGA publication or guideline that relates or may relate to clinical trials, or other such regulations or guidances governing the conduct of clinical research in the jurisdiction of the Study;
 - (3) the GCP Guideline;
 - (4) the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996; and
 - (5) the NHMRC National Statement on Ethical Conduct in Research Involving Humans (1999) or replacement, and any other relevant NHMRC publication or guideline that relates or may relate to clinical trials;"
 - (6) any Study specific and standard operating procedures provided by the CRG prior to the commencement of the Study; and
 - (7) any reasonable direction given by the CRG in order to ensure the safe conduct of the trial and compliance with applicable regulatory requirements.

with the words:

"

- (2) any condition of the Responsible HREC; and
- (3) the Protocol;

and additionally as applicable:

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- (4) the NHMRC National Statement on Ethical Conduct in Research Involving Humans (2007) or replacement, and any other relevant NHMRC publication or guideline that relates or may relate to clinical trials;
 - (5) the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996;
 - (6) the GCP Guideline; and
 - (7) the requirements of the TGA in Access to Unapproved Therapeutic Goods – Clinical Trials in Australia (October 2004) or replacement and any other TGA publication or guideline that relates or may relate to clinical trials, or other such regulations or guidances governing the conduct of clinical research in the jurisdiction of the Study.
 - (8) any Study specific and standard operating procedures provided by the CRG prior to the commencement of the Study; and
 - (9) any reasonable direction given by the CRG in order to ensure the safe conduct of the trial and compliance with applicable regulatory requirements.
7. Clause 3.3 is amended by inserting the words “(unless legally constrained from doing so)” after the words “notifies the CRG” in subclause (10)
 8. Clause 4.1 is amended as follows:
 - i) replace the words “The Institution will not engage in any conduct on the CRG’s behalf which is in violation of, or potentially in violation of, any applicable local or foreign laws or regulations” in subclause (4) with the words “The Institution will not engage in any conduct which is in violation of any applicable law ”
 - ii) insert the words “unless prevented from doing so by law or due to conflicting applicable Western Australia Government (including Western Australia Government Agency) policies.” in subclause (12) after the words “... as a result of such an audit”.
 9. Clause 9.1 is amended by inserting the words “use reasonable endeavours to” after the words “the Parties must not, and must”.
 10. Clause 9.2 is amended as follows:
 - i) the word “and” is deleted from subclause (10)
 - ii) the word “and” is inserted after the words “Institution’s insurer” in subclause (11)
 - iii) a new subclause, number (12) is inserted with the text “to Parliament (including committees of it), and Ministers of the Crown if legally directed to do so.”
 11. Clause 9.4 is amended by deleting the words “and are bound in similar terms to keep such information confidential”
 12. Clause 10.3 is amended by deleting all the words in the clause and inserting the following words “The Institution arranges self-insurance through the Insurance Commission of Western Australia, a body corporate constituted under the *Insurance Commission of Western Australia Act 1986*. The cover extends to employees of the Institution and has a maximum limit of \$250 million.
 13. Clause 12.3 is amended by inserting the words “use reasonable endeavours to” after the words “the Institution agrees to execute or”.
 14. Clause 13.2, subclause (3), is amended by replacing the words “clause 19.3” with the words “clauses 19.3 and 19.5 (as applicable)”.
 15. Clause 13.9 is amended by inserting the number “5.1(8)”.
 16. Clause 14.1 is amended by deleting the words “(“Initial Period”)”.
 17. Clauses 14.2, 14.3 and 14.4 are deleted.
 18. Insert a new clause 14.2 with the wording “In the event that the dispute is not settled within 28 days then the parties are free to pursue any other procedures available at law for the resolution of the dispute.”.
 19. Clause 15 is amended by inserting the word “exclusive” after the words “the parties submit to the”.
 20. Clause 19.2 is amended by deleting all the words in the clause and inserting the following words: “The Institution may assign this Agreement to any entity which assumes control of it but must give the CRG notice in writing of any such assignment and obtains from the relevant assignee a written undertaking in favour of the CRG to be bound by the terms of this Agreement.”.

21. Clause 19.3 is amended by deleting all the words in the clause and inserting the following words: "If the Institution assigns this Agreement under **clause 19.2**, and the relevant assignee is determined by the CRG, in its discretion, as unsuitable to perform its obligations under this Agreement, the CRG may terminate the agreement in accordance with **clause 13.2(3)**."
22. Insert a new clause after clause 19.3
"19.4 The CRG may assign the benefit of this Agreement provided it obtains from the relevant assignee a written undertaking in favour of the Institution to be bound by the terms of this Agreement."
23. Insert a new clause after clause 19.4
"19.5 If the CRG assigns this Agreement under **clause 19.4** and the relevant assignee is determined by the Institution, in its discretion, as unsuitable to perform its obligations under this Agreement, the Institution may terminate the Agreement in accordance with **clause 13.2(3)**."
24. Clause 21 is amended by deleting all the words and inserting the words "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 provided that if the party which benefited from the part so severed forms the opinion in its absolute discretion that any such severance materially prejudices its rights under the Agreement, the party so affected may by notice in writing to the other terminate this Agreement."