

Instructions:

1. Insert your logo in the box to the left
2. Resize logo by dragging right hand corner
3. Update the footer information
4. Delete these Instructions
5. Complete other information in the Form

Please ensure all sections are complete BEFORE submission. Study specific information needs to be entered:
 -the front page
 Schedule 1 – key information
 Schedule 2 – payments
 Schedule 6 - payments

Clinical Trial Research Agreement Medicines Australia – Standard Form

Is this the correct template?

The body of this Agreement (that is from the following page to the execution clauses) is intended to be identical to the standard form a copy of which is located at <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements>. **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 7 by way of Special Conditions.**

Any changes must have SEBS approval

Details of the parties

Name of Institution:	South Eastern Sydney Local Health District
Address:	District Executive Unit, Level 4 The Sutherland Hospital & Community Health Service Cnr The Kingsway and Kareena Road CARINGBAH NSW 2229
ABN:	70 442 041 439
Contact for Notices:	[principal investigator for site]
Fax for Notices:	[this can be also used for email address]
Phone Number:	[PI or coordinator to complete]

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

Study Name:	
Protocol Number:	
Date of Agreement:	

Protocol Number: [sponsor to complete]
 Site: [sponsor to complete]

This agreement is made between the Sponsor and Institution

Purpose of the Agreement

According to this Agreement:

- A. The Sponsor is responsible for the initiation, management, and financing of the Study.
- B. The Institution, through the Principal Investigator, is responsible for the conduct of the Study at the Study Site(s) which is/are under the control of the Institution.
- C. The Study will be conducted on the terms and conditions set out below.

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 its replacement.

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

Agreement means this Agreement, including all the Schedules.

Background Intellectual Property (Background IP) of a party 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 or on behalf of that party to the other for use in the Study (whether before or after the date of this Agreement) or used by that other party in conducting the Study, and all Intellectual Property in them, but excludes the Study Materials.

Biological Samples means any physical samples obtained from Study Participants in accordance with the Protocol for the purposes of the Study.

Case Report Form means a printed, optical or electronic document or database designed to record all of the information, which is required by the Protocol to be reported to the Sponsor on each Study Participant.

Confidential Information means:

- (1) in respect of the Sponsor:
 - (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 related to the Protocol, Study Materials and Investigational Product;
 - (c) know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the Sponsor or its Affiliates;
 - (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 Sponsor or its Affiliates;
- (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.

Equipment means the equipment supplied to the Institution by or on behalf of the Sponsor for the purposes of the Study, including that specified in **Schedule 1**.

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, or its replacement.

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 present and future industrial and intellectual property rights, including without limitation:

- (1) inventions, patents, 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, and any and all other rights to intellectual property which may subsist anywhere in the world; and
- (2) any application for or right to apply for registration of any of those rights.

Investigational Product is the medicine or device being trialled or tested in the Study, as set out in **Schedule 1**, 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.

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.

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

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

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 6** which describes the objective(s), design, methodology, statistical considerations and organisation of the Study, and subject to **clause 2.3**, as amended from time to time, as agreed by the parties, and most recently approved by the Reviewing 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, the Study Materials, in printed, electronic, oral or other form.

Publication has a corresponding meaning.

Regulatory Authority means any 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 audit, or require to be audited, 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.

Reviewing 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 TGA document "Access to Unapproved Therapeutic Goods – Clinical Trials in Australia" (October 2004) or its replacement.

Software means the software supplied to the Institution by or on behalf of the Sponsor for the purposes of the Study, including that specified in **Schedule 1**.

Sponsor means the corporate entity so described on the first page of this Agreement.

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

Study Completion means the database for the Study has been locked and all Essential Documents have been provided to the Sponsor, including a copy of the letter from the Reviewing HREC acknowledging receipt of the final report and/or closure letter from the Principal Investigator.

Study Materials means all the materials and information created for the Study, or required to be submitted to the Sponsor 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, but excluding the Institution's ordinary patient records.

Study Participant 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 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;
- (5) all the provisions in any schedule to this Agreement are incorporated in, and form part of, this Agreement and bind the parties;
- (6) a reference to a replacement of a document or standard, means any document or ruling which amends, updates, replaces or supersedes that document or standard;

- (7) 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;
- (8) a reference to a monetary amount means that amount in Australian currency; and
- (9) references to a party include its Personnel.

2. THE STUDY

- 2.1 The parties must comply with, and conduct the Study in accordance with, the Protocol and any conditions of the Reviewing 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 its replacement and any other TGA publication or guideline that relates to clinical trials, or other such regulations or guidance 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 (as accepted by the Australian Government); and
 - (5) the NHMRC National Statement on Ethical Conduct in Human Research (2007) or its replacement, and any other relevant NHMRC publication or guideline that relates to clinical trials.
- 2.2 If any issue relating to the safety of Study Participants arises which requires a deviation from the Protocol, the Institution through the Principal Investigator may immediately make such a deviation without breaching any obligations under this Agreement. If there is a need for such a deviation the Institution must notify the Sponsor and the Reviewing HREC 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.
- 2.3 From time to time, the Sponsor may modify the Protocol by written notice to the Institution and Principal Investigator. Except where the modification is necessary to eliminate an immediate hazard to Study Participants, or involves only logistical or administrative aspects of the trial, any modification may not be implemented before approval by the Reviewing HREC. If the parties determine that a modification will affect the cost of the Study, the parties shall amend **Schedule 2** as agreed between them.

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. 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

For the purpose of this Agreement only, and as between the Sponsor 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

The PI must read and understand the responsibilities as representative of SESLHD

The PI must be an employee of SESLHD

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

The Institution is responsible for ensuring that the Principal Investigator:

- (1) thoroughly familiarises themselves 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 Sponsor;
- (2) ensures written approval has been obtained to conduct the Study from the Reviewing HREC and the Institution prior to Study initiation. Written documentation of approval by the Reviewing HREC and the Institution must be provided to the Sponsor;
- (3) conducts the Study according to the Protocol without changes, except as provided in **clause 2.2** or **2.3**, or as agreed to in writing by the Sponsor and the Institution and approved in accordance with **clause 3.3(5)**;
- (4) completes (and obtains completion from relevant Personnel) and returns to the Sponsor a statement of financial disclosure (an example that meets this requirement is Food and Drug Administration Form 3455 'Disclosure: Financial Interests and Arrangements of Clinical Investigators) before the commencement of the Study and as otherwise required, and consents to the disclosure of the completed form to overseas regulatory agencies, if required;
- (5) ensures that any amendments to the Protocol are approved by the Reviewing HREC and Sponsor prior to implementation of the amendment;
- (6) ensures that the Sponsor's prior written consent is obtained to any advertisement in respect of the Study;
- (7) provides the Sponsor 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 their best endeavours to recruit the target number of Study Participants, within the recruitment period, specified in **Schedule 1**, provided that if the overall target number of Study Participants for the Study is reached, the Sponsor may direct the Institution to cease recruitment;
- (9) is available when a clinical research representative of the Sponsor 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 Sponsor, the Institution and the Reviewing 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 Reviewing HREC, with their policies and procedures;
- (11) completes Case Report Forms within the agreed time period. The Principal Investigator will ensure that Study Participants' identifying information are removed from all records being transferred to the Sponsor;
- (12) provides regular written progress reports to the Sponsor in relation to the Study as required by the Protocol;
- (13) completes and returns to the Sponsor 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; and
- (15) ensures that informed consent to participate in the Study is obtained from each Study Participant prior to their enrolment in the Study and documented using an information and consent document which has been reviewed and approved by the Sponsor, the Institution and the Reviewing HREC.

4. INSTITUTION OBLIGATIONS AND RESPONSIBILITIES

- 4.1 If the Principal Investigator leaves the Institution or otherwise ceases to be available then:
 - (1) the Institution must consult with the Sponsor and use reasonable endeavours to nominate as soon as practicable a replacement reasonably acceptable to both parties; and
 - (2) the Sponsor may require recruitment into the Study by the Institution to cease, or move the Study to a different Study Site.
- 4.2 If the Principal Investigator fails to carry out those obligations specified in **clauses 3.3(2), (3), (5), (8), (10), (11), (13) or (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.
- 4.3 The Institution warrants that, to the best of its knowledge, it and its affiliates and any other 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. Furthermore, the Institution shall notify the Sponsor as soon as practical after it becomes aware of any such disqualification, disbarment or ban.
- 4.4 The Institution will not engage in any conduct on the Sponsor's behalf which is in violation of, or potentially in violation of, any applicable local or foreign laws or regulations.
- 4.5 The Institution warrants, represents and undertakes to the Sponsor that it has not offered, promised or paid, either directly or indirectly, any Benefit to a government official (including, but not limited to, a healthcare professional employed by a government-owned healthcare facility) to induce such government official to act in any way in connection with his or her official duties with respect to services performed under this Agreement or to otherwise obtain an improper advantage for the Institution or the Sponsor (**Improper Payment**), and has not received an Improper Payment, and will not offer, promise, pay, authorise or receive any Improper Payment in the future. For the purposes of the foregoing, Benefit includes but is not limited to money, financial or other advantage, travel expenses, entertainment, business or investment opportunities, charitable donations or any other thing of value.
- 4.6 The Institution must have adequate security measures to ensure the safety and integrity of the Investigational Product, Essential Documents and Study records and reports, Equipment and any Study related materials held or located at the Study Site.
- 4.7 Subject to **clause 9**, the Institution will allow regular monitoring visits in accordance with the GCP Guideline, access for the purposes of audit 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 Sponsor, Regulatory Authority, Reviewing HREC or any third party designated by the Sponsor. Any such access is to take place at times mutually agreed, during business hours and subject to such reasonable conditions relating to occupational health and safety, security, and confidentiality as the Institution may require.

- 4.8 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 Reviewing HREC.
- 4.9 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, Investigational Product(s), and their Study-related duties and functions. The Personnel appointed by the Institution to assess Study Participants will attend an investigator meeting or a pre-study/initiation meeting, where appropriate.
- 4.10 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 the Sponsor. The Institution agrees to notify the Sponsor before destroying any Study Materials and agrees to retain the Study Materials for such longer period as reasonably required by the Sponsor at the Sponsor's expense.
- 4.11 The Institution will ensure that the Study is subject to the continuing oversight of the Reviewing HREC throughout its conduct.
- 4.12 If the Institution is contacted by any Regulatory Authority in connection with the conduct of the Study, the Institution shall immediately notify the Sponsor, unless prevented from doing so by law.
- 4.13 The Institution will provide the Sponsor 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 Sponsor in connection with the requirements of a Regulatory Authority or the Sponsor as a result of such an audit. The cost will be borne by the Sponsor unless such rectification is due to the default of the Institution or the Principal Investigator.
- 4.14 The Institution shall obtain approval, in writing, from the Sponsor for any press statements or promotional statements regarding the Study or the Investigational Product(s) before the statements are released, unless the statement or disclosure is required by:
- (1) law;
 - (2) any policy, guideline or direction of government or any government department or agency;
 - (3) any Regulatory Authority; or
 - (4) is, in the absolute discretion of the Institution, Minister for Health, Department of Health or any government official, reasonably necessary in the public interest or to protect the health and safety of any individual.

5. SPONSOR OBLIGATIONS AND RESPONSIBILITIES

- 5.1 Prior to the Agreement being executed, the Sponsor must provide the Principal Investigator, and, through the Principal Investigator, the Institution and the Reviewing HREC, with all current and relevant information regarding the Investigational Product as reasonably required to justify the nature, scope and duration of the Study.
- 5.2 The Sponsor will implement and maintain quality assurance and quality control systems with written standard operating procedures 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 2.1**.
- 5.3 The Sponsor will designate appropriately qualified personnel to advise on Study-related medical questions or problems.
- 5.4 The Sponsor will monitor the application of the Investigational Product in other places (both within and outside Australia) and 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.
- 5.5 The Sponsor 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 Participants.
- 5.6 The Sponsor will cooperate with the Institution and/or the Reviewing HREC in investigating any Adverse Event (including Serious Adverse Event) arising out of or in connection with the Study.
- 5.7 To assist the Institution to comply with **clause 8**, the Sponsor will provide the Institution with adequate information and all necessary Investigational Product accountability forms.
- 5.8 The Sponsor will provide indemnity to the Institution and members of the Reviewing HREC against claims arising from the Study on the terms and conditions set out in the relevant Medicines Australia Form of Indemnity for Clinical Trials as set out in **Schedule 3**.
- 5.9 The Sponsor will comply with the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-sponsored Trial as specified in **Schedule 5**.
- 5.10 The Sponsor will maintain insurance with respect to its activities and indemnity obligations under this Agreement in accordance with **Schedule 4**. This insurance is to be evidenced by a certificate of insurance, as requested by the Institution from time to time.

6. PAYMENTS

- 6.1 In consideration of the Institution conducting the Study, the Sponsor 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 Sponsor 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 Sponsor reserves the right to refuse to pay to the Institution payments specific to Study Participants entered into the Study who do not meet the entry criteria specified in the Protocol.

Please ensure payee and amount details are correct within schedule 2

- 6.3 If a Study Participant 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 Sponsor upon either receipt of a valid tax invoice or a "Recipient Created Tax Invoice" issued by the Sponsor.
- 6.5 The Sponsor and the Institution each warrant that they are registered under GST Law. Tax invoices must identify supplies for which GST is payable.
- 6.6 The final payment will be made following Study Completion.
- 6.7 No part of any consideration paid hereunder is for the recommending or arranging for the referral of business or the ordering of items or services.
- 6.8 Neither this Agreement nor any consideration paid hereunder is contingent upon the Institution's use or purchase of any of the Sponsor's products.

7. PROVISION OF EQUIPMENT & SOFTWARE

- 7.1 The Sponsor will provide the Institution and Principal Investigator with the Equipment and Software at the Sponsor's expense. Unless otherwise agreed by the parties in writing, the Equipment and Software will be used only by the Principal Investigator and Personnel involved in the conduct of the Study and only for the purposes of the Study.
- 7.2 If proper usage of the Equipment or Software requires training, the Institution agrees that:
- (1) the Principal Investigator and Institution's Personnel will make themselves available for training in using the Equipment and Software, at the Sponsor's expense; and
 - (2) the Equipment and Software will only be used as described in written directions provided by the Sponsor.
- 7.3 The Equipment will be at the risk of the Sponsor, but the Institution will take reasonable care in the use and secure storage of the same and the Institution is responsible for damage caused to or by the Equipment by the negligence of its Personnel.
- 7.4 At the completion of the Study or at the Sponsor's request, the Institution will, unless otherwise specified, return to Sponsor, at the Sponsor's expense, the Equipment and Software and all related training materials and documentation.
- 7.5 The Sponsor will cooperate with the Institution in maintaining, at the Sponsor's expense, 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.
- 7.6 The Institution will not copy the Software unless specifically authorised by the Sponsor.

8. INVESTIGATIONAL PRODUCT

- 8.1 The Institution must:
- (1) ensure that all Investigational Product made available by the Sponsor is used strictly according to the Protocol and are not used for any other purposes, unless agreed in writing by the Sponsor;
 - (2) provide a written explanation accounting for any missing Investigational Product;

- (3) not charge a Study Participant or third party payer for Investigational Product or for any services reimbursed by the Sponsor under this Agreement;
 - (4) keep all Investigational Product under appropriate storage conditions (including any conditions specified in the Protocol) and in a secured area accessible only to authorised Personnel; and
 - (5) ensure that complete and current records are maintained for all received, dispensed and returned Investigational Product.
- 8.2 The Sponsor will supply the Principal Investigator with such quantities of the Investigational Product as will be required for the purpose of the Study. All supplied Investigational Product will be packaged in safe and appropriately labelled containers. The Sponsor will at all times remain the sole owner of the Investigational Product.
- 8.3 On termination of this Agreement, the Institution must promptly return any unused Investigational Product to the Sponsor, or, if requested by the Sponsor, destroy it and provide evidence of such destruction.

9. CONFIDENTIALITY

- 9.1 Subject to **clause 9.2**, each party must not, and must ensure their Personnel do not, use or disclose any Confidential Information of the other party, other than where and only to the extent that such use or disclosure is necessary for the performance of the Study, the exercise of its rights or the performance of its obligations under this Agreement.
- 9.2 The Institution may use or disclose Sponsor 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;
 - (2) for the purposes of disclosing any material risks, identified during the Study or subsequent to it, to Study Participants, Principal Investigators, medical practitioners administering treatment to Study Participants, Reviewing HRECs and Regulatory Authorities;
 - (3) for the purposes of complying with the requirements of any Regulatory Authority;
 - (4) to enable the Reviewing HREC to monitor the Study;
 - (5) where the Sponsor consents in writing to the disclosure;
 - (6) as part of a publication issued under the provisions of **clause 11**;
 - (7) where release of the Confidential Information is required by law, with notice as soon as reasonably practical to the Sponsor, and subject to the Institution upon request providing reasonable assistance to enable the Sponsor to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure;
 - (8) for the purposes of the Institution seeking legal advice; or
 - (9) disclosure to the Institution's insurer.
- 9.3 Where Confidential Information is disclosed in accordance with **clause 9.2 (1), (4), (8) or (9)** 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 Sponsor may disclose Institution Confidential Information to its lawyers for the purposes of obtaining legal advice or to its Affiliates but only on a needs to know and confidential basis. The Sponsor may disclose Institution Confidential Information if required by law, with notice as soon as reasonably practical to the Institution, and subject to the Sponsor upon request providing reasonable assistance to enable the Institution to obtain a protective order or other remedy to resist disclosure or ensure confidential treatment for any required disclosure.
- 9.5 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.
- 9.6 Information will not be Confidential Information and subject to the provisions of this **clause 9** where:
- (1) the information has been independently received from a third party who is free to disclose it;
 - (2) the information is in or has entered the public domain other than as a result of a breach of this Agreement;
 - (3) the party already knew the information, the prior knowledge of which it can document by prior written records; or
 - (4) the party independently develops, discovers or arrives at the information without use, reference to, or reliance upon, the Confidential Information.

10. PRIVACY

- 10.1 Each party must ensure that any Personal Information of Study Participants or Personnel it obtains or holds as a result of the conduct of the Study is collected, stored, used and disclosed by it in accordance with the Relevant Privacy Laws.
- 10.2 Each party will promptly report to the other party any unauthorised access to, use or disclosure of Personal Information of Study Participants (“Incident”) of which it becomes aware, and will work with the other party to take reasonable steps to remedy the Incident.

11. PUBLICATIONS

- 11.1 The Institution, Principal Investigator and other investigators (each a **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.
- 11.2 If the Study is a Multi-centre Study, then the Institution agrees that no Publication of the Study results may be made until Publication of the results of the Multi-centre Study or 2 years after Study Completion, whichever is the sooner. The further provisions of this clause still apply to any such Publication.
- 11.3 The Institution must ensure that the Discloser gives a copy of any proposed Publication drafted by them and/or other Personnel involved in the conduct of the Study to the Sponsor at least 40 days before forwarding it to any person that is not bound by the confidentiality obligations set out in **clause 9**.
- 11.4 The Sponsor may, within that 40-day period do any one or more of the following:
- (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;
 - (2) request delay of Publication for no more than 120 days to allow the Sponsor to file patent applications or take other measures to preserve or secure its Intellectual Property, in which case the Institution must abide by that request; or

- (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.
- 11.5 If the Institution has not received any comments from the Sponsor on the proposed Publication within 40 days of giving a copy to the Sponsor under **clause 11.3**, the Discloser may proceed to make the Publication.
- 11.6 Where the Sponsor intends to Publish the method, results or conclusions from the Study, any person named as an author on that Publication will be given a reasonable opportunity to review the Publication. Any person acknowledged as an investigator of the Study in the Publication will be given a reasonable opportunity to request the removal of his or her name from the Publication and the Sponsor shall comply with any such request.
- 11.7 In all Publications the Sponsor's support of the Study shall be acknowledged.
- 11.8 The Sponsor may Publish a summary of the Study Results and conclusions on the Sponsor's on-line Clinical Trial Register before or after Publication by another method.
- 11.9 The Sponsor may freely use, copy and disseminate any manuscript following its Publication in a journal without further obligation to the Institution or Discloser.
- 11.10 The Sponsor may only use the Institution's and Investigators' names:
- (1) in relation to the publication of the Study on reputable clinical trials registers and websites in accordance with the CONSORT 2010 Statement;
 - (2) in Study publications and communications including Study newsletters made to the Institution and any other person which is subject to substantially the same confidentiality obligations as those set out in **clause 9**, in relation to performance of the Study; or
 - (3) in Study publications and communications made to any third party not subject to the confidentiality obligations set out in **clause 9**, with the Institution's prior written consent.

12. STUDY MATERIALS AND INTELLECTUAL PROPERTY

- 12.1 The Sponsor grants to the Institution and its Personnel the right to use the Background IP of the Sponsor and the Study Materials as required to carry out the Study and perform this Agreement. Except for this right, neither the Institution nor any of its Personnel acquires any right or interest in any Intellectual Property provided by or on behalf of the Sponsor.
- 12.2 In order to carry out the Study, the Institution may use Intellectual Property which is part of the Institution's Background IP. Any such Background IP remains the sole property of the Institution. The Institution grants to the Sponsor a non-exclusive, perpetual, royalty free licence to use (including the right to sub-licence) the Institution's Background IP solely for the purpose of 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 Sponsor, and the Institution presently assigns to the Sponsor all Intellectual Property rights 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 Sponsor's expense.
- 12.4 The Institution must promptly disclose and communicate in writing to the Sponsor full particulars of any Intellectual Property that the Institution or Principal

Investigator make, discover or conceive in the course of the Study that is directly related to the Study Materials.

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 Sponsor or Institution. In the ordinary course of events this Agreement terminates when the Sponsor makes its final payment to the Institution.
- 13.2 A party 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;
 - (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 Participants; and
 - (2) terminating this Agreement is the most appropriate way to respond to that risk.
- 13.4 The Sponsor may terminate this Agreement if the Institution breaches **clause 4.5** or if the Sponsor learns that the Institution is making, or has made, Improper Payments (within the meaning of **clause 4.5**) to government officials with respect to services performed on behalf of the Sponsor or any other company. Further, in the event of such termination, the Institution will not be entitled to any further payment or compensation.
- 13.5 The Sponsor may terminate this Agreement with 30 days prior written notice to the Institution. In the event of such early termination, the Sponsor 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 Sponsor (or destroy if requested by the Sponsor, and provide evidence of such destruction) any completed Case Report Forms and other materials received from the Sponsor before Study Completion.
- 13.7 In the event of termination the Sponsor must take all appropriate action to close out the Study Site in a timely manner.
- 13.8 In the event of early termination, the Sponsor will cooperate with the Institution to ensure that Study Participants who may be affected by termination receive adequate medical care. This may include the provision of Investigational Product in certain circumstances at the Sponsor's expense.
- 13.9 The following provisions survive termination of this Agreement, **clauses 1, 3.2, 3.3(11), 4.6, 4.7, 4.10, 4.12, 4.13, 4.14, 5.8, 5.9, 5.10, 6.1, 8.3, 9, 10, 11, 12, 13.5, 13.6, 13.7, 13.8, 13.9, 14, 15, 16, 18 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 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 within 14 days of the end of the Initial Period, 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.
- 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, then the parties are free to pursue any other procedures available at law for the resolution of the dispute.

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; or
 - (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; or
 - (2) if sent by pre-paid mail, on the third business day after posting; or
 - (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 (the **Assigning Party**) may assign its rights or novate its rights and obligations under this Agreement after obtaining the prior written consent of the other party (the **Other Party**).

- 19.2 The Assigning Party's request for the Other Party's consent to an assignment or novation of this Agreement must include:

- (1) the name and the address of the proposed assignee or novatee;
- (2) a copy of the proposed deed of assignment or novation; and
- (3) such other information as the Other Party reasonably requires.

- 19.3 Provided the proposed novatee is an Australian entity, the Other Party must give its consent promptly if:

- (1) the Assigning Party provides evidence that ought reasonably satisfy the Other Party that the proposed novatee is financially secure and has the ability to carry out the Assigning Party's obligations under this Agreement;
- (2) the proposed novatee signs a deed or agreement in which it covenants with the Other Party and the Assigning Party to perform the obligations of the Assigning Party under this Agreement;
- (3) the Assigning Party is not in breach of this Agreement; and
- (4) the Assigning Party pays the Other Party's reasonable costs of giving its consent.

- 19.4 The Assigning Party remains liable for its obligations under this Agreement even if it assigns its rights pursuant to **clause 19.1**.

20. SUBCONTRACTING

- 20.1 The Sponsor may subcontract any of its obligations under this Agreement, save for the obligations set out in **clauses 5.8, 5.9 and 5.10**. The Sponsor remains responsible for all subcontracted obligations and is liable for all acts and omissions of any subcontractor as if they were the Sponsor's acts and omissions. In the event that the Sponsor subcontracts with another party to perform any of the Sponsor's obligations under this Agreement, the Sponsor is bound by and will observe its obligations under **clause 9.1** in its dealings with the subcontractor.

- 20.2 No subcontractor will have any rights under this Agreement against the Institution or be entitled to receive any payment from the Institution.

- 20.3 For the purpose of this Agreement only, and as between the Sponsor and the Institution only, where the Institution subcontracts any of its obligations under this Agreement, the Institution remains responsible for all subcontracted obligations and is liable for all acts and omissions of any subcontractor as if they were the Institution's acts and omissions.

21. ENTIRE AGREEMENT

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

22. FURTHER DOCUMENTS

Each party will do anything (including executing any document), and will ensure that its Personnel do anything (including executing any document), that the other party may reasonably require to give full effect to this Agreement.

23. 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 this Agreement.

24. 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.

25. FORCE MAJEURE

If any party is delayed or prevented from the performance of any act required under this 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 (a **Force Majeure Event**), the affected party shall promptly notify the other party in writing, giving details of the Force Majeure Event, the acts affected by the Force Majeure Event and the extent to which they are affected, and performance of such acts shall be excused for the period of such event provided that if such interference lasts for any period in excess of 30 days either party may, by written notice to the other, terminate this Agreement.

26. COUNTERPARTS

This Agreement may be executed in any number of counterparts. All counterparts taken together are deemed to constitute one and the same Agreement.

27. 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.

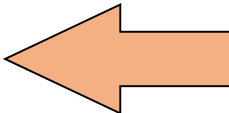
Signed on behalf of the **Sponsor**

Signed: **To be signed before submitting to Research Office via REGIS**

Name: _____
Position: _____
Date: / /

Signed on behalf of the **Institution**

Signed: _____
Name: _____
Position: _____
Date: / /



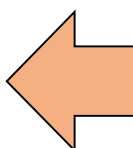
This is to be signed last by the Director of Research. Please ensure that the sponsor and PI have signed PRIOR to submitting through REGIS within your SSA application

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

Acknowledged by the **Principal Investigator**

Signed: **To be signed prior to submitting to the Research Office via REGIS**

Name: _____
Position: _____
Date: / /



PI to note that in signing. The PI has read, acknowledged and accepted their obligations under this agreement.

Schedule Key Information

(To be inserted by Sponsor)

Study Name: _____

Study Site/s: _____

Target number of Study Participants: Minimum: _____

Commencement is to be
AFTER authorisation

Maximum: _____

Recruitment Period: Start: / / End: / /

Principal Investigator Name: _____

Address: _____

State: _____ P/code: _____

Reviewing HREC: _____

Equipment provided by Sponsor: _____

Software provided by Sponsor: _____

Parties should
write here if
appropriate:
"There is no
investigational
product"

Investigational Product: _____

Studies in which there is no product:

In Schedule 1, parties should write in the 'Investigational Product' field: "There is no Investigational Product being used in this Study".
Because the definition of Investigational Product (in Clause 1 'Interpretation') refers directly to the description in Schedule 1, entering such a description renders all obligations relating to Investigational Product in the body of the CTRA to automatically fall silent.

Schedule 2 Payments

In accordance with clause 6.1, parties should use Schedule 2 to describe “the manner” in which the Sponsor will pay the Institution (ie/ through a third party payor). Institutions should ensure that invoices are made out to the Sponsor (with whom they have a contract) and sent “care of” the payor (who will pay the invoice).

Please paste/enter text below; delete this instruction and the suggested subject matter list once the payment schedule has been included.

Suggested High Level Subject matter

1. Trial Initiation
2. Patient Enrolment
3. Staged Payments
4. Trial Closeout and timing of final payment
5. Early Termination Fees
6. Fees for Protocol Variation
7. Matters to be reimbursed
 - Internet connectivity

ADDITIONAL REMINDERS IN COMPLETING THIS SECTION:

1. In accordance with Clause 6.1 of this CTRA, the local sponsor is responsible for paying GST. The site should ensure that there is a clear statement regarding the sponsor's responsibility of paying the GST in this section.

2. The payment terms is thirty (30) days from the receipt of a valid and accepted tax invoice. This should be clear in this section.

3. All clauses should directly address site payments. Any clauses or obligations which are considered/intended as special conditions should be listed under Schedule 7 and to avoid delay in review they should be SEBS approved. These clauses will not be accepted under Schedule 2. Examples are: a) Investigators should have GCP training b) Anti-bribery clauses- sponsor is to note that this is already covered in Clauses 4.4 and 4.5 of this CTRA

4. Payment details:

NSW Health has transitioned over to the new sundry debtor invoice and payment portal.

For more information please visit: <https://www.healthshare.nsw.gov.au/about/news/sundry>

Email: paynswhealth@health.nsw.gov.au

Request Payee Information for CTRA:

Please contact paynswhealth@health.nsw.gov.au directly to obtain your SESLHD account number and other banking details if required for the CTRA.

- Please specify in the subject heading '**Clinical Trials**' and whether it is a '**new trial**' or '**existing trial**'
 - If it is a new trial, please include the company ABN, e.g. *Clinical Trial - New Trial i.e.: (ABN 12345678912)*
 - If it is an existing trial, please include the customer number, e.g. *Clinical Trial – i.e.: Existing Trial (Customer Number 123456)*
- In the body of the email please include:
 - The ABN and name of the company
 - What you are specifically requesting, i.e.: vendor form needs to be completed, do you need the bank details to be provided on the letterhead, or do you just need the account number for the CTRA, etc
- Please only request one update per email

The new banking details will be present on the invoices received.

For NEW CTRA submissions:

We advise removing the current banking details from Schedule 2 and replacing with:

Payee Contact Information: paynswhealth@health.nsw.gov.au

- Phone number
- Email address

The sponsor also needs to let PayNSW know which LHD and site the request related to i.e. SESLHD/Prince of Wales Hospital, as the account is connected to the LHD.

Schedule 3

Form of Indemnity for Clinical Trials

(To be inserted by Sponsor)

This can be submitted in a separate document and will require the Director of Research's signature

The Sponsor agrees to execute and deliver to the Institution, as necessary, an indemnity in the form of the Medicines Australia Standard Form of Indemnity for Clinical Trials without amendment.

Schedule 4

For Collaborative clinical trials supported by a grant funding agreement:

Please see the Medicine's Australia website for variations consisting of clauses for each funder with the CRG CTRAs. The clauses are included in schedule 4 in the usual way. Please see <https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/> for the:

- clauses for cancer Aust./MRFF/NHMRC
- request template for SEBS
- submission closing and meeting dates

Insurance Arrangements

(To be inserted by Sponsor)

Please note:

- Insured entity has to be an Australian legal entity with an address in Australia
- Insurer has to be listed as an approved insurer in APRA. Overseas insurers should provide a letter stating "A" rating to the RGO
- Site to ensure that dates are current and preferably valid for at least 6 months prior to the study's commencement.
- Amount should be in Australian dollars only and if effected in multiple policies, the amount should be a minimum of AUD 20 Million. This wording is exact working in the NSW Health Policy PD2011_066.
- Deductible amount should in Australian dollars only. Amount must not be greater than AUD 25,000 even if effected by multiple policies.

Certificate of Insurance

For a Study conducted in Australia, the following details are mandatory:

- Insurance provider
- Insured Entity
- Additional Insured
- Protocol/ CTN number
- Limits of Liability in AUD/ Per occurrence amount and Annual Aggregate
- Excess/ deductible/ Self insured risk

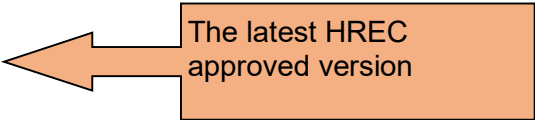
Schedule 5

Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Trial

Copy available online at:

<https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/>

**Schedule 6
Study Protocol Identification**



Full Title: _____

Title should be consistent with protocol, indemnity, and schedule 1

Version Number: _____

Latest HREC approved version

Date: _____

: / /

List of Key Attachments: _____

Schedule 7 Special Conditions

Please Paste/Enter Text Below

If the sponsor is requesting special conditions under this agreement, please upload the SEBS approved clauses annexed to the letter to the STE in REGIS. The clauses listed in this section should be verbatim to the SEBS approved clauses in the letter that will be provided. Combination of clauses and approval letters will not be accepted. If any special conditions do not have SEBS approval please contact the SESLHD Research Office SESLHD-RSO@health.nsw.gov.au